REGENERON PHARMACEUTICALS INC
Form 10-Q
May 08, 2014
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549
FORM 10-Q

(Mark One)

(X) QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended March 31, 2014

OR

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

Commission File Number 0-19034

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

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

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

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

Yes	X	No

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

Yes	X	No

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

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

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

Yes	No	X

Number of shares outstanding of each of the registrant's classes of common stock as of April 17, 2014:

Class of Common Stock	Number of Shares
Class A Stock, $.001 par value	2,000,781
Common Stock, $.001 par value	98,879,794

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"ARCALYST®", "EYLEA®", "ZALTRAP®", "VelocImmune®", "VelociGene®", "VelociMouse®", "VelociMab®", and "VelociSuite®" are trademarks of Regeneron Pharmaceuticals, Inc. Trademarks and trade names of other companies appearing in this report are, to the knowledge of Regeneron Pharmaceuticals, Inc., the property of their respective owners.

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

	March 31, 2014	December 31, 2013
ASSETS		
Current assets:		
Cash and cash equivalents	$461,858	$535,608
Marketable securities	186,275	158,376
Accounts receivable - trade, net	801,773	787,071
Accounts receivable from Sanofi	118,003	104,707
Accounts receivable from Bayer HealthCare	127,720	63,189
Inventories	86,545	70,354
Deferred tax assets	36,623	44,677
Prepaid expenses and other current assets	52,252	32,952
Total current assets	1,871,049	1,796,934
Marketable securities	534,689	389,891
Property, plant, and equipment, at cost, net of accumulated depreciation and amortization	600,864	526,983
Deferred tax assets	248,454	231,878
Other assets	5,340	5,327
Total assets	$3,260,396	$2,951,013
LIABILITIES and STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$237,935	$250,896
Deferred revenue from Sanofi, current portion	12,980	12,815
Deferred revenue - other, current portion	53,093	34,185
Facility lease obligations, current portion	1,060	939
Total current liabilities	305,068	298,835
Deferred revenue from Sanofi	73,694	76,522
Deferred revenue - other	128,539	107,677
Facility lease obligations	203,380	184,258
Convertible senior notes	326,673	320,315
Other long-term liabilities	11,794	11,330
Total liabilities	1,049,148	998,937
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 - 2,000,781 at March 31, 2014 and 2,020,481 at December 31, 2013	2	2
	99	97

Common Stock, $.001 par value; 160,000,000 shares authorized; shares issued and outstanding - 98,847,729 at March 31, 2014 and 97,666,814 at December 31, 2013		
Additional paid-in capital	2,236,931	2,045,857
Accumulated deficit	(27,249)	(92,692)
Accumulated other comprehensive income (loss)	1,465	(1,188)
Total stockholders' equity	2,211,248	1,952,076
Total liabilities and stockholders' equity	$3,260,396	$2,951,013

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

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

	Three months ended March 31,	
	2014	2013
Statements of Operations		
Revenues:		
Net product sales	$362,378	$318,740
Sanofi collaboration revenue	130,508	99,273
Bayer HealthCare collaboration revenue	125,312	14,907
Technology licensing and other revenue	7,542	6,744
	625,740	439,664
Expenses:		
Research and development	287,379	180,299
Selling, general, and administrative	108,850	77,260
Cost of goods sold	27,473	28,021
Cost of collaboration manufacturing	16,099	1,034
	439,801	286,614
Income from operations	185,939	153,050
Other income (expense):		
Investment income	937	456
Interest expense	(11,613)	(11,675)
	(10,676)	(11,219)
Income before income taxes	175,263	141,831
Income tax expense	(109,820)	(42,957)
Net income	$65,443	$98,874
Net income per share - basic	$0.66	$1.02
Net income per share - diluted	$0.58	$0.90
Weighted average shares outstanding - basic	98,709	96,878
Weighted average shares outstanding - diluted	112,151	109,369
Statements of Comprehensive Income		
Net income	$65,443	$98,874
Other comprehensive income (loss):		
Unrealized gain (loss) on marketable securities	2,653	(478)
Comprehensive income	$68,096	$98,396

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 three months ended March 31, 2014 and 2013
(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, 2013	2,020	$ 2	97,667	$ 97	$ 2,045,857	$ (92,692)	$ (1,188)	$ 1,952,076
Issuance of Common Stock in connection with exercise of stock options	—	—	1,338	2	53,918	—	—	53,920
Common Stock tendered upon exercise of stock options in connection with employee tax obligations	—	—	(198)	—	(63,086)	—	—	(63,086)
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution	—	—	21	—	—	—	—	—
Conversion of Class A Stock to Common Stock	(20)	—	20	—	—	—	—	—
Stock-based compensation charges	—	—	—	—	82,982	—	—	82,982
Excess tax benefit from stock-based compensation	—	—	—	—	117,260	—	—	117,260
Net income	—	—	—	—	—	65,443	—	65,443
Other comprehensive income	—	—	—	—	—	—	2,653	2,653
Balance, March 31, 2014	2,000	$ 2	98,848	$ 99	$ 2,236,931	$ (27,249)	$ 1,465	$ 2,211,248
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	—	—	396	—	9,804	—	—	9,804
Common Stock tendered upon exercise of stock options in connection with employee tax obligations	—	—	(17)	—	(3,085)	—	—	(3,085)
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution	—	—	38	—	—	—	—	—
Conversion of Class A Stock to Common Stock	(11)	—	11	—	—	—	—	—

Stock-based compensation charges	—	—	—	—	53,555	—	—	53,555
Excess tax benefit from stock-based compensation	—	—	—	—	2,293	—	—	2,293
Net income	—	—	—	—	—	98,874	—	98,874
Other comprehensive loss	—	—	—	—	—	—	(478)	(478)
Balance, March 31, 2013	2,058	$ 2	95,651	$ 95	$ 1,826,075	$ (418,180)	$ (1,644)	$ 1,406,348

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

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

	Three months ended March 31,	
	2014	2013
Cash flows from operating activities:		
Net income	$65,443	$98,874
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	11,530	9,407
Non-cash compensation expense	81,408	53,030
Non-cash interest expense	5,916	5,781
Other non-cash charges and expenses, net	3,761	7,174
Deferred taxes	(8,522)	39,525
Changes in assets and liabilities:		
Increase in Sanofi, Bayer HealthCare, and trade accounts receivable	(92,529)	(117,782)
Increase in inventories	(15,550)	(17,581)
Increase in prepaid expenses and other assets	(20,898)	(17,815)
Increase (decrease) in deferred revenue	37,107	(6,470)
(Decrease) increase in accounts payable, accrued expenses, and other liabilities	(14,139)	32,105
Total adjustments	(11,916)	(12,626)
Net cash provided by operating activities	53,527	86,248
Cash flows from investing activities:		
Purchases of marketable securities	(253,878)	(181,236)
Sales or maturities of marketable securities	82,469	54,754
Capital expenditures	(64,822)	(21,203)
Net cash used in investing activities	(236,231)	(147,685)
Cash flows from financing activities:		
Payments in connection with facility and capital lease obligations	(262)	(649)
Proceeds from issuance of Common Stock	55,042	12,964
Payments in connection with Common Stock tendered for employee tax obligations	(63,086)	(3,085)
Excess tax benefit from stock-based compensation	117,260	2,293
Net cash provided by financing activities	108,954	11,523
Net decrease in cash and cash equivalents	(73,750)	(49,914)
Cash and cash equivalents at beginning of period	535,608	230,276
Cash and cash equivalents at end of period	$461,858	$180,362

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, 2013 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, 2013. 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 in the United States totaled $359.0 million and $313.9 million for the three months ended March 31, 2014 and 2013, respectively. In addition, ARCALYST® net product sales totaled $3.4 million and $4.8 million for the three months ended March 31, 2014 and 2013, respectively.

For the three months ended March 31, 2014 and 2013, the Company recorded 79% and 77%, 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, and other sales-related deductions. The following table summarizes the provisions, and credits/payments, for these sales-related deductions during the three months ended March 31, 2014.

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

3. Collaboration Agreements

Sanofi

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

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

	Three months ended March 31,	
Sanofi Collaboration Revenue	2014	2013
ZALTRAP:		
Regeneron's share of losses in connection with commercialization of ZALTRAP	$(3,212)	$(7,789)
Reimbursement of Regeneron research and development expenses	1,092	2,089
Other	2,177	1,858
Total ZALTRAP	57	(3,842)
Antibody:		
Reimbursement of Regeneron research and development expenses	126,822	99,623
Other	3,629	3,492
Total Antibody	130,451	103,115
Total Sanofi collaboration revenue	$130,508	$99,273

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 that is resistant to or has progressed following an oxaliplatin-containing regimen, in the United States in the third quarter of 2012 and in certain European and other countries in the first quarter of 2013. 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. The Company is entitled to a receive a percentage of sales of ZALTRAP in Japan.

Under the Company's antibody collaboration agreement with Sanofi, agreed upon worldwide development expenses incurred by both companies during the term of the agreement are funded by Sanofi, except that following receipt of the first positive Phase 3 trial results for a co-developed drug candidate, which first occurred in the fourth quarter of 2013, subsequent Phase 3 trial-related costs for that drug candidate ("Shared Phase 3 Trial Costs") are shared 80% by Sanofi and 20% by Regeneron. Consequently, in the first quarter of 2014, the Company recognized as additional research and development expense $23.8 million of antibody development expenses that the Company was obligated to reimburse to Sanofi related to alirocumab and sarilumab.

In May 2013, the Company acquired from Sanofi full exclusive rights to antibodies targeting the platelet derived growth factor (PDGF) family of receptors. At the time of acquisition, antibodies to the PDGF receptor were in preclinical development for use in ophthalmology. With respect to PDGF antibodies, the Company made two $5.0 million development milestone payments to Sanofi in the first quarter of 2014, which were recorded in the Company's Statements of Operations as research and development expense, and is obligated to pay up to $30.0 million in additional potential development milestones as well as royalties on any future sales.

Bayer HealthCare LLC

The Company and Bayer HealthCare globally collaborate on the development and commercialization of EYLEA outside of the United States. Bayer HealthCare commenced sales of EYLEA outside the United States for the treatment of wet AMD in the fourth quarter of 2012 and for the treatment of macular edema secondary to CRVO in the fourth quarter of 2013. In addition, in January 2014, the Company entered into a license and collaboration agreement with Bayer HealthCare governing the joint development and commercialization outside the United States of an antibody product candidate to Platelet Derived Growth Factor Receptor Beta (PDGFR-beta).

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REGENERON PHARMACEUTICALS, INC.
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(Unless otherwise noted, dollars in thousands, except per share data)

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

	Three months ended March 31,	
Bayer HealthCare Collaboration Revenue	2014	2013
EYLEA:		
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$61,159	$6,362
Sales milestones	30,000	—
Cost-sharing of Regeneron EYLEA development expenses	20,347	5,888
Other	10,932	2,657
Total EYLEA	122,438	14,907
PDGFR-beta antibody:		
Cost-sharing of REGN2176-3 development expenses	513	—
Other	2,361	—
Total PDGFR-beta	2,874	—
Total Bayer HealthCare collaboration revenue	$125,312	$14,907

EYLEA

In the first quarter of 2014, the Company earned, and recorded as revenue, two $15.0 million sales milestones from Bayer HealthCare upon total aggregate net sales of EYLEA outside the United States exceeding $500 million and $600 million, respectively, over a twelve-month period. The Company is eligible to receive up to $60.0 million in additional sales milestone payments if twelve-month sales of EYLEA outside the United States achieve certain specified levels up to $1 billion. In addition, in connection with a November 2013 agreement under which Bayer HealthCare obtained rights to use certain of the Company’s EYLEA clinical data for a regulatory filing, the Company became eligible to receive up to $30.0 million in additional sales milestone payments if twelve-month sales of specific commercial supplies of EYLEA outside the United States achieve certain specified levels up to $200 million.

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

PDGFR-beta Antibody

In January 2014, the Company also entered into an agreement with Bayer HealthCare governing the joint development and commercialization outside the United States of an antibody product candidate to PDGFR-beta, including in combination with EYLEA, for the treatment of ocular diseases or disorders. REGN2176-3, a combination product candidate comprised of an antibody to PDGFR-beta co-formulated with EYLEA, is being developed under the agreement. Under the agreement, the Company will conduct the initial development of the PDGFR-beta antibody

through completion of the first proof-of-concept study, upon which Bayer HealthCare will have a right to opt-in to license and collaborate on further development and commercialization outside the United States.

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In connection with the agreement, Bayer HealthCare made a $25.5 million non-refundable upfront payment to the Company in January 2014, and is obligated to pay 25% of global development costs and 50% of development costs exclusively for the territory outside the United States under the initial development plan. In addition, Bayer HealthCare is obligated to reimburse the Company for 50% of development milestone payments to Sanofi related to the Company's acquisition of rights to antibodies targeting the PDGF family of receptors in May 2013, as described above. In that regard, Bayer HealthCare made two $2.5 million development milestone payments to the Company in the first quarter of 2014 (both of which, for the purpose of revenue recognition, were not considered substantive). Further, in connection with the Company’s initial development of the PDGFR-beta antibody through completion of the first proof-of-concept study, the Company is eligible to receive up to $15.0 million in future development milestone payments from Bayer HealthCare, although certain of these development milestone payments could be reduced by half if Bayer HealthCare does not opt-in to the collaboration.

From inception of the agreement until Bayer HealthCare has the right to opt-in to the collaboration, the Company's sole significant deliverable is research and development services provided in accordance with the agreement. Therefore, the $25.5 million upfront payment was allocated to this deliverable, initially recorded as deferred revenue, and will be recognized as revenue over the related performance period. In addition, the two $2.5 million non-substantive development milestone payments from Bayer HealthCare were also initially recorded as deferred revenue and will be recognized over the same performance period as the upfront payment.

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

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

The Company also has the right to opt-out of the collaboration upon completion of the first proof-of-concept study for the PDGFR-beta antibody. If the Company opts-out of the collaboration and Bayer HealthCare exercises its right to opt-in to the collaboration, Bayer HealthCare will obtain exclusive rights to the PDGFR-beta antibody (except as a combination product with EYLEA) outside of the United States, be responsible for all development costs outside of the United States, be responsible for all royalty and milestone payments to a third party, and will retain all of the profits from sales of the PDGFR-beta antibody outside of the United States.

