REGENERON PHARMACEUTICALS INC
Form 10-Q
August 06, 2013

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

(Mark One)
(X) QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended June 30, 2013

OR

( ) TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number 0-19034

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

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

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

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

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

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

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

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

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

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

Number of shares outstanding of each of the registrant’s classes of common stock as of July 17, 2013:

| Class of Common Stock | Number of Shares |
|---|---|
| Class A Stock, $0.001 par value | 2,038,920 |
| Common Stock, $0.001 par value | 96,710,115 |

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PART I. FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS
REGENERON PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)
(In thousands, except share data)

| | June 30, 2013 | December 31, 2012 |
|---|---|---|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | $381,675 | $230,276 |
| Marketable securities | 155,831 | 77,819 |
| Accounts receivable - trade, net | 767,865 | 593,207 |
| Accounts receivable from Sanofi | 108,151 | 99,913 |
| Deferred tax assets | 38,927 | 148,134 |
| Prepaid expenses and other current assets | 108,913 | 56,663 |
| Total current assets | 1,561,362 | 1,206,012 |
| | | |
| Restricted cash and marketable securities | | 8,186 |
| Marketable securities | 173,328 | 271,230 |
| Property, plant, and equipment, at cost, net of accumulated depreciation and amortization | 419,651 | 379,940 |
| Deferred tax assets | 208,707 | 192,022 |
| Other assets | 15,211 | 23,100 |
| Total assets | $2,378,259 | $2,080,490 |
| LIABILITIES and STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable and accrued expenses | $153,826 | $111,345 |
| Deferred revenue from Sanofi, current portion | 14,916 | 17,022 |
| Deferred revenue - other, current portion | 34,266 | 33,809 |
| Facility lease obligations, current portion | 794 | 1,374 |
| Total current liabilities | 203,802 | 163,550 |
| | | |
| Deferred revenue from Sanofi | 78,740 | 76,520 |
| Deferred revenue - other | 119,672 | 131,822 |
| Facility lease obligations | 164,392 | 159,436 |
| Convertible senior notes | 308,116 | 296,518 |
| Other long term liabilities | 10,200 | 7,259 |
| Total liabilities | 884,922 | 835,105 |
| | | |
| Commitments and contingencies | | |
| | | |
| 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 - 2,038,920 at June 30, 2013 and 2,069,187 at December 31, 2012 | 2 | 2 |
| Common Stock, $.001 par value; 160,000,000 shares authorized; shares issued and outstanding - 96,662,313 at June 30, 2013 and 95,223,525 at December 31, 2012 | 97 | 95 |

| | | |
|---|---|---|
| Additional paid-in capital | 1,827,471 | 1,763,508 |
| Accumulated deficit | (330,804) | (517,054) |
| Accumulated other comprehensive loss | (3,429) | (1,166) |
| Total stockholders' equity | 1,493,337 | 1,245,385 |
| Total liabilities and stockholders' equity | $2,378,259 | $2,080,490 |

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

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

| | Three months ended June 30, | | Six months ended June 30, | |
|---|---|---|---|---|
| | 2013 | 2012 | 2013 | 2012 |
| Statements of Operations | | | | |
| Revenues: | | | | |
| Net product sales | $333,893 | $199,519 | $652,633 | $327,450 |
| Sanofi collaboration revenue | 85,529 | 88,988 | 184,802 | 173,993 |
| Bayer HealthCare collaboration revenue | 31,104 | 9,124 | 46,011 | 21,607 |
| Technology licensing | 5,893 | 5,893 | 11,786 | 11,786 |
| Other revenue | 1,223 | 875 | 2,074 | 1,352 |
| | 457,642 | 304,399 | 897,306 | 536,188 |
| Expenses: | | | | |
| Research and development | 187,463 | 147,373 | 367,762 | 286,235 |
| Selling, general, and administrative | 72,463 | 47,705 | 149,723 | 106,133 |
| Cost of goods sold | 27,283 | 21,843 | 55,304 | 34,141 |
| Cost of collaboration manufacturing | 12,330 | | 13,364 | |
| | 299,539 | 216,921 | 586,153 | 426,509 |
| Income from operations | 158,103 | 87,478 | 311,153 | 109,679 |
| Other income (expense): | | | | |
| Investment income | 954 | 501 | 1,410 | 1,111 |
| Interest expense | (11,365) | (11,236) | (23,040) | (22,396) |
| | (10,411) | (10,735) | (21,630) | (21,285) |
| Income before income taxes | 147,692 | 76,743 | 289,523 | 88,394 |
| Income tax expense | (60,316) | | (103,273) | |
| Net income | $87,376 | $76,743 | $186,250 | $88,394 |
| Net income per share - basic | $0.89 | $0.81 | $1.91 | $0.94 |
| Net income per share - diluted | $0.79 | $0.70 | $1.69 | $0.81 |
| Weighted average shares outstanding - basic | 97,700 | 94,589 | 97,289 | 94,017 |
| Weighted average shares outstanding - diluted | 111,060 | 110,167 | 110,305 | 108,998 |
| Statements of Comprehensive Income | | | | |
| Net income | $87,376 | $76,743 | $186,250 | $88,394 |
| Other comprehensive loss: | | | | |
| Unrealized loss on marketable securities | (1,785) | (1,034) | (2,263) | (509) |
| Comprehensive income | $85,591 | $75,709 | $183,987 | $87,885 |

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

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REGENERON PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (Unaudited)
For the Six Months Ended June 30, 2013 and 2012
(In thousands)

| | Class A Stock | | Common Stock | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | Additional Paid-in Capital | Accumulated Deficit | Accumulated Other Comprehensive Income (Loss) | Total Stockholders' Equity |
| Balance, December 31, 2012 | 2,069 | $2 | 95,223 | $95 | $1,763,508 | $(517,054) | $ (1,166) | $ 1,245,385 |
| Issuance of Common Stock in connection with exercise of stock options | | | 1,661 | 2 | 30,496 | | | 30,498 |
| Common Stock tendered upon exercise of stock options in connection with employee tax obligations | | | (290) | | (73,137) | | | (73,137) |
| Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution | | | 38 | | | | | |
| Conversion of Class A Stock to Common Stock | (30) | | 30 | | | | | |
| Stock-based compensation charges | | | | | 98,728 | | | 98,728 |
| Excess tax benefit from stock-based compensation | | | | | 7,876 | | | 7,876 |
| Net income | | | | | | 186,250 | | 186,250 |
| Other comprehensive loss | | | | | | | (2,263) | (2,263) |
| Balance, June 30, 2013 | 2,039 | $2 | 96,662 | $97 | $1,827,471 | $(330,804) | $ (3,429) | $ 1,493,337 |
| Balance, December 31, 2011 | 2,109 | $2 | 90,692 | $91 | $1,754,824 | $(1,267,323) | $ (1,862) | $ 485,732 |
| Issuance of Common Stock in connection with exercise of stock options | | | 3,234 | 3 | 39,631 | | | 39,634 |
| Common Stock tendered upon exercise of stock options in connection with employee tax obligations | | | (568) | | (61,444) | | | (61,444) |
| Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution | | | 64 | | | | | |
| Issuance of restricted Common Stock under Long-Term Incentive Plan | | | 500 | | | | | |
| Conversion of Class A Stock to Common Stock | (20) | | 20 | | | | | |
| | | | | | 42,850 | | | 42,850 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Stock-based compensation charges | | | | | | | | |
| Net income | | | | | | 88,394 | | 88,394 |
| Other comprehensive loss | | | | | | | (509) | (509) |
| Balance, June 30, 2012 | 2,089 | $2 | 93,942 | $94 | $1,775,861 | $(1,178,929) | $ (2,371) | $ 594,657 |

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

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

| | Six months ended June 30, | |
|---|---|---|
| | 2013 | 2012 |
| Cash flows from operating activities: | | |
| Net income | $186,250 | $88,394 |
| Adjustments to reconcile net income to net cash provided by (used in) operating activities: | | |
| Depreciation and amortization | 19,109 | 17,833 |
| Non-cash compensation expense | 97,473 | 42,850 |
| Non-cash interest expense | 11,315 | 11,191 |
| Other non-cash charges and expenses, net | 18,323 | 11,056 |
| Deferred taxes | 92,522 | |
| Changes in assets and liabilities: | | |
| Increase in Sanofi and trade accounts receivable | (182,896) | (332,345) |
| Increase in prepaid expenses and other assets | (51,697) | (19,517) |
| Decrease in deferred revenue | (11,579) | (17,669) |
| Increase in accounts payable, accrued expenses, and other liabilities | 35,592 | 32,789 |
| Total adjustments | 28,162 | (253,812) |
| Net cash provided by (used in) operating activities | 214,412 | (165,418) |
| | | |
| Cash flows from investing activities: | | |
| Purchases of marketable securities | (282,643) | (270,907) |
| Sales or maturities of marketable securities | 307,244 | 171,881 |
| Purchase of restricted cash and marketable securities | | (469) |
| Capital expenditures | (55,656) | (23,927) |
| Net cash used in investing activities | (31,055) | (123,422) |
| | | |
| Cash flows from financing activities: | | |
| Payments in connection with facility and capital lease obligations | (997) | (1,014) |
| Proceeds from issuance of Common Stock | 34,300 | 39,631 |
| Payments in connection with Common Stock tendered for employee tax obligations | (73,137) | (61,444) |
| Excess tax benefit from stock-based compensation | 7,876 | |
| Net cash used in financing activities | (31,958) | (22,827) |
| | | |
| Net increase (decrease) in cash and cash equivalents | 151,399 | (311,667) |
| | | |
| Cash and cash equivalents at beginning of period | 230,276 | 483,610 |
| | | |
| Cash and cash equivalents at end of period | $381,675 | $171,943 |

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

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

1. Interim Financial Statements

The interim Condensed Consolidated Financial Statements of Regeneron Pharmaceuticals, Inc. (“Regeneron” or the “Company”) have been prepared in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all information and disclosures necessary for a presentation of the Company’s financial position, results of operations, and cash flows in conformity with accounting principles generally accepted in the United States of America. In the opinion of management, these financial statements reflect all normal recurring adjustments and accruals necessary for a fair statement of the Company’s financial position, results of operations, and cash flows for such periods. The results of operations for any interim periods are not necessarily indicative of the results for the full year. The December 31, 2012 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, 2012. Certain reclassifications have been made to prior period amounts to conform with the current period’s presentation.

2. Net Product Sales

EYLEA® net product sales totaled $329.8 million and $194.0 million for the three months ended June 30, 2013 and 2012, respectively, and $643.7 million and $317.5 million for the six months ended June 30, 2013 and 2012, respectively. In November 2011, the Company received marketing approval from the U.S. Food and Drug Administration ("FDA") for EYLEA (aflibercept) Injection for the treatment of neovascular age-related macular degeneration ("wet AMD"). In September 2012, the Company received marketing approval from the FDA for EYLEA for the treatment of macular edema following central retinal vein occlusion ("CRVO"). In addition, ARCALYST® net product sales totaled $4.1 million and $5.5 million for the three months ended June 30, 2013 and 2012, respectively, and $8.9 million and $9.9 million for the six months ended June 30, 2013 and 2012, respectively.

The Company recorded 76% and 79% for the three months ended June 30, 2013 and 2012, respectively, and 77% and 79% for the six months ended June 20, 2013 and 2012, respectively, of its total gross product revenue from sales to Besse Medical, a subsidiary of AmerisourceBergen Corporation.

Revenue from product sales is recorded net of applicable provisions for rebates and chargebacks under governmental programs (including Medicaid), distribution-related fees, prompt pay discounts, product returns, and other sales-related deductions. The following table summarizes the provisions, and credits/payments, for these sales-related deductions during the six months ended June 30, 2013.

| | Rebates & Chargebacks | Distribution-Related Fees | Other Sales-Related Deductions | Total |
|---|---|---|---|---|
| Balance as of December 31, 2012 | $2,983 | $15,298 | $545 | $18,826 |
| Provision related to current period sales | 11,121 | 29,422 | 498 | 41,041 |
| Credits/payments | (10,081) | (26,238) | (511) | (36,830) |
| Balance as of June 30, 2013 | $4,023 | $18,482 | $532 | $23,037 |

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

3. Collaboration Revenue

Sanofi Collaboration Revenue

The collaboration revenue the Company earned from Sanofi, as detailed below, consisted primarily of reimbursement for research and development expenses that the Company incurred, recognition of the Company's share of losses in connection with Sanofi's commercialization of ZALTRAP®, and recognition of revenue related to non-refundable up-front payments.

In addition, Sanofi collaboration revenue for the three months and six months ended June 30, 2013 was reduced by two $10.0 million up-front payments to Sanofi in connection with the Company's acquisition from Sanofi of full exclusive rights to two families of novel antibodies, as described below.

| | Three months ended June 30, | |
|---|---|---|
| Sanofi Collaboration Revenue | 2013 | 2012 |
| ZALTRAP: | | |
| Regeneron's share of losses in connection with commercialization of ZALTRAP | $(8,216) | $(8,430) |
| Reimbursement of Regeneron research and development and other expenses | 2,835 | 4,225 |
| Recognition of deferred revenue related to up-front payments | 1,384 | 2,889 |
| Total ZALTRAP | (3,997) | (1,316) |
| Antibody: | | |
| Reimbursement of Regeneron research and development expenses | 106,965 | 87,746 |
| Up-front payments to Sanofi for acquisition of rights related to two antibodies | (20,000) | |
| Recognition of deferred revenue related to up-front and other payments | 2,162 | 2,160 |
| Recognition of revenue related to VelociGene® agreement | 399 | 398 |
| Total Antibody | 89,526 | 90,304 |
| Total Sanofi collaboration revenue | $85,529 | $88,988 |

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

| | Six months ended June 30, | |
|---|---|---|
| Sanofi Collaboration Revenue | 2013 | 2012 |
| ZALTRAP: | | |
| Regeneron's share of losses in connection with commercialization of ZALTRAP | $(16,005) | $(12,135) |
| Reimbursement of Regeneron research and development and other expenses | 5,398 | 7,045 |
| Recognition of deferred revenue related to up-front payments | 2,767 | 5,372 |
| Total ZALTRAP | (7,840) | 282 |
| Antibody: | | |
| Reimbursement of Regeneron research and development expenses | 207,520 | 168,601 |
| Up-front payments to Sanofi for acquisition of rights related to two antibodies | (20,000) | |
| Recognition of deferred revenue related to up-front and other payments | 4,324 | 4,313 |
| Recognition of revenue related to VelociGene agreement | 798 | 797 |
| Total Antibody | 192,642 | 173,711 |
| Total Sanofi collaboration revenue | $184,802 | $173,993 |

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 countries in Europe in the first quarter of 2013. The Company and Sanofi globally collaborate on the development and commercialization of ZALTRAP. Under the terms of the companies' September 2003 collaboration agreement, as amended, Regeneron and Sanofi share co-promotion rights and profits and losses on sales of ZALTRAP outside of Japan. In Japan, the Company is entitled to a royalty on sales of ZALTRAP.

Acquisition from Sanofi of Rights to PDGF and Ang2 in Ophthalmology

In May 2013, the Company acquired from Sanofi full exclusive rights to two families of novel antibodies invented at Regeneron and previously included in the Company's antibody collaboration with Sanofi. The Company acquired full rights to antibodies targeting the PDGF (platelet derived growth factor) family of receptors and ligands in ophthalmology and all other indications and to antibodies targeting the Ang2 (angiopoietin-2) receptor and ligand in ophthalmology. Antibodies to the PDGF receptor and Ang2 are currently in preclinical development for use in ophthalmology.

With respect to PDGF antibodies, the Company made a $10.0 million up-front payment to Sanofi in May 2013, and will pay up to $40 million in potential development milestone payments and royalties on any future sales. With respect to Ang2 antibodies in ophthalmology, the Company also made a $10.0 million up-front payment to Sanofi in May 2013, and will pay a potential $5 million development milestone payment and royalties on any future sales.

Bayer HealthCare Collaboration Revenue

Bayer HealthCare commenced sales of EYLEA for the treatment of wet AMD in the fourth quarter of 2012 following receipt of regulatory approvals in the European Union and other regions. The Company and Bayer HealthCare globally collaborate on the development and commercialization of EYLEA outside of the United States.

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

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

| | Three months ended June 30, | |
|---|---|---|
| Bayer HealthCare Collaboration Revenue | 2013 | 2012 |
| Regeneron's net profit in connection with commercialization of EYLEA outside the United States | $19,055 | |
| Cost-sharing of Regeneron EYLEA development expenses | 3,667 | $7,147 |
| Reimbursement of other Regeneron EYLEA expenses | 6,405 | |
| Recognition of deferred revenue related to up-front and other milestone payments | 1,977 | 1,977 |
| | $31,104 | $9,124 |

| | Six months ended June 30, | |
|---|---|---|
| Bayer HealthCare Collaboration Revenue | 2013 | 2012 |
| Regeneron's net profit in connection with commercialization of EYLEA outside the United States | $25,417 | |
| Cost-sharing of Regeneron EYLEA development expenses | 9,638 | $17,653 |
| Reimbursement of other Regeneron EYLEA expenses | 7,002 | |
| Recognition of deferred revenue related to up-front and other milestone payments | 3,954 | 3,954 |
| | $46,011 | $21,607 |

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

4. Net Income Per Share

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

| | Three Months Ended June 30, | |
|---|---|---|
| | 2013 | 2012 |
| Net income - basic and diluted | $87,376 | $76,743 |
| | | |
| (Shares in thousands) | | |
| Weighted average shares - basic | 97,700 | 94,589 |
| Effect of dilutive securities: | | |
| Stock options | 10,291 | 14,055 |
| Restricted stock | 424 | 692 |
| Warrants | 2,645 | 831 |
| Dilutive potential shares | 13,360 | 15,578 |
| Weighted average shares - diluted | 111,060 | 110,167 |
| | | |
| Net income per share - basic | $0.89 | $0.81 |
| Net income per share - diluted | $0.79 | $0.70 |

| | Six Months Ended June 30, | |
|---|---|---|
| | 2013 | 2012 |
| Net income - basic and diluted | $186,250 | $88,394 |
| | | |
| (Shares in thousands) | | |
| Weighted average shares - basic | 97,289 | 94,017 |
| Effect of dilutive securities: | | |
| Stock options | 10,296 | 13,964 |
| Restricted stock | 383 | 676 |
| Warrants | 2,337 | 341 |
| Dilutive potential shares | 13,016 | 14,981 |
| Weighted average shares - diluted | 110,305 | 108,998 |
| | | |
| Net income per share - basic | $1.91 | $0.94 |
| Net income per share - diluted | $1.69 | $0.81 |

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

Shares which have been excluded from the June 30, 2013 and 2012 diluted per share amounts because their effect would have been antidilutive, include the following:

| | Three Months Ended June 30, | |
|---|---|---|
| (Shares in thousands) | 2013 | 2012 |
| Stock options | 1,247 | 89 |
| Convertible senior notes | 4,761 | 4,761 |
| | Six Months Ended June 30, | |
| (Shares in thousands) | 2013 | 2012 |
| Stock options | 3,599 | 47 |
| Restricted stock | | 11 |
| Convertible senior notes | 4,761 | 4,761 |

5. Marketable Securities

Marketable securities at June 30, 2013 and December 31, 2012 consist of debt and equity securities. The Company also held restricted marketable securities at December 31, 2012, which consisted of debt securities, as detailed below, that collateralized letters of credit and lease obligations. During the second quarter of 2013, these collateral requirements were rescinded, either due to cancellation of the associated letter of credit or easing of lender requirements on the Company. As a result, during the second quarter of 2013, all formerly restricted marketable securities were reclassified as unrestricted on the Company's balance sheet which, for the purpose of the Company's Statement of Cash Flows, was treated as a non-cash investing transaction.

