REGENERON PHARMACEUTICALS INC
Form 10-Q
July 25, 2012

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2012

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

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

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

Yes X No

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

Yes X No

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

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

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

Yes No X

Number of shares outstanding of each of the registrant s classes of common stock as of July 13, 2012:

Class of Common Stock	Number of Shares
Class A Stock, $0.001 par value	2,089,512
Common Stock, $0.001 par value	93,955,110

REGENERON PHARMACEUTICALS, INC.
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"ARCALYST®", "EYLEA®", "ZALTRAP®, *VelocImmune®* , *VelociGene®* , *VelociMouse®* , *VelociMab®* , and *VelociSuite™* are trademarks of Regeneron Pharmaceuticals, Inc. All other trademarks in this Form 10-Q are the property of their respective owners.

PART I. FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS

REGENERON PHARMACEUTICALS, INC.
CONDENSED BALANCE SHEETS (Unaudited)
(In thousands, except share data)

	June 30, 2012	December 2011
ASSETS		
Current assets:		
Cash and cash equivalents	$ 171,943	$ 483,
Marketable securities	129,079	43,
Accounts receivable - trade, net	349,645	28,
Accounts receivable from Sanofi	85,735	74,
Prepaid expenses and other current assets	32,791	22,
Total current assets	769,193	652,
Restricted cash and marketable securities	8,141	7,
Marketable securities	288,321	275,
Property, plant, and equipment, at cost, net of accumulated depreciation and amortization	372,278	367,
Other assets	19,567	19,
Total assets	$ 1,457,500	$ 1,323,
LIABILITIES and STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 126,768	$ 95,
Deferred revenue from Sanofi, current portion	21,790	20,
Deferred revenue - other, current portion	33,479	31,
Facility lease obligations, current portion	1,183	1,
Total current liabilities	183,220	148,
Deferred revenue from Sanofi	78,281	86,
Deferred revenue - other	149,031	162,
Facility lease obligations	159,558	159,
Convertible senior notes	285,491	275,
Other long term liabilities	7,262	6,
Total liabilities	862,843	837,
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $.01 par value; 30,000,000 shares authorized; issued and outstanding - none		
Class A Stock, convertible, $.001 par value; 40,000,000 shares authorized; shares issued and outstanding - 2,089,512 at June 30, 2012 and 2,109,512 at December 31, 2011	2	
Common Stock, $.001 par value; 160,000,000 shares authorized; shares issued and outstanding - 93,941,788 at June 30, 2012 and 90,692,071 at December 31, 2011	94	
Additional paid-in capital	1,775,861	1,754,
Accumulated deficit	(1,178,929)	(1,267,
Accumulated other comprehensive loss	(2,371)	(1,

Total stockholders' equity	594,657	485,
Total liabilities and stockholders' equity	$ 1,457,500	$ 1,323,

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

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

	Three months ended June 30,		Six months ended June 30,	
	2012	**2011**	**2012**	**2011**
Condensed Statements of Operations				
Revenues:				
Net product sales	$ 199,519	$ 5,039	$ 327,450	$ 9,466
Sanofi collaboration revenue	88,988	84,446	173,993	169,775
Bayer HealthCare collaboration revenue	9,124	11,123	21,607	23,604
Technology licensing	5,893	5,228	11,786	13,073
Contract research and other	875	1,974	1,352	4,096
	304,399	107,810	536,188	220,014
Expenses:				
Research and development	147,373	143,149	286,235	272,541
Selling, general, and administrative	47,705	24,585	106,133	47,996
Cost of goods sold	21,843	395	34,141	777
	216,921	168,129	426,509	321,314
Income (loss) from operations	87,478	(60,319)	109,679	(101,300)
Other income (expense):				
Investment income	501	998	1,111	2,035
Interest expense	(11,236)	(4,047)	(22,396)	(7,766)
	(10,735)	(3,049)	(21,285)	(5,731)
Net income (loss) before income tax benefit	76,743	(63,368)	88,394	(107,031)
Income tax benefit		863		1,079
Net income (loss)	$ 76,743	$ (62,505)	$ 88,394	$ (105,952)
Net income (loss) per share - basic	$ 0.81	$ (0.69)	$ 0.94	$ (1.18)
Net income (loss) per share - diluted	$ 0.70	$ (0.69)	$ 0.81	$ (1.18)
Weighted average shares outstanding - basic	94,589	90,436	94,017	89,799
Weighted average shares outstanding - diluted	110,167	90,436	108,998	89,799
Condensed Statements of Comprehensive Income (Loss)				
Net income (loss)	$ 76,743	$ (62,505)	$ 88,394	$ (105,952)
Other comprehensive income (loss):				
Unrealized (loss) gain on marketable securities, net of tax	(1,034)	1,271	(509)	1,587
Comprehensive income (loss)	$ 75,709	$ (61,234)	$ 87,885	$ (104,365)