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

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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 March 31,	
	2014	2013
Net income - basic and diluted	$65,443	$98,874
(Shares in thousands)		
Weighted average shares - basic	98,709	96,878
Effect of dilutive securities:		
Stock options	9,879	10,276
Restricted stock	401	325
Warrants	3,162	1,890
Dilutive potential shares	13,442	12,491
Weighted average shares - diluted	112,151	109,369
Net income per share - basic	$0.66	$1.02
Net income per share - diluted	$0.58	$0.90

Shares which have been excluded from the March 31, 2014 and 2013 diluted per share amounts because their effect would have been antidilutive, include the following:

	Three months ended March 31,	
(Shares in thousands)	2014	2013
Stock options	3,646	3,868
Convertible senior notes	4,761	4,761

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

5. Marketable Securities

Marketable securities at March 31, 2014 and December 31, 2013 consist of both debt securities issued by investment grade institutions as well as equity securities. The following tables summarize the Company's investments in marketable securities at March 31, 2014 and December 31, 2013.

At March 31, 2014	Amortized Cost Basis	Unrealized Gains	Losses	Fair Value
U.S. government and government agency obligations	$78,196	$82	$(13)	$78,265
Corporate bonds	579,600	517	(489)	579,628
Municipal bonds	43,276	138	(13)	43,401
International government agency obligations	8,214	3	—	8,217
Certificates of deposit	7,914	4	—	7,918
Equity securities	1,166	2,369	—	3,535
Total marketable securities	$718,366	$3,113	$(515)	$720,964
At December 31, 2013				
U.S. government and government agency obligations	$107,493	$55	$(27)	$107,521
Corporate bonds	369,321	233	(361)	369,193
Commercial paper	23,891	53	—	23,944
Municipal bonds	36,935	45	(59)	36,921
International government agency obligations	2,007	1	—	2,008
Certificates of deposit	7,509	5	—	7,514
Equity securities	1,166	—	—	1,166
Total marketable securities	$548,322	$392	$(447)	$548,267

The Company classifies its debt securities based on their contractual maturity dates. The debt securities listed at March 31, 2014 mature at various dates through August 2024. The fair values of debt security investments by contractual maturity as of March 31, 2014 and December 31, 2013 consist of the following:

	March 31, 2014	December 31, 2013
Maturities within one year	$186,275	$158,376
Maturities after one year through five years	525,961	383,410
Maturities after five years through ten years	4,042	4,138
Maturities after ten years	1,151	1,177
	$717,429	$547,101

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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 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 March 31, 2014 and December 31, 2013.

	Less than 12 Months		12 Months or Greater		Total	
At March 31, 2014	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
U.S. government and government agency obligations	$5,983	$(13)	—	—	$5,983	$(13)
Corporate bonds	268,174	(489)	—	—	268,174	(489)
Municipal bonds	12,187	(13)	—	—	12,187	(13)
	$286,344	$(515)	—	—	$286,344	$(515)
At December 31, 2013						
U.S. government and government agency obligations	$49,241	$(27)	—	—	$49,241	$(27)
Corporate bonds	176,140	(361)	—	—	176,140	(361)
Municipal bonds	14,431	(59)	—	—	14,431	(59)
	$239,812	$(447)	—	—	$239,812	$(447)

Realized gains and losses are included as a component of investment income. For the three months ended March 31, 2014 and 2013, total realized gains and losses on sales of marketable securities were not material. Changes in the Company's accumulated other comprehensive income (loss) for the three months ended March 31, 2014 and 2013 related to unrealized gains and losses on available-for-sale marketable securities. For the three months ended March 31, 2014 and 2013, amounts reclassified from accumulated other comprehensive income (loss) into investment income in the Company's Statements of Operations were related to realized gains and losses on sales of marketable securities.

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

6. Fair Value Measurements

The Company's assets that are measured at fair value on a recurring basis, at March 31, 2014 and December 31, 2013, consist of the following:

At March 31, 2014	Fair Value	Fair Value Measurements at Reporting Date Using Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)
Available-for-sale marketable securities:			
U.S. government and government agency obligations	$78,265	—	$78,265
Corporate bonds	579,628	—	579,628
Municipal bonds	43,401	—	43,401
International government agency obligations	8,217	—	8,217
Certificates of deposit	7,918	—	7,918
Equity securities	3,535	$3,535	—
	$720,964	$3,535	$717,429
At December 31, 2013			
Available-for-sale marketable securities:			
U.S. government and government agency obligations	$107,521	—	$107,521
Corporate bonds	369,193	—	369,193
Commercial paper	23,944	—	23,944
Municipal bonds	36,921	—	36,921
International government agency obligations	2,008	—	2,008
Certificates of deposit	7,514	—	7,514
Equity securities	1,166	$1,166	—
	$548,267	$1,166	$547,101

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 months ended March 31, 2014 and 2013.

There were no purchases, sales, or maturities of Level 3 marketable securities and no unrealized gains or losses related to Level 3 marketable securities for the three months ended March 31, 2014 and 2013. There were no transfers of marketable securities between Levels 1, 2, or 3 classifications during the three months ended March 31, 2014 and 2013.

As of March 31, 2014 and December 31, 2013, 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 $1,437.7 million and $1,327.2 million as of March 31, 2014 and December 31, 2013, respectively, and was determined based on Level 2 inputs, such as market

and observable sources.

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REGENERON PHARMACEUTICALS, INC.
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7. Inventories

Inventories consist of the following:

	March 31, 2014	December 31, 2013
Raw materials	$6,792	$9,120
Work-in-process	47,858	35,868
Finished goods	13,230	14,352
Deferred costs	18,665	11,014
	$86,545	$70,354

Deferred costs represent the costs of product manufactured and shipped to the Company's collaborators for which recognition of revenue has been deferred. For the three months ended March 31, 2014 and 2013, cost of goods sold included inventory write-downs and reserves totaling $1.1 million and $3.2 million, respectively.

8. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following:

	March 31, 2014	December 31, 2013
Accounts payable	$32,692	$61,936
Accrued payroll and related costs	41,754	69,429
Accrued clinical trial expense	30,828	23,654
Accrued sales-related charges, deductions, and royalties	94,554	66,855
Other accrued expenses and liabilities	38,107	29,022
	$237,935	$250,896

9. Income Taxes

The Company is subject to U.S. federal, state, and foreign income taxes. For the three months ended March 31, 2014 and 2013, the Company recorded an income tax provision of $109.8 million and $43.0 million, respectively. The Company's effective tax rate for the three months ended March 31, 2014 and 2013 was 62.7% and 30.3%, respectively. The Company's effective tax rate for the three months ended March 31, 2014 was negatively impacted by (i) expiration at the end of 2013 of the federal tax credit for increased research activities, (ii) losses incurred in foreign jurisdictions with rates lower than the federal statutory rate, and (iii) recently enacted New York State tax legislation. This tax legislation reduced the New York State income tax rate to zero percent for "qualified manufacturers", including Regeneron, effective in 2014; however, it also resulted in the Company reducing its related deferred tax assets as a discrete item in the first quarter of 2014. As a result, this tax legislation caused a net increase in the Company's effective tax rate by 10.4% for the first quarter of 2014.

The Company's effective tax rate for the three months ended March 31, 2013 included, as a discrete item, the favorable impact of the enactment of 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 well as for 2013. As a result, the Company's 2012 research tax credit reduced its effective tax rate for the three months ended March 31, 2013 by 12.3%.

Tax years subsequent to 2009 remain open to examination by federal tax authorities. The Company's 2011 federal income tax return is currently under audit by the Internal Revenue Service. In addition, the Company's 2009, 2010, and 2011 New York State returns are currently under audit by state tax authorities.

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REGENERON PHARMACEUTICALS, INC.
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10. Statement of Cash Flows

Supplemental disclosure of non-cash investing and financing activities:

Included in accounts payable and accrued expenses at March 31, 2014 and December 31, 2013 were $17.6 million and $16.1 million, respectively, of accrued capital expenditures. Included in accounts payable and accrued expenses at March 31, 2013 and December 31, 2012 were $10.1 million and $8.6 million, respectively, of accrued capital expenditures.

Pursuant to the application of FASB authoritative guidance to the Company's lease of office and laboratory facilities in Tarrytown, New York, the Company recognized a facility lease obligation of $19.4 million during the three months ended March 31, 2014 in connection with capitalizing, on the Company's books, the landlord's costs of constructing new facilities that the Company has leased. The Company did not recognize any such facility lease obligation during the three months ended March 31, 2013.

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 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.

Proceedings Relating to ‘287 Patent and '018 Patent

The Company is a party to patent infringement litigation involving its European Patent No. 1,360,287 (the "'287 Patent") and its U.S. Patent No. 8,502,018 (the "'018 Patent"), both of which concern genetically altered mice capable of producing chimeric antibodies that are part human and part mouse. Chimeric antibody sequences can be used to produce high-affinity fully human monoclonal antibodies. In these proceedings (the "'287 Patent Infringement Litigation" and "'018 Patent Infringement Litigation," respectively), the Company claims infringement of several claims of the '287 Patent and the '018 Patent (as applicable), and seeks, among other types of relief, an injunction and an account of profits in connection with the defendants' infringing acts, which may include, among other things, the making, use, keeping, sale, or offer for sale of genetically engineered mice (or certain cells from which they are derived) that infringe one or more claims of the '287 Patent and the '018 Patent (as applicable).

As the '287 Patent Infringement Litigation and '018 Patent Infringement Litigation proceedings are at an early stage, at this time the Company is not able to predict the outcome of, or an estimate of gain, if any, related to, these proceedings.

12. Subsequent Events

In April 2014, the Company received notification that $61.1 million principal amount of the Company's 1.875% convertible senior notes were surrendered for conversion, and settlement is anticipated during the second quarter of 2014. In accordance with the terms of the notes, the Company elected to settle these conversion obligations through a combination of cash, in an amount up to the principal amount of the converted notes, and shares in respect of any excess thereof (based on the average of the volume-weighted-average prices of the Common Stock during the 40 trading-day cash settlement averaging period specified in the indenture governing the notes). In connection with these note conversions, the Company exercised a proportionate amount of its convertible note hedges, for which the Company expects to receive shares of Common Stock equivalent to the number of shares the Company will be required to issue to settle the non-cash portion of the related note conversions.

In May 2014, the Company entered into a research collaboration and license agreement with Avalanche Biotechnologies, Inc., a privately held company, to discover, develop, and commercialize novel gene therapy products for the treatment of ophthalmologic diseases. In connection with the agreement, the Company is required to make a $2.0 million upfront payment and a $6.0 million pre-payment of collaboration research costs, and is obligated to pay

potential additional research costs, potential development and regulatory milestones (for products directed to as many as eight therapeutic targets), and royalties on any future sales of such products. The Company has also purchased an aggregate of $5.0 million of Avalanche preferred stock. Under the agreement, the Company will collaborate with Avalanche to conduct research for the discovery of novel gene therapy vectors. Subsequent to the filing of an Investigational New Drug application ("IND") with the FDA for a product candidate, Regeneron may exercise its right to obtain exclusive worldwide rights to further research, develop, and commercialize such product candidates directed to the applicable therapeutic target. In addition, Avalanche has the option to share in development costs and profits for products directed toward up to two therapeutic targets of its choice.

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

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

Overview

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

Our total revenues were $625.7 million in the first quarter of 2014, compared to $439.7 million in the first quarter of 2013. Our net income was $65.4 million, or $0.58 per diluted share, in the first quarter of 2014, compared to net income of $98.9 million, or $0.90 per diluted share, in the first quarter of 2013. Refer to the "Results of Operations" section below for further details of our financial results.

We currently have three marketed products:

- EYLEA (aflibercept) Injection, known in the scientific literature as VEGF Trap-Eye, which is available in the United States, European Union (EU), Japan, and certain other countries outside the United States for the treatment of neovascular age-related macular degeneration (wet AMD) and macular edema following central retinal vein occlusion (CRVO). We are collaborating with Bayer HealthCare on the global development and commercialization of EYLEA outside the United States.
-

ZALTRAP® (ziv-aflibercept) Injection for Intravenous Infusion, known in the scientific literature as VEGF Trap, which is available in the United States, EU, and certain other countries for treatment, in combination with 5-fluorouracil, leucovorin, irinotecan (FOLFIRI), of patients with metastatic colorectal cancer (mCRC) that is resistant to or has progressed following an oxaliplatin-containing regimen. 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.

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

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We have 17 product candidates in clinical development, all of which were discovered in our research laboratories. These consist of two Trap-based clinical programs and 15 fully human monoclonal antibody product candidates, as summarized below:

Trap-based Clinical Programs

EYLEA

In Phase 3 clinical development for the treatment of diabetic macular edema (DME), macular edema following branch retinal vein occlusion (BRVO), and myopic choroidal neovascularization (mCNV), in collaboration with Bayer HealthCare.

ZALTRAP

In Phase 1b clinical development with angiopoietin-2 inhibitor (nesvacumab) in oncology in collaboration with Sanofi.

Antibody-based Clinical Programs

In Collaboration with Sanofi

Sarilumab (REGN88)

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

Alirocumab (REGN727)

Antibody to Proprotein Convertase Subtilisin/Kexin type 9 (PCSK9).
In Phase 3 clinical development for low-density lipoprotein (LDL) cholesterol reduction.

Dupilumab (REGN668)

Antibody to the interleukin-4 receptor alpha (IL-4R).
In clinical development in atopic dermatitis (Phase 2b), asthma (Phase 2b), and nasal polyposis (Phase 2).

Enoticumab (REGN421)

Antibody to Delta-like ligand-4 (Dll4), a novel angiogenesis target.
In Phase 1 clinical development in oncology.

Nesvacumab (REGN910)

Antibody to angiopoietin-2 (Ang2), a novel angiogenesis target.
In Phase 1 clinical development in oncology.

REGN1033

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

REGN2009

Antibody in Phase 1 clinical development against an undisclosed target.

REGN2222

Antibody in Phase 1 clinical development against an undisclosed target.

In Collaboration with Bayer HealthCare

Developed Independently

REGN1400

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

REGN1154

Antibody in Phase 1 clinical development against an undisclosed target.

REGN1500

Antibody in Phase 1 clinical development against an undisclosed target.

REGN1193

Antibody in Phase 1 clinical development against an undisclosed target.

REGN1908-1909

Antibody combination in Phase 1 clinical development against an undisclosed target.

Fasinumab (REGN475)

Antibody to Nerve Growth Factor (NGF).
In development for the treatment of pain; currently on clinical hold by the Food and Drug Administration (FDA).

REGN2176-3	Combination product comprised of an antibody to Platelet Derived Growth Factor Receptor Beta (PDGFR-beta) co-formulated with EYLEA for use in ophthalmology. In Phase 1 clinical development for the treatment of wet AMD.

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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. We continue to invest in the development of enabling technologies to assist in our efforts to identify, develop, manufacture, and commercialize new product candidates.