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

The following tables summarize the Company's investments in marketable securities at June 30, 2013 and December 31, 2012.

| At June 30, 2013 | Amortized Cost Basis | Unrealized Gains | Losses | Fair Value |
|---|---|---|---|---|
| Unrestricted | | | | |
| U.S. government and government agency obligations | $85,662 | $52 | $(309) | $85,405 |
| Corporate bonds | 157,593 | 6 | (271) | 157,328 |
| Commercial paper | 62,159 | | | 62,159 |
| Municipal bonds | 17,172 | 1 | (22) | 17,151 |
| International government agency obligations | 4,824 | | (8) | 4,816 |
| Equity securities | 4,044 | | (1,744) | 2,300 |
| | $331,454 | $59 | $(2,354) | $329,159 |
| At December 31, 2012 | | | | |
| Unrestricted | | | | |
| U.S. government and government agency obligations | $327,502 | $661 | $(17) | $328,146 |
| Municipal bonds | 17,542 | | (32) | 17,510 |
| Equity securities | 4,044 | | (651) | 3,393 |
| | 349,088 | 661 | (700) | 349,049 |
| Restricted | | | | |
| U.S. government obligations | 5,902 | 9 | (2) | 5,909 |
| | $354,990 | $670 | $(702) | $354,958 |

The Company classifies its debt securities based on their contractual maturity dates. The debt securities listed at June 30, 2013 mature at various dates through January 2016. The fair values of debt security investments by contractual maturity as of June 30, 2013 and December 31, 2012 consist of the following:

| | June 30, 2013 | December 31, 2012 |
|---|---|---|
| Unrestricted | | |
| Maturities within one year | $155,831 | $77,819 |
| Maturities after one year through five years | 171,028 | 267,837 |
| | 326,859 | 345,656 |
| Restricted | | |
| Maturities within one year | | 2,781 |
| Maturities after one year through five years | | 3,128 |
| | | 5,909 |
| | $326,859 | $351,565 |

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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, at June 30, 2013 and December 31, 2012.

| | Less than 12 Months | | 12 Months or Greater | | Total | |
|---|---|---|---|---|---|---|
| At June 30, 2013 | Fair Value | Unrealized Loss | Fair Value | Unrealized Loss | Fair Value | Unrealized Loss |
| Unrestricted | | | | | | |
| U.S. government and government agency obligations | $69,106 | $(309) | | | $69,106 | $(309) |
| Corporate bonds | 142,244 | (271) | | | 142,244 | (271) |
| Municipal bonds | 7,678 | (22) | | | 7,678 | (22) |
| International government agency obligations | 4,816 | (8) | | | 4,816 | (8) |
| Equity security | | | $2,300 | $(1,744) | 2,300 | (1,744) |
| | $223,844 | $(610) | $2,300 | $(1,744) | $226,144 | $(2,354) |
| At December 31, 2012 | | | | | | |
| Unrestricted | | | | | | |
| U.S. government and government agency obligations | $44,738 | $(17) | | | $44,738 | $(17) |
| Municipal bonds | 17,510 | (32) | | | 17,510 | (32) |
| Equity security | | | $3,393 | $(651) | 3,393 | (651) |
| | 62,248 | (49) | 3,393 | (651) | 65,641 | (700) |
| Restricted | | | | | | |
| U.S. government obligations | 1,194 | (2) | | | 1,194 | (2) |
| | $63,442 | $(51) | $3,393 | $(651) | $66,835 | $(702) |

Realized gains and losses are included as a component of investment income. For both the three and six months ended June 30, 2013, total realized gains on sales of marketable securities were $0.5 million and there were no realized losses. For both the three and six months ended June 30, 2012, total realized gains and losses on sales of marketable securities were not material.

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6. Fair Value Measurements

The Company's assets that are measured at fair value on a recurring basis, at June 30, 2013 and December 31, 2012, consist of the following:

| At June 30, 2013 | 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) |
|---|---|---|---|
| Unrestricted | | | |
| Available-for-sale marketable securities: | | | |
| U.S. government and government agency obligations | $85,405 | | $85,405 |
| Corporate bonds | 157,328 | | 157,328 |
| Commercial paper | 62,159 | | 62,159 |
| Municipal bonds | 17,151 | | 17,151 |
| International government agency obligations | 4,816 | | 4,816 |
| Equity security | 2,300 | $2,300 | |
| | $329,159 | $2,300 | $326,859 |
| At December 31, 2012 | | | |
| Unrestricted | | | |
| Available-for-sale marketable securities: | | | |
| U.S. government and government agency obligations | $328,146 | | $328,146 |
| Municipal bonds | 17,510 | | 17,510 |
| Equity security | 3,393 | $3,393 | |
| | 349,049 | 3,393 | 345,656 |
| Restricted | | | |
| Available-for-sale marketable securities: | | | |
| U.S. government obligations | 5,909 | | 5,909 |
| | $354,958 | $3,393 | $351,565 |

Marketable securities included in Level 2 were valued using a market approach utilizing prices and other relevant information, such as interest rates, yield curves, prepayment speeds, loss severities, credit risks and default rates, generated by market transactions involving identical or comparable assets. The Company considers market liquidity in determining the fair value for these securities. The Company did not record any charges for other-than-temporary impairment of its Level 2 marketable securities during the three and six months ended June 30, 2013 and 2012. There were no purchases, sales, or maturities of Level 3 marketable securities and no unrealized gains or losses related to Level 3 marketable securities for the three and six months ended June 30, 2013 and 2012. There were no transfers of marketable securities between Levels 1, 2, or 3 classifications during the three and six months ended June 30, 2013 and 2012.

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As of June 30, 2013 and December 31, 2012, the Company had $400.0 million in aggregate principal amount of 1.875% convertible senior notes that will mature on October 1, 2016 unless earlier converted or repurchased. The fair value of the outstanding convertible senior notes was estimated to be $1,117.5 million and $843.2 million as of June 30, 2013 and December 31, 2012, respectively, and was determined based on Level 2 inputs.

7. Inventory

Inventory, which was included in prepaid expenses and other current assets in the Company's balance sheets, consists of the following:

| | June 30, 2013 | December 31, 2012 |
|---|---|---|
| Raw materials | $5,380 | $4,862 |
| Work in process | 34,580 | 14,656 |
| Finished goods | 10,429 | 2,570 |
| Deferred costs | 6,770 | 6,550 |
| | $57,159 | $28,638 |

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

As of June 30, 2013 and December 31, 2012, inventory included reserves of $6.2 million and $3.6 million, respectively. For the three months ended June 30, 2013 and 2012, cost of goods sold included inventory write-downs and reserves totaling $1.7 million and $6.5 million, respectively. For the six months ended June 30, 2013 and 2012, cost of goods sold included inventory write-downs and reserves totaling $4.9 million and $8.4 million, respectively.

8. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following:

| | June 30, 2013 | December 31, 2012 |
|---|---|---|
| Accounts payable | $24,418 | $38,934 |
| Accrued payroll and related costs | 39,760 | 19,987 |
| Accrued clinical trial expense | 20,295 | 10,985 |
| Accrued sales-related charges, deductions, and royalties | 49,408 | 21,870 |
| Other accrued expenses and liabilities | 19,945 | 19,569 |
| | $153,826 | $111,345 |

With respect to non-cash investing activities in connection with the Company's Statements of Cash Flows, included in accounts payable and accrued expenses at June 30, 2013 and December 31, 2012 were $8.1 million and $8.6 million, respectively, of accrued capital expenditures. Included in accounts payable and accrued expenses at June 30, 2012 and December 31, 2011 were $5.9 million and $6.2 million, respectively, of accrued capital expenditures.

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9. Leases

In April 2013, the Company entered into a new lease agreement for additional laboratory and office space to be constructed in two new buildings (the "Buildings"), which are expected to be completed in late 2015, at the Company's current Tarrytown, New York location. The initial term of the lease, which is expected to commence in mid-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 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 the Company's involvement in the Buildings' construction and its responsibility for directly paying for a substantial portion of tenant improvements, the Company is deemed, in substance, to be the owner of the landlord's Buildings in accordance with the application of FASB authoritative guidance. Consequently, in addition to capitalizing the tenant improvements, the Company will capitalize the landlord's costs of constructing these new facilities, offset by a corresponding lease obligation on the Company's balance sheet. The Company will allocate a portion of its future lease payments to the Buildings and the land on which the Buildings are being constructed. The land element of the lease is treated for accounting purposes as an operating lease.

Commencing in the second quarter of 2013, the Company began capitalizing the landlord's costs of constructing the new Buildings, which totaled $4.7 million at June 30, 2013, and recognized a corresponding facility lease obligation of $4.7 million. Such amounts were included as a non-cash activity within the Company's Condensed Consolidated Statements of Cash Flows. Rent expense in connection with the land element of these new facilities commenced in April 2013 and is recorded as a deferred liability until lease payments commence in mid-2014.

In April 2013, the Company also executed an early renewal of certain laboratory and office space that it currently leases at its Tarrytown location. The early renewal extended the term of the lease from June 2024 to June 2029.

10. Income Taxes

The Company is subject to U.S. federal, state, and foreign income taxes. The Company's effective tax rate for the three and six months ended June 30, 2013 was 40.8% and 35.7%, respectively. The six month effective tax rate included, as a discrete item in the first quarter of 2013, the impact of enacting The American Taxpayer Relief Act in January 2013. The American Taxpayer Relief Act included a provision to extend the income tax credit for increased research activities retroactively to the tax year ended December 31, 2012. As a result, the Company's 2012 research tax credit reduced its effective tax rate for the six months ended June 30, 2013 by 6.0%.

For the three and six months ended June 30, 2013, the Company recorded an income tax provision of $60.3 million and $103.3 million, respectively.

Tax years subsequent to 2009 remain open to examination by federal tax authorities. In addition, New York state has commenced an examination of the Company's 2009, 2010, and 2011 tax years.

For the three and six months ended June 30, 2012, income tax expense relating to the Company's pre-tax income was fully offset by a reversal of a portion of the Company's valuation allowance. As of June 30, 2012, the Company continued to recognize a full valuation allowance against its net operating loss carry-forward and other deferred tax assets since the Company had an extended history of losses. In the fourth quarter of 2012, the Company recorded an income tax benefit attributable to the release of substantially all of the remaining valuation allowance against the Company's deferred tax assets. The decision to release this valuation allowance was made after the Company determined that it was more likely than not that these deferred tax assets would be realized.

11. Legal Matters

From time to time, the Company is a party to legal proceedings in the course of the Company's business. The Company does not expect any such current ordinary course legal proceedings to have a material adverse effect on the Company's business or financial condition. Costs associated with the Company's involvement in legal proceedings are expensed as incurred.

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Genentech Patent Litigation

In November 2010, the Company commenced a lawsuit against Genentech in the U.S. District Court for the Southern District of New York (the "Court"), seeking a declaratory judgment that no activities relating to the Company's VEGF Trap infringe any valid claim of certain Genentech patents referred to as the Davis-Smyth patents (the "First Davis-Smyth Case"). Genentech answered the complaint and asserted counterclaims that the Company's prior or planned activities relating to VEGF Trap have infringed or will infringe claims of four of the Davis-Smyth patents and requested a judgment against the Company for damages, including for willful infringement, and other relief as the Court deems appropriate.

On December 31, 2011, the Company entered into a Non-Exclusive License and Partial Settlement Agreement with Genentech (the "Original Genentech Agreement") that covered making, using, and selling EYLEA in the United States for the prevention and treatment of human eye diseases and disorders in the United States, and ended the litigation relating to those matters. Under the Original Genentech Agreement, the Company received a non-exclusive license to the Davis-Smyth patents, and certain other patents owned or co-owned by Genentech. The Original Genentech Agreement did not cover any non-U.S. patent rights or non-U.S. patent disputes, and did not cover any use of aflibercept other than for prevention and treatment of human eye diseases and disorders in the United States. The Original Genentech Agreement provided for the Company to make payments to Genentech based on U.S. sales of EYLEA through May 7, 2016, the date the Davis-Smyth patents expire. Under the Original Genentech Agreement, the Company made a $60.0 million payment when cumulative U.S. sales of EYLEA reached $400 million, and is obligated to pay royalties of 4.75% on cumulative relevant sales of EYLEA between $400 million and $3 billion and 5.5% on any cumulative relevant sales of EYLEA over $3 billion.

As a result of the Original Genentech Agreement, on January 17, 2012, Genentech filed a second amended answer and counterclaim in the First Davis-Smyth Case, in which it amended its counterclaims alleging infringement of four of the Davis-Smyth patents. On December 23, 2011, Genentech initiated a related case in the Court against Regeneron and Sanofi alleging infringement of four of the Davis-Smyth Patents by activities relating to VEGF Trap (but excluding EYLEA) (the "Second Davis-Smyth Case"). As in the First Davis-Smyth Case, in the new complaint Genentech requested a judgment against the Company for damages, including for willful infringement, and other relief as the Court deems appropriate. On September 21, 2012, Genentech asserted two additional Davis-Smyth patents, and one additional application (which was allowed and issued as a patent on September 25, 2012) in both the First Davis-Smyth Case and the Second Davis-Smyth Case.

Effective May 17, 2013, the Company and Genentech entered into an Amended and Restated Non-Exclusive License and Settlement Agreement with Genentech (the "Amended Genentech Agreement"), which amended the Original Genentech Agreement to now include all sales of EYLEA worldwide and ended the litigation relating to those matters. Under the Amended Genentech Agreement, the Company received a worldwide non-exclusive license to the Davis-Smyth patents, and certain other patents, owned or co-owned by Genentech for the prevention or treatment of eye diseases and eye disorders in a human through administration of EYLEA to the eye. Under the Amended Genentech Agreement, the Company will make payments to Genentech based on sales of EYLEA in the United States, and EYLEA manufactured in the United States and sold outside the United States, through May 7, 2016 using the same milestone and royalty rates as in the Original Genentech Agreement. EYLEA is sold outside the United States by affiliates of Bayer HealthCare under the Company's license and collaboration agreement. All payments to Genentech under the Original Genentech Agreement and the Amended Genentech Agreement have been or will be made by the Company. Bayer HealthCare will share in all such payments based on the proportion of ex-U.S. EYLEA sales to worldwide EYLEA sales and determined consistent with the license and collaboration agreement.

Also on May 17, 2013, the Company entered into a Non-Exclusive License and Settlement Agreement (the "ZALTRAP Agreement") with Genentech and Sanofi under which the Company and Sanofi received a worldwide non-exclusive license to the Davis-Smyth patents, and certain other patents, in all indications for human use other than

the prevention or treatment of eye diseases and eye disorders through administration to the eye. Under the terms of the ZALTRAP Agreement, payments will be made to Genentech based on sales of ZALTRAP in the United States and of ZALTRAP that is manufactured in the United States and sold outside the United States through May 7, 2016. A payment of $19 million will be made upon cumulative relevant sales of ZALTRAP reaching $200 million. In addition, royalty payments will be made to Genentech based upon 4.5% of cumulative relevant sales of ZALTRAP between $400 million and $1 billion and 6.5% of any cumulative relevant sales of ZALTRAP over $1 billion. All payments to Genentech under the ZALTRAP Agreement will be made by Sanofi, and the Company will share in all such payments. In connection with Amended Genentech Agreement and the ZALTRAP Agreement, both the First Davis-Smyth Case and the Second Davis-Smyth Case have been dismissed.

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The Company initiated patent-related actions against Genentech in Germany, the United Kingdom, and Italy relating in each case to a patent that expired on October 28, 2012. In the United Kingdom, an adverse decision at first instance dated March 22, 2012 was appealed to the UK Court of Appeal. The Court of Appeal decision dated February 21, 2013 found the designation of European patent EP 1 238 986 in the United Kingdom to be valid and that potential acts relating to VEGF Trap-Eye in the United Kingdom before expiration of the patent on October 28, 2012 would infringe this patent. The Company sought permission to appeal to the Supreme Court of the United Kingdom. On May 17, 2013, the Company entered into an agreement with Genentech, Bayer Pharma AG, Bayer Australia Limited and Regeneron UK Ltd., pursuant to which the parties agreed to dismiss proceedings involving these and certain other Genentech patents, and the Company and the Bayer HealthCare affiliates were granted certain covenants not to sue as to these and other patents. These proceedings have been dismissed.

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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 financial performance of Regeneron Pharmaceuticals, Inc., and actual events or results may differ materially from these forward-looking statements. These statements concern, and these risks and uncertainties include, among others, the nature, timing, and possible success and therapeutic applications of EYLEA®, ZALTRAP®, and ARCALYST® and our product candidates, potential new indications for marketed products, and research and clinical programs now underway or planned; the likelihood and timing of possible regulatory approval and commercial launch of our late-stage product candidates and new indications for marketed products; determinations by regulatory and administrative governmental authorities which may delay or restrict our ability to continue to develop or commercialize EYLEA, ZALTRAP, and ARCALYST and other product and drug candidates and possible new indications for marketed products; the ability for us to manufacture and manage supply chains for multiple products and product candidates; competing drugs and product candidates that may be superior to EYLEA, ZALTRAP, and ARCALYST and our product and drug candidates and possible new indications for marketed products; uncertainty of market acceptance of EYLEA, ZALTRAP, and ARCALYST and our product and drug candidates and possible new indications for marketed products; coverage and reimbursement determinations by third-party payers, including Medicare and Medicaid; unforeseen safety issues resulting from the administration of products and product candidates in patients; unanticipated expenses; the costs of developing, producing, and selling products; the ability for us to meet any of our financial projections or guidance 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 canceled or terminated without any further product success; and risks associated with third-party intellectual property and pending or future litigation relating thereto. These statements are made by us based on management's current beliefs and judgment. In evaluating such statements, shareholders and potential investors should specifically consider the various factors identified under the caption “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, except as required by law.

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. Our total revenues were $457.6 million in the second quarter and $897.3 million in the first half of 2013, compared to $304.4 million in the second quarter and $536.2 million in the first half of 2012. Our net income was $87.4 million, or $0.79 per diluted share, in the second quarter and $186.3 million, or $1.69 per diluted share, in the first half of 2013, compared to net income of $76.7 million, or $0.70 per diluted share, in the second quarter and $88.4 million, or $0.81 per diluted share, in the first half of 2012.

We currently have three marketed products:

- EYLEA® (aflibercept) Injection, known in the scientific literature as VEGF Trap-Eye, which is available in the United States for the treatment of neovascular age-related macular degeneration (wet AMD) and macular edema following central retinal vein occlusion (CRVO), and in the United Kingdom, Germany, Switzerland, Australia, Japan, and certain other countries for the treatment of wet AMD. Net product sales of EYLEA in the United States were $329.8 million in the second quarter and $643.7 million in the first half of 2013, compared to $194.0 million in the second quarter and $317.5 million in the first half of 2012. EYLEA net product sales outside of the United States, which are recorded by Bayer HealthCare, commenced in the fourth quarter of 2012, and were $95.6 million in the second quarter and $160.4 million in the first half of 2013.

We commenced sales of EYLEA for the treatment of wet AMD in November 2011 and for the treatment of macular edema following CRVO in September 2012, following receipt of regulatory approval in the United States. Bayer HealthCare commenced sales of EYLEA for the treatment of wet AMD in the fourth quarter of 2012 following receipt

of regulatory approvals in the European Union (EU) and other regions. Bayer HealthCare has additional regulatory applications for EYLEA for the treatment of wet AMD pending in other countries. In addition, Bayer HealthCare has submitted applications for marketing authorization for EYLEA in Europe, Japan, and other countries for the treatment of macular edema following CRVO. In July 2013, the European Committee for Medicinal Products for Human Use (CHMP) recommended approval of EYLEA to the European Medicines Agency (EMA) for the treatment of macular edema secondary to CRVO.

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In August 2013, we and Bayer HealthCare announced positive week 52 results from the Phase 3 VIVID-DME and VISTA-DME trials of EYLEA for the treatment of diabetic macular edema (DME), as described below under "Clinical Programs: EYLEA - Ophthalmologic Diseases." Based on discussions with the U.S. Food and Drug Administration (FDA), we now expect to submit an application for U.S. marketing approval for the treatment of DME in 2013, approximately one year ahead of the previously announced timeline. Bayer HealthCare plans to submit an application for marketing approval for the treatment of DME in Europe in 2013.

We are collaborating with Bayer HealthCare on the global development and commercialization of EYLEA outside the United States. Bayer HealthCare markets 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 a royalty on sales of EYLEA, as described below. We maintain exclusive rights to EYLEA in the United States and are entitled to all profits from any such sales.

- ZALTRAP® (ziv-aflibercept) Injection for Intravenous Infusion, known in the scientific literature as VEGF Trap, which is available in the United States 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. In February 2013, the European Commission (EC) granted marketing authorization in the European Union for ZALTRAP 25mg/ml concentrate for solution for infusion in combination with FOLFIRI chemotherapy in adults with mCRC that is resistant to or has progressed after an oxaliplatin-containing regimen. Regulatory applications for marketing authorization of ZALTRAP for the treatment of previously treated mCRC patients in other countries have also been submitted and are currently under review by the respective regulatory agencies.