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

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY (Unaudited)
For the six months ended June 30, 2012 and 2011
(In thousands)

	Class A Stock		Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	T
	Shares	Amount	Shares	Amount	Capital	Deficit	Income (Loss)	E
Balance, December 31, 2011	2,109	$ 2	90,692	$ 91	$ 1,754,824	$ (1,267,323)	$ (1,862)	$
Issuance of Common Stock in connection with exercise of stock options			3,234	3	39,631			
Common Stock tendered upon exercise of stock options in connection with employee tax obligations			(568)		(61,444)			
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			64					
Issuance of restricted Common Stock under Long-Term Incentive Plan			500					
Conversion of Class A Stock to Common Stock	(20)		20					
Stock-based compensation charges					42,850			
Net income						88,394		
Other comprehensive loss							(509)	
Balance, June 30, 2012	2,089	$ 2	93,942	$ 94	$ 1,775,861	$ (1,178,929)	$ (2,371)	$
Balance, December 31, 2010	2,182	$ 2	87,238	$ 87	$ 1,575,780	$ (1,045,563)	$ (2,491)	$
Issuance of Common Stock in connection with exercise of stock options			2,127	2	28,501			
Common Stock tendered upon exercise of stock options in connection with employee tax obligations			(101)		(4,709)			
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			92		3,405			
Issuance of restricted Common Stock under Long-Term Incentive Plan			5					
Conversion of Class A to Common Stock	(55)		55					
Stock-based compensation charges					27,385			
Net loss						(105,952)		
Other comprehensive income, net of tax							1,587	
Balance, June 30, 2011	2,127	$ 2	89,416	$ 89	$ 1,630,362	$ (1,151,515)	$ (904)	$

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

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

	Six months ended June 30,	
	2012	**2011**
Cash flows from operating activities:		
Net income (loss)	$ 88,394	$ (105,952)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	17,833	14,880
Non-cash compensation expense	42,850	27,197
Other non-cash charges and expenses, net	13,373	832
Changes in assets and liabilities:		
Increase in Sanofi and trade accounts receivable	(332,345)	(1,138)
(Increase) decrease in prepaid expenses and other assets	(10,643)	1,528
Decrease in deferred revenue	(17,669)	(20,554)
Increase in accounts payable, accrued expenses, and other liabilities	32,789	38,577
Total adjustments	(253,812)	61,322
Net cash used in operating activities	(165,418)	(44,630)
Cash flows from investing activities:		
Purchases of marketable securities	(270,907)	(15,638)
Sales or maturities of marketable securities	171,881	216,631
Increase in restricted cash and marketable securities	(469)	(681)
Capital expenditures	(23,927)	(37,030)
Net cash (used in) provided by investing activities	(123,422)	163,282
Cash flows from financing activities:		
Payments in connection with facility and capital lease obligations	(1,014)	(704)
Net proceeds from issuances of Common Stock	39,631	28,501
Payments in connection with Common Stock tendered for employee tax obligations	(61,444)	(4,709)
Net cash (used in) provided by financing activities	(22,827)	23,088
Net (decrease) increase in cash and cash equivalents	(311,667)	141,740
Cash and cash equivalents at beginning of period	483,610	112,572
Cash and cash equivalents at end of period	$ 171,943	$ 254,312

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

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)
(Unless otherwise noted, dollars in thousands, except per share data)

1. Interim Financial Statements

The interim Condensed 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, 2011 Condensed 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, 2011.

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

2. Product Revenue

In November 2011, the Company received marketing approval from the U.S. Food and Drug Administration (FDA) for EYLEA® (aflibercept) Injection for the treatment of neovascular wet age-related macular degeneration (wet AMD). EYLEA net product sales totaled $194.0 million and $317.5 million for the three and six months ended June 30, 2012, respectively.

In February 2008, the Company received marketing approval from the FDA for ARCALYST® Injection for Subcutaneous Use for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS). ARCALYST net product sales totaled $5.5 million and $5.0 million for the three months ended June 30, 2012 and 2011, respectively, and $9.9 million and $9.5 million for the six months ended June 30, 2012 and 2011, respectively.

The Company sells EYLEA in the United States to three distributors and several specialty pharmacies. The Company sells ARCALYST in the United States to two specialty pharmacies. Under these distribution models, the distributors and specialty pharmacies (collectively, the Company s customers) generally take physical delivery of product. For EYLEA, the distributors and specialty pharmacies generally sell the product directly to healthcare providers; whereas for ARCALYST, the specialty pharmacies sell the product directly to patients. The Company records revenue from product sales upon delivery to its customers. For both the three and six months ended June 30, 2012, the Company recorded 79% of its gross product revenue from sales to Besse Medical, a subsidiary of AmerisourceBergen Corporation.