We recently launched a new human genetics initiative via a wholly owned subsidiary, Regeneron Genetics Center LLC (RGC). RGC will perform sequencing and genotyping to generate de-identified genomic data. The objective of RGC is to expand the use of human genetics for discovering and validating genetic factors that cause or influence a range of diseases where there are major unmet medical needs, with the prospect of improving the drug discovery and development process. RGC intends to pursue both large population-based efforts as well as family-based approaches.

Marketed Products

EYLEA (aflibercept) Injection

Net product sales of EYLEA in the United States were $359.0 million in the first quarter of 2014, compared to $313.9 million in the first quarter of 2013. Bayer HealthCare records revenue from sales of EYLEA outside the United States, which were $218.1 million in the first quarter of 2014 and $62.0 million in the first quarter 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 outside the United States, and for the treatment of macular edema secondary to CRVO in the fourth quarter of 2013 following receipt of regulatory approvals in the EU and Japan. Bayer HealthCare has additional regulatory applications for EYLEA for the treatment of wet AMD and macular edema secondary to CRVO pending in other countries.

In August 2013, we and Bayer HealthCare announced positive week 52 results from the Phase 3 VISTA-DME and VIVID-DME trials of EYLEA for the treatment of DME, as described below under "Trap-based and Late-Stage Antibody-based Clinical Programs: EYLEA - Ophthalmologic Diseases." Based on the positive results of these studies, we submitted a supplemental Biologics License Application (BLA) for U.S. regulatory approval of EYLEA in DME in the fourth quarter of 2013; the target date for an FDA decision on the supplemental BLA is August 18, 2014. Applications for marketing approval for the treatment of DME in the EU and Japan have also been submitted by Bayer HealthCare. In addition, in February 2014, we and Bayer HealthCare announced positive week 100 results from the Phase 3 VISTA-DME trial, as described below under "Trap-based Clinical Programs: EYLEA - Ophthalmologic Diseases." In October 2013, we announced positive week 24 results from the Phase 3 VIBRANT trial of EYLEA for the treatment of macular edema following BRVO, as described below under "Trap-based Clinical Programs: EYLEA - Ophthalmologic Diseases." Based on the positive results of this study, a supplemental BLA for U.S. regulatory approval of EYLEA in macular edema following BRVO was submitted, and the target date for an FDA decision on the supplemental BLA is October 23, 2014.

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

ZALTRAP (ziv-aflibercept) Injection for Intravenous Infusion

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 receive a percentage of the sales of ZALTRAP. 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 $21.6 million in the first quarter of 2014 and $14.1 million in the first quarter of 2013. 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.

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ARCALYST (rilonacept) Injection for Subcutaneous Use

ARCALYST (rilonacept) Injection for Subcutaneous Use is available in the United States for the treatment of CAPS in adults and children 12 years and older. CAPS are a group of rare, inherited, auto-inflammatory conditions characterized by life-long, recurrent symptoms of rash, fever/chills, joint pain, eye redness/pain, and fatigue. Intermittent, disruptive exacerbations or flares can be triggered at any time by exposure to cooling temperatures, stress, exercise, or other unknown stimuli. Net product sales of ARCALYST totaled $3.4 million in the first quarter of 2014 and $4.8 million in the first quarter of 2013.

Trap-based Clinical Programs

EYLEA - Ophthalmologic Diseases

Overview

Vascular Endothelial Growth Factor (VEGF) is a naturally occurring protein in the body. Its normal role in a healthy organism is to trigger formation of new blood vessels (angiogenesis) supporting the growth of the body's tissues and organs. However, in certain diseases, such as wet AMD, it is also associated with the growth of abnormal new blood vessels in the eye, which exhibit abnormal increased permeability that leads to edema. Scarring and loss of fine-resolution central vision often results. 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.

EYLEA is being evaluated in Phase 3 programs in patients with DME and macular edema following BRVO. 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.

Wet AMD

Phase 3 SIGHT Trial. 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 fully enrolled.

RE-VIEW Study. In the fourth quarter of 2012, we initiated a study (RE-VIEW) to fulfill a post-marketing requirement by the FDA, which is evaluating the effect of EYLEA on corneal endothelium. The trial is fully enrolled.

DME

Phase 3 VISTA-DME and VIVID-DME Trials. In August 2013, we and Bayer HealthCare announced that in the Phase 3 VISTA-DME and VIVID-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. Based on the positive results of these studies, during the fourth quarter of 2013, we submitted a supplemental BLA for U.S. regulatory approval of EYLEA in DME; the target date for an FDA decision on the supplemental BLA is August 18, 2014. Bayer HealthCare also submitted applications for marketing approval for the treatment of DME in the EU in the fourth quarter of 2013 and Japan in the first quarter of 2014. Both the VISTA-DME and VIVID-DME trials are planned to continue up to 148 weeks.

We are conducting the VISTA-DME study in the United States. Bayer HealthCare is conducting the VIVID-DME study in Europe, Japan, and Australia. Patients in both trials were randomized to receive either EYLEA 2 mg monthly, EYLEA 2 mg every two months (after 5 initial monthly injections), or the comparator treatment of laser photocoagulation. Previously, we reported that both trials achieved their primary endpoint of a statistically significant mean improvement in BCVA at 12 months versus baseline for EYLEA at both dosing schedules versus laser

photocoagulation.

In addition, in February 2014, we and Bayer HealthCare announced that in the Phase 3 VISTA-DME trial of EYLEA for the treatment of DME, EYLEA 2 mg dosed monthly and EYLEA 2 mg dosed every two months (after 5 initial monthly injections) showed a sustained improvement from baseline in BCVA at week 100, compared to laser photocoagulation. After two years, patients receiving EYLEA 2 mg monthly had a mean change from baseline in BCVA of 11.5 letters and patients receiving EYLEA

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2 mg every other month (after 5 initial monthly injections) had a mean change from baseline in BCVA of 11.1 letters, compared to patients receiving laser photocoagulation who had a mean change from baseline in BCVA of 0.9 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. The most frequent ocular treatment emergent AEs (TEAEs) observed included conjunctival hemorrhage, eye pain, and vitreous floaters. The most frequent non-ocular TEAEs included hypertension, nasopharyngitis, anemia, and urinary tract infection, which occurred with similar frequency in the treatment groups and the laser control group.

Phase 3 VIVID-Japan and VIVID EAST-DME Studies. 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. Bayer HealthCare recently reported positive results from the VIVID-Japan study, which did not change the overall safety profile for EYLEA in DME, and submitted an application for marketing authorization of EYLEA for the treatment of DME 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). This trial is fully enrolled.

Macular Edema Following BRVO

Phase 3 VIBRANT Study. In October 2013, we reported positive top-line results from the VIBRANT trial. The study achieved its primary endpoint of a statistically significant difference for EYLEA dose 2 mg monthly versus laser in proportion of patients who gained at least 15 letters of visual acuity at 24 weeks versus baseline. The incidence of serious AEs (SAEs) was similar in both study arms. The most common ocular AEs in the EYLEA treated patients were conjunctival hemorrhage and eye pain. There were no cases of intraocular inflammation. There was one ocular SAE in a patient in the EYLEA group, which was a traumatic cataract. Based on the positive results of the VIBRANT study, a supplemental BLA for U.S. regulatory approval of EYLEA in BRVO was submitted; the target date for an FDA decision on the supplemental BLA is October 23, 2014.

In January 2014, Bayer HealthCare exercised its right to opt-in to the global development and commercialization of EYLEA outside the United States for the treatment of macular edema following BRVO as described below under "Collaborations with Bayer HealthCare - EYLEA outside the United States."

Other

Phase 3 MYRROR Study. In June 2013, we and Bayer HealthCare announced positive top-line results for EYLEA from the Phase 3 MYRROR study in myopic choroidal neovascularization (mCNV). In this trial, patients receiving EYLEA at an initial dose of 2 mg, followed by treatment on an as-needed (PRN) basis, achieved a statistically significant mean improvement in BCVA from baseline to week 24 versus the sham control. 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. Bayer HealthCare submitted an application for regulatory approval for this indication in Japan in the fourth quarter of 2013.

ZALTRAP (ziv-aflibercept) - Oncology

ZALTRAP is a fusion protein that is designed to bind all forms of VEGF-A, VEGF-B, and PlGF, and prevent their interaction with cell surface receptors. VEGF-A (and to a lesser degree, PlGF) is required for angiogenesis that is 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.

Late-Stage Antibody-based Clinical Programs

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

Overview

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

Rheumatoid Arthritis

Phase 3 SARIL-RA-MOBILITY Trial. In the fourth quarter of 2013, we and Sanofi announced that in the SARIL-RA-MOBILITY Phase 3 clinical trial in adult patients with active RA who were inadequate responders to MTX therapy, sarilumab treatment in combination with MTX improved disease signs and symptoms as well as

physical function, and inhibited progression of joint damage. The 52 week SARIL-RA-MOBILITY Phase 3 trial enrolled approximately 1,200 patients with active, moderate-to-severe rheumatoid arthritis, and who were inadequate responders to MTX therapy. Patients were randomized to one of three subcutaneous treatment groups, all in combination with MTX and dosed every other week: sarilumab 200 mg, sarilumab 150 mg, or placebo.

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Both sarilumab groups showed clinically relevant and statistically significant improvements compared to the placebo group in all three co-primary endpoints ($p < 0.0001$).

In the SARIL-RA-MOBILITY trial, infections were the most frequently reported adverse events and were reported with a higher incidence in the sarilumab groups compared to placebo, all in combination with MTX. Among patients treated with sarilumab, a dose dependent decrease in mean neutrophil counts was observed. Serious infections were not associated with grades 3 and 4 neutropenia in this study. Increases in mean LDL cholesterol and transaminases were observed.

The efficacy and safety data from the SARIL-RA-MOBILITY study will be presented at an upcoming medical conference.

Additional Phase 3 Studies. We and Sanofi have also 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 a safety study 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.

Non-infectious Uveitis

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

Alirocumab (REGN727; PCSK9 Antibody) for LDL cholesterol reduction

Overview

Elevated LDL cholesterol (“bad cholesterol”) level is a validated risk factor leading to cardiovascular disease. Statins are a class of drugs that lower LDL through inhibition of HMG-CoA, an enzyme regulating the early and rate-limiting step in cholesterol biosynthesis that ultimately results in an increase in LDL receptors to increase the uptake of plasma LDL lipoproteins. PCSK9 is a secreted protein that plays a key role in modulating LDL cholesterol (LDL-C) 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-C, 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.

Clinical Programs

Phase 2 Studies. 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-C from baseline up to 72% on top of standard of care statin therapy. In the Phase 2 program, injection site reactions were the most common AEs with alirocumab, and were rare. Rare cases of hypersensitivity reaction were also reported. SAEs were reported in 1.8% of patients in the active treatment arms and 2.6% of patients in the placebo groups.

In the first quarter of 2014, the first Phase 2 study with alirocumab in Japanese patients met its primary endpoint. The results demonstrated that the mean LDL-C percentage reduction from baseline to week 12, the primary efficacy

endpoint of the study, was significantly greater in patients randomized to receive one of three doses of alirocumab administered every other week (Q2W) - 150 mg, 75 mg, and 50 mg, in combination with statin therapy, compared to patients receiving placebo. At week 12, the mean percentage reduction in LDL-C from baseline in patients receiving alirocumab 50 mg Q2W was 55%, alirocumab 75 mg Q2W was 62% and alirocumab 150 mg Q2W was 72%, compared to 3 percent in the placebo group. TEAEs in this study were reported by 52% of patients in the alirocumab 50 mg group, 48% of patients in the 75 mg group, and 64% of patients in the 150 mg group, compared to 32% in the placebo group. The most frequently reported TEAEs were nasopharyngitis, injection site reaction, back pain, cystitis and ligament sprain.

Phase 3 ODYSSEY Program. We and Sanofi initiated the global Phase 3 ODYSSEY program for alirocumab in the second quarter of 2012. The ODYSSEY program is expected to enroll more than 23,000 patients. This includes eleven clinical trials evaluating the effect of alirocumab, dosed every two weeks, on lowering LDL cholesterol. In addition, the 18,000 patient ODYSSEY

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OUTCOMES trial, assessing reduction in serious cardiovascular events, is currently enrolling patients, while the other trials exploring every two week dosing in the ODYSSEY program are fully enrolled. LDL cholesterol reduction is expected to be the primary efficacy endpoint for initial regulatory filings. Additionally, the ODYSSEY program includes two trials of alirocumab dosed every four weeks, ODYSSEY CHOICE I, which was initiated in the fourth quarter, and ODYSSEY CHOICE II, which was initiated in the first quarter of 2014; both of these trials are fully enrolled. Patients in the ODYSSEY CHOICE I trial receive alirocumab 300 mg in combination with statins each month and patients in the CHOICE II trial receive alirocumab 150 mg monotherapy and in combination with non-statin lipid lowering therapy each month. The ODYSSEY studies are being conducted in clinical centers around the world including North America, Western and Eastern Europe, South America, Australia, and Asia.

The first trial to report data from the Phase 3 ODYSSEY program was the ODYSSEY MONO trial (in the fourth quarter of 2013), which evaluated the efficacy and safety of alirocumab monotherapy versus ezetimibe monotherapy in patients with primary hypercholesterolemia. The study achieved its primary efficacy endpoint and demonstrated that patients randomized to receive alirocumab monotherapy experienced a mean reduction in LDL-C levels of 47.2% from baseline to week 24, compared to 15.6% in patients receiving ezetimibe monotherapy ($p<0.0001$). The percentage of patients who reported TEAEs was 78.4% in the ezetimibe group and 69.2% in the alirocumab group. The most common class of AEs was infections (39.2% with ezetimibe vs. 42.3% with alirocumab), which included nasopharyngitis, influenza, and upper respiratory tract infection. Injection-site reactions occurred in less than 2% of patients in both groups. Muscle-related AEs occurred in 3.9% of patients treated with ezetimibe and 3.8% of patients treated with alirocumab.

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

Overview

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

Atopic Dermatitis

Phase 2a Trial. Data from a European Phase 2a study of dupilumab in atopic dermatitis were presented during the annual meeting of the American Academy of Allergy Asthma and Immunology in March 2014. In this study of 109 patients with moderate-to-severe atopic dermatitis, dupilumab 300 mg administered weekly was associated with rapid and marked sustained improvements in several endpoints such as Eczema Severe Score Index (EASI), Scoring of Atopic Dermatitis (SCORAD), Investigator's Global Assessment Score (IGA), baseline Body Surface Area (BSA), and pruritus. After 12 weeks of treatment, patients receiving dupilumab achieved statistically superior clinical outcomes compared to patients in the placebo group in all measures of disease activity and pruritus. There were notably fewer patients with skin infections associated with dupilumab treatment (5.5%), compared with placebo (24.1%). There were no infection related SAEs or eczema herpeticum in the dupilumab group. In the placebo group, three patients with skin infections and four patients with atopic dermatitis exacerbations required hospitalization. The most common TEAEs were nasopharyngitis, headache, and conjunctivitis.