We and Sanofi globally collaborate on the development and commercialization of ZALTRAP, and share profits and losses from commercialization of ZALTRAP, except for Japan, where we are entitled to a royalty on sales of ZALTRAP, as described below. ZALTRAP net product sales, which are recorded by Sanofi, commenced in the United States in August 2012 and in Europe in the first quarter of 2013, and were $18.6 million in the second quarter and $32.7 million in the first half of 2013.

- 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 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 totaled $4.1 million in the second quarter and $8.9 million in the first half of 2013, compared to $5.5 million in the second quarter and $9.9 million in the first half of 2012.

We have 14 product candidates in clinical development, all of which were discovered in our research laboratories. Our Trap-based clinical programs are:

- EYLEA, which is in clinical trials for the treatment of DME and macular edema following branch retinal vein occlusion (BRVO), in collaboration with Bayer HealthCare; and
- ZALTRAP, which is being studied in combination with our angiopoietin-2 inhibitor (nesvacumab) in oncology in collaboration with Sanofi.

Our antibody-based clinical programs include twelve fully human monoclonal antibodies. The following seven are being developed in collaboration with Sanofi:

- Sarilumab (REGN88), an antibody to the interleukin-6 receptor (IL-6R), which is being developed in rheumatoid arthritis and non-infectious uveitis;
-

Alirocumab (REGN727), an antibody to Proprotein Convertase Subtilisin/Kexin type 9 (PCSK9), which is being developed for low-density lipoprotein (LDL) cholesterol reduction;

- Dupilumab (REGN668), an antibody to the interleukin-4 receptor (IL-4R), which is being developed in atopic dermatitis and allergic asthma;
- Enoticumab (REGN421), an antibody to Delta-like ligand-4 (Dll4), a novel angiogenesis target, which is being developed in oncology;
- Nesvacumab (REGN910), an antibody to angiopoietin-2 (Ang2), another novel angiogenesis target, which is being developed in oncology;
- REGN1033, an antibody to myostatin (GDF8), which is being developed in metabolic disorders; and

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- REGN2009, an antibody in clinical development against an undisclosed target.

In addition, we are developing the following five antibodies independently:

- REGN1400, an antibody to ErbB3, which is being developed in oncology;
- REGN1154, an antibody in clinical development against an undisclosed target;
- REGN1500, an antibody in clinical development against an undisclosed target;
- REGN1193, an antibody in clinical development against an undisclosed target; and
- Fasinumab (REGN475), an antibody to Nerve Growth Factor (NGF), which is being developed for the treatment of pain and which is currently on clinical hold by the FDA.

Development of REGN846, which completed a Phase 1 study against an undisclosed target, was discontinued in the second quarter of 2013.

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. Our long-term objective is 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. Under the terms of our antibody collaboration with Sanofi, which was expanded during 2009, we plan to advance a total of 20 to 30 candidates into clinical development over the life of the agreement. We continue to invest in the development of enabling technologies to assist in our efforts to identify, develop, manufacture, and commercialize new product candidates.

Clinical Programs:

1. EYLEA - Ophthalmologic Diseases

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. In CRVO and BRVO, a blockage occurs in the main blood vessel that transports deoxygenated blood away from the retina. VEGF levels are elevated in response, contributing to macular edema. For clinically significant DME, VEGF-mediated leakage of fluid from blood vessels in the eye results in interference with vision.

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.

We, together with our ex-U.S. collaborator Bayer HealthCare, are evaluating EYLEA in Phase 3 programs in patients with DME, macular edema following BRVO, and, in Asia, myopic choroidal neovascularization (mCNV) of the retina as a result of pathologic myopia. Wet AMD, diabetic retinopathy (which includes DME), and retinal vein occlusion 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.

In August 2013, we and Bayer HealthCare announced that in the Phase 3 VIVID-DME and VISTA-DME trials of EYLEA for the treatment of DME, EYLEA 2 milligrams (mg) dosed monthly and EYLEA 2 mg dosed every two

months (after 5 initial monthly injections) achieved the primary endpoint of a significantly greater improvement in best-corrected visual acuity (BCVA) from baseline compared to laser photocoagulation at 52 weeks. Both EYLEA treatment arms demonstrated similar improvements in BCVA.

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Based on discussions with the FDA, we now expect to submit an application for U.S. marketing approval for the treatment of DME in 2013, approximately one year ahead of the previously announced timeline. Bayer HealthCare plans to submit an application for marketing approval for the treatment of DME in Europe in 2013.

We are conducting the VISTA-DME study in the United States. Bayer HealthCare is conducting the VIVID-DME study in Europe, Japan, and Australia. These two trials are similarly designed, randomized, double-masked, active control trials to evaluate the safety and efficacy of EYLEA in patients with DME. Patients in both trials were randomized to receive either EYLEA 2 mg monthly, EYLEA 2 mg every two months (after 5 initial monthly injections), or the comparator treatment of laser photocoagulation.

In the VISTA-DME trial, after one year patients receiving EYLEA 2 mg monthly had a mean change from baseline in BCVA of 12.5 letters ($p<0.0001$ compared to laser) and patients receiving EYLEA 2 mg every other month (after 5 initial monthly injections) had a mean change from baseline in BCVA of 10.7 letters ($p<0.0001$ compared to laser), compared to patients receiving laser photocoagulation who had a mean change from baseline in BCVA of 0.2 letters.

In the VIVID-DME trial, after one year patients receiving EYLEA 2 mg monthly had a mean change from baseline in BCVA of 10.5 letters ($p<0.0001$ compared to laser) and patients receiving EYLEA 2 mg every other month (after 5 initial monthly injections) had a mean change from baseline in BCVA of 10.7 letters ($p<0.0001$ compared to laser), compared to patients receiving laser photocoagulation who had a mean change from baseline in BCVA of 1.2 letters.

In these trials, EYLEA was generally well tolerated with a similar overall incidence of adverse events (AEs), ocular serious AEs, and non-ocular serious AEs across the treatment groups and the laser control group. Arterial thromboembolic events as defined by the Anti-Platelet Trialists' Collaboration (non-fatal stroke, non-fatal myocardial infarction, and vascular death) also occurred at similar rates across the treatment groups and the laser control group. AEs were typical of those seen in other studies in patients with diabetes receiving intravitreal anti-VEGF therapy. The most frequent ocular treatment emergent AEs (TEAEs) observed in the VIVID-DME and VISTA-DME trials included conjunctival hemorrhage, eye pain, and vitreous floaters. The most frequent non-ocular TEAEs included hypertension and nasopharyngitis, which occurred with similar frequency in the treatment groups and the laser control group.

Full one-year data from the VIVID-DME and VISTA-DME trials will be presented at upcoming medical conferences. Both trials are planned to continue up to 148 weeks. An additional Phase 3 safety study in Japan (VIVID-Japan) was initiated in the first quarter of 2012 and is required for approval in Japan. In February 2013, we and Bayer HealthCare also initiated another Phase 3 study to evaluate the efficacy and safety of EYLEA in DME in Russia, China, and other Asian countries (VIVID EAST-DME).

In the fourth quarter of 2011, we and Bayer HealthCare initiated a Phase 3 trial in China evaluating the efficacy and safety of EYLEA in wet AMD (SIGHT). The trial is expected to include approximately 300 patients.

In the second quarter of 2012, we initiated a multinational study of EYLEA in patients with macular edema following BRVO (VIBRANT). This study is fully enrolled, and primary endpoint data are expected by the end of 2013.

In the fourth quarter of 2012, we initiated a study to fulfill a post-marketing requirement by the FDA, RE-VIEW, which will evaluate the effect of EYLEA on corneal endothelium.

In June 2013, we and Bayer HealthCare announced positive top-line results for EYLEA from the Phase 3 MYRROR study in mCNV. In this trial, patients receiving EYLEA at an initial dose of 2 mg, followed by treatment on an as-needed (PRN) basis, had a mean improvement in BCVA from baseline at week 24 of 12.1 letters, compared to a loss of 2.0 letters in patients receiving sham injections ($p < 0.0001$). The most common adverse events observed in the MYRROR trial that occurred with a frequency of 2% or more were conjunctival hemorrhage, dry eye, eye pain, headache, and nasopharyngitis. Data from this study will be presented at an upcoming medical conference. Bayer HealthCare expects to submit the first application for regulatory approval for this indication in Asia by the end of 2013.

2. ZALTRAP (ziv-aflibercept) - Oncology

ZALTRAP is a fusion protein that is designed to bind all forms of VEGF-A, VEGF-B, and P1GF, and prevent their interaction with cell surface receptors. VEGF-A (and to a lesser degree, P1GF) is required for the growth of new blood vessels (a process known as angiogenesis) that are needed for tumors to grow.

During the third quarter of 2012, we and Sanofi initiated a Phase 1b study of a combination of ZALTRAP and our angiopoietin-2 inhibitor (nesvacumab) in patients with advanced solid malignancies.

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

IL-6 is a key cytokine involved in the pathogenesis of rheumatoid arthritis, causing inflammation and joint destruction. A therapeutic antibody to IL-6R, ACTEMRA® (tocilizumab), a registered trademark of Chugai Seiyaku Kabushiki Kaisha, has been approved for the treatment of rheumatoid arthritis.

Sarilumab is a fully human monoclonal antibody to IL-6R generated using our VelocImmune technology. In July 2011, we and Sanofi announced that in the Phase 2b stage of the SARIL-RA-MOBILITY trial in rheumatoid arthritis (RA), patients treated with sarilumab in combination with a standard RA treatment, methotrexate (MTX), achieved a significant and clinically meaningful improvement in signs and symptoms of moderate-to-severe RA compared to patients treated with MTX alone. The primary endpoint of the study was the proportion of patients achieving at least a 20% improvement in RA symptoms (ACR20) after 12 weeks.

The Phase 3 Part B SARIL-RA-MOBILITY study in patients with RA is fully enrolled. This trial will assess the improvement in signs and symptoms at 24 weeks and the treatment effect of sarilumab on radiographic progression at one year. In addition, we and Sanofi have initiated additional Phase 3 studies, SARIL-RA-TARGET, SARIL-RA-COMPARE, and SARIL-RA- ASCERTAIN. The broad SARIL-RA clinical development program is focused on adult populations with moderate-to-severe RA who are inadequate responders to either MTX or tumor necrosis factor alpha (TNF-alpha) inhibitor therapy. SARIL-RA-TARGET is a randomized, double-blind, placebo-controlled study evaluating sarilumab in combination with non-biologic, disease-modifying anti-rheumatic drugs (DMARDS) in moderate-to-severe active RA patients with inadequate responses to, or who are intolerant of, one or more TNF-alpha inhibitors. The SARIL-RA-COMPARE study is evaluating the safety and efficacy of sarilumab plus MTX compared to etanercept (a TNF-alpha inhibitor) plus MTX in adult patients with moderate-to-severe RA who demonstrate an inadequate response to adalimumab as their first TNF-alpha inhibitor therapy. The SARIL-RA-ASCERTAIN study is evaluating the safety and tolerability of sarilumab versus a calibrator, tocilizumab, both in combination with MTX, in patients with RA who are inadequate responders to, or intolerant of, TNF-alpha inhibitors.Patients who complete SARIL-RA-MOBILITY, SARIL-RA-TARGET, or SARIL-RA-ASCERTAIN are offered enrollment into the ongoing SARIL-RA-EXTEND, which is an open-label, long-term safety study of sarilumab.

A Phase 1 study was initiated in May 2013 in Japan assessing the safety and tolerability of sarilumab in patients with RA.

In addition, a Phase 2 study, SARIL-NIU-SATURN, will commence in the third quarter of 2013 and is a placebo-controlled proof of concept study evaluating the safety and efficacy of sarilumab in non-infectious uveitis.

4. Alirocumab (REGN727; PCSK9 Antibody) for LDL cholesterol reduction

Elevated LDL cholesterol (“bad cholesterol”) level is a validated risk factor leading to cardiovascular disease. Statins are a class of drugs that lower LDL through inhibition of HMG-CoA, an enzyme regulating the early and rate-limiting step in cholesterol biosynthesis. PCSK9 is a secreted protein that plays a key role in modulating LDL cholesterol levels in the body. PCSK9 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 cholesterol, but also a significant reduction in the risk of coronary heart disease. We used our VelocImmune technology to generate a fully human monoclonal antibody inhibitor of PCSK9, called alirocumab, that is intended to lower LDL cholesterol.

Alirocumab has been studied in three Phase 2 clinical studies, two in patients with primary hypercholesterolemia and one in patients with heterozygous familial hypercholesterolemia (heFH). In the Phase 2 studies, alirocumab significantly reduced LDL-cholesterol from baseline up to 72% on top of standard of care statin therapy. Consistent and robust reductions in other lipid parameters, including a reduction in lipoprotein-a (Lp(a)) were also observed. Lp(a) is another form of bad cholesterol which is believed to be a risk factor for coronary heart disease and strokes when elevated. In the Phase 2 program, injection site reactions were the most common adverse events with alirocumab, and were rare. Rare cases of hypersensitivity reaction were also reported. Serious adverse events (SAEs) were reported in 1.8% of patients (5/275) in the active treatment arms and 2.6% of patients (2/77) in the placebo groups.

We and Sanofi initiated the global Phase 3 ODYSSEY program for alirocumab in June 2012. The ODYSSEY program will enroll more than 22,000 patients. This includes eleven clinical trials evaluating the effect of alirocumab, dosed every two weeks, on lowering LDL cholesterol. The 18,000 patient ODYSSEY OUTCOMES trial, assessing reduction in serious cardiovascular events, and several other trials in the ODYSSEY program, are currently enrolling patients. LDL cholesterol reduction is expected to be the primary efficacy endpoint for initial regulatory filings. In addition, a trial of alirocumab dosed every four weeks (ODYSSEY CHOICE) will commence by the end of 2013. The ODYSSEY studies are being conducted in clinical centers around the world including the United States, Canada, Western and Eastern Europe, South America, Australia, and Asia.

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We expect to report initial results from the Phase 3 ODYSSEY MONO trial by the end of 2013. The ODYSSEY MONO trial is evaluating the efficacy and safety of alirocumab monotherapy versus ezetimibe monotherapy in patients with primary hypercholesterolemia.

5. Dupilumab (REGN668; IL-4R Antibody) for allergic and immune conditions

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 dermatitis and allergic asthma. Dupilumab is a fully human monoclonal antibody generated using our VelocImmune technology that is designed to bind to IL-4R.

Dupilumab demonstrated positive proof of concept in patients with atopic dermatitis and allergic asthma. Data from two Phase 1b trials in atopic dermatitis was presented at the American Academy of Dermatology annual meeting in March 2013. The efficacy data showed that treatment with four weekly subcutaneous injections of dupilumab at either 150 mg or 300 mg per week, significantly improved the signs and symptoms of patients with moderate-to-severe atopic dermatitis whose disease was not adequately controlled with topical medications. The most common AEs were nasopharyngitis (19.6% vs 12.5% for placebo) and headache (11.8% vs 6.3% for placebo).

Data from a Phase 2a trial in allergic asthma were presented at the American Thoracic Society in May 2013, and were also published in the New England Journal of Medicine in June 2013. In this study, patients receiving dupilumab experienced an 87% reduction in the incidence of asthma exacerbations compared to patients receiving placebo ($p<0.0001$). Clinically meaningful and statistically significant improvements were observed for lung function and other asthma control parameters, such as forced expiratory volume over one second ($FEV_1$) (difference from baseline to week 12 between dupilumab and placebo of 0.27 L, $p < 0.001$). Treatment-emergent AEs were reported by a similar proportion of patients in both groups (76.9% placebo; 80.8% dupilumab). AEs were generally non-specific and of mild-to-moderate intensity. The most common AEs for placebo and dupilumab were injection-site reaction (9.6% and 28.8%), nasopharyngitis (3.8% and 13.5%), upper respiratory tract infection (17.3% and 13.5%), headache (5.8% and 11.5%) and nausea (1.9% and 7.7%).

In the second quarter of 2013, a Phase 2b trial in allergic asthma and a Phase 2b trial in atopic dermatitis were both initiated and are currently enrolling patients.

6. Enoticumab (REGN421; Dll4 Antibody) for advanced malignancies

In many clinical settings, positively or negatively regulating blood vessel growth could have important therapeutic benefits, as could the repair of damaged and leaky vessels. VEGF was the first growth factor shown to be specific for blood vessels, by virtue of having its receptor primarily expressed on blood vessel cells. In the December 21, 2006 issue of the journal Nature, we reported data from a preclinical study demonstrating that blocking an important cell signaling molecule, known as Dll4, inhibited the growth of experimental tumors by interfering with their ability to produce a functional blood supply. The inhibition of tumor growth was seen in a variety of tumor types, including those that were resistant to blockade of VEGF, suggesting a novel anti-angiogenesis therapeutic approach. Moreover, inhibition of tumor growth is enhanced by the combination of Dll4 and VEGF blockade in many preclinical tumor models.

Enoticumab is a fully human monoclonal antibody to Dll4 generated using our VelocImmune technology, and is in Phase 1 clinical development.

7. Nesvacumab (REGN910; Ang2 Antibody) for oncology and ophthalmology

The angiopoietins, which were discovered at Regeneron, are ligands for the endothelial cell receptor Tie2 and are essential for vascular development and angiogenesis. Unlike other family members, angiopoietin-2 (Ang2) is strongly upregulated by endothelial cells at sites of angiogenesis and vascular remodeling, including tumors. Enhanced anti-tumor effects have been observed in preclinical models with combined blockade of both VEGF and Ang2.

Nesvacumab is a fully human monoclonal antibody generated using our VelocImmune technology that is designed to block Ang2. Nesvacumab is in Phase 1 clinical development in oncology. In addition, during the third quarter of 2012, we and Sanofi initiated a Phase 1b study evaluating nesvacumab in combination with ZALTRAP in patients with advanced solid malignancies.

In May 2013, we acquired from Sanofi full rights to antibodies targeting the Ang2 receptor and ligand in ophthalmology, as described below. We expect to file an investigational new drug application (IND) for Ang2 in

ophthalmology by the end of 2013.

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8. REGN1033 (GDF8 Antibody)
In January 2012, we initiated a Phase 1 clinical study for REGN1033, a fully human monoclonal GDF8 antibody generated using our VelocImmune technology. Myostatin has been validated as a target to increase muscle mass and strength through genetic mutations in both animals and humans that abrogate its bioactivity.
9. REGN2009
REGN2009 is a fully human monoclonal antibody generated using our VelocImmune technology, against an undisclosed target. In June 2013, we initiated a Phase 1 clinical study.
10. REGN1400 (ErbB3 Antibody) for oncology
REGN1400 is a fully human monoclonal antibody generated using our VelocImmune technology, against ErbB3. In the fourth quarter of 2012, REGN1400 entered into Phase 1 clinical development in oncology.
11. REGN1154
REGN1154 is a fully human monoclonal antibody generated using our VelocImmune technology, against an undisclosed target. In March 2012, we initiated a Phase 1 clinical study in Australia. Sanofi decided not to opt-in to the REGN1154 program and we have sole global rights. Under the terms of our agreement, Sanofi is entitled to receive a mid-single digit royalty on any future sales of REGN1154.
12. REGN1500
REGN1500 is a fully human monoclonal antibody generated using our VelocImmune technology, against an undisclosed target. In December 2012, we initiated a Phase 1 clinical study. Sanofi decided not to opt-in to the REGN1500 program and we have sole global rights. Under the terms of our agreement, Sanofi is entitled to receive a mid-single digit royalty on any future sales of REGN1500.
13. REGN1193
REGN1193 is a fully human monoclonal antibody generated using our VelocImmune technology, against an undisclosed target. A Phase 1 clinical study of REGN1193 will commence in the third quarter of 2013. Sanofi decided not to opt-in to the REGN1193 program and we have sole global rights. Under the terms of our agreement, Sanofi is entitled to receive a mid-single digit royalty on any future sales of REGN1193.
14. Fasinumab (REGN475; NGF Antibody) for pain (on clinical hold)
Fasinumab is a fully human monoclonal antibody to NGF, generated using our VelocImmune technology, which is designed to block pain sensitization in neurons. Preclinical experiments indicate that fasinumab specifically binds to and blocks NGF activity and does not bind to or block cell signaling for the closely related neurotrophins NT-3 and BDNF.
In December 2012, the FDA placed fasinumab and other investigational agents targeting NGF on clinical hold based on preclinical findings with other anti-NGF agents in development. Prior to the FDA clinical hold action, we were planning to initiate late-stage clinical trials with fasinumab. There are currently no ongoing trials with fasinumab that are either enrolling or treating patients.
Sanofi elected not to continue co-development of fasinumab, and we have sole global rights. Under the terms of our agreement, Sanofi is entitled to receive a mid-single digit royalty on any future sales of fasinumab.