Revenue from product sales are recorded net of applicable provisions for prompt pay discounts, rebates and chargebacks under governmental programs (including Medicaid), product returns, distribution-related fees, and other sales-related deductions. The following table summarizes the provisions, and credits/payments, for government rebates and chargebacks, distribution-related fees, and other sales-related deductions; such amounts were not material as of and for the six months ended June 30, 2011.

	Rebates & Chargebacks	Distribution-Related Fees	Other Sales-Related Deductions	Total
Balance as of December 31, 2011	$ 585	$ 1,451	$ 182	$ 2,218
Provision related to current period sales	6,152	17,917	2,407	26,476
Credits/payments	(1,957)	(8,314)	(1,093)	(11,364)
Balance as of June 30, 2012	$ 4,780	$ 11,054	$ 1,496	$ 17,330

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)
(Unless otherwise noted, dollars in thousands, except per share data)

3. Per Share Data

The Company s basic net income (loss) per share amounts have been computed by dividing net income (loss) by the weighted average number of shares of Common Stock and Class A Stock outstanding. Net income (loss) 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 is based on the weighted average number of shares of Common Stock and Class A Stock outstanding plus additional weighted average common stock equivalent shares outstanding during the period when the effect is dilutive. For the three and six months ended June 30, 2011, the Company reported a net loss; therefore, no common stock equivalents were included in the computation of diluted net loss per share for this period, since such inclusion would have been antidilutive. The calculations of basic and diluted net income (loss) per share are as follows:

	Three Months Ended June 30,	
	2012	**2011**
Numerator		
Net income (loss) - basic and diluted	$ 76,743	$ (62,505)
Denominator (in thousands)		
Weighted average shares - basic	94,589	90,436
Effect of dilutive securities:		
Stock options	14,055	
Restricted stock	692	
Warrants	831	
Dilutive potential shares	15,578	
Weighted average shares - diluted	110,167	90,436
Net income (loss) per share - basic	$ 0.81	$ (0.69)
Net income (loss) per share - diluted	$ 0.70	$ (0.69)

	Six Months Ended June 30,	
	2012	**2011**
Numerator		
Net income (loss) - basic and diluted	$ 88,394	$ (105,952)
Denominator (in thousands)		
Weighted average shares - basic	94,017	89,799
Effect of dilutive securities:		
Stock options	13,964	
Restricted stock	676	
Warrants	341	
Dilutive potential shares	14,981	
Weighted average shares - diluted	108,998	89,799
Net income (loss) per share - basic	$ 0.94	$ (1.18)
Net income (loss) per share - diluted	$ 0.81	$ (1.18)

Shares issuable upon the exercise of stock options and warrants, vesting of restricted stock awards, and conversion of convertible senior notes, which have been excluded from the June 30, 2012 and 2011 diluted per share amounts because their effect would have been antidilutive, include the following:

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)
(Unless otherwise noted, dollars in thousands, except per share data)

	Three Months Ended June 30,	
	2012	**2011**
Stock options:		
Weighted average number, in thousands	89	20,967
Weighted average exercise price	$ 124.64	$ 20.71
Restricted stock:		
Weighted average number, in thousands		846
Convertible senior notes:		
Weighted average number, in thousands	4,761	
Warrants:		
Weighted average number, in thousands	3,930	

	Six Months Ended June 30,	
	2012	**2011**
Stock options:		
Weighted average number, in thousands	47	21,668
Weighted average exercise price	$ 123.29	$ 20.48
Restricted stock:		
Weighted average number, in thousands	11	846
Convertible senior notes:		
Weighted average number, in thousands	4,761	
Warrants:		
Weighted average number, in thousands	4,420	

4. Statement of Cash Flows

Supplemental disclosure of noncash investing and financing activities:

Included in accounts payable and accrued expenses at June 30, 2012 and December 31, 2011 were $5.9 million and $6.2 million, respectively, of accrued capital expenditures. Included in accounts payable and accrued expenses at June 30, 2011 and December 31, 2010 were $3.4 million and $10.7 million, respectively, of accrued capital expenditures. In addition, during the six months ended June 30, 2012, the Company incurred non-cash charges of $1.5 million in connection with disposals and retirements of fixed assets.

Included in marketable securities at June 30, 2012 and December 31, 2011 were $0.9 million and $0.7 million, respectively, of accrued interest income. Included in marketable securities at June 30, 2011 and December 31, 2010 were $0.8 million and $1.4 million, respectively, of accrued interest income.

5. Marketable Securities

Marketable securities at June 30, 2012 and December 31, 2011 consisted of debt securities, as detailed below, and equity securities. The aggregate fair value of the equity securities was $2.4 million and $3.0 million at June 30, 2012 and December 31, 2011, respectively, and the aggregate cost basis was $4.0 million at both June 30, 2012 and December 31, 2011. The Company also held restricted marketable securities at both June 30, 2012 and December 31, 2011, which consisted of debt securities, as detailed below, that collateralize letters of credit and lease

obligations.