Phase 2b Trial. In the second quarter of 2013, a Phase 2b trial in atopic dermatitis was initiated, and is currently fully enrolled.

Asthma

Phase 2a Trial. Data from a Phase 2a trial in asthma patients with elevated eosinophils 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 at 300 mg weekly for 12 weeks 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). TEAEs were reported by a similar proportion of patients in both treatment 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, nasopharyngitis, upper respiratory tract

infection, headache, and nausea.

Phase 2b Trial. In the second quarter of 2013, a Phase 2b trial in asthma was initiated and is currently enrolling patients.

Nasal Polyposis

Phase 2 Study. In the third quarter of 2013, a Phase 2 study in nasal polyposis was initiated and is currently enrolling patients.

Other Antibody-based Clinical Programs

Each of the antibodies in the table below was generated using our VelocImmune technology.

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Program	Overview	Clinical Status
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. Enoticumab is a fully human monoclonal antibody to Dll4.	In Phase 1 clinical development.
Nesvacumab (REGN910; Ang2 Antibody) for oncology*	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, 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 that is designed to block Ang2.	In Phase 1 clinical development in oncology. In Phase 1b clinical development in combination with ZALTRAP in patients with advanced solid malignancies.
REGN1033 (GDF8 Antibody)*	REGN1033 is a fully human monoclonal antibody to GDF8. 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.	In Phase 2 clinical development.
REGN2009*	REGN2009 is a fully human monoclonal antibody against an undisclosed target.	In Phase 1 clinical development.
REGN2222*	REGN 2222 is a fully human monoclonal antibody against an undisclosed target.	In the second quarter of 2014, we initiated a Phase 1 clinical study.
REGN1400 (ErbB3 Antibody) for oncology	REGN1400 is a fully human monoclonal antibody against ErbB3.	In Phase 1 clinical development.
REGN1154**	REGN1154 is a fully human monoclonal antibody against an undisclosed target.	Our Phase 1 clinical study in Australia has been completed. We are currently evaluating next steps for this program.
REGN1500**	REGN1500 is a fully human monoclonal antibody against an undisclosed target.	In Phase 1 clinical development.
REGN1193**	REGN1193 is a fully human monoclonal antibody against an undisclosed target.	In Phase 1 clinical development.
REGN1908-1909**	REGN1908-1909 is a fully human monoclonal antibody combination against an undisclosed target.	In Phase 1 clinical development.
REGN2176-3 (PDGFR-beta Antibody in	REGN2176-3 is a combination product comprised of an antibody to PDGFR-beta, which was generated using our	In February 2014, we initiated a Phase 1 clinical study for the treatment of wet AMD.

combination with EYLEA) for ophthalmology***	VelocImmune technology, co-formulated with EYLEA for use in ophthalmology.	
Fasinumab (REGN475; NGF Antibody) for pain (on clinical hold)	Fasinumab is a fully human monoclonal antibody to NGF 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.

* Being developed in collaboration with Sanofi.
** Sanofi did not opt-in to, or elected not to continue co-development of, the 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 the product candidate.
*** Being developed in collaboration with Bayer HealthCare.

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Research Programs

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

Research and Development Technologies

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

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

We have utilized our VelociSuite technologies to develop a class of potential drug candidates, known as bi-specific antibodies. In the area of immunotherapies in oncology, we are exploring the use of bi-specific antibodies that target tumor antigens and the CD3 receptor on T-cells to harness the oncolytic properties of T-cells. Our first such

bi-specific antibody, which we expect to advance into clinical development later in 2014, targets CD20 and CD3.
Regeneron Genetics Center. We recently launched a new human genetics initiative via a wholly owned subsidiary, Regeneron Genetics Center LLC. RGC will leverage de-identified clinical and molecular data from human volunteers for medically relevant associations in a blinded fashion designed to preserve patients' privacy. The objective of RGC is to expand the use of human genetics for discovering and validating genetic factors that cause or influence a range of diseases where there are major unmet medical needs, with the prospect of improving the drug discovery and development process. RGC intends to pursue both large population-based efforts as well as family-based approaches.

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Central to the work of RGC will be a collaboration with the Geisinger Health System of Pennsylvania. During the initial five-year collaboration term, Geisinger plans to collect samples from more than 100,000 consented patient volunteers, while RGC will perform sequencing and genotyping to generate de-identified genomic data.

Collaboration Agreements

Collaborations with Sanofi

ZALTRAP. Since September 2003, we and Sanofi have been parties to a global collaboration for the development and commercialization of ZALTRAP. Under the current terms of our collaboration agreement 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 receive a percentage of approximately 35% on sales of ZALTRAP, subject to certain potential adjustments.

Under the collaboration agreement, 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 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, for the foreseeable future, our share of any ZALTRAP profits will be used to reimburse Sanofi for this repayment obligation.

Antibodies. Since November 2007, we and Sanofi have been parties to a global, strategic collaboration to discover, develop, and commercialize fully human monoclonal antibodies. The collaboration is governed by a Discovery and Preclinical Development Agreement and a License and Collaboration Agreement (each as amended). Pursuant to the collaboration, Sanofi is funding up to $160 million per year of our antibody discovery activities over the period from 2010-2017 to identify and validate potential drug discovery targets and develop fully human monoclonal antibodies against these targets. We lead the design and conduct of research activities under the collaboration, including target identification and validation, antibody development, research and preclinical activities through filing of an IND or its equivalent, toxicology studies, and manufacture of preclinical and clinical supplies. Sanofi has an option to extend certain antibody development and preclinical activities relating to selected program targets for up to an additional three years after 2017.

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

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

Collaborations with Bayer HealthCare

EYLEA outside the United States. Since October 2006, we and Bayer HealthCare have been parties to a license and collaboration agreement for the global development and commercialization outside the United States of EYLEA. Under the agreement, we and Bayer HealthCare collaborate on, and share the costs of, the development of EYLEA

through an integrated global plan. Bayer HealthCare markets EYLEA outside the United States, where, for countries other than Japan, the companies share equally in profits and losses from sales of EYLEA. In 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 an agreement under which we are entitled to receive a tiered percentage of between 33.5% and 40.0% of EYLEA net sales in Japan. In certain specified circumstances, the Japan arrangement may revert to a profit share arrangement. In January 2014, Bayer HealthCare decided to participate in the global development and commercialization of EYLEA outside the United States for the treatment of macular edema following BRVO. In connection with this decision, Bayer HealthCare

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reimbursed us for a defined share of the EYLEA global development costs that we had incurred prior to February 2014 for the BRVO indication. In addition, all future agreed upon global EYLEA development expenses incurred in connection with BRVO will be shared equally, and profits or losses on sales of EYLEA outside of the United States for the treatment of macular edema following BRVO will also be shared (for countries other than Japan). As described above, we are entitled to receive a tiered percentage of EYLEA net sales in Japan.

Since inception of the agreement, we have received $110.0 million of development milestone payments and $75.0 million of sales milestone payments from Bayer HealthCare. In addition, we may earn up to $90.0 million in additional sales milestone payments if twelve-month sales of EYLEA outside the United States achieve certain specified levels.

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

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

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

In connection with the agreement, Bayer HealthCare made a $25.5 million non-refundable upfront payment to us in January 2014, and is obligated to pay 25% of global development costs and 50% of development costs exclusively for the territory outside the United States under the initial development plan. In addition, Bayer HealthCare is obligated to reimburse us for 50% of development milestone payments to Sanofi related to our acquisition of rights to antibodies targeting the PDGF family of receptors in May 2013. In that regard, Bayer HealthCare made two $2.5 million development milestone payments to us in the first quarter of 2014. Further, in connection with our initial development of the PDGFR-beta antibody through completion of the first proof-of-concept study, we are eligible to receive up to $15.0 million in future development milestone payments from Bayer HealthCare, although certain of these development milestone payments could be reduced by half if Bayer HealthCare does not opt-in to the collaboration.

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

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

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

sales of the PDGFR-beta antibody outside of the United States.

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

Collaboration with Avalanche Biotechnologies, Inc.

In May 2014, we entered into a research collaboration and license agreement with Avalanche Biotechnologies, Inc., a privately held company, to discover, develop, and commercialize novel gene therapy products for the treatment of ophthalmologic diseases.

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In connection with the agreement, we are required to make a $2.0 million upfront payment and a $6.0 million pre-payment of collaboration research costs, and are obligated to pay potential additional research costs, potential development and regulatory milestones (for products directed to as many as eight therapeutic targets), and royalties on any future sales of such products. We have also purchased an aggregate of $5.0 million of Avalanche preferred stock. Under the agreement, we will collaborate with Avalanche to conduct research for the discovery of novel gene therapy vectors. Subsequent to the filing of an Investigational New Drug application ("IND") with the FDA for a product candidate, we may exercise our right to obtain exclusive worldwide rights to further research, develop, and commercialize such product candidates directed to the applicable therapeutic target. In addition, Avalanche has the option to share in development costs and profits for products directed toward up to two therapeutic targets of its choice.

General

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

Our ability to continue to generate profits and to generate positive cash flow from operations over the next several years depends significantly on our continued success in commercializing EYLEA. We expect to continue to incur substantial expenses related to our research and development activities, a significant portion of which we expect to be reimbursed by our collaborators. Also, our research and development activities outside our collaborations, the costs of which are not reimbursed, will expand and require additional resources. Our operating results may fluctuate from quarter to quarter and will depend on, among other factors, the net sales of our marketed products, the scope and progress of our research and development efforts, the timing of certain expenses, and the continuation of our collaborations with Sanofi and Bayer HealthCare, including our share of collaboration profits or losses from sales of commercialized products and the amount of reimbursement of our research and development expenses that we receive from collaborators. We cannot predict whether or when new products or new indications for 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.

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The planning, execution, and results of our clinical programs are significant factors that can affect our operating and financial results. In our clinical programs, key events in 2014 to date were, and plans for the next twelve months are, as follows:

Trap-based Clinical Programs:	
2014 Events to Date	2014-2015 Plans (next 12 months)
EYLEA	
Bayer HealthCare received regulatory approval for EYLEA in certain countries for the treatment of patients with wet AMD and continued to pursue regulatory applications for marketing approval in additional countries	Bayer HealthCare to file for China regulatory approval for the treatment of wet AMD Bayer HealthCare to file for additional ex-US regulatory approvals in DME and additional Asia regulatory approvals in myopic CNV
Bayer HealthCare received regulatory approval for EYLEA in certain countries for the treatment of patients with macular edema secondary to CRVO and continued to pursue regulatory applications for marketing approval in additional countries	Report one-year results from the Phase 3 VIBRANT BRVO study Bayer HealthCare to file for regulatory approvals outside the United States for the treatment of macular edema following BRVO
Bayer HealthCare opted-in to the global development and commercialization outside the United States for the treatment of macular edema following BRVO	Regulatory agency decisions on applications in the United States and outside the United States for the treatment of DME and macular edema following BRVO
Reported positive two-year results from the Phase 3 VISTA-DME study	Report two year results from Phase 3 VIVID-DME study
Bayer HealthCare reported positive results from the VIVID-Japan study and submitted an application for marketing authorization of EYLEA for the treatment of DME in Japan	
Supplemental BLA accepted for regulatory approval in the United States for the treatment of macular edema following BRVO	
ZALTRAP	
Sanofi received regulatory approval in additional countries for ZALTRAP for patients with mCRC that is resistant to or has progressed following an oxaliplatin-containing regimen	Regulatory agency decisions outside the United States on additional applications for ZALTRAP in the treatment of previously treated mCRC patients

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Antibody-based Clinical Programs:

	2014 Events to Date	2014-2015 Plans (next 12 months)
Sarilumab (IL-6R Antibody)	Obtained positive results from Phase 1b RA trial in Japan	Continue enrollment in Phase 3 SARIL-RA program Continue patient enrollment in SARIL-NIU-SATURN Phase 2 study in non-infectious uveitis Initiate additional clinical studies
Alirocumab (PCSK9 Antibody)	Initiated Phase 3 ODYSSEY CHOICE II trial Completed patient enrollment in the ODYSSEY CHOICE I and CHOICE II trials Initiated Phase 3 program in Japan	Continue enrollment of Phase 3 ODYSSEY OUTCOMES trial Report results from additional Phase 3 ODYSSEY trials
Dupilumab (IL-4R Antibody)	Reported positive Phase 2a data in atopic dermatitis	Complete patient enrollment in Phase 2 asthma trials Report results from Phase 2b study in atopic dermatitis Initiate Phase 3 trial in atopic dermatitis
Enoticumab (Dll4 Antibody)	Completed patient enrollment in the Phase 1 expansion study	
Nesvacumab (Ang2 Antibody)	Continued patient enrollment in Phase 1 program	Complete patient enrollment in the Phase 1b program in advanced malignancies Initiate clinical development in ophthalmology
REGN1033 (GDF8 Antibody)	Continued patient enrollment in Phase 1 and Phase 2a studies	Complete patient enrollment in Phase 1 and Phase 2a programs
REGN2009 (target not disclosed)	Continued patient enrollment in Phase 1 program	Continue patient enrollment in Phase 1 program
REGN2222 (target not disclosed)	Initiated Phase 1 program	Continue patient enrollment in Phase 1 program
REGN1400 (ErbB3 Antibody)	Continued patient enrollment in Phase 1 program	Continue patient enrollment in Phase 1 program
REGN1154 (target not disclosed)		Determine future development plan
REGN1500 (target not disclosed)	Continued patient enrollment in Phase 1 program	Continue patient enrollment in Phase 1 program
REGN1193 (target not disclosed)	Continued patient enrollment in Phase 1 program	Continue patient enrollment in Phase 1 program
REGN1908-1909 (target not disclosed)	Completed patient enrollment of First in Human study	
REGN2176-3 (PDGFR-beta Antibody in combination with EYLEA)	Initiated 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 March 31, 2014 and 2013

Net Income

Net income for the three months ended March 31, 2014 and 2013 consists of the following:

(In millions)	2014	2013
Revenues	$625.7	$439.7
Operating expenses	(439.8)	(286.6)
Other expenses	(10.7)	(11.2)
Income before income taxes	175.2	141.9
Income tax expense	(109.8)	(43.0)
Net income	$65.4	$98.9

Revenues

Revenues for the three months ended March 31, 2014 and 2013 consist of the following:

(In millions)	2014	2013
Net product sales	$362.4	$318.7
Collaboration revenue:		
Sanofi	130.5	99.3
Bayer HealthCare	125.3	14.9
Total collaboration revenue	255.8	114.2
Technology licensing and other revenue	7.5	6.8
Total revenues	$625.7	$439.7

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 March 31, 2014, EYLEA net product sales increased to $359.0 million from $313.9 million for the three months ended March 31, 2013 due to higher sales volume. For the three months ended March 31, 2014 and 2013, we also recognized ARCALYST net product sales of $3.4 million and $4.8 million, respectively.