Acquisition of Ophthalmology Development Programs from Sanofi
In May 2013, we acquired from Sanofi full exclusive rights to two families of novel antibodies invented at Regeneron and previously included in our antibody collaboration with Sanofi. We acquired full rights to antibodies targeting the PDGF (platelet derived growth factor) family of receptors and ligands in ophthalmology and all other indications and to antibodies targeting the Ang2 receptor and ligand in ophthalmology. Antibodies to the PDGF receptor and Ang2 are currently in preclinical development for use in ophthalmology.

With respect to PDGF antibodies, we made a $10.0 million up-front payment to Sanofi in May 2013, and will pay up to $40 million in potential development milestone payments and royalties on any future sales. With respect to Ang2 antibodies in ophthalmology, we also made a $10.0 million up-front payment to Sanofi in May 2013, and will pay a potential $5 million development milestone payment and royalties on any future sales.

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We and Sanofi will continue to develop antibodies to Ang2 outside of ophthalmology under our antibody collaboration agreement, including nesvacumab, as described above.

Research Programs

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

Research and Development Technologies

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

Our scientists have developed two different technologies to design protein therapeutics to block the action of specific cell surface or secreted proteins. The first technology, termed the "Trap" technology, was used to generate our three approved products, 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.

Collaboration Agreements

Collaborations with Sanofi

ZALTRAP. We and Sanofi globally collaborate on the development and commercialization of ZALTRAP. Under the terms of our September 2003 collaboration agreement, as amended, we and Sanofi share co-promotion rights and share profits and losses from commercialization of ZALTRAP outside of Japan. In Japan, we are entitled to a royalty of approximately 35% on sales of ZALTRAP, subject to certain potential adjustments.

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Under the ZALTRAP collaboration agreement, as amended, agreed upon worldwide development expenses incurred by both companies during the term of the agreement are funded by Sanofi. If the collaboration becomes profitable, we will be obligated to reimburse Sanofi out of our share of ZALTRAP profits (including royalties on sales of ZALTRAP in Japan) for 50% of the development expenses that they funded. The reimbursement payment in any quarter will equal 5% of the then outstanding repayment obligation, but never more than our share of the ZALTRAP profits in the quarter unless we elect to reimburse Sanofi at a faster rate. As a result, we expect that, initially, our share of any ZALTRAP profits will be used to reimburse Sanofi for this repayment obligation.

Antibodies. In November 2007, we and Sanofi entered into a global, strategic collaboration to discover, develop, and commercialize fully human monoclonal antibodies. The collaboration is governed by a Discovery and Preclinical Development Agreement and a License and Collaboration Agreement. In connection with the execution of the discovery agreement in 2007, we received a non-refundable, up-front payment of $85.0 million from Sanofi. Pursuant to the collaboration, Sanofi is funding our research to identify and validate potential drug discovery targets and develop fully human monoclonal antibodies against these targets. We lead the design and conduct of research activities under the collaboration, including target identification and validation, antibody development, research and preclinical activities through filing of an IND or its equivalent, toxicology studies, and manufacture of preclinical and clinical supplies.

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

Sanofi will lead commercialization activities for products developed under the license agreement, subject to our right to co-promote such products. The parties will equally share profits and losses from sales within the United States. The parties will share profits outside the United States on a sliding scale based on sales starting at 65% (Sanofi)/35% (us) and ending at 55% (Sanofi)/45% (us), and will share losses outside the United States at 55% (Sanofi)/45% (us). In addition to profit sharing, we are entitled to receive up to $250 million in sales milestone payments, with milestone payments commencing after aggregate annual sales outside the United States exceed $1.0 billion on a rolling 12-month basis.

In November 2009, we and Sanofi amended these agreements to expand and extend our antibody collaboration. The goal of the expanded collaboration is to advance a total of 20 to 30 new antibody product candidates into clinical development from 2010 through 2017.

Under the amended discovery agreement, Sanofi agreed to fund up to $160 million per year of our antibody discovery activities over the period from 2010-2017. Sanofi has an option to extend the discovery program for up to an additional three years after 2017 for further antibody development and preclinical activities. Pursuant to the collaboration, Sanofi funded $30 million of agreed-upon costs we incurred to expand our manufacturing capacity at our Rensselaer, New York facilities.

In August 2008, we entered into an agreement with Sanofi, which extended through December 2012, to use our VelociGene platform to supply Sanofi with genetically modified mammalian models of gene function and disease. Under this agreement, Sanofi is paying us a total of $21.5 million for knock-out and transgenic models of gene function for target genes identified by Sanofi. These models are used by Sanofi for its internal research programs that are outside of the scope of our antibody collaboration.

Collaboration with Bayer HealthCare

In October 2006, we entered into a license and collaboration agreement with Bayer HealthCare 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 May 2012, Bayer HealthCare's Japanese subsidiary, Bayer Yakuhin, Ltd., and Santen Pharmaceutical Co., Ltd. entered into an agreement to co-promote EYLEA in Japan. In conjunction with this agreement, we and Bayer HealthCare amended our existing global license and collaboration agreement for EYLEA to convert the 50/50 profit share for Japan into a royalty agreement under which we are entitled to receive a tiered royalty of between 33.5% and 40.0% of EYLEA annual net sales in Japan. In certain specified circumstances, the Japan royalty may revert to a profit share arrangement.

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We may also receive up to $25 million in additional milestone payments related to marketing approvals of EYLEA in other indications in major market countries outside the United States, and can earn up to $135 million in sales milestone payments if twelve-month sales of EYLEA outside the United States achieve certain specified levels starting at $200 million.

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 royalties on sales of EYLEA in Japan). The reimbursement payment in any quarter will equal 5% of the then outstanding repayment obligation, but never more than our share of the collaboration profits in the quarter unless we elect to reimburse Bayer HealthCare at a faster rate. As a result, we expect that, initially, a portion of our share of EYLEA profits outside the United States will be used to reimburse Bayer HealthCare for this repayment obligation.

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

License Agreement with Astellas

In March 2007, we entered into a six-year, non-exclusive license agreement with Astellas Pharma Inc. to allow Astellas to utilize our VelocImmune technology in its internal research programs to discover human monoclonal antibodies. In July 2010, the license agreement with Astellas was amended and extended through June 2023. Under the terms of the amended agreement, Astellas made a $165.0 million up-front payment to us in August 2010. In addition, Astellas will make a $130.0 million second payment to us in June 2018 unless the license agreement has been terminated prior to that date. Astellas has the right to terminate the agreement at any time by providing 90 days' advance written notice. Under certain limited circumstances, such as our material breach of the agreement, Astellas may terminate the agreement and receive a refund of a portion of its up-front payment or, if such termination occurs after June 2018, a portion of its second payment, to us under the July 2010 amendment to the agreement. We are entitled to receive a mid-single digit royalty on any future sales of antibody products discovered by Astellas using our VelocImmune technology.

Royalty Agreement with Novartis Pharma AG

Under a June 2009 agreement with Novartis (that replaced a previous collaboration and license agreement), we receive royalties on worldwide sales of Novartis' canakinumab, a fully human anti-interleukin-IL1ß antibody. The royalty rates in the agreement start at 4% and reach 15% when annual sales exceed $1.5 billion. Canakinumab is marketed for the treatment of CAPS and gouty arthritis, and is in earlier stage development for atherosclerosis and other inflammatory diseases. We are unable to predict whether these royalties will ever contribute materially to our results of operations or financial condition.

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General

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

Beginning in the first quarter of 2012, we reported profitability; prior to that, we generally incurred net losses. Our ability to continue to generate profits and to generate positive cash flow from operations over the next several years depends significantly on our 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. Our operating results may fluctuate from quarter to quarter and will depend on, among other factors, the net sales of our marketed products, the scope and progress of our research and development efforts, the timing of certain expenses, and the continuation of our collaborations with Sanofi and Bayer HealthCare, including our share of collaboration profits or losses, or royalties, 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 our marketed products will receive regulatory approval or, if any such approval is received, whether we will be able to successfully commercialize such product(s) and whether or when they may become profitable.

The planning, execution, and results of our clinical programs are significant factors that can affect our operating and financial results. In our clinical programs, key events in 2013 to date were, and plans for the next 12 months are, as follows:

Trap-based Clinical Programs:

| 2013 Events to Date | 2013-14 Plans (next 12 months) |
|---|---|
| EYLEA | |
| Bayer HealthCare received regulatory approval for EYLEA in New Zealand, South Korea, and other countries for the treatment of patients with wet AMD and continued to pursue regulatory applications for marketing approval in other countries | Regulatory agency decisions on additional applications outside the United States for the treatment of wet AMD and macular edema following CRVO |
| Bayer HealthCare received regulatory approval for EYLEA in first country outside the United States for the treatment of patients with macular edema following CRVO and continued to pursue regulatory applications for marketing approval in other countries | Report six month primary endpoint results for VIBRANT study in macular edema following BRVO |
| Completed enrollment of VIBRANT study in macular edema following BRVO | File for regulatory approval in the United States for the treatment of DME |
| Initiated Phase 3 VIVID EAST-DME study in Russia, China, and other Asian countries | Bayer HealthCare to file for ex-US regulatory approval in DME and myopic CNV |
| Reported positive one year results from the Phase 3 VIVID-DME and VISTA-DME studies | |
| Reported positive results from the Phase 3 MYRROR study in myopic CNV | |
| ZALTRAP | |
| European Commission granted marketing authorization in the European Union for ZALTRAP for patients with | Regulatory agency decisions outside the United States on additional applications for ZALTRAP in the |

| | |
|---|---|
| mCRC that is resistant to or has progressed following an oxaliplatin-containing regimen | treatment of previously treated mCRC patients |

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Antibody-based Clinical Programs:

| | 2013 Events to Date | 2013-14 Plans (next 12 months) |
|---|---|---|
| Sarilumab (IL-6R Antibody) | Continued enrollment in Phase 3 SARIL-RA program<br>Initiated SARIL-RA-ASCERTAIN and SARIL-RA-COMPARE Phase 3 studies in rheumatoid arthritis | Report results from SARIL-RA-MOBILITY study<br>Commence SARIL-NIU-SATURN Phase 2 study in non-infectious uveitis |
| Alirocumab (PCSK9 Antibody) | Continued patient enrollment in Phase 3 ODYSSEY trials | Continue enrollment of the Phase 3 ODYSSEY trials<br>Report results from several Phase 3 ODYSSEY trials, including results from ODYSSEY MONO trial<br>Initiate Phase 3 ODYSSEY CHOICE trial |
| Dupilumab (IL-4R Antibody) | Reported results for Phase 1b studies in atopic dermatitis<br>Reported results from Phase 2a study in allergic asthma. Results were also published online in the New England Journal of Medicine<br>Initiated patient enrollment in Phase 2b trials in allergic asthma and atopic dermatitis | Report results from Phase 2a study in atopic dermatitis |
| Enoticumab (Dll4 Antibody) | Continued patient enrollment in Phase 1 program | Complete patient enrollment in the expansion of the Phase 1 program |
| Nesvacumab (Ang2 Antibody) | Continued patient enrollment in Phase 1 program | Complete patient enrollment in the Phase 1b program in advanced malignancies<br>Initiate clinical development in ophthalmology |
| REGN1033 (GDF8 Antibody) | Continued patient enrollment in Phase 1 program | Initiate Phase 2a study |
| REGN1400 (ErbB3 Antibody) | Continued patient enrollment in Phase 1 program | Continue patient enrollment in Phase 1 program |
| REGN1154 (target not disclosed) | Completion of Phase 1 program | |
| REGN1500 (target not disclosed) | Continued patient enrollment in Phase 1 program | Continue patient enrollment in Phase 1 program |
| REGN1193 (target not disclosed) | Initiated Phase 1 program | Initiate and continue patient enrollment in Phase 1 program |
| REGN2009 (target not disclosed) | Initiated patient enrollment in Phase 1 program | Continue patient enrollment in Phase 1 program |
| Fasinumab (NGF Antibody) | On clinical hold | Determine future development plan |

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Results of Operations

Three Months Ended June 30, 2013 and 2012

Net Income

We reported net income of $87.4 million, or $0.79 per diluted share, for the second quarter of 2013, compared to $76.7 million, or $0.70 per diluted share, for the second quarter of 2012. The increase in net income resulted primarily from an increase in net product sales of EYLEA, which we launched in November 2011, partly offset by higher operating and income tax expenses, as described below.

Revenues

Revenues for the three months ended June 30, 2013 and 2012 consist of the following:

| (In millions) | 2013 | 2012 |
|---|---|---|
| Net product sales | $333.9 | $199.5 |
| Collaboration revenue: | | |
| Sanofi | 85.5 | 89.0 |
| Bayer HealthCare | 31.1 | 9.1 |
| Total collaboration revenue | 116.6 | 98.1 |
| Technology licensing revenue | 5.9 | 5.9 |
| Other revenue | 1.2 | 0.9 |
| Total revenue | $457.6 | $304.4 |

Net Product Sales

Net product sales consist of U.S. sales of EYLEA and ARCALYST. In November 2011, we received marketing approval from the FDA for EYLEA for the treatment of wet AMD, at which time product sales commenced. In addition, in September 2012, we received marketing approval from the FDA for EYLEA for the treatment of macular edema following CRVO. For the three months ended June 30, 2013 and 2012, we recognized EYLEA net product sales of $329.8 million and $194.0 million, respectively. For the three months ended June 30, 2013 and 2012, we also recognized ARCALYST net product sales of $4.1 million and $5.5 million, respectively.

For the three months ended June 30, 2013 and 2012, we recorded 76% and 79%, respectively, of our total gross product revenue from sales to Besse Medical, a subsidiary of AmerisourceBergen Corporation.

We record product sales net of allowances and accruals for rebates and chargebacks under governmental programs (including Medicaid), distribution-related fees, prompt pay discounts, product returns, and other sales-related deductions. The following table summarizes the provisions, and credits/payments, for sales-related deductions for the three months ended June 30, 2013 and 2012.

| (In millions) | Rebates & Chargebacks | Distribution-Related Fees | Other Sales-Related Deductions | Total |
|---|---|---|---|---|
| Balance as of March 31, 2013 | $3.7 | $ 17.7 | $0.5 | $21.9 |
| Provision related to current period sales | 5.6 | 15.5 | 0.3 | 21.4 |
| Credits/payments | (5.2) | (14.7) | (0.3) | (20.2) |
| Balance as of June 30, 2013 | $4.1 | $ 18.5 | $0.5 | $23.1 |
| | | | | |
| Balance as of March 31, 2012 | $2.8 | $ 5.5 | $0.5 | $8.8 |
| Provision related to current period sales | 3.8 | 11.0 | 1.6 | 16.4 |
| Credits/payments | (1.8) | (5.4) | (0.6) | (7.8) |
| Balance as of June 30, 2012 | $4.8 | $ 11.1 | $1.5 | $17.4 |

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Sanofi Collaboration Revenue

The collaboration revenue we earned from Sanofi, as detailed below, consisted primarily of reimbursement for research and development expenses that we incurred, recognition of our share of losses in connection with Sanofi's commercialization of ZALTRAP, and recognition of revenue related to non-refundable up-front payments.

In addition, Sanofi collaboration revenue for the three months ended June 30, 2013 was reduced by two $10.0 million up-front payments to Sanofi in connection with our acquisition from Sanofi of full exclusive rights to two families of novel antibodies, as described below.

| Sanofi Collaboration Revenue | Three months ended June 30, | |
|---|---|---|
| (In millions) | 2013 | 2012 |
| ZALTRAP: | | |
| Regeneron's share of losses in connection with commercialization of ZALTRAP | $(8.2) | $(8.4) |
| Reimbursement of Regeneron research and development and other expenses | 2.8 | 4.2 |
| Recognition of deferred revenue related to up-front payments | 1.4 | 2.9 |
| Total ZALTRAP | (4.0) | (1.3) |
| Antibody: | | |
| Reimbursement of Regeneron research and development expenses | 107.0 | 87.8 |
| Up-front payments to Sanofi for acquisition of rights related to two antibodies | (20.0) | |
| Recognition of deferred revenue related to up-front and other payments | 2.1 | 2.1 |
| Recognition of revenue related to VelociGene agreement | 0.4 | 0.4 |
| Total Antibody | 89.5 | 90.3 |
| Total Sanofi collaboration revenue | $85.5 | $89.0 |

Sanofi commenced sales of ZALTRAP (ziv-aflibercept) Injection for Intravenous Infusion, in combination with FOLFIRI, for patients with 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 countries in Europe in the first quarter of 2013.

Regeneron's share of the loss in connection with commercialization of ZALTRAP, as shown in the table below, represents our 50% share of ZALTRAP net product sales less cost of goods sold and shared commercialization and other expenses.

| Regeneron's share of losses in connection with commercialization of ZALTRAP | Three months ended June 30, | |
|---|---|---|
| (In millions) | 2013 | 2012 |
| Net product sales recorded by Sanofi | $18.6 | |
| Regeneron's share of collaboration losses | (8.2) | $(8.4) |

Our share of the loss in the second quarter of 2013 consisted of costs in connection with launching ZALTRAP which were only partly offset by net product sales. Sanofi provides us with an estimate of our share of the profit or loss from commercialization of ZALTRAP for the most recent fiscal quarter. Sanofi's estimates of net products sales and related expenses for such quarter are reconciled to their actual net product sales and related expenses in the subsequent fiscal quarter, and our portion of the profit or loss is adjusted accordingly, as necessary.

Recognition of deferred revenue related to the ZALTRAP up-front payments from Sanofi decreased in the second quarter of 2013, compared to the same period of 2012, due to lengthening the estimated performance period over which this deferred revenue is being recognized, effective in the first quarter of 2013. In connection with recognition of deferred revenue related to ZALTRAP, as of June 30, 2013, $8.7 million of the original $105.0 million of up-front payments was deferred and will be recognized as revenue in future periods.

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In the second quarter of 2013, Sanofi's reimbursement of our antibody expenses consisted of $44.0 million under our discovery agreement and $63.0 million of development costs under our license agreement, compared to $46.5 million and $41.3 million, respectively, in the second quarter of 2012. The higher reimbursement of development costs in the second quarter of 2013, compared to the same period of 2012, was primarily due to increased development activities for dupilumab and alirocumab.

In May 2013, we acquired from Sanofi full exclusive rights to two families of novel antibodies invented at Regeneron and previously included in our antibody collaboration with Sanofi. We acquired full rights to antibodies targeting the PDGF family of receptors and ligands in ophthalmology and all other indications and to antibodies targeting the Ang2 receptor and ligand in ophthalmology. With respect to PDGF antibodies, we made a $10.0 million up-front payment to Sanofi in May 2013. With respect to Ang2 antibodies in ophthalmology, we also made a $10.0 million up-front payment to Sanofi in May 2013.

As it relates to recognition of deferred revenue, in connection with the November 2009 amendment of the discovery agreement, Sanofi has funded $30 million of agreed-upon costs incurred by us to expand our manufacturing capacity at our Rensselaer, New York facilities. Revenue related to such funding from Sanofi was deferred and is being recognized as collaboration revenue prospectively over the related performance period in conjunction with the recognition of the original $85.0 million up-front payment. As of June 30, 2013, $64.9 million of the up-front and other payments was deferred and will be recognized as revenue in future periods.