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)
(Unless otherwise noted, dollars in thousands, except per share data)

The following tables summarize the amortized cost basis of debt securities included in marketable securities, the aggregate fair value of those securities, and gross unrealized gains and losses on those securities at June 30, 2012 and December 31, 2011. The Company classifies its debt securities, other than mortgage-backed securities, based on their contractual maturity dates. Maturities of mortgage-backed securities have been estimated based primarily on repayment characteristics and experience of the senior tranches that the Company holds. The debt securities listed at June 30, 2012, excluding mortgage-backed securities, mature at various dates through June 2015. The mortgage-backed securities listed at June 30, 2012 mature at various dates through December 2019.

At June 30, 2012	Amortized Cost Basis	Fair Value	Unrealized Gains	Unrealized (Losses)	Net
Unrestricted					
Maturities within one year:					
U.S. government obligations	$ 65,959	$ 66,025	$ 78	$ (12)	$ 66
U.S. government guaranteed corporate bonds	50,635	50,654	23	(4)	19
Municipal bonds	12,385	12,386	1		1
	128,979	129,065	102	(16)	86
Maturities after one year through five years:					
U.S. government obligations	285,363	285,763	437	(37)	400
Mortgage-backed securities	102	29		(73)	(73)
	285,465	285,792	437	(110)	327
Maturities after five years through ten years:					
Mortgage-backed securities	161	88		(73)	(73)
	414,605	414,945	539	(199)	340
Restricted					
Maturities within one year:					
U.S. government obligations	3,847	3,853	6		6
Maturities after one year through five years:					
U.S. government obligations	4,187	4,191	7	(3)	4
	8,034	8,044	13	(3)	10
	$ 422,639	$ 422,989	$ 552	$ (202)	$ 350

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

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

At December 31, 2011	Amortized Cost Basis	Fair Value	Unrealized Gains	Unrealized (Losses)	Net
Unrestricted					
Maturities within one year:					
U.S. government obligations	$ 12,025	$ 12,067	$ 42		$ 42
U.S. government guaranteed corporate bonds	15,263	15,316	53		53
U.S. government guaranteed collateralized mortgage obligations	623	622		$ (1)	(1)
Municipal bonds	15,314	15,326	13	(1)	12
	43,225	43,331	108	(2)	106
Maturities after one year through five years:					
U.S. government obligations	272,433	272,752	400	(81)	319
Mortgage-backed securities	104	28		(76)	(76)
	272,537	272,780	400	(157)	243
Maturities after five years through ten years:					
Mortgage-backed securities	164	87		(77)	(77)
	315,926	316,198	508	(236)	272
Restricted					
Maturities within one year:					
U.S. government obligations	3,347	3,357	10		10
Maturities after one year through five years:					
U.S. government obligations	2,572	2,583	11		11
	5,919	5,940	21		21
	$ 321,845	$ 322,138	$ 529	$ (236)	$ 293

At June 30, 2012 and December 31, 2011, marketable securities included an additional unrealized loss of $1.6 million and $1.0 million, respectively, related to one equity security in the Company s marketable securities portfolio.

The following table shows the fair value of the Company s marketable securities that have unrealized losses and that are deemed to be only temporarily impaired, aggregated by investment category and length of time that the individual securities have been in a continuous unrealized loss position, at June 30, 2012 and December 31, 2011.

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

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

	Less than 12 Months		12 Months or Greater		Total	
At June 30, 2012	**Fair Value**	**Unrealized Loss**	**Fair Value**	**Unrealized Loss**	**Fair Value**	**Unrealized Loss**
Unrestricted						
U.S. government obligations	$ 89,055	$ (49)			$ 89,055	$ (49)
U.S. government guaranteed corporate bonds	24,969	(4)			24,969	(4)
Equity security	2,455	(1,589)			2,455	(1,589)
Mortgage-backed securities			$ 117	$ (146)	117	(146)
	116,479	(1,642)	117	(146)	116,596	(1,788)
Restricted						
U.S. government obligations	2,413	(3)			2,413	(3)
	2,413	(3)			2,413	(3)
	$ 118,892	$ (1,645)	$ 117	$ (146)	$ 119,009	$ (1,791)
At December 31, 2011						
Unrestricted						
U.S. government obligations	$ 103,529	$ (81)			$ 103,529	$ (81)
U.S. government guaranteed collateralized mortgage obligations	623	(1)			623	(1)
Municipal bonds	4,603	(1)			4,603	(1)
Equity security	3,019	(1,025)			3,019	(1,025)
Mortgage-backed securities			$ 116	$ (152)	116	(152)
	$ 111,774	$ (1,108)	$ 116	$ (152)	$ 111,890	$ (1,260)

Realized gains and losses are included as a component of investment income. For the three and six months ended June 30, 2012 and 2011, total realized gains and losses on sales of marketable securities were not material.