For the three months ended March 31, 2014 and 2013, we recorded 79% and 77%, respectively, of our total gross product revenue from sales to Besse Medical, a subsidiary of AmerisourceBergen Corporation.

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Revenue from product sales is recorded net of applicable provisions for rebates and chargebacks under governmental programs (including Medicaid), distribution-related fees, prompt pay discounts, and other sales-related deductions. The following table summarizes the provisions, and credits/payments, for sales-related deductions for the three months ended March 31, 2014 and 2013.

(In millions)	Rebates & Chargebacks	Distribution-Related Fees	Other Sales-Related Deductions	Total
Balance as of December 31, 2013	$4.4	$19.7	$0.5	$24.6
Provision related to current period sales	6.9	16.9	0.4	24.2
Credits/payments	(6.7)	(16.3)	(0.4)	(23.4)
Balance as of March 31, 2014	$4.6	$20.3	$0.5	$25.4
Balance as of December 31, 2012	$3.0	$15.3	$0.5	$18.8
Provision related to current period sales	5.5	13.9	0.2	19.6
Credits/payments	(4.8)	(11.5)	(0.2)	(16.5)
Balance as of March 31, 2013	$3.7	$17.7	$0.5	$21.9

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, our share of losses in connection with Sanofi's commercialization of ZALTRAP, and recognition of previously deferred revenue related to non-refundable up-front payments.

Sanofi Collaboration Revenue	Three months ended March 31,	
(In millions)	2014	2013
ZALTRAP:		
Regeneron's share of losses in connection with commercialization of ZALTRAP	$(3.2)	$(7.8)
Reimbursement of Regeneron research and development expenses	1.1	2.1
Other	2.2	1.9
Total ZALTRAP	0.1	(3.8)
Antibody:		
Reimbursement of Regeneron research and development expenses	126.8	99.6
Other	3.6	3.5
Total Antibody	130.4	103.1
Total Sanofi collaboration revenue	$130.5	$99.3

Sanofi commenced sales of ZALTRAP for treatment, in combination with FOLFIRI, of 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 European and other countries 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 March 31,	
(In millions)	2014	2013
Net product sales recorded by Sanofi	$21.6	$14.1
Regeneron's share of collaboration losses	(3.2)	(7.8)

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Our share of the loss in the first quarter of 2014 and 2013 represents our share of the costs of launching and commercializing ZALTRAP, 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; these estimates are reconciled to actual results in the subsequent fiscal quarter, and our portion of the profit or loss is adjusted accordingly, as necessary.

In the first quarter of 2014, Sanofi's reimbursement of our antibody research and development expenses consisted of $40.2 million under our discovery agreement and $86.6 million of development costs under our license agreement, compared to $44.4 million and $55.2 million, respectively, in the first quarter of 2013. The higher reimbursement of development costs in the first quarter of 2014, compared to the same period in 2013, was primarily due to increased development activities for dupilumab.

Other Sanofi antibody revenue relates primarily to recognition of deferred revenue from an $85.0 million up-front payment and other payments. As of March 31, 2014, $58.4 million of the up-front and other payments was deferred and will be recognized as revenue in future periods.

Bayer HealthCare Collaboration Revenue

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

Bayer HealthCare Collaboration Revenue	Three months ended March 31,	
(In millions)	2014	2013
EYLEA:		
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$61.2	$6.4
Sales milestones	30.0	—
Cost-sharing of Regeneron EYLEA development expenses	20.3	5.9
Other	10.9	2.7
Total EYLEA	122.4	15.0
PDGFR-beta antibody:		
Cost-sharing of REGN2176-3 development expenses	0.5	—
Other	2.4	—
Total PDGFR-beta antibody	2.9	—
Total Bayer HealthCare collaboration revenue	$125.3	$15.0

Bayer HealthCare commenced sales of EYLEA outside the United States for the treatment of wet AMD in the fourth quarter of 2012 and for the treatment of macular edema secondary to CRVO in the fourth quarter of 2013.

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

Regeneron's Net Profit from EYLEA Sales Outside the United States	Three months ended March 31,	
(In millions)	2014	2013
Net product sales outside the United States	$218.1	$62.0
Regeneron's share of collaboration profit from sales outside the United States	75.6	19.6
Reimbursement of EYLEA development expenses incurred by Bayer HealthCare in accordance with Regeneron's payment obligation	(14.4)	(13.2)
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$61.2	$6.4

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Bayer HealthCare records revenue from sales of EYLEA outside the United States. Bayer HealthCare provides us with an estimate of our share of the profit or loss, including the percentage of sales in Japan that we earned, from commercialization of EYLEA outside the United States for the most recent fiscal quarter; these estimates are reconciled to actual results in the subsequent fiscal quarter, and our portion of the profit or loss is adjusted accordingly, as necessary. In the first quarter of 2014 and 2013, our share of the profit we earned from commercialization of EYLEA outside the United States was partly offset by our contractual obligation to reimburse Bayer HealthCare for a portion of the agreed-upon development expenses previously incurred by Bayer HealthCare. In the first quarter of 2014, we earned, and recorded as revenue, two $15.0 million sales milestones from Bayer HealthCare upon total aggregate net sales of EYLEA outside the United States exceeding $500 million and $600 million, respectively, over a twelve-month period.

Cost-sharing of our global EYLEA development expenses with Bayer HealthCare increased in the first quarter of 2014 compared to the same period in 2013. In January 2014, Bayer HealthCare decided to participate in the global development and commercialization of EYLEA outside the United States for the treatment of macular edema following BRVO. In connection with this decision, Bayer HealthCare reimbursed us $15.7 million for a defined share of the EYLEA global development costs that we had incurred prior to February 2014 for the BRVO indication, which was recognized as Bayer HealthCare collaboration revenue in the first quarter of 2014. In addition, all future agreed upon global EYLEA development expenses incurred in connection with BRVO will be shared equally, and any future profits or losses on sales of EYLEA outside of the United States for the treatment of macular edema following BRVO will also be shared.

Other EYLEA revenue principally consists of (i) reimbursement of other Regeneron EYLEA expenses, primarily related to Bayer HealthCare's share of royalties payable to Genentech which commenced in May 2013 pursuant to the license and settlement agreement as described below under "Liquidity and Capital Resources - License and Settlement Agreements with Genentech - EYLEA", in connection with sales of EYLEA outside the United States, and (ii) recognition of deferred revenue related to EYLEA up-front and 2007 non-substantive milestone payments from Bayer HealthCare. As of March 31, 2014, $19.8 million of the EYLEA up-front and 2007 milestone payments was deferred and will be recognized ratably as revenue in future periods.

Cost-sharing of REGN2176-3 development expenses with Bayer HealthCare commenced in the first quarter of 2014 in connection with the execution of the companies' PDGFR-beta antibody collaboration agreement as described above under "Collaboration with Bayer HealthCare - PDGFR-beta antibody outside the United States."

Other PDGFR-beta antibody revenue consists of recognition of deferred revenue related to the PDGFR-beta up-front and non-substantive milestones received in the first quarter of 2014. In connection with the agreement, Bayer HealthCare made a $25.5 million non-refundable upfront payment to us in January 2014, as well as two $2.5 million development milestone payments to us in the first quarter of 2014 (which, for the purpose of revenue recognition, were not considered substantive). As of March 31, 2014, $28.2 million of the PDGFR-beta up-front and 2014 milestone payments was deferred and will be recognized ratably as revenue in future periods.

Technology Licensing and Other Revenue

In connection with the amendment and extension of our VelocImmune license agreement with Astellas, in August 2010, we received a $165.0 million up-front payment, which was deferred upon receipt and is being recognized as revenue ratably over a seven-year period beginning in June 2011. In the first quarter of both 2014 and 2013, we recognized $5.9 million of technology licensing and other revenue related to this agreement. As of March 31, 2014, $98.7 million of the August 2010 technology licensing payment received from Astellas was deferred and will be recognized as revenue in future periods.

Under a June 2009 agreement with Novartis, we receive royalties on worldwide sales of Novartis' canakinumab. In the first quarter of 2014 and 2013, technology licensing and other revenue included $1.6 million and $0.8 million, respectively, of royalties from Novartis.

Expenses

Total operating expenses increased to $439.8 million in the first quarter of 2014 from $286.6 million in the first quarter of 2013. Our average headcount in the first quarter of 2014 increased to 2,389 from 1,996 in the same period

in 2013, principally in connection with expanding our research and development, and commercialization activities. Operating expenses in the first quarter of 2014 and 2013 included a total of $81.4 million and $53.0 million, respectively, of non-cash compensation expense related to employee stock option and restricted stock awards (Non-cash Compensation Expense). The increase in total Non-cash Compensation Expense in the first quarter of 2014 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 2013 compared to recent prior years.

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Research and Development Expenses

Research and development expenses increased to $287.4 million in the first quarter of 2014 from $180.3 million in the same period of 2013. The following table summarizes the major categories of our research and development expenses for the three months ended March 31, 2014 and 2013:

Research and Development Expenses	Three months ended March 31,		Increase
(In millions)	2014	2013	(Decrease)
Payroll and benefits [1]	$97.2	$69.1	$28.1
Clinical trial expenses	48.2	24.7	23.5
Clinical manufacturing costs [2]	54.4	48.6	5.8
Research and other development costs	27.8	14.1	13.7
Occupancy and other operating costs	30.0	21.4	8.6
Cost-sharing of Bayer HealthCare and Sanofi development expenses [3]	29.8	2.4	27.4
Total research and development expenses	$287.4	$180.3	$107.1

[1] Includes Non-cash Compensation Expense of $37.6 million for the three months ended March 31, 2014 and $23.7 million for the three months ended March 31, 2013.

[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 $5.7 million for the three months ended March 31, 2014 and $3.1 million for the three months ended March 31, 2013.

[3] Under our collaborations with Bayer HealthCare and Sanofi, in periods when Bayer HealthCare or Sanofi incur certain development expenses, we also recognize, as additional research and development expense, the portion of our collaboration partners' development expenses that we are obligated to reimburse. Our collaboration partners provide us with estimated development expenses for the most recent fiscal quarter. Bayer HealthCare and Sanofi’s estimates are reconciled to their actual expenses for such quarter in the subsequent fiscal quarter, and our portion of our collaboration partners' 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 and dupilumab. Clinical manufacturing costs increased primarily due to higher costs related to manufacturing dupilumab, partly offset by lower costs related to manufacturing clinical supplies of alirocumab. Research and other development costs increased primarily due to two $5.0 million development milestone payments we made to Sanofi in the first quarter of 2014 in connection with our acquisition from Sanofi full exclusive rights to antibodies targeting the PDGF family of receptors in May 2013. Occupancy and other operating costs increased principally in connection with our higher headcount, expanded research and development activities, and higher information technology and facility-related costs at our Tarrytown and Rensselaer, New York sites. Cost-sharing of Bayer HealthCare and Sanofi development expenses increased primarily due to our obligation to fund 20% of Sanofi's Phase 3 alirocumab and sarilumab development costs, which commenced during the fourth quarter of 2013.

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

Project Costs	Three months ended March 31,		Increase
(In millions)	2014	2013	(Decrease)
EYLEA	$33.4	$30.4	$3.0
Alirocumab	53.5	31.2	22.3
Sarilumab	19.4	5.5	13.9
Dupilumab	43.1	12.2	30.9
Other antibody candidates in clinical development	43.8	27.9	15.9
Other research programs and unallocated costs	94.2	73.1	21.1
Total research and development expenses	$287.4	$180.3	$107.1

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 BLA must be submitted to, and accepted by, the FDA, and the FDA must approve the BLA prior to commercialization of the drug. It is not uncommon for the FDA to request additional data following its review of a BLA, which can significantly increase the drug development timeline and expenses. We may elect either on our own, or at the request of the FDA, to conduct further studies that are referred to as Phase 3b and 4 studies. Phase 3b studies are initiated and either completed or substantially completed while the BLA is under FDA review. These studies are conducted under an IND. Phase 4 studies, also referred to as post-marketing studies, are studies that are initiated and conducted after the FDA has approved a product for marketing. In addition, as discovery research, preclinical development, and clinical programs progress, opportunities to expand development of drug candidates into new disease indications can emerge. We may elect to add such new disease indications to our development efforts (with the approval of our collaborator for joint development programs), thereby extending the period in which we will be developing a product.

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

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

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased to $108.9 million in the first quarter of 2014 from $77.3 million in the first quarter of 2013 primarily due to higher expenses in connection with 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 under "Expenses" above. Selling, general, and administrative expenses included $37.6 million and $25.8 million of Non-cash Compensation Expense in the first quarter of 2014 and 2013,

respectively.

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Cost of Goods Sold

Cost of goods sold was $27.5 million in the first quarter of 2014 and $28.0 million in the first quarter of 2013. Cost of goods sold primarily consisted of royalties, as well as costs in connection with producing EYLEA and ARCALYST commercial supplies. In addition, in the first quarter of 2014 and 2013, cost of goods sold included inventory write-downs and reserves totaling $1.1 million and $3.2 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 increased to $16.1 million in the first quarter of 2014 from $1.0 million in the first quarter of 2013 primarily due to royalties payable to Genentech, which commenced in May 2013 pursuant to the license and settlement agreement as described below under "Liquidity and Capital Resources - License and Settlement Agreements with Genentech - EYLEA", in connection with sales of EYLEA outside the United States. Cost of collaboration manufacturing also includes 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

Total other expenses, net, decreased to $10.7 million in the first quarter of 2014 from $11.2 million in the first quarter of 2013, and consisted of investment income and interest expense. Interest expense in the first quarter of 2014 and 2013 primarily includes interest associated with our $400.0 million aggregate principal amount of 1.875% convertible senior notes, including amortization of the note discount and debt issuance costs, and interest associated with our facility lease obligations.

Income Taxes

In the first quarter of 2014 and 2013, we recorded income tax expense of $109.8 million and $43.0 million, respectively. The effective tax rate for the first quarter of 2014 was 62.7% and was negatively impacted by (i) expiration at the end of 2013 of the federal tax credit for increased research activities, (ii) losses incurred in foreign jurisdictions with rates lower than the federal statutory rate, and (iii) recently enacted New York State tax legislation. This tax legislation reduced the New York State income tax rate to zero percent for "qualified manufacturers", including Regeneron, effective in 2014; however, it also resulted in the reduction of our related deferred tax assets as a discrete item in the first quarter of 2014. As a result, this tax legislation caused a net increase in our effective tax rate by 10.4% for the first quarter of 2014.