Bayer HealthCare Collaboration Revenue

The collaboration revenue we earned from Bayer HealthCare, as detailed below, consisted of recognition of our share of profits in connection with commercialization of EYLEA outside the United States, cost-sharing of Regeneron EYLEA development expenses and reimbursement of other Regeneron EYLEA expenses, and recognition of revenue related to a non-refundable $75.0 million up-front payment received in 2006 and a $20.0 million milestone payment received in 2007 (which, for the purpose of revenue recognition, was not considered substantive).

| Bayer HealthCare Collaboration Revenue | Three months ended June 30, | |
|---|---|---|
| (In millions) | 2013 | 2012 |
| Regeneron's net profit in connection with commercialization of EYLEA outside the United States | $19.0 | |
| Cost-sharing of Regeneron EYLEA development expenses | 3.7 | $7.1 |
| Reimbursement of other Regeneron EYLEA expenses | 6.4 | |
| Recognition of deferred revenue related to up-front and other milestone payments | 2.0 | 2.0 |
| Total Bayer HealthCare collaboration revenue | $31.1 | $9.1 |

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Bayer HealthCare commenced sales of EYLEA for the treatment of wet AMD in the fourth quarter of 2012 following receipt of regulatory approvals in the European Union, Japan, and other countries. 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<br>(In millions) | Three months ended<br>June 30, 2013 |
|---|---|
| Net product sales outside the United States recorded by Bayer HealthCare | $95.6 |
| Regeneron's share of collaboration profit from sales outside the United States | 34.2 |
| Reimbursement of EYLEA development expenses incurred by Bayer HealthCare in accordance with Regeneron's payment obligation | (15.2) |
| Regeneron's net profit in connection with commercialization of EYLEA outside the United States | $19.0 |

Our share of the profit and the Japan royalties we earned from commercialization of EYLEA outside the United States were partly offset by our contractual obligation to reimburse Bayer HealthCare for a portion of the agreed-upon development expenses previously incurred by Bayer HealthCare. Bayer HealthCare provides us with an estimate of our share of the profit or loss from commercialization of EYLEA outside the United States for the most recent fiscal quarter. Bayer HealthCare's estimates of net product sales and related expenses for such quarter are reconciled to their actual net product sales and related expenses in the subsequent fiscal quarter, and our portion of the profit or loss is adjusted accordingly, as necessary.

Cost-sharing of our global EYLEA development expenses with Bayer HealthCare decreased in the second quarter of 2013 compared to the same period in 2012. In the second quarter of 2013, we incurred lower costs in connection with our EYLEA clinical development programs in wet AMD and macular edema following CRVO.

Reimbursement of other Regeneron EYLEA expenses in the second quarter of 2013 primarily related to Bayer HealthCare's share of royalties payable to Genentech in connection with ex-US sales of EYLEA.

As of June 30, 2013, $25.7 million of the up-front and 2007 milestone payments was deferred and will be recognized as revenue in future periods.

Technology Licensing Revenue

In connection with the amendment and extension of our VelocImmune license agreement with Astellas, in August 2010, we received a $165.0 million up-front payment, which was deferred upon receipt and is being recognized as revenue ratably over a seven-year period beginning in June 2011. In the second quarter of both 2013 and 2012, we recognized $5.9 million of technology licensing revenue related to this agreement. As of June 30, 2013, $116.4 million of the August 2010 technology licensing payment received from Astellas was deferred and will be recognized as revenue in future periods.

Other Revenue

Under a June 2009 agreement with Novartis, we receive royalties on worldwide sales of Novartis' canakinumab. In the second quarter of 2013 and 2012, other revenue included $1.1 million and $0.8 million, respectively, of royalties from Novartis.

Expenses

Total operating expenses increased to $299.5 million in the second quarter of 2013 from $216.9 million in the second quarter of 2012. Our average headcount in the second quarter of 2013 increased to 2,083 from 1,783 in the same period of 2012, principally in connection with expanding our research and development, and commercialization, activities.

Operating expenses in the second quarter of 2013 and 2012 included a total of $44.4 million and $19.6 million, respectively, of non-cash compensation expense related to employee stock option and restricted stock awards (Non-cash Compensation Expense). The increase in total Non-cash Compensation Expense in the second quarter of 2013 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 2012 compared to recent prior years.

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Research and Development Expenses

Research and development expenses increased to $187.5 million in the second quarter of 2013 from $147.4 million in the same period of 2012. The following table summarizes the major categories of our research and development expenses for the three months ended June 30, 2013 and 2012:

| Research and Development Expenses | Three months ended June 30, | | Increase |
|---|---|---|---|
| (In millions) | 2013 | 2012 | (Decrease) |
| Payroll and benefits [1] | $71.2 | $50.8 | $20.4 |
| Clinical trial expenses | 27.1 | 19.3 | 7.8 |
| Clinical manufacturing costs [2] | 43.3 | 39.3 | 4.0 |
| Research and other development costs | 17.0 | 13.0 | 4.0 |
| Occupancy and other operating costs | 22.9 | 20.4 | 2.5 |
| Cost-sharing of Bayer HealthCare EYLEA development expenses [3] | 6.0 | 4.6 | 1.4 |
| Total research and development expenses | $187.5 | $147.4 | $40.1 |

(1) Includes Non-cash Compensation Expense of $24.7 million for the three months ended June 30, 2013 and $10.3 million for the three months ended June 30, 2012.

(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. Includes Non-cash Compensation Expense of $3.0 million for the three months ended June 30, 2013 and $1.2 million for the three months ended June 30, 2012.

(3) Under our collaboration with Bayer HealthCare, in periods when Bayer HealthCare incurs EYLEA development expenses, we also recognize, as additional research and development expense, the portion of Bayer HealthCare's EYLEA development expenses that we are obligated to reimburse. Bayer HealthCare provides us with estimated EYLEA development expenses for the most recent fiscal quarter. Bayer HealthCare's estimate is reconciled to its actual expenses for such quarter in the subsequent fiscal quarter and our portion of its EYLEA 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 higher costs for clinical studies of alirocumab, dupilumab, and EYLEA, partly offset by lower costs related to our Phase 3 program for ARCALYST, which has concluded. Clinical manufacturing costs increased primarily due to higher costs related to manufacturing dupilumab and other antibody candidates, partly offset by lower costs related to manufacturing clinical supplies of ARCALYST.

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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 collaboration with Bayer HealthCare, the portion of Bayer HealthCare's EYLEA development expenses that we are obligated to reimburse. Our estimates of research and development costs for clinical development programs are shown below.

| Project Costs | Three months ended June 30, | | Increase |
|---|---|---|---|
| (In millions) | 2013 | 2012 | (Decrease) |
| EYLEA | $32.0 | $27.3 | $4.7 |
| ARCALYST | 1.1 | 15.0 | (13.9) |
| ZALTRAP | 2.7 | 5.7 | (3.0) |
| Alirocumab | 26.9 | 18.0 | 8.9 |
| Sarilumab | 6.1 | 5.9 | 0.2 |
| Dupilumab | 20.7 | 5.7 | 15.0 |
| Other antibody candidates in clinical development | 22.0 | 9.5 | 12.5 |
| Other research programs and unallocated costs | 76.0 | 60.3 | 15.7 |
| Total research and development expenses | $187.5 | $147.4 | $40.1 |

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 Biologics License Application (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 or additional indications for our marketed products in clinical development will generate material product revenues and net cash inflows.

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Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased to $72.5 million in the second quarter of 2013 from $47.7 million in the same period of 2012 due to higher expenses in connection with commercialization of EYLEA, including the Branded Prescription Drug Fee (as described in the Liquidity and Capital Resources section below) and contributions to a not-for-profit organization that assists patients with chronic disease conditions, and higher Non-cash Compensation Expense principally for the reason described above. Selling, general, and administrative expenses included $16.3 million and $7.8 million of Non-cash Compensation Expense in the second quarter of 2013 and 2012, respectively.

Cost of Goods Sold

Cost of goods sold increased to $27.3 million in the second quarter of 2013 from $21.8 million in the same period of 2012 due primarily to increased sales of EYLEA. Cost of goods sold primarily consisted of royalties, as well as costs in connection with producing EYLEA and ARCALYST commercial supplies. In addition, cost of goods sold in the second quarter of 2013 and 2012 included inventory write-downs and reserves totaling $1.7 million and $6.5 million, respectively. We record a charge to cost of goods sold to write down our inventory to its estimated realizable value if certain batches or units of product do not meet quality specifications or are expected to expire prior to sale.

Cost of Collaboration Manufacturing

We manufacture commercial supplies of product for our collaborators. Cost of collaboration manufacturing in the second quarter of 2013 was $12.3 million, which primarily consisted of third party royalties, as well as costs in connection with producing commercial supplies for our collaborators. 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.

Other Income and Expense

Interest expense increased slightly to $11.4 million in the second quarter of 2013 from $11.2 million in the same period of 2012. In October 2011, we issued $400.0 million aggregate principal amount of 1.875% convertible senior notes. Total interest expense in the second quarter of 2013 and 2012 associated with these notes, including amortization of the note discount and debt issuance costs, was $7.3 million and $7.2 million, respectively.

Income Taxes

In the second quarter of 2013, we recorded a $60.3 million income tax provision. The effective tax rate for the second quarter was 40.8%.

In the second quarter of 2012, income tax expense relating to our pre-tax income was fully offset by a reversal of a portion of our valuation allowance. As of June 30, 2012, we continued to recognize a full valuation allowance against our net operating loss carry-forward and other deferred tax assets since we had an extended history of losses. In the fourth quarter of 2012, we recorded an income tax benefit attributable to the release of substantially all of the remaining valuation allowance against our deferred tax assets. The decision to release this valuation allowance was made after we determined that it was more likely than not that these deferred tax assets would be realized.

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Six Months Ended June 30, 2013 and 2012

Net Income

We reported net income of $186.3 million, or $1.69 per diluted share, for the first half of 2013, compared to $88.4 million, or $0.81 per diluted share, for the first half of 2012. The increase in net income resulted primarily from an increase in net product sales of EYLEA, which we launched in November 2011, partly offset by higher operating and income tax expenses, as described below.

Revenues

Revenues for the six months ended June 30, 2013 and 2012 consist of the following:

| (In millions) | 2013 | 2012 |
|---|---|---|
| Net product sales | $652.6 | $327.4 |
| Collaboration revenue: | | |
| Sanofi | 184.8 | 174.0 |
| Bayer HealthCare | 46.0 | 21.6 |
| Total collaboration revenue | 230.8 | 195.6 |
| Technology licensing revenue | 11.8 | 11.8 |
| Other revenue | 2.1 | 1.4 |
| Total revenue | $897.3 | $536.2 |

Net Product Sales

Net product sales consist of U.S. sales of EYLEA and ARCALYST. In November 2011, we received marketing approval from the FDA for EYLEA for the treatment of wet AMD, at which time product sales commenced. In addition, in September 2012, we received marketing approval from the FDA for EYLEA for the treatment of macular edema following CRVO. For the six months ended June 30, 2013 and 2012, we recognized EYLEA net product sales of $643.7 million and $317.5 million, respectively. For the six months ended June 30, 2013 and 2012, we also recognized ARCALYST net product sales of $8.9 million and $9.9 million, respectively.

For the six months ended June 30, 2013 and 2012, we recorded 77% and 79%, respectively, of our total gross product revenue from sales to Besse Medical, a subsidiary of AmerisourceBergen Corporation.

We record product sales net of allowances and accruals for rebates and chargebacks under governmental programs (including Medicaid), distribution-related fees, prompt pay discounts, product returns, and other sales-related deductions. The following table summarizes the provisions, and credits/payments, for sales-related deductions for the six months ended June 30, 2013 and 2012.

| (In millions) | Rebates & Chargebacks | Distribution-Related Fees | Other Sales-Related Deductions | Total |
|---|---|---|---|---|
| Balance as of December 31, 2012 | $3.0 | $ 15.3 | $0.5 | $18.8 |
| Provision related to current period sales | 11.1 | 29.4 | 0.5 | 41.0 |
| Credits/payments | (10.1) | (26.2) | (0.5) | (36.8) |
| Balance as of June 30, 2013 | $4.0 | $ 18.5 | $0.5 | $23.0 |
| | | | | |
| Balance as of December 31, 2011 | $0.6 | $ 1.5 | $0.2 | $2.3 |
| Provision related to current period sales | 6.2 | 17.9 | 2.4 | 26.5 |
| Credits/payments | (2.0) | (8.3) | (1.1) | (11.4) |
| Balance as of June 30, 2012 | $4.8 | $ 11.1 | $1.5 | $17.4 |

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Sanofi Collaboration Revenue

The collaboration revenue we earned from Sanofi, as detailed below, consisted primarily of reimbursement for research and development expenses that we incurred, recognition of our share of losses in connection with Sanofi's commercialization of ZALTRAP, and recognition of revenue related to non-refundable up-front payments.

In addition, Sanofi collaboration revenue for the six months ended June 30, 2013 was reduced by two $10.0 million up-front payments to Sanofi in connection with our acquisition from Sanofi of full exclusive rights to two families of novel antibodies, as described below.

| Sanofi Collaboration Revenue | Six months ended June 30, | |
|---|---|---|
| (In millions) | 2013 | 2012 |
| ZALTRAP: | | |
| Regeneron's share of losses in connection with commercialization of ZALTRAP | $(16.0) | $(12.1) |
| Reimbursement of Regeneron research and development and other expenses | 5.4 | 7.0 |
| Recognition of deferred revenue related to up-front payments | 2.8 | 5.4 |
| Total ZALTRAP | (7.8) | 0.3 |
| Antibody: | | |
| Reimbursement of Regeneron research and development expenses | 207.5 | 168.6 |
| Up-front payments to Sanofi for acquisition of rights related to two antibodies | (20.0) | |
| Recognition of deferred revenue related to up-front and other payments | 4.3 | 4.3 |
| Recognition of revenue related to VelociGene agreement | 0.8 | 0.8 |
| Total Antibody | 192.6 | 173.7 |
| Total Sanofi collaboration revenue | $184.8 | $174.0 |

Sanofi commenced sales of ZALTRAP (ziv-aflibercept) Injection for Intravenous Infusion, in combination with FOLFIRI, for patients with 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 countries in Europe in the first quarter of 2013.

Regeneron's share of the loss in connection with commercialization of ZALTRAP, as shown in the table below, represents our 50% share of ZALTRAP net product sales less cost of goods sold and shared commercialization and other expenses.

| Regeneron's share of losses in connection with commercialization of ZALTRAP | Six months ended June 30, | |
|---|---|---|
| (In millions) | 2013 | 2012 |
| Net product sales recorded by Sanofi | $32.7 | |
| Regeneron's share of collaboration losses | (16.0) | $(12.1) |

Our share of the loss increased in the first half of 2013, compared to the first half of 2012, because of higher costs in connection with launching ZALTRAP which were only partly offset by net product sales. Sanofi provides us with an estimate of our share of the profit or loss from commercialization of ZALTRAP for the most recent fiscal quarter. Sanofi's estimates of net products sales and related expenses for such quarter are reconciled to their actual net product sales and related expenses in the subsequent fiscal quarter, and our portion of the profit or loss is adjusted accordingly, as necessary.

Recognition of deferred revenue related to the ZALTRAP up-front payments from Sanofi decreased in the first half of 2013, compared to the same period of 2012, due to lengthening the estimated performance period over which this deferred revenue is being recognized, effective in the first quarter of 2013.

In the first half of 2013, Sanofi's reimbursement of our antibody expenses consisted of $88.7 million under our discovery agreement and $118.8 million of development costs under our license agreement, compared to $91.1 million and $77.5 million,

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respectively, in the first half of 2012. The higher reimbursement of development costs in the first half of 2013, compared to the same period of 2012, was primarily due to increased development activities for alirocumab and dupilumab.

As described above, in May 2013, we made two $10.0 million up-front payments to Sanofi in connection with acquiring from Sanofi full exclusive rights to antibodies targeting the PDGF family of receptors and ligands in ophthalmology and all other indications and to antibodies targeting the Ang2 receptor and ligand in ophthalmology.

As it relates to recognition of deferred revenue, in connection with the November 2009 amendment of the discovery agreement, Sanofi has funded $30 million of agreed-upon costs incurred by us to expand our manufacturing capacity at our Rensselaer, New York facilities. Revenue related to such funding from Sanofi was deferred and is being recognized as collaboration revenue prospectively over the related performance period in conjunction with the recognition of the original $85.0 million up-front payment.

Bayer HealthCare Collaboration Revenue

The collaboration revenue we earned from Bayer HealthCare, as detailed below, consisted primarily of recognition of our share of profits in connection with commercialization of EYLEA outside the United States, cost-sharing of Regeneron EYLEA development expenses and reimbursement of other Regeneron EYLEA expenses, and recognition of revenue related to a non-refundable $75.0 million up-front payment received in 2006 and a $20.0 million milestone payment received in 2007 (which, for the purpose of revenue recognition, was not considered substantive).

| Bayer HealthCare Collaboration Revenue | Six months ended June 30, | |
|---|---|---|
| (In millions) | 2013 | 2012 |
| Regeneron's net profit in connection with commercialization of EYLEA outside the United States | $25.4 | |
| Cost-sharing of Regeneron EYLEA development expenses | 9.6 | $17.6 |
| Reimbursement of other Regeneron EYLEA expenses | 7.0 | |
| Recognition of deferred revenue related to up-front and other milestone payments | 4.0 | 4.0 |
| Total Bayer HealthCare collaboration revenue | $46.0 | $21.6 |

Bayer HealthCare commenced sales of EYLEA for the treatment of wet AMD in the fourth quarter of 2012 following receipt of regulatory approvals in the European Union, Japan, and other countries. 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 | Six months ended |
|---|---|
| (In millions) | June 30, 2013 |
| Net product sales outside the United States recorded by Bayer HealthCare | $160.4 |
| Regeneron's share of collaboration profit from sales outside the United States | 53.8 |
| Reimbursement of EYLEA development expenses incurred by Bayer HealthCare in accordance with Regeneron's payment obligation | (28.4) |
| Regeneron's net profit in connection with commercialization of EYLEA outside the United States | $25.4 |

Our share of the profit and the Japan royalties we earned from commercialization of EYLEA outside the United States were partly offset by our contractual obligation to reimburse Bayer HealthCare for a portion of the agreed-upon development expenses previously incurred by Bayer HealthCare. Bayer HealthCare provides us with an estimate of our share of the profit or loss from

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commercialization of EYLEA outside the United States for the most recent fiscal quarter. Bayer HealthCare's estimates of net product sales and related expenses for such quarter are reconciled to their actual net product sales and related expenses in the subsequent fiscal quarter, and our portion of the profit or loss is adjusted accordingly, as necessary.

Cost-sharing of our global EYLEA development expenses with Bayer HealthCare decreased in the first half of 2013 compared to the same period in 2012. In the first half of 2013, we incurred lower costs in connection with our EYLEA clinical development programs in wet AMD and macular edema following CRVO.

Reimbursement of other Regeneron EYLEA expenses in the first half of 2013 primarily related to Bayer HealthCare's share of royalties payable to Genentech in connection with ex-US sales of EYLEA.

Technology Licensing Revenue

In connection with the amendment and extension of our VelocImmune license agreement with Astellas, in August 2010, we received a $165.0 million up-front payment, which was deferred upon receipt and is being recognized as revenue ratably over a seven-year period beginning in June 2011. In the first half of both 2013 and 2012, we recognized $11.8 million of technology licensing revenue related to this agreement.

Other Revenue

Under a June 2009 agreement with Novartis, we receive royalties on worldwide sales of Novartis' canakinumab. In the first half of 2013 and 2012, other revenue included $2.1 million and $1.3 million, respectively, of royalties from Novartis.

Expenses

Total operating expenses increased to $586.2 million in the first half of 2013 from $426.5 million in the first half of 2012. Our average headcount in the first half of 2013 increased to 2,039 from 1,756 in the same period of 2012, principally in connection with expanding our research and development, and commercialization, activities.

Operating expenses in the first half of 2013 and 2012 included a total of $97.5 million and $42.9 million, respectively, of Non-cash Compensation Expense. The increase in total Non-cash Compensation Expense in the first half of 2013 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 2012 compared to recent prior years.

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Research and Development Expenses

Research and development expenses increased to $367.8 million in the first half of 2013 from $286.2 million in the same period of 2012. The following table summarizes the major categories of our research and development expenses for the six months ended June 30, 2013 and 2012:

| Research and Development Expenses | Six months ended June 30, | | Increase |
|---|---|---|---|
| (In millions) | 2013 | 2012 | (Decrease) |
| Payroll and benefits [1] | $140.3 | $102.2 | $38.1 |
| Clinical trial expenses | 51.8 | 42.6 | 9.2 |
| Clinical manufacturing costs [2] | 91.9 | 66.3 | 25.6 |
| Research and other development costs | 31.1 | 25.8 | 5.3 |
| Occupancy and other operating costs | 44.3 | 39.2 | 5.1 |
| Cost-sharing of Bayer HealthCare EYLEA development expenses [3] | 8.4 | 10.1 | (1.7) |
| Total research and development expenses | $367.8 | $286.2 | $81.6 |

(1) Includes Non-cash Compensation Expense of $48.4 million for the six months ended June 30, 2013 and $19.8 million for the six months ended June 30, 2012.