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed 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 June 30, 2012 and December 31, 2011, were as follows:

		Fair Value Measurements at Reporting Date Using		
At June 30, 2012	**Fair Value**	**Quoted Prices in Active Markets for Identical Assets (Level 1)**	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**
Unrestricted				
Available-for-sale marketable securities:				
U.S. government obligations	$ 351,788		$ 351,788	
U.S. government guaranteed corporate bonds	50,654		50,654	
Municipal bonds	12,386		12,386	
Mortgage-backed securities	117		117	
Equity security	2,455	$ 2,455		
	417,400	2,455	414,945	
Restricted				
Available-for-sale marketable securities:				
U.S. government obligations	8,044		8,044	
	$ 425,444	$ 2,455	$ 422,989	
At December 31, 2011				
Unrestricted				
Available-for-sale marketable securities:				
U.S. government obligations	$ 284,819		$ 284,819	
U.S. government guaranteed corporate bonds	15,316		15,316	
U.S. government guaranteed collateralized mortgage obligations	622		622	
Municipal bonds	15,326		15,326	
Mortgage-backed securities	115		115	
Equity security	3,019	$ 3,019		
	319,217	3,019	316,198	
Restricted				
Available-for-sale marketable securities:				
U.S. government obligations	5,940		5,940	
	$ 325,157	$ 3,019	$ 322,138	

Marketable securities included in Level 2 were valued using a market approach utilizing prices and other relevant information, such as interest rates, yield curves, prepayment speeds, loss severities, credit risks and default rates, generated by market transactions involving identical or comparable assets. The Company considers market liquidity in determining the fair value for these securities. The Company did not record

any charges for other-than-temporary impairment of its Level 2 marketable securities during the three and six months ended June 30, 2012 and 2011.

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The Company holds one Level 3 marketable security, which had a fair value of $0 at June 30, 2012 and December 31, 2011. This Level 3 security was valued using information provided by the Company s investment advisors and other sources, including quoted bid prices which took into consideration the security s lack of liquidity. 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 and six months ended June 30, 2012 and 2011. There were no transfers of marketable securities between Levels 1, 2, or 3 classifications during the three and six months ended June 30, 2012 and 2011.

As of June 30, 2012, the Company had $400.0 million in aggregate principal amount of 1.875% convertible senior notes that will mature on October 1, 2016 unless earlier converted or repurchased. The fair value of the outstanding convertible senior notes was estimated to be $605.8 million as of June 30, 2012, and was determined based on quoted market rates.

7. Inventory

Inventories as of June 30, 2012 and December 31, 2011 consist of the following:

	June 30, 2012	December 31, 2011
Raw materials	$ 6,975	$ 4,666
Work in process	13,609	10,806
Finished goods	3,841	1,142
	$ 24,425	$ 16,614

At June 30, 2012, $10.5 million of inventories were included in prepaid expenses and other current assets and $13.9 million of inventories were included in other assets. At December 31, 2011, $3.7 million of inventories were included in prepaid expenses and other current assets and $12.9 million of inventories were included in other assets.

For the three and six months ended June 30, 2012, cost of goods sold included inventory write-downs and reserves totaling $6.5 million and $8.4 million, respectively. For the three and six months ended June 30, 2011, there were no inventory write-downs or reserves included in cost of goods sold.

8. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses as of June 30, 2012 and December 31, 2011 consist of the following:

	June 30, 2012	December 31, 2011
Accounts payable	$ 25,672	$ 27,736
Accrued payroll and related costs	35,458	42,835
Accrued clinical trial expense	14,029	9,850
Accrued sales-related deductions and royalties	36,386	3,947
Other accrued expenses and liabilities	15,223	11,257
	$ 126,768	$ 95,625

9. Income Taxes

For the three and six months ended June 30, 2012, income tax expense relating to the Company s pre-tax income was fully offset by a reversal of a portion of the Company s valuation allowance. The Company continues to recognize a full valuation allowance against its net operating loss carry-forward and other deferred tax assets since the Company has an extended history of losses.

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For the three and six months ended June 30, 2011, the Company incurred a net loss for tax purposes and recognized a full valuation allowance against deferred tax assets. For the three and six months ended June 30, 2011, the Company recognized an income tax benefit of $0.9 million and $1.1 million, respectively, in connection with the net tax effect of the change in the Company s unrealized gain/(loss) on available-for-sale marketable securities, which is included in other comprehensive income (loss).

10. Legal Matters

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

Genentech Patent Litigation

The Company is aware of issued patents and pending patent applications owned by Genentech that claim certain chimeric VEGF receptors. The Company does not believe that ZALTRAP® or EYLEA infringe any valid claim in these patents or patent applications. The Company is involved in five patent litigations with Genentech, two in the United States and three in Europe. In November 2010, the Company commenced a lawsuit against Genentech in the U.S. District Court for the Southern District of New York (the Court), seeking a declaratory judgment that no activities relating to the Company s VEGF Trap infringe any valid claim of certain Genentech patents referred to as the Davis-Smyth patents (the First Davis-Smyth Case). Genentech answered the complaint and asserted counterclaims that the Company s prior or planned activities relating to VEGF Trap have infringed or will infringe claims of four of the five Davis-Smyth patents and requested a judgment against the Company for damages, including for willful infringement, and other relief as the Court deems appropriate.