The effective tax rate for the first quarter of 2013 was 30.3%, which included, as a discrete item, 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 for the tax year ended December 31, 2012. As a result, our 2012 research tax credit reduced our effective tax rate for the first quarter of 2013 by 12.3%.

Liquidity and Capital Resources

Sources and Uses of Cash for the Three Months Ended March 31, 2014 and 2013

At March 31, 2014, we had $1,182.8 million in cash, cash equivalents, and marketable securities compared with $1,083.9 million at December 31, 2013. In connection with our U.S. product launch of EYLEA in the fourth quarter of 2011, we offered extended payment terms to our EYLEA customers. EYLEA net trade accounts receivable were $800.2 million at March 31, 2014 and $785.8 million at December 31, 2013. During the three months ended March 31, 2014, we collected $368.1 million of EYLEA trade receivables. Effective January 2014, we have shortened the payments terms to certain of our EYLEA customers, which will reduce our cash collection cycle.

Cash Provided by Operating Activities

Net cash provided by operating activities was $53.5 million in the first quarter of 2014. Our net income of $65.4 million in the first quarter of 2014 included the following non-cash expenses: (i) Non-cash Compensation Expense of $81.4 million, (ii) depreciation and amortization of $11.5 million, and (iii) non-cash interest expense of $5.9 million, primarily resulting from the amortization of the discount and debt issuance costs in connection with our convertible

senior notes, which were issued in October 2011. In addition, deferred tax assets at March 31, 2014 increased by $8.5 million, compared to end-of-year 2013, primarily due to an increase in Non-cash Compensation Expense and deferred revenue, partly offset by the reduction of our deferred tax assets related to the recently enacted New York State tax legislation, which reduced our New York State income tax rate to zero percent effective in 2014.

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At March 31, 2014, Sanofi, Bayer HealthCare, and trade accounts receivable increased by $92.5 million, compared to end-of-year 2013, primarily due to higher trade accounts receivable in connection with U.S. EYLEA product sales, higher amounts receivable from Sanofi in connection with reimbursement of our antibody development costs, and higher amounts receivable from Bayer HealthCare in connection with the commercialization of EYLEA outside the United States. Inventories increased by $15.6 million, compared to end-of-year 2013, primarily in connection with increased production of EYLEA commercial supplies. Prepaid expenses and other assets increased by $20.9 million, compared to end-of-year 2013, primarily due to higher prepaid sales-related fees. Our deferred revenue at March 31, 2014 increased by $37.1 million, compared to end-of-year 2013, primarily due to (i) the receipt of a $25.5 million upfront payment as well as two $2.5 million non-substantive development milestone payments in connection with our PDGFR-beta antibody collaboration agreement with Bayer HealthCare, and (ii) higher deferred revenue in connection with manufacturing commercial supplies of EYLEA for Bayer HealthCare. This revenue is deferred until the product is sold by Bayer HealthCare to third-party customers. These increases were partly offset by 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 decreased by $14.1 million at March 31, 2014, compared to end-of-year 2013, primarily due to lower payroll-related liabilities as our year-end 2013 employee cash bonuses were paid in the first quarter of 2014 and lower liabilities for vendor invoices received but not yet paid, partly offset by higher accruals for sales-related charges.

Net cash provided by operating activities was $86.2 million in the first quarter of 2013. Our net income of $98.9 million in the first quarter of 2013 included (i) Non-cash Compensation Expense of $53.0 million, (ii) depreciation and amortization of $9.4 million, (iii) non-cash interest expense of $5.8 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 inventory write-downs and reserves of $3.2 million. In addition, deferred tax assets at March 31, 2013 decreased by $39.5 million, compared to end-of-year 2012, due to utilization of these assets to offset income taxes payable for the first quarter of 2013.

At March 31, 2013, Sanofi, Bayer HealthCare, and trade accounts receivable increased by $117.8 million, compared to end-of-year 2012, primarily due to higher trade accounts receivable in connection with EYLEA product sales. Inventories increased by $17.6 million, compared to end-of-year 2012, primarily in connection with production of EYLEA commercial supplies. Prepaid expenses and other current assets increased by $17.8 million, compared to end-of-year 2012, primarily due to higher prepaid sales-related fees. Accounts payable, accrued expenses, and other liabilities increased by $32.1 million at March 31, 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.

Cash Used in Investing Activities

Net cash used in investing activities was $236.2 million and $147.7 million in the first quarter of 2014 and 2013, respectively. In the first quarter of 2014 and 2013, purchases of marketable securities exceeded sales or maturities by $171.4 million and $126.5 million, respectively. Capital expenditures of $64.8 million and $21.2 million, in the first quarter of 2014 and 2013, respectively, included costs in connection with purchasing manufacturing equipment, expanding our Rensselaer, New York manufacturing facilities, and tenant improvement and associated costs related to our leased facilities in Tarrytown, New York.

Cash Provided by Financing Activities

Net cash provided by financing activities was $109.0 million and $11.5 million in the first quarter of 2014 and 2013, respectively. Proceeds from issuances of Common Stock, in connection with exercises of employee stock options, were $55.0 million in the first quarter of 2014 compared to $13.0 million in the first quarter of 2013. In addition, payments for employee tax obligations in connection with stock option exercises were $63.1 million in the first quarter of 2014 compared to $3.1 million in the first quarter of 2013. Cash flows from financing activities also increased by $117.3 million and $2.3 million in the first quarter of 2014 and 2013, respectively, due to utilization of excess tax benefits in connection with stock option exercises, which offset cash tax obligations.

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Fair Value of Marketable Securities

At March 31, 2014 and December 31, 2013, we held $720.9 million and $548.3 million, respectively, of marketable securities which consisted of debt securities issued by investment grade institutions as well as equity securities. The composition of our portfolio of marketable securities on these dates was as follows:

	March 31, 2014		December 31, 2013	
Investment type	Fair Value	Percent	Fair Value	Percent
U.S. government and government agency obligations	$78.3	11 %	$107.5	20 %
Corporate bonds	579.6	81 %	369.2	68 %
Commercial paper	—	—	24.0	4 %
Municipal bonds	43.4	6 %	36.9	7 %
International government agency obligations	8.2	1 %	2.0	—
Certificates of deposit	7.9	1 %	7.5	1 %
Equity securities	3.5	—	1.2	—
Total marketable securities	$720.9	100 %	$548.3	100 %

In addition, at March 31, 2014 and December 31, 2013, we had $461.9 million and $535.6 million, respectively, of cash and cash equivalents, primarily held in bank deposits and money market funds.

License and Settlement Agreements with Genentech - EYLEA

In December 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 $60.0 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.

In May 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 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 are obligated to 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 EYLEA sales outside the United States to worldwide EYLEA sales and determined consistent with the license and collaboration agreement.

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Tarrytown, New York Lease

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

Capital Expenditures

Our cash expenditures for property, plant, and equipment totaled $64.8 million in the first quarter of 2014 and $21.2 million in the first quarter of 2013.

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 $280 to $350 million during the remainder of 2014 primarily in connection with expanding our manufacturing facilities at our Rensselaer facility, tenant improvements primarily related to the two new buildings under construction 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.

Funding Requirements

We expect continued growth in our expenditures, particularly in connection with our research and development activities (including preclinical and clinical testing), capital expenditures, and commercialization of EYLEA. We believe that our existing capital resources, funds generated by anticipated EYLEA 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 antibodies collaboration 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 (i) agreed-upon development expenses that both companies incur in connection with our EYLEA collaboration, and (ii) development costs under the initial development plan in connection with our PDGFR-beta antibody collaboration.

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, in connection with EYLEA outside the United States, 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 EYLEA collaboration with Bayer HealthCare, our percentage on product sales in Japan) otherwise payable to us, unless, in some cases, we elect to reimburse these expenses at a faster rate. In particular, as of December 31, 2013, our contingent reimbursement obligation to Sanofi for ZALTRAP was

approximately $443 million, while our contingent reimbursement obligation to Bayer HealthCare for EYLEA was approximately $272 million. Therefore, we expect that, for the foreseeable future, 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.

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. With respect to PDGF antibodies, we made two $5.0 million development milestone payments in the first quarter of 2014, and are obligated to pay up to $30.0 million in potential additional development milestones as well as royalties on any future sales.

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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 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 quarter of 2014 and 2013, we made cash payments of $63.1 million and $3.1 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 and the sales prices of our Common Stock, and may continue to be substantial.

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

In April 2014, we received notification that $61.1 million principal amount of our 1.875% convertible senior notes were surrendered for conversion, and settlement is anticipated during the second quarter of 2014. In accordance with the terms of the notes, we elected to settle these conversion obligations through a combination of cash, in an amount up to the principal amount of the converted notes, and shares in respect of any excess thereof (based on the average of the volume-weighted-average prices of the Common Stock during the 40 trading-day cash settlement averaging period specified in the indenture governing the notes). In connection with these note conversions, we exercised a proportionate amount of our convertible note hedges, for which we expect to receive shares of Common Stock equivalent to the number of shares we will be required to issue to settle the non-cash portion of the related note conversions.

We may also from time to time seek to repurchase or retire our outstanding convertible senior notes, or other outstanding securities, through cash purchases or exchanges for other securities, in open market purchases, privately negotiated transactions, or otherwise; amounts involved may be material.

Due to the amounts of our net operating loss and tax credit carry-forwards available for tax purposes, which totaled $450.4 million and $120.1 million, respectively, at December 31, 2013, we do not anticipate making significant payments for cash income taxes for at least the next twelve months, although we do expect to make payments of alternative minimum tax in 2014 for which we will receive a credit against income taxes in future years.

In connection with our EYLEA collaboration with Bayer HealthCare, we are entitled to receive up to $60.0 million in additional sales milestones based on total twelve-month sales of EYLEA outside the United States achieving certain

specified levels up to $1 billion. In addition, in connection with a November 2013 agreement under which Bayer HealthCare obtained rights to use certain of our EYLEA clinical data for a regulatory filing, we became eligible to receive up to $30.0 million in additional sales milestone payments if twelve-month sales of specific commercial supplies of EYLEA outside the United States achieve certain specified levels up to $200 million.

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In connection with our PDGFR-beta antibody agreement with Bayer HealthCare, we are eligible to receive up to $15.0 million in future development milestone payments from Bayer HealthCare (representing 50% of the development milestone payments potentially due to Sanofi as described above), although certain of these development milestone payments could be reduced by half if Bayer HealthCare does not opt-in to the collaboration. Furthermore, if Bayer HealthCare exercises their right to opt-in to the collaboration, they will be obligated to pay a $20.0 million opt-in payment to us, and pay a $20.0 million development milestone to us upon receipt of the first marketing approval in the European Union or Japan.

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 2013 Form 10-K. There have been no material changes to our market risks or to our management of such risks during the three months ended March 31, 2014.

ITEM 4. CONTROLS AND PROCEDURES

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

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 March 31, 2014 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From time to time, we are a party to legal proceedings in the course of our business. We do not expect any such current legal proceedings to have a material adverse effect on our business or financial condition.

Proceedings Relating to '287 Patent and '018 Patent

We are parties to patent infringement litigation involving our European Patent No. 1,360,287 (the "'287 Patent") and our U.S. Patent No. 8,502,018 (the "'018 Patent"), both of which concern genetically altered mice capable of producing chimeric antibodies that are part human and part mouse. Chimeric antibody sequences can be used to produce high-affinity fully human monoclonal antibodies. In these proceedings (referred to below as "'287 Patent Infringement Litigation" and "'018 Patent Infringement Litigation," respectively), we claim infringement of several claims of the '287 Patent and the '018 Patent (as applicable), and seek, among other types of relief, an injunction and an account of profits in connection with the defendants' infringing acts, which may include, among other things, the making, use, keeping, sale, or offer for sale of genetically engineered mice (or certain cells from which they are derived) that infringe one or more claims of the '287 Patent and the '018 Patent (as applicable).

On January 3, 2014, we commenced '287 Patent Infringement Litigation against Novo Nordisk A/S, a company based in Denmark, in the English High Court of Justice, Chancery Division, Patents Court, in London. On March 27, 2014, Novo Nordisk served a defense to our lawsuit and counterclaimed alleging invalidity of the '287 Patent. Novo Nordisk also intervened in the opposition to the '287 Patent in the European Patent Office on April 3, 2014.

On March 11, 2014, we commenced '287 Patent Infringement Litigation and '018 Patent Infringement Litigation against Merus B.V., a company based in Utrecht, The Netherlands, in the District Court of The Hague and the United States District Court for the Southern District of New York, respectively. Merus previously filed an opposition to the '287 Patent in the European Patent Office in June 2013.

Also on March 11, 2014, we commenced '018 Patent Infringement Litigation against Ablexis, LLC, a Delaware corporation with a principal place of business in San Francisco, California, in the United States District Court for the

Southern District of New York.

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ITEM 1A. RISK FACTORS

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

Risks Related to Commercialization of EYLEA

We are substantially dependent on the success of EYLEA. If we 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 represent a substantial portion of our revenues and this concentration of our net sales in a single product makes us substantially dependent on that product. For the three months ended March 31, 2014 and 2013, EYLEA net sales in the United States represented 57% and 71% of our total revenues, respectively. If we were to experience difficulty with the commercialization of EYLEA in the United States, if Bayer HealthCare were to experience any difficulty with the commercialization of EYLEA outside the United States, or if we and Bayer HealthCare are unable to maintain current marketing approvals of EYLEA, we may experience a reduction in revenue and may not be able to sustain profitability, and our business, prospects, operating results, and financial condition would be materially harmed. In addition, if we are unable to obtain approval of EYLEA in the United States for the treatment of DME, 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, EU, Japan, and certain other countries outside of the United States for treatment of wet AMD and 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 the EU, and, in other countries, the commercialization of EYLEA is subject to additional 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 "Risks Related to Manufacturing and Supply—If we fail to meet the stringent requirements of governmental regulation in the manufacture of drug products or product candidates, we could incur substantial remedial costs, delays in the development or approval of our product candidates or new indications for our marketed products and/or in their commercial launch if they obtain regulatory approval, and a reduction in sales" below.

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

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 business, prospects, operating results, and financial condition.

Our 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 "Risks Related to Commercialization of Products—The successful commercialization of our marketed products, as well as our late-stage product candidates or new indications for our marketed products, if approved, will depend on obtaining 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" below.