(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. Includes Non-cash Compensation Expense of $6.1 million for the six months ended June 30, 2013 and $2.2 million for the six months ended June 30, 2012.

(3) Under our collaboration with Bayer HealthCare, in periods when Bayer HealthCare incurs EYLEA development expenses, we also recognize, as additional research and development expense, the portion of Bayer HealthCare's EYLEA development expenses that we are obligated to reimburse. Bayer HealthCare provides us with estimated EYLEA development expenses for the most recent fiscal quarter. Bayer HealthCare's estimate is reconciled to its actual expenses for such quarter in the subsequent fiscal quarter and our portion of its EYLEA 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 higher costs for clinical studies of alirocumab, dupilumab, and other early stage antibody candidates, partly offset by lower costs related to our Phase 3 trials of EYLEA in wet AMD and macular edema following CRVO, and ARCALYST, which have concluded. Clinical manufacturing costs increased primarily due to higher costs related to manufacturing alirocumab and dupilumab, partly offset by lower costs related to manufacturing sarilumab and clinical supplies of ARCALYST.

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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 collaboration with Bayer HealthCare, the portion of Bayer HealthCare's EYLEA development expenses that we are obligated to reimburse. Our estimates of research and development costs for clinical development programs are shown below.

| Project Costs | Six months ended June 30, | | Increase |
|---|---|---|---|
| (In millions) | 2013 | 2012 | (Decrease) |
| EYLEA | $62.4 | $62.2 | $0.2 |
| ARCALYST | 3.7 | 25.8 | (22.1) |
| ZALTRAP | 5.7 | 8.5 | (2.8) |
| Alirocumab | 58.1 | 25.1 | 33.0 |
| Sarilumab | 11.6 | 17.2 | (5.6) |
| Dupilumab | 32.9 | 10.8 | 22.1 |
| Other antibody candidates in clinical development | 44.3 | 19.1 | 25.2 |
| Other research programs and unallocated costs | 149.1 | 117.5 | 31.6 |
| Total research and development expenses | $367.8 | $286.2 | $81.6 |

For the reasons described above under "Research and Development Expenses" for the three months ended June 30, 2013 and 2012, 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 or additional indications for our marketed products in clinical development will generate material product revenues and net cash inflows.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased to $149.7 million in the first half of 2013 from $106.1 million in the same period of 2012 due to higher expenses in connection with commercialization of EYLEA, including the Branded Prescription Drug Fee (as described in the Liquidity and Capital Resources section below) and contributions to a not-for-profit organization that assists patients with chronic disease conditions, and higher Non-cash Compensation Expense principally for the reason described above. Selling, general, and administrative expenses included $42.1 million and $20.4 million of Non-cash Compensation Expense in the first half of 2013 and 2012, respectively.

Cost of Goods Sold

Cost of goods sold increased to $55.3 million in the first half of 2013 from $34.1 million in the same period of 2012 due primarily to increased sales of EYLEA. Cost of goods sold primarily consisted of royalties, as well as costs in connection with producing EYLEA and ARCALYST commercial supplies. In addition, cost of goods sold in the first half of 2013 and 2012 included inventory write-downs and reserves totaling $4.9 million and $8.4 million, respectively. We record a charge to cost of goods sold to write down our inventory to its estimated realizable value if certain batches or units of product do not meet quality specifications or are expected to expire prior to sale.

Cost of Collaboration Manufacturing

We manufacture commercial supplies of product for our collaborators. Cost of collaboration manufacturing in the first half of 2013 was $13.4 million, which primarily consisted of third party royalties, as well as costs in connection with producing commercial supplies for our collaborators. 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.

Other Income and Expense

Interest expense increased slightly to $23.0 million in the first half of 2013 from $22.4 million in the same period of 2012. In October 2011, we issued $400.0 million aggregate principal amount of 1.875% convertible senior notes. Total interest expense in

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the first half of 2013 and 2012 associated with these notes, including amortization of the note discount and debt issuance costs, was $15.0 million and $14.3 million, respectively.

Income Taxes

In the first half of 2013, we recorded a $103.3 million income tax provision. The effective tax rate for the first half was 35.7%, which included, as a discrete item in the first quarter of 2013, the impact of enacting The American Taxpayer Relief Act in January 2013. The American Taxpayer Relief Act included a provision to extend the income tax credit for increased research activities retroactively to the tax year ended December 31, 2012. As a result, our 2012 research tax credit reduced our effective tax rate for the first half of 2013 by 6.0%.

In the first half of 2012, income tax expense relating to our pre-tax income was fully offset by a reversal of a portion of our valuation allowance. As of June 30, 2012, we continued to recognize a full valuation allowance against our net operating loss carry-forward and other deferred tax assets since we had an extended history of losses. In the fourth quarter of 2012, we recorded an income tax benefit attributable to the release of substantially all of the remaining valuation allowance against our deferred tax assets. The decision to release this valuation allowance was made after we determined that it was more likely than not that these deferred tax assets would be realized.

Liquidity and Capital Resources

In 2012, we became profitable and began to generate cash from our product sales of EYLEA. From our inception in 1988, we have financed our operations primarily through offerings of our equity securities, private placements of convertible debt, purchases of our equity securities by our collaborators, including Sanofi, revenue earned under our past and present research and development agreements, including our agreements with Sanofi and Bayer HealthCare, EYLEA and ARCALYST product revenue, our technology licensing agreements, our past contract manufacturing agreements, and investment income.

Sources and Uses of Cash for the Six Months Ended June 30, 2013 and 2012

At June 30, 2013, we had $710.8 million in cash, cash equivalents, and marketable securities compared with $587.5 million (including $8.2 million of restricted cash and marketable securities) at December 31, 2012. In connection with our product launch of EYLEA in November 2011, we have offered extended payment terms to our EYLEA customers. As a result, due to the growth of our EYLEA product sales, our net trade accounts receivable have increased to $767.9 million at June 30, 2013 from $593.2 million at December 31, 2012. During the six months ended June 30, 2013, we collected $508.7 million of EYLEA trade receivables, and we expect such collections to increase during the rest of the year.

Cash Provided by (Used in) Operating Activities

Net cash provided by operating activities was $214.4 million in the first half of 2013. Our net income of $186.3 million in the first half of 2013 included the following non-cash expenses: (i) Non-cash Compensation Expense of $97.5 million, (ii) depreciation and amortization of $19.1 million, (iii) non-cash interest expense of $11.3 million, resulting from the amortization of the discount and debt issuance costs in connection with our convertible senior notes, which were issued in October 2011, and (iv) other non-cash charges, including $4.9 million of inventory write-downs and reserves and $10.8 million of other non-cash tax related charges. In addition, deferred tax assets at June 30, 2013 decreased by $92.5 million, compared to end-of-year 2012, primarily due to utilization of these assets to offset income taxes payable for the first half of 2013.

At June 30, 2013, Sanofi and trade accounts receivable increased by $182.9 million, compared to end-of-year 2012, primarily due to higher trade accounts receivable in connection with EYLEA product sales, as described above. Prepaid expenses and other assets increased by $51.7 million, compared to end-of-year 2012, primarily due to higher balances of capitalized inventory costs, principally in connection with EYLEA commercial supplies, and a higher

receivable balance due from Bayer HealthCare in connection with the launch of EYLEA outside the United States. Our deferred revenue at June 30, 2013 decreased by $11.6 million, compared to end-of-year 2012, primarily due to amortization of a previously deferred $165.0 million payment under our license agreement with Astellas and amortization of previously deferred payments under our Sanofi and Bayer HealthCare collaborations, partly offset by costs of product manufactured and shipped to Sanofi and Bayer HealthCare for which recognition of revenue has been deferred. Accounts payable, accrued expenses, and other liabilities increased by $35.6 million at June 30, 2013, compared to end-of-year 2012, primarily due to higher sales-related charges, deductions, and royalties related to EYLEA and higher payroll-related liabilities.

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Net cash used in operating activities was $165.4 million in the first half of 2012. Our net income of $88.4 million in the first half of 2012 included the following non-cash expenses: (i) Non-cash Compensation Expense of $42.9 million, (ii) depreciation and amortization of $17.8 million, (iii) non-cash interest expense of $11.2 million, including $10.5 million resulting from the amortization of the discount and debt issuance costs in connection with our convertible senior notes, which were issued in October 2011, and (iv) other non-cash charges, including $8.4 million of inventory write-downs and reserves.

At June 30, 2012, Sanofi and trade accounts receivable increased by $332.3 million, compared to end-of-year 2011, primarily due to higher trade accounts receivable in connection with higher EYLEA product sales and the extended payment terms granted to our EYLEA customers, as described above. Prepaid expenses and other assets increased by $19.5 million, compared to end-of-year 2011, primarily due to due to higher balances of capitalized inventory costs, principally in connection with EYLEA commercial supplies. Our deferred revenue at June 30, 2012 decreased by $17.7 million, compared to end-of-year 2011, primarily due to amortization of a previously received and deferred $165.0 million payment under our license agreement with Astellas and amortization of previously deferred payments under our Sanofi and Bayer HealthCare collaborations. Accounts payable, accrued expenses, and other liabilities increased by $32.8 million at June 30, 2012, compared to end-of-year 2011, primarily due to higher sales-related deductions and royalties in connection with EYLEA.

Cash Used in Investing Activities

Net cash used in investing activities was $31.1 million and $123.4 million in the first half of 2013 and 2012, respectively. In the first half of 2013, sales or maturities of marketable securities exceeded purchases by $24.6 million. In the first half of 2012, purchases of marketable securities exceeded sales or maturities of marketable securities by $99.0 million. Capital expenditures of $55.7 million and $23.9 million in the first half of 2013 and 2012, respectively, included costs in connection with expanding our Rensselaer, New York manufacturing facilities and tenant improvement and associated costs related to our leased facilities in Tarrytown, New York.

Cash Used in Financing Activities

Net cash used in financing activities was $32.0 million and $22.8 million in the first half of 2013 and 2012, respectively. Proceeds from issuances of Common Stock were $34.3 million in the first half of 2013, compared to $39.6 million in the first half of 2012. In addition, payments for employee tax obligations in connection with stock option exercises were $73.1 million in the first half of 2013, compared to $61.4 million in the first half of 2012.

Fair Value of Marketable Securities

At June 30, 2013 and December 31, 2012, we held marketable securities whose aggregate fair value totaled $329.2 million and $354.9 million, respectively. The composition of our portfolio of marketable securities on these dates was as follows:

| | June 30, 2013 | | December 31, 2012 | |
|---|---|---|---|---|
| Investment type | Fair Value | Percent | Fair Value | Percent |
| Unrestricted | | | | |
| U.S. government and government agency obligations | $85.4 | 26 % | $328.1 | 92 % |
| Corporate bonds | 157.3 | 48 % | | |
| Commercial paper | 62.2 | 19 % | | |
| Municipal bonds | 17.2 | 5 % | 17.5 | 5 % |
| International government agency obligations | 4.8 | 1 % | | |
| Equity securities | 2.3 | 1 % | 3.4 | 1 % |
| Total unrestricted marketable securities | 329.2 | 100 % | 349.0 | 98 % |
| Restricted | | | | |
| U.S. government obligations | | | 5.9 | 2 % |
| Total marketable securities | $329.2 | 100 % | $354.9 | 100 % |

In addition, at June 30, 2013, we had $381.7 million of cash and cash equivalents, primarily held in bank deposits and money market funds. At December 31, 2012, we had $232.6 million of cash, cash equivalents, and restricted cash, primarily held in money market funds that invest in U.S. government securities. During the second quarter of 2013,

either due to cancellation of the

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associated letter of credit or easing of lender requirements, all formerly restricted marketable securities were reclassified as unrestricted on our balance sheet.

Capital Expenditures

Our cash expenditures for property, plant, and equipment totaled $55.7 million for the first six months of 2013 and $23.9 million in the first six months of 2012.

In July 2013, we reached preliminary agreement to acquire a 400,000 square foot facility in Limerick, Ireland, subject to entering into definitive agreements as well as securing permits from the local government in Limerick. We intend to renovate this facility to accommodate and support our growth, primarily in connection with expanding our manufacturing capacity to support our global supply chain.

We expect to incur capital expenditures of approximately $225 to $300 million during the remainder of 2013 and 2014 primarily in connection with expanding our manufacturing facilities at our Rensselaer facility, tenant improvements at our leased Tarrytown facilities, purchasing and commencing renovations on the new Limerick facility described above (predicated on finalizing its purchase), and purchases of equipment.

License and Settlement Agreements with Genentech

On December 31, 2011, we entered into a Non-Exclusive License and Partial Settlement Agreement with Genentech (the Original Genentech Agreement) that covered making, using, and selling EYLEA in the United States for the prevention and treatment of human eye diseases and disorders in the United States, and ended the litigation relating to those matters. The Original Genentech Agreement provided for us to make payments to Genentech based on U.S. sales of EYLEA through May 7, 2016, the date the Davis-Smyth patents expire. Under the Original Genentech Agreement, we made a $60 million milestone payment when cumulative U.S. sales reached $400 million and are obligated to pay royalties of 4.75% on cumulative relevant sales of EYLEA between $400 million and $3 billion and 5.5% on any cumulative relevant sales of EYLEA over $3 billion.

Effective May 17, 2013, we entered into an Amended and Restated Non-Exclusive License and Settlement Agreement with Genentech (the Amended Genentech Agreement), which amended the Original Genentech Agreement to now include all sales of EYLEA worldwide and ended the litigation relating to those matters. Under the Amended Genentech Agreement, we received a worldwide non-exclusive license to the Davis-Smyth patents, and certain other patents, owned or co-owned by Genentech for the prevention or treatment of human eye diseases and eye disorders through administration of EYLEA to the eye. Under the Amended Genentech Agreement, we will make payments to Genentech based on sales of EYLEA in the United States and EYLEA manufactured in the United States and sold outside the United States through May 7, 2016 using the same milestone and royalty rates as in the Original Genentech Agreement. EYLEA is sold outside the United States by affiliates of Bayer HealthCare under our license and collaboration agreement. All payments to Genentech under the Original Genentech Agreement and the Amended Genentech Agreement have been or will be made by Regeneron. Bayer HealthCare will share in all such payments based on the proportion of ex-U.S. EYLEA sales to worldwide EYLEA sales and determined consistent with the license and collaboration agreement.

Also on May 17, 2013, we entered into a Non-Exclusive License and Settlement Agreement (the ZALTRAP Agreement), with Genentech, Sanofi U.S. Services, Inc. and Sanofi-Aventis U.S. LLC (the latter two entities, collectively, Sanofi) under which we and Sanofi received a worldwide non-exclusive license to the Davis-Smyth patents, and certain other patents, in all indications for human use other than the prevention or treatment of eye diseases and eye disorders through administration to the eye. Under the terms of the ZALTRAP Agreement, payments will be made to Genentech based on sales of ZALTRAP in the United States and of ZALTRAP that is manufactured in the United States and sold outside the United States through May 7, 2016. A payment of $19 million will be made upon cumulative relevant sales of ZALTRAP reaching $200 million. In addition, royalty payments will be made to Genentech based upon 4.5% of cumulative relevant sales of ZALTRAP between $400 million and $1 billion and 6.5% of any cumulative relevant sales of ZALTRAP over $1 billion. All payments to Genentech under the ZALTRAP Agreement will be made by Sanofi, and we will share in all such payments.

Tarrytown, New York Leases

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 are expected to be

completed in late 2015, at our current Tarrytown, New York location. The initial term of the lease, which is expected to commence in mid-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 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 FASB authoritative guidance. Consequently, we

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will capitalize the landlord's costs of constructing these new facilities a non-cash transaction, offset by a corresponding lease obligation on our balance sheet. We will allocate a portion of our future lease payments to the Buildings and the land on which the Buildings are being constructed. The land element of the lease is treated for accounting purposes as an operating lease.

In April 2013, we also executed an early renewal of approximately 360,000 square feet of space that we currently lease at our Tarrytown location. The early renewal extended the term of the lease from June 2024 to June 2029.

Funding Requirements

We expect continued growth in our expenditures, particularly in connection with our research and development activities (including preclinical and clinical testing), commercialization of EYLEA and ZALTRAP, and capital expenditures. We believe that our existing capital resources, funds generated by anticipated EYLEA net product sales, and funding for reimbursement of development costs that we are entitled to receive under our collaboration agreements will enable us to meet our projected operating needs for the foreseeable future. As described above, research and development expenses that we incur in connection with our ZALTRAP and antibodies collaborations are generally funded by Sanofi, except that following receipt of the first positive Phase 3 trial results for a co-developed antibody drug candidate, subsequent Phase 3 trial-related costs for that drug candidate are shared 80% by Sanofi and 20% by us. In addition, as described above, we and Bayer HealthCare share agreed-upon development expenses that both companies incur in connection with our EYLEA collaboration.

As described above, 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 and to antibodies targeting the Ang2 receptor and ligand in ophthalmology. With respect to PDGF antibodies, we made a $10.0 million up-front payment to Sanofi in May 2013, and will pay up to $40 million in potential development milestone payments and royalties on any future sales. With respect to Ang2 antibodies in ophthalmology, we also made a $10.0 million up-front payment to Sanofi in May 2013, and will pay a potential $5 million development milestone payment and royalties on any future sales.

Under our collaboration agreements with Sanofi and Bayer HealthCare, we and our collaborator will 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 becomes profitable, we have contingent contractual obligations to reimburse Sanofi and Bayer HealthCare for a defined percentage (generally 50%) of agreed-upon development expenses incurred by Sanofi and Bayer HealthCare, respectively. These reimbursements would be deducted each quarter, in accordance with a formula, from our share of the collaboration profits (and, for our ZALTRAP collaboration with Sanofi and our Bayer HealthCare collaboration, royalties 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, 2012, our reimbursement obligation to Sanofi for ZALTRAP was approximately $419 million, while our reimbursement obligation to Bayer HealthCare for EYLEA was approximately $264 million. Therefore, we expect that, initially, our share of profits from sales of ZALTRAP, and a portion of our share of profits from sales of EYLEA outside the United States, will be used to reimburse our collaborators for these obligations.

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 new indications for our marketed products, 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 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.

Our commercialization costs over the next few years will depend on, among other things, whether or not new indications for our marketed products or our antibody product candidates in later stage clinical development receive regulatory approval, the market potential for such new indications or 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 commercial products. In the future, if we are able to successfully develop, market, and sell EYLEA for other indications, or 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 Patient Protection and Affordable Care Act 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

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

As described above, in the first six months of 2013 and 2012, we made cash payments of $73.1 million and $61.4 million, respectively, for employee tax obligations in connection with stock option exercises. Future cash requirements for such payments will depend on various factors, including the level of stock option grants and exercises, the level of restricted stock grants, 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 continue to be substantial.

Due to the amounts of our net operating loss and tax credit carry-forwards available for tax purposes, which totaled $876.6 million and $71.2 million, respectively, at December 31, 2012, we do not anticipate incurring significant cash obligations for federal and state corporate income taxes in the near future.

In connection with our collaboration with Bayer HealthCare, we are entitled to receive up to $25 million in future milestone payments related to marketing and pricing approvals of EYLEA in major market countries outside the United States, as well as up to $135 million in sales milestones based on total twelve-month sales of EYLEA outside the United States achieving certain specified levels starting at $200 million. Under the terms of our ZALTRAP collaboration agreement with Sanofi, we are also entitled to receive milestone payments upon receipt of additional specified marketing approvals.

Other than letters of credits totaling $1.5 million as of June 30, 2013, we have no off-balance sheet arrangements. A $3.4 million letter of credit was canceled in April 2013 in connection with the amendment of our Tarrytown lease, as described above. As of June 30, 2013, we had no other established banking arrangements through which we could obtain short-term financing or a line of credit. In October 2010, we filed a shelf registration statement on Form S-3, which will expire in October 2013, registering the sale, in one or more offerings, of an indeterminate amount of equity or debt securities, together or separately. There is no assurance, however, that we will be able to complete any offerings of securities under this shelf or other registration statements. Factors influencing the availability of additional financing include our progress in product development and commercialization, investor perception of our prospects, and the general condition of the financial markets.