On December 31, 2011, the Company entered into a Non-Exclusive License and Partial Settlement Agreement with Genentech (the Genentech Agreement) that covers 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 ends the litigation relating to those matters. Under the Genentech Agreement, the Company received a non-exclusive license to the Davis-Smyth patents, and certain other technology patents owned or co-owned by Genentech. The Genentech Agreement does not cover any non-U.S. patent rights or non-U.S. patent disputes, and does not cover any use of aflibercept other than for prevention and treatment of human eye diseases and disorders in the United States. The First Davis-Smyth Case is continuing with respect to matters not covered by the Genentech Agreement. The Genentech Agreement provides for the Company to make payments to Genentech based on U.S. sales of EYLEA through May 7, 2016, the date the Davis-Smyth patents expire. The Company will make a lump-sum payment of $60 million once cumulative U.S. sales of EYLEA reach $400 million. The Company will also pay royalties of 4.75% on cumulative U.S. sales of EYLEA between $400 million and $3 billion and 5.5% on any cumulative U.S. sales of EYLEA over $3 billion. As a result of the Genentech Agreement, on January 17, 2012 Genentech filed a second amended answer and counterclaim in the First Davis-Smyth Case, in which it amended its counterclaims alleging infringement of four of the five Davis-Smyth patents. On December 23, 2011, Genentech initiated a related case in the Court against Regeneron and Sanofi alleging infringement of four of the five Davis-Smyth Patents by activities relating to VEGF Trap (but excluding EYLEA) (the Second Davis-Smyth Case). As in the First Davis-Smyth Case, in the new complaint Genentech requests a judgment against the Company for damages, including for willful infringement, and other relief as the Court deems appropriate.

The Company believes Genentech's remaining claims in the First Davis Smyth Case and the Second Davis Smyth Case are without merit and intends to continue to defend against all of Genentech s remaining claims vigorously. As this litigation is at an early stage, at this time the Company is not able to predict the probability of the outcome or an estimate of loss, if any, related to these matters.

The Company has initiated patent-related actions against Genentech in Germany, the United Kingdom, and Italy relating in each case to a patent that expires on October 28, 2012. The Company may initiate other actions in other countries outside the United States, which could have similar or other adverse outcomes that would materially harm its business and which, irrespective of the outcomes, may also entail significant costs and expenses. In the United Kingdom, an adverse decision dated March 22, 2012 is under appeal. This decision found the designation of European patent EP 1 238 986 in the United Kingdom to be valid and potential acts relating to VEGF Trap Eye in the United Kingdom before expiration of the patent on October 28, 2012 to infringe this patent.

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11. Recently Issued Accounting Standards

Presentation of comprehensive income

In June and December 2011, the Financial Accounting Standards Board (FASB) amended its authoritative guidance on the presentation of comprehensive income. Under the amendments, an entity has the option to present comprehensive income and net income either in a single continuous statement or in two separate but consecutive statements. This amendment, therefore, eliminated the option to present the components of other comprehensive income as part of the statement of changes in stockholders' equity. The amendment did not change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income. The Company adopted this amended guidance for the fiscal year beginning January 1, 2012. As this guidance relates to presentation only, the adoption of this guidance did not have any other effect on the Company's financial statements.

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

The discussion below contains forward-looking statements that involve risks and uncertainties relating to future events and the future financial performance of Regeneron Pharmaceuticals, Inc., and actual events or results may differ materially from these forward-looking statements. These statements concern, and these risks and uncertainties include, among others, the nature, timing, and possible success and therapeutic applications of EYLEA® and ARCALYST® and our product candidates, potential new indications for marketed products, and research and clinical programs now underway or planned; the likelihood and timing of possible regulatory approval and commercial launch of our late-stage product candidates and new indications for marketed products; determinations by regulatory and administrative governmental authorities which may delay or restrict our ability to continue to develop or commercialize EYLEA and other product and drug candidates and possible new indications for marketed products; the ability for us to manufacture and manage supply chains for multiple products and product candidates; competing drugs that may be superior to EYLEA and our product and drug candidates and possible new indications for marketed products; uncertainty of market acceptance of EYLEA and our product and drug candidates and possible new indications for marketed products; coverage and reimbursement determinations by third-party payers, including Medicare and Medicaid; unforeseen safety issues resulting from the administration of products and product candidates in patients; unanticipated expenses; the costs of developing, producing, and selling products; the ability for us to meet any of our financial projections or guidance and changes to the assumptions underlying those projections or guidance; the potential for any license or collaboration agreement, including our agreements with Sanofi and Bayer HealthCare LLC, to be canceled or terminated without any product success; and risks associated with third-party intellectual property and pending or future litigation relating thereto. These statements are made by us based on management's current beliefs and judgment. In evaluating such statements, shareholders and potential investors should specifically consider the various factors identified under the caption Risk Factors which could cause actual events and results to differ materially from those indicated by such forward-looking statements. We do not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law.