The commercial success of EYLEA 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 (including CRVO and BRVO), and in August 2012 for the treatment of DME. Lucentis® was also approved by the European Medicines Agency for wet AMD in January 2007, for DME in January 2011, for the treatment of macular edema following RVO (including CRVO and BRVO) in June 2011, and for mCNV in July 2013. 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. Novartis is developing ESBA1008 (RTH258), a humanized monoclonal single-chain FV (scFv) antibody fragment targeting VEGF-A for wet AMD, and initiated Phase 2 trials comparing ESBA1008 and EYLEA in 2013. Allergan is developing an anti-VEGF-A DARPin® for wet AMD and related conditions and a Phase 2 trial is ongoing. Additionally, companies are developing products (or combinations of products) to treat wet AMD that act by blocking VEGF and VEGF receptors, as well as other targets (for example, PDGF). Ophthotech Corporation is developing Fovista,™ an aptamer directed against platelet-derived growth factor subunit B (PDGF-B), as a product candidate intended to be used in combination with an anti-VEGF therapy in wet AMD. In 2013, Ophthotech initiated Phase 3 trials in AMD evaluating multiple combinations of Fovista,™ including Lucentis® + Fovista,™ Avastin® + Fovista,™ and EYLEA + Fovista.™ Genentech initiated a Phase 1 trial of a bi-specific antibody targeting both VEGF and Ang2 for 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 "Risks Related to Commercialization of Products—We may be unsuccessful in continuing the

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commercialization of our marketed products or in commercializing our product candidates or new indications for our marketed products, if approved, which would materially and adversely affect our business, profitability, and future prospects" below.

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 marketed products, 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 and our business, prospects, operating results, and financial condition 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 similarly 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, prospects, operating results, and financial condition.

Before approving a new drug or biologic product, the FDA requires that the facilities at which the product will be manufactured or advanced through the supply chain be in compliance with current Good Manufacturing Practices, or cGMP, requirements and regulations governing the manufacture, shipment, and storage of the product. 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

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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.

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

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

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

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

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

Many of our clinical trials are conducted under the oversight of Independent Data Monitoring Committees (IDMCs). These independent oversight bodies are made up of external experts who review the progress of ongoing clinical trials, including available safety and efficacy data, and make recommendations concerning a trial's continuation, modification, or termination based on interim, unblinded data. Any of our ongoing clinical trials may be discontinued or amended in response to recommendations made by responsible IDMCs based on their review of such interim trial

results. For example, in September 2009, a Phase 3 trial that was evaluating ZALTRAP as a first-line treatment for metastatic pancreatic cancer in combination with gemcitabine was discontinued at the recommendation of an IDMC after a planned analysis of interim efficacy data determined that the trial would not meet its efficacy endpoint. The recommended termination of any of our ongoing late-stage clinical trials by an IDMC could negatively impact the future development of our product candidate(s), and our business, prospects, operating results, and financial condition may be materially harmed.

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

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Serious complications or side effects in connection with the use of our products and in clinical trials for our product candidates and new indications for our marketed products could cause our regulatory approvals to be revoked or limited or lead to delay or discontinuation of development of our product candidates or new indications for our marketed products, which could severely harm our business, prospects, operating results, and financial condition.
During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the drug candidate being studied caused these conditions. Various illnesses, injuries, and discomforts have been reported from time-to-time during clinical trials of our product candidates and new indications for our marketed products. It is possible that as we test our drug candidates or new indications in larger, longer, and more extensive clinical programs, or as use of these drugs becomes more widespread if they receive regulatory approval, illnesses, injuries, and discomforts that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by patients. Many times, side effects are only detectable after investigational drugs are tested in large-scale, Phase 3 clinical trials or, in some cases, after they are made available to patients after approval. If additional clinical experience indicates that any of our product candidates or new indications for our marketed products has many side effects or causes serious or life-threatening side effects, the development of the product candidate may be delayed or fail, or, if the product candidate has received regulatory approval, such approval may be revoked, which would severely harm our business, prospects, operating results, and financial condition.
EYLEA is being studied in diseases of the eye in addition to 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 further successfully develop and/or commercialize EYLEA and ZALTRAP. 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 EYLEA or ZALTRAP.
We and Sanofi are conducting a global development program, currently in Phase 3, studying alirocumab, our PCSK9 antibody for the reduction of LDL cholesterol, as discussed above in Part I, Item 2. "Management’s Discussion and Analysis of Financial Condition and Results of Operations - Late-Stage Antibody-based Clinical Programs." As part of this development program, we and Sanofi collect adverse events and report them to the FDA and foreign regulatory authorities. 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. In a recent Phase 3 trial comparing alirocumab with ezetimibe, the most common class of adverse events was infections (39.2% with ezetimibe vs. 42.3% with alirocumab), which included nasopharyngitis, influenza, and upper respiratory tract infection. Injection-site reactions occurred in less than 2% of patients in both groups. Muscle-related adverse events occurred in 3.9% of patients treated with ezetimibe and 3.8% of patients treated with alirocumab. We and Sanofi have been advised by the FDA that it has become aware of neurocognitive adverse events in the PCSK9 inhibitor class. Neurocognitive adverse events have also been associated with the use of statins for lowering LDL cholesterol. We do not know the circumstances under which the FDA became aware of these adverse events or whether these adverse events were observed with a drug candidate tested as monotherapy or in combination with a statin or other cholesterol-lowering agent. The FDA has requested that we and Sanofi make an assessment of potential neurocognitive adverse events across the global development program for alirocumab, especially in the longer-term studies. Additionally, the FDA requested that we address the feasibility of incorporating neurocognitive testing into at least a subset of patients in our ODYSSEY OUTCOMES trial or other long-term Phase 3 trial(s). While we are not aware of any neurocognitive adverse event signal relating to alirocumab, if this or another adverse event signal is detected, the further development

of alirocumab may be delayed or fail, or its commercial value diminished, which could severely harm our future prospects.

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 due to the FDA's concern that this case was suggestive of a class effect. 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, prospects, operating results, and financial condition.

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

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 only to the extent that our proprietary technologies and other information are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of biotechnology companies, including our company, involves complex legal and factual questions and, therefore, enforceability cannot be predicted with certainty. Our patents may be challenged, invalidated, held to be unenforceable, or circumvented. Patent applications filed outside the United States may be challenged by other parties, for example, by filing an opposition. Such opposition proceedings are increasingly common in the EU and are costly to defend. We have pending patent applications in the United States Patent and Trademark Office, the European Patent Office, and the patent offices of other foreign jurisdictions, and it is likely that we will need to defend patent applications from challenges by others from time to time in the future. Certain patent applications filed in the United States may also be challenged by parties who file a request for post-grant review under the America Invents Act of 2011. We expect that post-grant review proceedings will become common in the United States and will be costly to defend. Our patent rights may not provide us with a proprietary position or competitive advantages against competitors. Furthermore, even if the outcome is favorable to us, the enforcement of our intellectual property rights can be extremely expensive and time consuming.

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, patents or other proprietary rights of others.

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

proprietary composition covering an antibody or the antibody's target.

We have been in the past, are currently, and may in the future be involved in patent litigation. For example, we are currently parties to patent infringement proceedings relating to our European Patent No. 1,360,287 and our U.S. Patent No. 8,502,018, both of which concern genetically altered mice capable of producing chimeric antibodies that are part human and part mouse, as described in Part II, Item 1. "Legal Proceedings." We are aware of patents and pending applications owned by others that respectively claim antibodies to IL-6R, IL-4R, and PCSK9 and methods of treating rheumatoid arthritis, atopic dermatitis and asthma, and hypercholesterolemia with such antibodies. We are developing sarilumab, an antibody to IL-6R, for the treatment of rheumatoid arthritis; dupilumab, an antibody to IL-4R, for the treatment of atopic dermatitis, asthma, and nasal polyposis; and alirocumab, a PCSK9 antibody, for LDL cholesterol reduction. Although we do not believe that sarilumab, dupilumab, or alirocumab infringes any valid claim in these patents or patent applications, these other parties could initiate a lawsuit for patent infringement and assert their patents are valid and cover sarilumab, dupilumab, or alirocumab, as applicable. We are also aware of a U.S. patent jointly

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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. None of ARCALYST, ZALTRAP, or EYLEA is a recombinant antibody. 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 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 make recombinant antibodies in, or to import them into, the United States. Further, we are aware of a number of patent applications of others that, if granted with claims as currently drafted, may cover our current or planned activities. It could be determined that our products and/or actions in manufacturing or selling our product candidates infringe such patents.

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

We seek to obtain licenses to patents when, in our judgment, such licenses are needed or advisable. If any licenses are required, we may not be able to obtain such licenses on commercially reasonable terms, if at all. The failure to obtain any such license could prevent us from developing or commercializing any one or more of our 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 materially harm us. Absent patent protection or regulatory exclusivity for our products, it is possible, both in the United States and elsewhere, that generic and/or biosimilar versions of those products may be approved and marketed, which would likely result in substantial and rapid reductions in revenues from sales of those products.

Under the federal Patient Protection and Affordable Care Act, or PPACA, enacted in 2010, there is 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, to commercialize our other product candidates or other indications for our marketed products if they receive regulatory approval, and to advance our clinical pipeline.

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. As we increase our production in anticipation of potential regulatory approval for our late-stage antibody product candidates, our current manufacturing capacity may not be sufficient, and we may depend on our collaborators or contract manufacturers, to produce adequate quantities of drug material for both commercial and clinical purposes. We rely entirely on other parties and our collaborators for filling and finishing services. Generally, in order for other parties to perform any step in the manufacturing and supply chain, we must transfer technology to the other party, which can be time consuming and may not be successfully accomplished without considerable cost and expense, or at all. We will have to depend on these other parties to perform effectively on a timely basis and to comply with regulatory requirements. If for any reason they are unable to do so, and as a result we are unable to directly or through other parties manufacture and supply sufficient commercial and clinical quantities of our products on acceptable terms, or if we should encounter delays or other difficulties in our relationships with our corporate collaborators, contract manufacturers, or other parties involved in our supply chain which adversely affect the timely manufacture and supply of our products or product candidates, our business, prospects, operating results, and financial condition may be materially harmed.

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

We have commenced construction of additional manufacturing space at our Rensselaer, New York site to increase our manufacturing capacity. In addition, we 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, to expand our manufacturing capacity to support our global supply chain. In the future, we may lease, operate, purchase, or construct additional facilities to conduct expanded manufacturing activities. Expanding our manufacturing capacity to supply commercial quantities of the active pharmaceutical ingredients for our marketed products and our late-stage product candidates if they are approved for marketing, and to supply clinical drug material to support the continued growth of our clinical programs, will require substantial additional expenditures and various regulatory approvals and permits. In addition, our contemplated acquisition of the Limerick, Ireland facility remains subject to entering into definitive agreements as well as securing permits from the local government, and there is no guarantee that a final agreement will be reached on terms favorable to us or that we will be able to obtain the required permits in the contemplated timeframe, or at all. Further, we will need to hire and train significant numbers of employees and managerial personnel to staff our expanding manufacturing and supply chain operations. Start-up costs can be large, and scale-up entails significant risks related to process development and manufacturing yields. In addition, we may face difficulties or delays in developing or acquiring the necessary production equipment and technology to manufacture sufficient quantities of our product candidates at reasonable costs and in compliance with applicable regulatory requirements. The FDA and analogous foreign regulatory authorities must determine that our existing and any expanded manufacturing facilities comply, or continue to comply, with cGMP requirements for both clinical and commercial production and license them, or continue to license them, accordingly, and such facilities must also comply with applicable environmental, safety, and other governmental permitting requirements. We may not successfully expand or establish sufficient manufacturing capabilities or manufacture our products economically or in compliance with cGMPs and other regulatory requirements, and we and our collaborators may not be able to

build or procure additional capacity in the required timeframe to meet commercial demand for our late-stage product candidates if they receive regulatory approval, and to continue to meet the requirements of our clinical programs. This would interfere with our efforts to successfully commercialize EYLEA, 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.

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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 patents of others.

Our ability to continue to manufacture EYLEA, ZALTRAP, and ARCALYST in our Rensselaer, New York facilities and, in the future, our ability to manufacture our marketed products at additional facilities, or to utilize third parties to produce our products, to supply raw materials or other products, or to perform fill/finish services or other steps in our manufacture and supply chain, depends on our and their ability to operate without infringing the patents or other intellectual property rights of others. Other parties may allege that our manufacturing activities, or the activities of third parties involved in our manufacture and supply chain, 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 to which those intellectual property rights apply, which could materially harm our business, prospects, operating results, and financial condition.

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 excess inventory or unused capacity at our manufacturing facilities and at the facilities of third parties.

We have large-scale manufacturing operations in Rensselaer, New York. We use our facilities to produce 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, bulk product of ARCALYST for the treatment of CAPS, and clinical and preclinical candidates for ourselves and our collaborations. We also plan to use such facilities to produce bulk product for commercial supply of new indications of our marketed products and new product candidates if they are approved for marketing. If our clinical candidates are discontinued or their clinical development is delayed, if the launch of new indications for our marketed products or new product candidates is delayed or does not occur, or if such products are launched and the launch is unsuccessful or the product is subsequently recalled or marketing approval is rescinded, we may have to absorb one hundred percent of related overhead costs and inefficiencies, as well as similar costs of third-party contract manufacturers performing services for us. In addition, if we experience excess inventory, it may be necessary to write down or even write off such excess inventory, which could adversely affect our operating results.

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, some of which are difficult to source, are provided by single-source unaffiliated third-party suppliers. In addition, we rely on certain third parties to perform filling, finishing, distribution, laboratory testing, and other services related to the manufacture of EYLEA, ZALTRAP, 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 (including recalls), adverse financial developments at or affecting the supplier, failure by the supplier to comply with cGMPs, contamination, business interruptions, or labor shortages or disputes. 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.

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

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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, prospects, operating results, and financial condition. Any finding of non-compliance could also increase our costs, cause us to delay the development of our product candidates, result in delay in our obtaining, or our not obtaining, regulatory approval of product candidates or new indications for our marketed products, and cause us to lose revenue from any marketed products, which could be seriously detrimental to our business, prospects, operating results, and financial condition.

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

- off-label use of Avastin® to EYLEA;
- the ability of patients, retinal specialists, and other providers to obtain and maintain sufficient coverage and reimbursement from third-party payers, including Medicare and Medicaid in the United States and other government and private payers in the United States and foreign jurisdictions;
- our ability to maintain sales of EYLEA in the face of competitive products, including those currently in clinical development; and
- the effect of 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

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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, as well as financial, marketing, and human resources, than we do. Our smaller competitors may also enhance their competitive position if they acquire or discover patentable inventions, form collaborative arrangements, or merge with large pharmaceutical companies. Even if we achieve commercialization of our product candidates, our competitors have achieved, and may continue to achieve, product commercialization before our products are approved for marketing and sale.