## 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 2012 Form 10-K. There have been no material changes to our market risks or to our management of such risks during 2013.

## ITEM 4. CONTROLS AND PROCEDURES

Our management, with the participation of our chief executive officer and chief financial officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”)), as of the end of the period covered by this report. Based on this evaluation, our chief executive officer and chief 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 chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended June 30, 2013 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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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. We do not expect any such current ordinary course legal proceedings to have a material adverse effect on our business or financial condition.

Genentech Patent Litigation

In November 2010, we commenced a lawsuit against Genentech in the U.S. District Court for the Southern District of New York (the Court), seeking a declaratory judgment that no activities relating to our VEGF Trap infringe any valid claim of certain Genentech patents referred to as the Davis-Smyth patents (the First Davis-Smyth Case). Genentech answered the complaint and asserted counterclaims that our prior or planned activities relating to VEGF Trap have infringed or will infringe claims of four of the Davis-Smyth patents and requested a judgment against us for damages, including for willful infringement, and other relief as the Court deems appropriate.

On December 31, 2011, we entered into a Non-Exclusive License and Partial Settlement Agreement with Genentech (the Original Genentech Agreement) that covered making, using, and selling EYLEA in the United States for the prevention and treatment of human eye diseases and disorders in the United States, and ended the litigation relating to those matters. Under the Original Genentech Agreement, we received a non-exclusive license to the Davis-Smyth patents, and certain other patents owned or co-owned by Genentech. The Original Genentech Agreement did not cover any non-U.S. patent rights or non-U.S. patent disputes, and did not cover any use of aflibercept other than for prevention and treatment of human eye diseases and disorders in the United States. The Original Genentech Agreement provided for us to make payments to Genentech based on U.S. sales of EYLEA through May 7, 2016, the date the Davis-Smyth patents expire. Under the Original Genentech Agreement, we made a $60.0 million milestone payment when cumulative U.S. sales of EYLEA reached $400 million and are obligated to pay royalties of 4.75% on cumulative relevant sales of EYLEA between $400 million and $3 billion and 5.5% on any cumulative relevant sales of EYLEA over $3 billion.

As a result of the Original Genentech Agreement, on January 17, 2012, Genentech filed a second amended answer and counterclaim in the First Davis-Smyth Case, in which it amended its counterclaims alleging infringement of four of the Davis-Smyth patents. On December 23, 2011, Genentech initiated a related case in the Court against Regeneron and Sanofi alleging infringement of four of the Davis-Smyth Patents by activities relating to VEGF Trap (but excluding EYLEA) (the Second Davis-Smyth Case). As in the First Davis-Smyth Case, in the new complaint Genentech requested a judgment against us for damages, including for willful infringement, and other relief as the Court deems appropriate. On September 21, 2012, Genentech asserted two additional Davis-Smyth patents, and one additional application (which was allowed and issued as a patent on September 25, 2012) in both the First Davis-Smyth Case and the Second Davis-Smyth Case.

Effective May 17, 2013, we entered into an Amended and Restated Non-Exclusive License and Settlement Agreement with Genentech (the Amended Genentech Agreement), which amended the Original Genentech Agreement to now include all sales of EYLEA worldwide and ended the litigation relating to those matters. Under the Amended Genentech Agreement, we received a worldwide non-exclusive license to the Davis-Smyth patents, and certain other patents, owned or co-owned by Genentech for the prevention or treatment of human eye diseases and eye disorders through administration of EYLEA to the eye. Under the Amended Genentech Agreement, we will make payments to Genentech based on sales of EYLEA in the United States and EYLEA manufactured in the United States and sold outside the United States through May 7, 2016 using the same milestone and royalty rates as in the Original Genentech Agreement. EYLEA is sold outside the United States by affiliates of Bayer HealthCare under our license and collaboration agreement. All payments to Genentech under the Original Genentech Agreement and the Amended Genentech Agreement have been or will be made by Regeneron. Bayer HealthCare will share in all such payments based on the proportion of ex-U.S. EYLEA sales to worldwide EYLEA sales and determined consistent with the license and collaboration agreement.

Also on May 17, 2013, we entered into a Non-Exclusive License and Settlement Agreement (the ZALTRAP Agreement), with Genentech, Sanofi U.S. Services, Inc. and Sanofi-Aventis U.S. LLC (the latter two entities,

collectively, Sanofi) under which we and Sanofi received a worldwide non-exclusive license to the Davis-Smyth patents, and certain other patents, in all indications for human use other than the prevention or treatment of eye diseases and eye disorders through administration to the eye. Under the terms of the ZALTRAP Agreement, payments will be made to Genentech based on sales of ZALTRAP in the United States and of ZALTRAP that is manufactured in the United States and sold outside the United States through May 7, 2016. A payment of $19 million will be made upon cumulative relevant sales of ZALTRAP reaching $200 million. In addition, royalty payments will be made to Genentech based upon 4.5% of cumulative relevant sales of ZALTRAP between $400 million and $1 billion and 6.5% of any cumulative relevant sales of ZALTRAP over $1 billion. All payments to Genentech under the ZALTRAP Agreement

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will be made by Sanofi, and we will share in all such payments. In connection with Amended Genentech Agreement and the ZALTRAP Agreement, both the First Davis-Smyth Case and the Second Davis-Smyth Case have been dismissed.

We initiated patent-related actions against Genentech in Germany, the United Kingdom, and Italy relating in each case to a patent that expired on October 28, 2012. In the United Kingdom, an adverse decision at first instance dated March 22, 2012 was appealed to the UK Court of Appeal. The Court of Appeal decision dated February 21, 2013 found the designation of European patent EP 1 238 986 in the United Kingdom to be valid and that potential acts relating to VEGF Trap-Eye in the United Kingdom before expiration of the patent on October 28, 2012 would infringe this patent. We sought permission to appeal to the Supreme Court of the United Kingdom. On May 17, 2013, we entered into an agreement with Genentech, Bayer Pharma AG, Bayer Australia Limited and Regeneron UK Ltd., pursuant to which the parties agreed to dismiss proceedings involving these and certain other Genentech patents, and Regeneron and the Bayer HealthCare affiliates were granted certain covenants not to sue as to these and other patents. These proceedings have been dismissed.

## ITEM 1A. RISK FACTORS

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

### Risks Related to Our Financial Results and Need for Additional Financing

We have a history of operating losses and have only recently achieved profitability. If we cannot sustain profitability, our business, prospects, 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. From inception on January 8, 1988 through June 30, 2013, we had a cumulative loss of $330.8 million. 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 current sales of EYLEA and ARCALYST, and our share of the profits from Sanofi's sales of ZALTRAP and 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, 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 ongoing launch and marketing of EYLEA and the potential commercial launches of our late-stage product candidates and new indications for our marketed products, manufacturing scale-up, expenses related to clinical trials testing EYLEA, fasinumab, REGN1154, REGN 1193, REGN1400, or REGN1500, and expenses related to the potential requirement 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. 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 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 for the treatment of wet AMD and macular edema following CRVO, 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.

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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. 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.

Risks Related to Commercialization of EYLEA

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

EYLEA net sales make up a substantial portion of our revenues and this concentration of our net sales in a single product makes us substantially dependent on that product. 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 operating results and financial condition would be materially harmed. In addition, if we are unable to obtain approval of EYLEA in the United States for the treatment of DME and macular edema following BRVO, or if Bayer HealthCare is unable to obtain approval of EYLEA in additional countries or in additional indications, our prospects would be materially harmed.

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

EYLEA is currently available in the United States for treatment of wet AMD and macular edema following CRVO, and in the United Kingdom, Germany, Switzerland, Australia, Japan and certain other countries for the treatment of wet AMD. In addition, EYLEA has received regulatory approval in the first country outside of the United States for the treatment of macular edema following CRVO. We are subject to significant ongoing regulatory obligations with respect to EYLEA for the treatment of wet AMD and macular edema following CRVO in the United States, and, outside the United States, the commercialization of EYLEA is subject to significant ongoing regulatory obligations and oversight in those countries where the product is approved. If we fail to maintain regulatory compliance for EYLEA for the treatment of wet AMD and macular edema following CRVO, we may lose marketing approval, 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 “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.”

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

There are risks inherent in intravitreal injections, including intravitreal injections with EYLEA, such as intraocular inflammation, sterile and culture positive endophthalmitis, corneal decomposition, retinal detachment, retinal tear, and other side effects, all of which are reported from time to time to the FDA. 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.

Our regulatory approval for sales of EYLEA is limited to the treatment of wet AMD and macular edema following CRVO and is limited geographically. If we don't receive approval for EYLEA for other indications, or if approvals are not obtained for sales in other countries, sales and profits will be limited.

We and Bayer HealthCare have received regulatory approvals for sale of EYLEA for the treatment of wet AMD and macular edema following CRVO in certain countries throughout the world. If we do not receive approval for EYLEA for other uses, or if approvals for sales in other countries are not obtained, sales will be limited and our potential for profits will be limited. As a result, our business, prospects, operating results, and financial condition would be materially impacted.

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Our 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 sales and revenue and harm our business, prospects, operating results, and financial condition.

Our current sales in the United States of EYLEA are dependent, in part, on the availability and extent of reimbursement from third-party payers, including private payer healthcare and insurance programs and government programs such as Medicare and Medicaid. Sales of EYLEA in other countries are dependent, in 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 "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 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 agree to 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."

The commercial success of EYLEA currently being marketed for the treatment of wet AMD and macular edema following CRVO is subject to strong competition.

The market for eye disease products is very competitive. Novartis and Genentech are collaborating on the commercialization and further development of a VEGF antibody fragment, Lucentis® for the treatment of wet AMD, macular edema following CRVO, DME, visual impairment due to mCNV, 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, CRVO, and BRVO, and in August 2012 for the treatment of 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, CRVO, and BRVO in June 2011, and for mCNV in July 2013. 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, in January 2012, Genentech submitted an IND for such an extended delivery device. 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 June 2012, Ophthotech announced results of a Phase 2b study in wet AMD that it claimed demonstrated that Fovista™ administered in combination with Lucentis® resulted in increased visual outcomes compared to Lucentis® monotherapy. Allergan is developing an anti-VEGF-A DARPin®, as well as a dual anti-VEGF-A/PDGF-B DARPin®, and its corresponding backups for the treatment of wet AMD and related conditions. Novartis is developing ESBA1008, an antibody fragment targeting VEGF-A for the treatment of wet AMD.

In addition, ophthalmologists are using with success off-label, third-party repackaged versions of Genentech's approved VEGF antagonist, Avastin®, for the treatment of wet AMD, DME, and RVO. The relatively low cost of therapy with Avastin® in patients with wet AMD presents a significant competitive challenge in this indication. 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 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 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 wet AMD, macular edema following CRVO, or other eye indications. See also “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.”

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Our product sales could be reduced by imports from countries where our products are available at lower prices.
Our sales of products in the United States may be reduced if our products are imported into the United States from lower priced markets, whether legally or illegally. 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 will be 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 is marketed in those nations and imported into the United States. 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 could be reduced.

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

If we do not obtain and maintain regulatory approval for our products and 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 products EYLEA, ZALTRAP, and ARCALYST, and obtain regulatory approval for our product candidates, or new indications of our marketed products, including EYLEA for the treatment of ophthalmologic diseases other than wet AMD and macular edema following CRVO, the value of our company, our operating results, and our prospects will be materially harmed. Our product candidates, including EYLEA for DME and macular edema following BRVO, may not receive regulatory approval. If we are unable to obtain regulatory approval for EYLEA in DME and macular edema following BRVO, or if we are materially delayed in doing so, our business, prospects, operating results, and financial condition will be materially harmed. In addition, if we fail to maintain regulatory approval for EYLEA for the treatment of wet AMD and macular edema following CRVO, we may lose marketing approval and the ability to generate EYLEA product sales revenue, which would materially and negatively impact our business, prospects, operating results, and financial condition.
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. Foreign governments also regulate drugs distributed in their country and approval in any country is likely to be a lengthy and expensive process, and approval is highly uncertain.
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.
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. 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 and requirements include all of the risks associated with FDA approval as well as country specific regulations, and 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. 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. We are testing EYLEA in late-stage clinical trials in additional indications. Clinical trials may not demonstrate statistically sufficient effectiveness and safety to obtain the requisite regulatory approvals for these product candidates in these indications. In a number of instances, we have terminated the development of product candidates due to a lack of or only modest effectiveness. Moreover, even if we obtain positive results from preclinical testing or clinical trials, we may not achieve the same success in future trials. 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 April 2011, we announced that our Phase 3 VELOUR trial of ZALTRAP met its primary endpoint of improving overall survival in the treatment of patients with previously treated mCRC. Based upon these positive results, we and Sanofi submitted regulatory applications for marketing approval to the FDA and EMA, and, in August 2012, the FDA approved ZALTRAP in combination with FOLFIRI chemotherapy regimen for patients with mCRC that is resistant to or has progressed following an oxaliplatin-containing regimen. However, in April 2011, we and Sanofi also announced the results from another 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. The VENICE trial did not meet the pre-specified criterion of improvement in overall survival.

In January 2012, Roche announced that a Phase 3 trial of Avastin® (bevacizumab) had met the primary endpoint of overall survival in mCRC in patients who had previously received Avastin® with standard chemotherapy. The positive results of this trial in a similar patient population could impact the potential commercial opportunity for ZALTRAP in mCRC.

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

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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 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.

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.

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 fail or be delayed, or if the product candidate has received regulatory approval such approval may be revoked, which would severely harm our business.

EYLEA is being studied in diseases of the eye in addition to wet AMD and macular edema following CRVO. There are many potential safety concerns associated with significant blockade of VEGF that may limit our ability to successfully develop and/or commercialize ZALTRAP and 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. In addition, patients given infusions of any protein, including ZALTRAP delivered through intravenous administration, may develop severe hypersensitivity reactions or infusion reactions. 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, 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 the development and/or commercialization of ZALTRAP for the treatment of mCRC or EYLEA for the treatment of diseases of the eye.

We have studied fasinumab in a variety of pain indications, including osteoarthritis of the knee. In December 2010, the FDA placed fasinumab and other investigational agents targeting NGF on clinical hold after a case of rapidly progressive osteoarthritis leading to joint replacement was seen in another company's anti-NGF program. At that time, the FDA expressed concern that this case, which followed previously-reported cases of joint replacements in patients on an anti-NGF drug candidate being developed by a different pharmaceutical company, provided evidence to suggest a class effect. An FDA Arthritis Advisory Committee met on March 12, 2012 to discuss possible safety issues related to anti-NGF compounds and voted unanimously in favor of a role for the ongoing development of anti-NGF agents in osteoarthritis. The Arthritis Advisory Committee also voted twenty to one in favor of a role for development of anti-NGF agents to manage the pain associated with conditions for which there are no agents with demonstrated analgesic efficacy. In December 2012, the FDA removed the clinical hold on fasinumab after reviewing our proposed Phase 3 program in osteoarthritis. However, shortly thereafter, the entire class was again placed on clinical hold as a

result of preclinical data from other investigational agents targeting NGF in development. There are currently no trials with fasinumab that are either enrolling or treating patients. Discussions with the FDA about fasinumab are ongoing.

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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.

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.

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.

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 own employees, our collaborators or otherwise, it would help our competitors and adversely affect our business. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our rights 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, or circumvented. Patent applications filed outside the United States may be challenged by third parties who file an opposition. Such opposition proceedings are increasingly common in the European Union and are costly to defend. We have pending patent applications in the European Patent Office and it is likely that we will need to defend patent applications from third-party challengers from time to time in the future. Certain patent applications filed in the United States may also be challenged by third 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. We have pending patent applications in the United States Patent and Trademark Office and it is likely that we will need to defend patent applications from third-party challengers from time to time in the future. 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.

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

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Other parties may allege that they have 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 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, and may be in the future, involved in patent litigation. We are aware of patents and pending applications owned by Roche that claim antibodies to IL-6R and methods of treating rheumatoid arthritis with such antibodies. We are developing sarilumab, an antibody to IL-6R, for the treatment of rheumatoid arthritis. Although we do not believe that sarilumab infringes any valid claim in these patents or patent applications, Roche could initiate a lawsuit for patent infringement and assert its patents are valid and cover sarilumab. We are also aware of a U.S. patent jointly owned by Genentech and City of Hope relating to the production of recombinant antibodies in host cells. We currently produce our antibody product candidates using recombinant antibodies from host cells and may choose to produce additional antibody product candidates in this manner. Neither ARCALYST, ZALTRAP, nor EYLEA are recombinant antibodies. If any of our antibody product candidates are produced in a manner subject to valid claims in the Genentech patent, then we may need to obtain a license from Genentech, should one be available. Genentech

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has licensed this patent to several different companies under confidential license agreements. If we desire a license for any of our antibody product candidates and are unable to obtain a license on commercially reasonable terms or at all, we may be restricted in our ability to use Genentech's techniques to make recombinant antibodies in or to import them into the United States. Further, we are aware of a number of other third-party patent applications 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 drug candidates, and a court may find that we are infringing validly issued patents of third parties. In the event that the manufacture, use, or sale of any of our drug candidates, or our other late-stage product candidates, infringes on the patents or violates other proprietary rights of third parties, we may be prevented from pursuing product development, manufacturing, and commercialization of those drugs and may be required to pay costly damages. Such a result 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 product candidates, which could severely harm our business.

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

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

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

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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 and to commercialize our other product candidates or other indications for our marketed products if they receive regulatory approval.

Our manufacturing facility would be inadequate to produce the active pharmaceutical ingredients of (a) EYLEA, 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. We rely entirely on third-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 such third parties manufacture and supply sufficient commercial quantities of our products on acceptable terms, or if we should encounter delays or other difficulties in our relationships with our corporate collaborators, third-party manufacturers, or other parties involved in our supply chain which adversely affect the timely manufacture and supply of our products, our business, prospects, operating results, and financial condition may be materially harmed.

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 and, 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, 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, ZALTRAP, 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 our 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 third-party patents.

Our ability to continue to manufacture EYLEA, ZALTRAP, and ARCALYST in our Rensselaer, New York 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 third parties. Other parties may allege that our manufacturing activities, or the activities of third parties involved in our manufacture and supply chain, infringe patents or other intellectual property rights. A judicial decision in favor of one or more parties making such allegations could preclude the manufacture of our products where those intellectual property rights apply which could materially harm our business, operating results, and financial condition.

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If sales of EYLEA and ZALTRAP do not meet the levels currently expected, or if the launch of new indications for EYLEA or of any of our product candidates is delayed or unsuccessful, we may face costs related to 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 facilities to produce bulk product of ARCALYST for the treatment of CAPS, bulk product of EYLEA for the treatment of wet AMD and macular edema following CRVO, bulk product of ZALTRAP for the treatment of patients with mCRC that is resistant to or has progressed following an oxaliplatin-containing regimen, and clinical and preclinical candidates for ourselves and our collaborations, and 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.

Third-party service or supply failures, or other failures, business interruptions, or natural 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 at the facilities.

Also, certain raw materials or other products necessary for the manufacture and formulation of EYLEA, ZALTRAP, ARCALYST, and our product candidates 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 EYLEA, ZALTRAP, and ARCALYST, and our 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, adverse financial developments at or affecting the supplier, failure by the supplier to comply with cGMPs, business interruptions, or labor shortages or disputes. This, in turn, could materially and adversely affect our ability to manufacture or supply EYLEA, ZALTRAP, ARCALYST, and our 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.

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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, 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 and prospects. 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.

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.

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.

Currently, we have three marketed products, EYLEA, ZALTRAP, and ARCALYST. While we have established our own sales and marketing organization for EYLEA in the United States for the treatment of wet AMD and macular edema following CRVO, we have limited commercialization experience and we have no sales, marketing, commercial, or distribution capabilities outside the United States. In addition, EYLEA faces intense competition from Lucentis® and from off-label use of Avastin®, both of which have been on the market for a number of years and, potentially, from new competitive products currently in clinical development. 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 launch and marketing of EYLEA, including pricing strategy and the 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®, and the willingness of retinal specialists and patients to switch from Lucentis® or off-label use of Avastin® to EYLEA;

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- 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 new competitive products currently in clinical development; and
- the effect of new health care legislation currently being implemented in the United States.