Overview

Regeneron Pharmaceuticals, Inc. is a fully integrated biopharmaceutical company that discovers, invents, develops, manufactures, and commercializes medicines for the treatment of serious medical conditions. We currently have two marketed products:

- EYLEA® (aflibercept) Injection, known in the scientific literature as VEGF Trap-Eye, which is available in the United States for the treatment of neovascular age-related macular degeneration (wet AMD). Wet AMD is the leading cause of acquired blindness for people over the age of 65 in the United States and Europe.
- ARCALYST® (rilonacept) Injection for Subcutaneous Use, which is available by prescription in the United States for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS), in adults and children 12 and older.

Net product sales of our two marketed products totaled $199.5 million in the second quarter and $327.5 million in the first half of 2012. This contributed to our overall net income of $76.7 million in the second quarter and $88.4 million in the first half of 2012. Our operating results over the next several years will be largely dependent upon our ability to continue to successfully commercialize EYLEA and the market penetration it achieves.

We have 13 product candidates in clinical development, all of which were discovered in our research laboratories. Our Trap-based, late-stage programs are:

- EYLEA, which is being developed for the treatment of additional serious eye diseases;
- ZALTRAP® (aflibercept), known in the scientific literature as VEGF Trap, which is being developed in oncology in collaboration with Sanofi; and
- ARCALYST, which is being developed for the prevention of gout flares in patients initiating uric acid-lowering treatment.

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

- Sarilumab (REGN88), an antibody to the interleukin-6 receptor (IL-6R), which is being developed in rheumatoid arthritis;
- REGN727, an antibody to Proprotein Convertase Subtilisin/Kexin type 9 (PCSK9), which is being developed for low-density lipoprotein (LDL) cholesterol reduction;
- REGN668, an antibody to the interleukin-4 receptor (IL-4R), which is being developed in atopic dermatitis and eosinophilic asthma;
- REGN421, an antibody to Delta-like ligand-4 (Dll4), a novel angiogenesis target, which is being developed in oncology;
- REGN910, an antibody to Angiopoietin-2 (ANG2), another novel angiogenesis target, which is being developed in oncology;
- REGN728, an antibody in clinical development against an undisclosed target; and
- REGN1033, an antibody in clinical development against an undisclosed target.

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

- REGN475, an antibody to Nerve Growth Factor (NGF), which is being developed for the treatment of pain (currently on clinical hold);
- REGN846, an antibody in clinical development against an undisclosed target, which is being developed in atopic dermatitis; and
- REGN1154, an antibody in clinical development against an undisclosed target.

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

We believe that our ability to develop product candidates is enhanced by the application of our *VelociSuite* technology platforms. Our discovery platforms are designed to identify specific proteins of therapeutic interest for a particular disease or cell type and validate these targets through high-throughput production of genetically modified mice using our *VelociGene*® technology to understand the role of these proteins in normal physiology, as well as in models of disease. Our human monoclonal antibody technology (*VelocImmune*®) and cell line expression technologies (*VelociMab*®) may then be utilized to discover and produce new product candidates directed against the disease target. Our antibody product candidates currently in clinical trials were developed using *VelocImmune*. Under the terms of our antibody collaboration with Sanofi, which was expanded during 2009, we plan to advance a total of 20 to 30 candidates into clinical development over the life of the agreement. We continue to invest in the development of enabling technologies to assist in our efforts to identify, develop, manufacture, and commercialize new product candidates.

Commercial Products:

EYLEA (aflibercept) Injection wet AMD

In November 2011, we received U.S. marketing approval from the U.S. Food and Drug Administration (FDA) for EYLEA Injection for the treatment of patients with wet AMD. Net product sales of EYLEA were $194.0 in the second quarter and $317.5 million in the first half of 2012.

EYLEA, known in the scientific literature as VEGF Trap-Eye, is a fusion protein locally administered in the eye that is designed to bind Vascular Endothelial Growth Factor-A (VEGF-A) and Placental Growth Factor (PlGF) proteins that are involved in the abnormal growth of new blood vessels. The abnormal growth of new blood vessels could leak blood and fluid, which causes disruption and dysfunction of the retina creating distortion and/or blind spots in central vision.