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 Pharmaceuticals (a subsidiary of Amgen), 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. 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. 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 very competitive, as described in greater detail above under "Risks Related to Commercialization of EYLEA-The commercial success of EYLEA is subject to strong competition."

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

We are aware of several pharmaceutical and biotechnology companies actively engaged in the research and development of antibody products against targets that are also the targets of our early- and late-stage product candidates. For example, Pfizer (in partnership with Eli Lilly), Johnson & Johnson, and AbbVie are developing antibody product candidates against NGF. Genentech/Roche is marketing an antibody against IL-6R (tocilizumab) for the treatment of rheumatoid arthritis, and several other companies, including Johnson & Johnson (in partnership with GlaxoSmithKline), Bristol-Myers Squibb (in partnership with Alder Biopharmaceuticals), Ablynx (in partnership with AbbVie), and Pfizer have antibodies against IL-6 or IL-6R in clinical development. Several companies, including Amgen, Pfizer, Genentech, Bristol-Myers Squibb, and Eli Lilly, have development programs for antibodies against PCSK9. Amgen's PCSK9 program appears to be the most advanced of the competitors, having already announced positive results from multiple Phase 3 trials, and may obtain marketing approval in one or more countries before our PCSK9 antibody is approved. Alnylam, in partnership with The Medicines Company, has a clinical program underway with an RNAi molecule against PCSK9. In addition, there are therapeutic products targeting PCSK9 operating through other mechanisms of action in development, including an oral product. A number of companies are developing antibodies that, if approved, may compete with dupilumab, our IL-4R antibody, if it is approved, including Roche (an antibody against IL-6), Teva (an antibody against IL-5), AstraZeneca (antibodies against IL-5R and IL-13), and Novartis (a bi-specific antibody against IL-4 and IL-13). Further, Amgen, Genentech, and AstraZeneca have development programs underway for antibodies against Ang2 for indications in oncology. Celgene (in partnership with OncoMed Pharmaceuticals, Inc.) and AstraZeneca have antibodies that target Dll4 in clinical development. For

muscle-wasting conditions, both Pfizer and Eli Lilly have anti-GDF8 monoclonal antibodies in development, and Novartis has a competing antibody targeting ActRIIB.

If any of these or other competitors announces a successful clinical study involving a product that may be competitive with one of our product candidates or the grant of marketing approval by a regulatory agency for a competitive product, such developments may have an adverse effect on our business or future prospects. In addition, the first product to reach the market in a therapeutic area is often at a significant competitive advantage relative to later entrants to the market. Accordingly, the relative speed with which we, or our collaborators, can develop our products candidates, complete the clinical trials and approval processes, and, if such product candidates are approved for marketing and sale, supply commercial quantities to the market is expected to continue to be an important competitive factor. Due to the uncertainties associated with developing biopharmaceutical products, we may

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not be the first to obtain marketing approval for a product against any particular target, which may have a material adverse effect on our business or future prospects.

The successful commercialization of our marketed products, as well as our late-stage product candidates or new indications for our marketed products, if approved, will depend on obtaining 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 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 continue to 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 EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human

use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Our results of operations may suffer if we or our collaborators are unable to market our products in foreign countries or if coverage and reimbursement for our products in foreign countries is limited or delayed.

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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. Under this distribution model, the distributors and specialty pharmacies generally take physical delivery of product and generally sell the product directly to healthcare providers. For the three months ended March 31, 2014 and 2013, we recorded 79% 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, or is perceived to harm them even when such harm is unrelated to our products, we could be subject to costly and damaging product liability claims.

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

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, prospects, operating results, and financial condition. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be challenged under one or more of such laws.

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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 provisions imposing reporting and disclosure requirements on pharmaceutical manufacturers for any "transfers of value" made or distributed to prescribers and other healthcare providers. These statutory provisions and related regulations (commonly known as the "Sunshine Act") 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 started to be required to collect information regarding such payments in August 2013 and submitted our 2013 Reporting Entity and Payment Aggregate Data in March 2014, as required by the Sunshine Act. 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, prospects, operating results, and financial condition.

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

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

In particular, our business activities outside of the United States are subject to the Foreign Corrupt Practices Act, or FCPA, and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate, including the U.K. Bribery Act. The FCPA generally prohibits 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 Securities and Exchange Commission, or SEC, and Department of Justice have increased their FCPA enforcement activities with respect to pharmaceutical companies. There is no certainty that all of our employees, agents, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results, and financial

condition.

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

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

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

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

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

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

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

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

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

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

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

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

Most health care providers, including research institutions from which we or our collaborators obtain patient information, are subject to privacy and security regulations promulgated under HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act. For example, as part of our human genetics initiative, our wholly-owned subsidiary, Regeneron Genetics Center LLC, is collaborating with the Geisinger Health System, which is subject to such regulations, and may enter into collaboration arrangements with additional institutions in the future. Our clinical research efforts are not directly regulated by HIPAA. However, conduct by a person that may not be prosecuted directly under HIPAA's criminal provisions could potentially be prosecuted under aiding-and-abetting or conspiracy laws. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a health care provider or research institution that has not satisfied HIPAA's disclosure standards. In addition, international data protection laws, including the EU Data Protection Directive and member state implementing legislation, may apply to some or all of the clinical data obtained outside of the U.S. Furthermore, certain privacy laws and genetic testing laws may apply directly to our operations and/or those of our collaborators and may impose restrictions on our use and dissemination of individuals' health information. Moreover, patients about whom we or our collaborators obtain information, as well as the providers who share this information with us, may have contractual rights that limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

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

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, unless we enter into a partnership agreement with another party, we would be required to fund and oversee on our own the clinical trials, any regulatory responsibilities, and the ensuing commercialization efforts to support those antibody products. For example, Sanofi has elected not to continue co-development of fasinumab, 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.

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If our collaboration with Sanofi for ZALTRAP is terminated, or Sanofi materially breaches its obligations thereunder, our business, prospects, operating results, 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.

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, in cooperation with Santen Pharmaceuticals Co. Ltd. pursuant to a Co-Promotion and Distribution Agreement with Bayer HealthCare's Japanese affiliate. EYLEA is currently available in the United States, EU, Japan, and certain other countries outside of the United States for treatment of wet AMD and macular edema following CRVO. We cannot assure you that additional regulatory approvals will be received for EYLEA outside the United States or that EYLEA will 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 in the United States and for many other related activities in connection with the commercialization of this marketed product. 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 will suffer.

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Risk Related to Employees

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

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

Information Technology Risks

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

Our business is increasingly dependent on critical, complex, and interdependent information technology systems, including Internet-based systems, to support business processes as well as internal and external communications. The size and complexity of our computer systems make 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 result in legal proceedings, liability under laws that protect the privacy of personal information, disruptions to our operations, and damage to our reputation, which could have a material adverse effect on our business, prospects, operating results, and financial condition.

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

We have a history of operating losses and have only recently achieved profitability. If we cannot sustain profitability, our business, prospects, operating results, and financial condition would be materially harmed.

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

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

We expend substantial resources for research and development, including costs associated with clinical testing of our product candidates and new indications of our marketed products, the commercialization of products, and capital expenditures. We believe our existing capital resources, 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 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 of antibody product candidates we are developing on our own (without Sanofi), and expenses related to the requirement, following receipt of the first positive Phase 3 trial results for a co-developed drug candidate, for us to fund 20% of Phase 3 clinical trial costs for any of our antibody product candidates being developed in collaboration with Sanofi.

We cannot be certain that our existing capital resources and our current and anticipated revenues will be sufficient to meet our operating needs. We may require additional financing in the future and we may not be able to raise additional funds on acceptable

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

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

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

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

As of March 31, 2014, we had $461.9 million in cash and cash equivalents and $721.0 million in marketable securities. Our investments consist primarily of fixed-income securities, including investment-grade corporate bonds, direct obligations of the U.S. government and its agencies, and other debt securities guaranteed by the U.S. government. These investments are subject to external factors that may adversely affect their market value or liquidity, such as interest rate, liquidity, market, and issuer credit risks, including actual or anticipated changes in credit ratings. If our investments suffer market price declines that are other than temporary, their value could be impaired, which may have an adverse effect on our financial condition and operating results.

Risks Related to Our Common Stock

Our stock price is extremely volatile.

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

- fluctuations in our operating results, in particular net product sales of EYLEA and, to a lesser degree, sales of ZALTRAP;
- 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;
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progress, delays, or results in clinical trials of our or our competitors' product candidates or new indications for marketed products;
- announcement of technological innovations or product candidates by us or competitors;
- claims by others that our products or technologies infringe their patents;
- challenges by others to our patents in the European Patent Office and in the U.S. Patent and Trademark Office;
- public concern as to the safety or effectiveness of any of our marketed products or product candidates or new indications for our marketed products;
- pricing or reimbursement actions 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;

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- developments in the biotechnology industry or in government regulation of healthcare, including those relating to compounding;
- large sales of our Common Stock by our executive officers, directors, or significant shareholders;
- changes in tax rates, laws, or interpretation of tax laws;
- arrivals and departures of key personnel; and
- general market conditions.

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. In the past, securities class action litigation has often been initiated against companies following periods of volatility in their stock price. This type of litigation could result in substantial costs and divert our management's attention and resources, and could also require us to make substantial payments to satisfy judgments or to settle litigation, which may harm our business, prospects, operating results, and financial condition.

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

A small number of our shareholders beneficially own a substantial amount of our Common Stock. As of April 17, 2014, our five largest shareholders plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 50.4% 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, 2014. As of April 17, 2014, Sanofi beneficially owned 20,018,090 shares of our Common Stock, representing approximately 20.2% of the shares of Common Stock then outstanding. Under our 2014 amended and restated investor agreement with Sanofi, Sanofi has three demand rights to require us to use all reasonable efforts to conduct a registered underwritten offering with respect to shares of our Common Stock held by Sanofi from time to time; however, shares of our Common Stock held by Sanofi from time to time may not be sold until the later of (i) December 20, 2020 and (ii) the expiration of our discovery and preclinical development agreement with Sanofi relating to our antibody collaboration (as amended) if the agreement is extended beyond December 20, 2020. These restrictions on dispositions are subject to earlier termination upon the occurrence of certain events, such as the consummation of a change-of-control transaction involving us or a dissolution or liquidation of our company. In February 2013, we received from Sanofi a notification under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 that it intends to acquire additional Common Stock through open market purchases and direct purchases from shareholders. If Sanofi, our other significant shareholders, or we sell substantial amounts of our Common Stock in the public market, or there is a perception that such sales may occur, the market price of our Common Stock could fall. Sales of Common Stock by our significant shareholders, including Sanofi, also might make it more difficult for us to raise funds by selling equity or equity-related securities in the future at a time and price that we deem appropriate.

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

Holders of Class A Stock, who are generally the shareholders who purchased their stock from us before our initial public offering, are entitled to ten votes per share, while holders of Common Stock are entitled to one vote per share. As of April 17, 2014, holders of Class A Stock held 16.8% of the combined voting power of all shares of Common Stock and Class A Stock then outstanding. These shareholders, if acting together, would be in a position to significantly influence the election of our directors and the vote on certain corporate transactions that require majority or supermajority approval of the combined classes, including mergers and other business combinations. This may result in our taking corporate actions that other shareholders may not consider to be in their best interest and may affect the price of our Common Stock. As of April 17, 2014:

- our current executive officers and directors beneficially owned 10.1% 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, 2014, and 22.0% 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, 2014; and

- our five largest shareholders plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 50.4% 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, 2014. In addition, these five shareholders plus our Chief Executive Officer held approximately 55.7% 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, 2014. Pursuant to the January 2014 amended and restated investor agreement with us, Sanofi has agreed to vote its shares as recommended by our board of directors, except that it may elect to vote proportionally with the votes cast by all of our other

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shareholders with respect to certain change-of-control transactions and to vote in its sole discretion with respect to liquidation or dissolution of our company, stock issuances equal to or exceeding 20% of the then outstanding shares or voting rights of Common Stock and Class A Stock (taken together), and new equity compensation plans or amendments if not materially consistent with our historical equity compensation practices.

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

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

In connection with our offering of our 1.875% Convertible Senior Notes due October 1, 2016 ("convertible senior notes" or "notes"), we entered into convertible note hedge transactions with four financial institutions (the "hedge counterparties"), the purpose of which was to reduce the potential dilution to our Common Stock and/or offset potential cash payments in excess of the principal amount of the notes (as applicable) upon conversion of the notes. In the event that the hedge counterparties fail to deliver shares to us or potential cash payments (as applicable) as required under the convertible note hedge documents, we would not receive the benefit of such transactions. Separately, we also entered into warrant transactions with the hedge counterparties. The warrant transactions could separately have a dilutive effect from the issuance of Common Stock pursuant to the warrants.

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.

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

The anti-takeover effects of provisions of our charter, by-laws, and of New York corporate law, as well as the contractual provisions in our investor and collaboration agreements and certain provisions of our compensation plans and agreements and our convertible senior notes and related warrant and hedge transactions, could deter, delay, or

prevent an acquisition or other “change in control” of us and could adversely affect the price of our Common Stock.
Our 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;

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

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

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

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

In addition, our Change in Control Severance Plan and the employment agreement with our Chief Executive Officer provide for severance benefits in the event of termination as a result of a change in control of our company. Also, 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. Further, under the amended and restated investor agreement between us and Sanofi, we are required under certain circumstances to appoint an individual agreed upon by us and Sanofi to our board of directors, as described above under "Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval and over our management." These contractual provisions may also have the effect of deterring, delaying, or preventing an acquisition or other change in control.

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ITEM 6. EXHIBITS

(a) Exhibits

Exhibit Number		Description
10.1	(a)	Amended and Restated Investor Agreement, dated as of January 11, 2014, by and among Sanofi, sanofi-aventis US LLC, Aventis Pharmaceuticals Inc., sanofi-aventis Amerique du Nord, and Regeneron Pharmaceuticals, Inc.
10.2*		License and Collaboration Agreement, dated as of January 10, 2014, by and between Bayer HealthCare LLC and Regeneron Pharmaceuticals, Inc.
31.1	–	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
31.2	–	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
32	–	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350.
101	–	Interactive Data File
101.INS	–	XBRL Instance Document
101.SCH	–	XBRL Taxonomy Extension Schema
101.CAL	–	XBRL Taxonomy Extension Calculation Linkbase
101.DEF	–	XBRL Taxonomy Extension Definition Document
101.LAB	–	XBRL Taxonomy Extension Label Linkbase
101.PRE	–	XBRL Taxonomy Extension Presentation Linkbase

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(a) Incorporated by reference to Exhibit 10.1 to the Form 8-K for Regeneron Pharmaceuticals, Inc., filed January 13, 2014.

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

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: May 8, 2014

By: /s/ Robert E. Landry

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