Under the terms of our license and collaboration agreement with Bayer HealthCare, 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. In addition, if we or our collaborators are unable to successfully commercialize new product candidates or new indications for our marketed product, our future prospects would be materially impaired.

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, and 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.

As previously noted, Genentech has an approved VEGF antagonist, Avastin®, on the market for treating certain cancers and many different pharmaceutical and biotechnology companies are working to develop competing VEGF antagonists, including Novartis, Amgen, Inc., Imclone LLC/Eli Lilly, Pfizer, Inc., AstraZeneca, and GlaxoSmithKline. Some of these molecules may offer competitive advantages over our molecule. Each of Pfizer, Onyx (together with its partner Bayer HealthCare), and GlaxoSmithKline are marketing and selling oral medications that target tumor cell growth and new vasculature formation that fuels the growth of tumors. It will be difficult for ZALTRAP to compete against Avastin® and the FDA approved kinase inhibitors, because doctors and patients will have significant experience using these medicines. In addition, an oral medication may be considerably less expensive for patients than a biologic medication, providing a competitive advantage to companies that market such products.

The market for eye disease products is also very competitive. Novartis and Genentech 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, 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, CRVO, and BRVO, and in August 2012 for the treatment of 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, CRVO, and BRVO in June 2011, and for mCNV in July 2013. 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 siRNAs that modulate gene expression. For example, in January 2012, Genentech submitted an IND for such an extended delivery device. Ophthotech Corporation is developing Fovista™, an aptamer directed against PDGF-ß, as a product candidate intended to be used in combination with an anti-VEGF therapy. In June 2012, Ophthotech announced results of a Phase 2b study that it claimed demonstrated that Fovista™ administered in combination with Lucentis® resulted in increased visual outcomes compared to Lucentis® monotherapy. Allergan is developing an anti-VEGF-A DARPin®, as well as a dual anti-VEGF-A/PDGF-ß DARPin®, and its corresponding backups for the treatment of wet AMD and related conditions. Novartis is developing ESBA1008, an antibody fragment targeting VEGF-A for the treatment of wet AMD.

In addition, ophthalmologists are using with success off-label, third-party repackaged versions of Genentech's approved VEGF antagonist, Avastin®, for the treatment of wet AMD, DME, and macular edema following RVO. The relatively low cost of therapy with Avastin® in patients with wet AMD presents a significant competitive challenge in this indication. Long-term, controlled clinical trials comparing Lucentis® to Avastin® in the treatment of wet AMD are

being conducted. One-year data from the CATT study 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 Avastin® was non-inferior to Lucentis® in mean visual acuity gain; as-needed dosing was not non-inferior to monthly dosing. It may be difficult for EYLEA in this or other eye indications for which it may be approved to compete against Lucentis® and off-label use of Avastin® because 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 Avastin® in treating patients with wet AMD, may well exacerbate the competitive challenge which EYLEA will face in this or other eye indications for which it may be approved. In addition, while we believe that ZALTRAP would not be well tolerated if administered directly to the eye, there is a risk that third parties will attempt to repackage ZALTRAP for off-label use and sale for the treatment of wet AMD and other diseases of

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the eye, which would present a potential low-cost competitive threat to EYLEA for wet AMD, macular edema following CRVO, or other eye indications.

There are both small molecules and antibodies in development by other companies that are designed to block the synthesis of IL-1 or inhibit the signaling of IL-1. For example, Eli Lilly, Xoma (in collaboration with Servier), and Novartis are each developing antibodies to IL-1 and both Amgen and MedImmune are developing antibodies to the IL-1 receptor. In 2009, Novartis received regulatory approval in the United States and Europe for Ilaris®, a fully human anti-interleukin-1ß (IL-1ß) antibody, for the treatment of CAPS. Ilaris® has been approved by the FDA for the treatment of systemic juvenile idiopathic arthritis and by the EMEA for the treatment of certain patients with gouty arthritis and is also in development for atherosclerosis and a number of other inflammatory diseases. Novartis' IL-1 antibody and these other drug candidates could offer competitive advantages over ARCALYST. For example, Ilaris® is dosed once every eight weeks compared to the once-weekly dosing regimen for ARCALYST. The successful development and/or commercialization of these competing molecules could adversely affect sales of ARCALYST for the treatment of CAPS.

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.

Numerous other companies are developing therapeutic antibody products. Companies such as Pfizer, Johnson & Johnson, AstraZeneca, Amgen, Biogen Idec, Novartis, Genentech/Roche, Bristol-Myers Squib, AbbVie, and GlaxoSmithKline have generated therapeutic products that are currently in development or on the market that are derived from recombinant DNA that comprise human antibody sequences.

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-stage product candidates. For example, Pfizer, Johnson & Johnson, and AbbVie are developing antibody product candidates against NGF. Genentech/Roche is marketing an antibody against IL-6R (tocilizumab) for the treatment of rheumatoid arthritis, and several other companies, including Centocor/Johnson & Johnson, Bristol-Myers Squibb and UCB, have antibodies against IL-6 in clinical development for this disease. GlaxoSmithKline, in partnership with OncoMed Pharmaceuticals, has a Dll4 antibody in clinical development for the treatment of solid tumors. Amgen previously had an antibody against IL-4R in clinical development for the treatment of asthma. Several companies, including Amgen, Pfizer, and Roche, have development programs for antibodies against PCSK9. Amgen, Pfizer, and AstraZeneca have development programs underway for antibodies against Ang2. Alnylam, in partnership with The Medicines Company, has a clinical program underway with an RNAi molecule against PCSK9. 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.

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 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 agree to 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, and other third-party payers, including Medicare and Medicaid, do not 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, making drugs that are not preferred by such payers more expensive for patients, and require prior authorization or failure on another type of treatment before covering a particular drug. In particular, payers may impose these obstacles to coverage on higher-priced drugs, as our product candidates are likely to be.

Government and other third-party payers 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 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

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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 for the treatment of wet AMD, macular edema following CRVO, and other eye diseases, and ZALTRAP for the treatment of patients with mCRC that is resistant to or has progressed following an oxaliplatin-containing regimen, will likely be too expensive for most patients to afford without health insurance coverage, if these products are unable to obtain adequate coverage and reimbursement by third-party payers, including Medicare and Medicaid in the United States, our ability to successfully commercialize these products would be materially adversely impacted. Third-party payers, including Medicare and Medicaid in the United States, may not cover and/or reimburse for these products at levels required for us to successfully commercialize these products. Any limitation imposed by third-party payers on the use of our products if they are approved for marketing, or any action or decision by CMS or analogous foreign agencies or authorities which for any reason denies coverage or reimbursement for our products or provides coverage or reimbursement at levels that harm our products' competitiveness or leads to lower prices for those products, will have a material negative effect on our ability to sustain profitability. In certain foreign countries, pricing, coverage, and level of reimbursement of prescription drugs are subject to governmental control, and we and our collaborators may be unable to obtain coverage, pricing, and/or reimbursement on terms that are favorable to us or necessary for us or our collaborators to successfully commercialize our products in those countries. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union 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 three distributors and several specialty pharmacies. We sell ARCALYST in the United States to two specialty pharmacies. Under these distribution models, the distributors and specialty pharmacies generally take physical delivery of product. For EYLEA, the distributors and specialty pharmacies generally sell the product directly to healthcare providers, whereas for ARCALYST, the specialty pharmacies sell the product directly to patients. For the three and six months ended June 30, 2013, we recorded 76% and 77%, 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, 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. 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. Our product

liability insurance may not cover all potential liabilities or may not completely cover any liability arising from any such litigation. Moreover, in the future we may not have access to liability insurance or be able to maintain our insurance on acceptable terms.

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

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

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

In recent years, several states and localities, including California, the District of Columbia, Massachusetts, Minnesota, Nevada, New Mexico, Vermont, and West Virginia, 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. In addition, as part of the PPACA, the federal government recently enacted the Physician Payment Sunshine Act and related regulations. The Physician Payment Sunshine Act will require pharmaceutical manufacturers to report annually to the Secretary of the U.S. Department of Health and Human Services payments or other transfers of value made to physicians or teaching hospitals. In February 2013, regulations were released that contain detailed guidance regarding the information that must be collected and reported. We will be required to collect information regarding such payments starting in August 2013 and to begin reporting such information in March 2014. Over the next several years, we will need to dedicate significant resources to enhance our systems and processes in order to comply with these regulations. The PPACA also includes various provisions designed to strengthen significantly 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. Many of these requirements and standards are new and 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 and financial results and condition.

Risks from the improper conduct of employees, agents, or contractors, or collaborators could adversely affect our business or reputation.

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 privacy laws. 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. The FCPA generally prohibits the 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 SEC and Department of Justice have increased their FCPA enforcement activities with respect to pharmaceutical companies.

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We have compliance controls, policies, and procedures in place; however, 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. Any violation of these laws may result in civil and criminal penalties, and could have a material adverse impact on our business.

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 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, viruses, 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 and financial results and 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 Securities and Exchange Commission (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. 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;
- 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 and the cost of currency exchange;
-

adverse tax consequences, including those that might result from the failure to operate in conformity with the requirements for certain tax treatment, tax incentives, or grants;

- tariffs, trade protection measures, import or export licensing requirements, trade embargos, and other trade barriers;
- difficulties in attracting and retaining qualified personnel; and
- cultural differences in the conduct of business.

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Risks Related to Our Reliance on Third Parties

If our antibody collaboration 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. Sanofi has committed to pay up to $160 million per year, or a total of $1.28 billion, between 2010 and 2017 to fund our efforts to identify and validate drug discovery targets and pre-clinically develop fully human monoclonal antibodies against such targets. Sanofi also initially funds almost all of the development expenses incurred by both companies in connection with the clinical development of antibodies that Sanofi elects to co-develop with us. We rely on Sanofi to fund these activities. In addition, with respect to those antibodies that Sanofi elects to co-develop with us, such as sarilumab, alirocumab, dupilumab, enoticumab, nesvacumab, REGN1033, and REGN2009, we rely on Sanofi to lead much of the clinical development efforts and assist with obtaining regulatory approval, particularly outside the United States. We also rely on Sanofi to lead the commercialization efforts to support all of the antibody products that are co-developed by Sanofi and us if they receive regulatory approval. If Sanofi does not elect to co-develop the antibodies that we discover or opts-out of their development, 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, and decided not to opt-in to the REGN1154, REGN 1193, REGN1500, and other programs. If Sanofi terminates the antibody collaboration 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. Even though none of the antibodies from this collaboration may ever be successfully developed and commercialized, if Sanofi does not perform its obligations with respect to antibodies that it elects to co-develop, our ability to develop, manufacture, and commercialize these antibody product candidates will be significantly adversely affected.

If our collaboration with Sanofi for ZALTRAP is terminated, or Sanofi materially breaches its obligations thereunder, our business, prospects, and financial condition, and our ability to develop and commercialize ZALTRAP would be materially harmed.

We rely heavily on Sanofi to lead much of the development of ZALTRAP and the commercialization of ZALTRAP. If Sanofi fails to perform its obligations in a timely manner, or at all, our ability to develop and commercialize ZALTRAP in previously-treated mCRC will be significantly adversely affected. Sanofi has the right to terminate its collaboration agreement with us at any time upon twelve months advance notice. If Sanofi were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our collaborator, which we would have to develop or outsource at substantial additional costs to us. In particular, we have limited commercial capabilities outside the United States and would have to develop or outsource these capabilities. Termination of the Sanofi collaboration agreement for ZALTRAP would create substantial new and additional risks to the successful development and commercialization of ZALTRAP.

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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 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, with Santen Pharmaceuticals Co. Ltd. pursuant to a Co-Promotion and Distribution Agreement with Bayer HealthCare's Japanese affiliate. EYLEA has received regulatory approvals for the treatment of wet AMD in Australia, Japan, and certain European and Latin American countries. While we cannot assure you that EYLEA will receive additional regulatory approvals outside the United States or be successfully commercialized, 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 partner, 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 EYLEA for the treatment of wet AMD and macular edema following CRVO, ZALTRAP for the treatment of patients with mCRC, ARCALYST for the treatment of CAPS, 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 rely on third-party service providers to support the distribution of EYLEA and ARCALYST in the United States and for many other related activities in connection with the commercialization of these marketed products. Despite our arrangements with them, these third parties may not perform adequately. If these service providers do not perform their services adequately, our sales of EYLEA for the treatment of wet AMD and macular edema following CRVO and ARCALYST for the treatment of CAPS 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 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., our Chief Scientific Officer and President, Regeneron Laboratories, and Neil Stahl, Ph.D., our Senior Vice President, Research and Development Sciences. As we commercialize EYLEA in the United States for the treatment of wet AMD and macular edema following CRVO, 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 them potentially vulnerable to breakdown, malicious intrusion, and computer viruses which may result in the impairment of production and key business processes.

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 disruptions and breaches of security could have a material adverse effect on our business, prospects, operating results, and financial condition.

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. In addition, to a lesser degree, sales of ZALTRAP and ARCALYST and, 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;
- 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;
- third-party claims that our products or technologies infringe their patents;
- third-party challenges 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, EYLEA, ZALTRAP, or ARCALYST, or product candidates or new indications for our marketed products;
- pricing or reimbursement actions or decisions by government authorities or insurers affecting the coverage or reimbursement 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 collaborative partners or key customers;
- developments in the biotechnology industry or in government regulation of healthcare;
- large sales of our Common Stock by our executive officers, directors, or significant shareholders;
- arrivals and departures of key personnel; and
- general market conditions.

In addition, in the fourth quarter of 2012, we determined, based on our facts and circumstances, that it was more likely than not that a substantial portion of our deferred tax assets would be realized and, as a result, substantially all of our valuation allowance against deferred tax assets was released. Therefore, beginning in 2013, we began recording

income tax expense, which results in a significant reduction in our net income and net income per share and may have an impact on the market price of our Common Stock.

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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. Broad market fluctuations may also adversely affect the market price of our Common Stock.

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 April 17 2013, our five largest shareholders plus Leonard S. Schleifer, M.D, Ph.D., our Chief Executive Officer, beneficially owned 55.6% 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 April 17, 2013. In September 2003, Sanofi (then Aventis Pharmaceuticals Inc.) purchased 2,799,552 newly issued, unregistered shares of our Common Stock, and in December 2007 Sanofi purchased an additional 12,000,000 newly issued, unregistered shares of our Common Stock. Under our investor agreement, as amended, with Sanofi, these shares may not be sold until December 20, 2017 except under limited circumstances and subject to earlier termination of these restrictions upon the occurrence of certain events. In addition, in October 2010, Sanofi purchased an additional 1,017,401 shares of Common Stock in our underwritten public offering. As of April 17, 2013, Sanofi beneficially owned 15,816,953 shares of our Common Stock, representing approximately 16.5% of the shares of Common Stock then outstanding. 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. If Sanofi, or our other significant shareholders or we, sell substantial amounts of our Common Stock in the public market, or there is a perception that such sales may occur, the market price of our Common Stock could fall. Sales of Common Stock by our significant shareholders, including Sanofi, also might make it more difficult for us to raise funds by selling equity or equity-related securities in the future at a time and price that we deem appropriate.

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

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 April 17, 2013, holders of Class A Stock held 17.7% 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 April 17, 2013:

- our current executive officers and directors beneficially owned 10.9% 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 April 17, 2013, and 23.4% 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 April 17, 2013; and
- our five largest shareholders plus Leonard S. Schleifer, M.D., Ph.D. our Chief Executive Officer, beneficially owned approximately 55.6% 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 April 17, 2013. In addition, these five shareholders held approximately 59.9% 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 April 17, 2013.

Pursuant to an investor agreement, as amended, Sanofi has agreed to vote its shares, at Sanofi's election, either as recommended by our board of directors or proportionally with the votes cast by our other shareholders, except with respect to certain change of control transactions, liquidation or dissolution, stock issuances equal to or exceeding 10% of the then outstanding shares or voting rights of Common Stock and Class A Stock, and new equity compensation plans or amendments if not materially consistent with our historical equity compensation practices.

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The anti-takeover effects of provisions of our charter, by-laws, and of New York corporate law and the contractual "standstill" provisions in our investor agreement with Sanofi, 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 restated 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 immediately above captioned "Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval."

Until the later of the fifth anniversaries of the expiration or earlier termination of our antibody collaboration agreements with Sanofi or our ZALTRAP collaboration with Sanofi, Sanofi will be bound by certain "standstill" provisions, as amended, which contractually prohibit Sanofi from acquiring more than certain specified percentages of our Class A Stock and Common Stock (taken together) or otherwise seeking to obtain control of our company.

In addition, we have a Change in Control Severance Plan and our Chief Executive Officer has an employment agreement that provides severance benefits in the event our officers are terminated as a result of a change in control of our company. Many of our stock options issued under our Second Amended and Restated 2000 Long-Term Incentive Plan, as amended and restated, may become fully vested in connection with a "change in control" of our company, as defined in the plan. These contractual provisions may also have the effect of deterring, delaying, or preventing an acquisition or other change in control.

Risks Relating to Our Convertible Senior Notes and Related Hedge Transactions

The convertible note hedges and warrant transactions we entered into in connection with our 1.875% 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 convertible note hedge transactions are expected 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 the case may be upon conversion of the notes. In the event that the hedge counterparties fail to deliver shares to us or potential cash payments as the case may be 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.

In connection with hedging these transactions, the hedge counterparties and/or their affiliates may enter 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 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.

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In addition, we intend to exercise options under the convertible note hedge transactions whenever notes are converted. In order to unwind its 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 fundamental change provisions of our 1.875% Convertible Senior Notes and certain of the terms of the convertible note hedge and warrant transactions may delay or prevent an otherwise beneficial takeover attempt of us.

The fundamental change purchase rights, which will allow noteholders to 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, and the provisions requiring an increase to the conversion rate for conversions in connection with make-whole fundamental changes, as set forth in the indenture, 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 convertible note 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.

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ITEM 6. EXHIBITS

(a) Exhibits

| Exhibit Number | | Description |
|---|---|---|
| 10.1 | – | Mt. Pleasant Lease by and between BMR-Landmark at Eastview LLC and Regeneron Pharmaceuticals, Inc., dated April 3, 2013. |
| 10.2 | – | Eleventh Amendment to Lease by and between BMR-Landmark at Eastview LLC and Regeneron Pharmaceuticals, Inc., dated April 3, 2013. |
| 10.3 | – | Twelfth Amendment to Lease by and between BMR-Landmark at Eastview LLC and Regeneron Pharmaceuticals, Inc., dated May 31, 2013. |
| 10.4 | – | Thirteenth Amendment to Lease by and between BMR-Landmark at Eastview LLC and Regeneron Pharmaceuticals, Inc., dated May 31, 2013. |
| 10.5* | – | First Amendment to Amended and Restated License and Collaboration Agreement by and between Regeneron Pharmaceuticals, Inc. and Aventis Pharmaceuticals Inc., dated May 1, 2013. |
| 10.6* | – | Letter Agreement by and between Regeneron Pharmaceuticals, Inc. and Aventis Pharmaceuticals Inc., dated May 2, 2013. |
| 10.7* | – | Amended and Restated Non-Exclusive License and Settlement Agreement by and between Genentech, Inc. and Regeneron Pharmaceuticals, Inc., effective May 17, 2013. |
| 10.8* | – | Non-Exclusive License and Settlement Agreement by and between Genentech, Inc., Regeneron Pharmaceuticals, Inc., Sanofi-Aventis U.S. Inc. and Sanofi U.S. LLC, effective May 17, 2013. |
| 10.9 | – | Agreement dated May 17, 2013 between Bayer Pharma AG, Bayer Australia Limited, Regeneron Pharmaceuticals, Inc., Regeneron UK Ltd and Genentech Inc. |
| 31.1 | – | Certification of CEO pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934. |
| 31.2 | – | Certification of CFO pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934. |
| 32 | – | Certification of CEO and CFO 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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* The Company has requested confidential treatment of certain information contained in this exhibit. Such information has been filed separately with the Commission pursuant to the Company's application for confidential treatment.

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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: August 6, 2013

By: /s/ MURRAY A. GOLDBERG

Murray A. Goldberg
Senior Vice President, Finance & Administration,
Chief Financial Officer, and Assistant
Secretary
(Principal Financial Officer and
Duly Authorized Officer)