We are collaborating with Bayer HealthCare on the global development of EYLEA. In February 2012, Bayer HealthCare received marketing approval in Australia for EYLEA for the treatment of patients with wet AMD, and is expected to launch in the second half of 2012. In June 2012, Bayer HealthCare received marketing approval in Colombia for EYLEA for the treatment of patients with wet AMD, and is expected to launch in the second half of 2012. Bayer HealthCare has also submitted applications for marketing authorization in the European Union, Japan, and other countries for wet AMD, and expects regulatory decisions beginning in the second half of 2012. Bayer HealthCare will market EYLEA outside the United States, where, for countries other than Japan, the companies will share equally the profits from any future sales of EYLEA. We are entitled to a royalty on annual sales of EYLEA in Japan, as described below. We maintain exclusive rights to EYLEA in the United States and are entitled to all profits from any such sales.

ARCALYST CAPS

Net product sales of ARCALYST (rilonacept) for the treatment of CAPS were $5.5 million in the second quarter of 2012, compared to $5.0 million in the same quarter of 2011. ARCALYST net product sales in the first half of 2012 were $9.9 million, compared to $9.5 million in the first half of 2011. We do not expect future net product sales of ARCALYST for the treatment of CAPS to be significant.

ARCALYST is a protein-based product designed to bind the interleukin-1 (called IL-1) cytokine and prevent its interaction with cell surface receptors. ARCALYST is available by prescription in the United States for the treatment of CAPS, including FCAS and MWS in adults and children 12 and older. CAPS are a group of rare, inherited, auto-inflammatory conditions characterized by life-long, recurrent symptoms of rash, fever/chills, joint pain, eye redness/pain, and fatigue. Intermittent, disruptive exacerbations or flares can be triggered at any time by exposure to cooling temperatures, stress, exercise, or other unknown stimuli.

Clinical Programs:

1. EYLEA Ophthalmologic Diseases

We, together with our ex-U.S. collaborator Bayer HealthCare, are evaluating EYLEA in Phase 3 programs in patients with central retinal vein occlusion (CRVO), branch retinal vein occlusion (BRVO), diabetic macular edema (DME), and choroidal neovascularisation (CNV) of the retina as a result of pathologic myopia. Wet AMD, diabetic retinopathy (which includes DME), and retinal vein occlusion are three of the leading causes of adult blindness in the developed world. In these conditions, severe visual loss is caused by a combination of retinal edema and neovascular proliferation.

A study to fulfill a post-marketing requirement by the FDA, RE-VIEW (Rigorous Evaluation of Vision and safety with Intravitreal aflibercept injection dosed Every 8 Weeks over 2 years in wet AMD), will evaluate the effect of EYLEA on corneal endothelium. This study is expected to be initiated in the fourth quarter of 2012.

In November 2011, we submitted a supplemental Biologics License Application (sBLA) for U.S. regulatory approval of EYLEA in CRVO based on the positive results in the Phase 3 COPERNICUS and GALILEO studies. Under the Prescription Drug User Fee Act (PDUFA), we were granted a target date for an FDA decision on our EYLEA sBLA of September 23, 2012. Bayer HealthCare plans to submit regulatory applications in this indication in Europe in late 2012 or early 2013 and in Japan during the second half of 2012.

In the second quarter of 2011, we and Bayer HealthCare initiated Phase 3 studies to evaluate the safety and efficacy of EYLEA in DME. We are conducting one of these studies, VISTA-DME, in the United States. Bayer HealthCare is conducting the second study, VIVID-DME, in Europe, Japan, and Australia. Both the VISTA-DME and VIVID-DME trials are fully enrolled. An additional Phase 3 safety study in Japan was initiated in the first quarter of 2012 by Bayer HealthCare (VIVID-Japan). This study anticipates the enrollment of approximately 65 patients and is required for approval in Japan.

In the first quarter of 2011, we and Bayer HealthCare initiated a Phase 3 trial in Asia in collaboration with the Singapore Eye Research Institute (SERI) investigating the efficacy and safety of EYLEA in patients with CNV of the retina as a result of pathologic myopia. The study will enroll approximately 110 patients.

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 neovascular wet AMD (SIGHT). The trial is expected to include approximately 300 patients and will be the largest retinal trial conducted in China. The SIGHT trial is being led by Bayer HealthCare.

In the second quarter of 2012, we initiated a multinational study of EYLEA in patients with BRVO (VIBRANT). Patients will be treated with either six monthly intravitreal injections of EYLEA 2.0 mg or laser. The primary endpoint of the VIBRANT study is the proportion of patients who gain at least 15 letters in Best Corrected Visual Acuity (BCVA) after six months of treatment as measured by the Early Treatment Diabetic Retinopathy Study (ETDRS) eye chart.

Collaboration with Bayer HealthCare

In October 2006, we entered into a license and collaboration agreement with Bayer HealthCare for the global development and commercialization outside the United States of EYLEA. Under the agreement, we and Bayer HealthCare collaborate on, and share the costs of, the development of EYLEA through an integrated global plan. Bayer HealthCare will market EYLEA outside the United States, where, for countries other than Japan, the companies will share equally in profits from any future 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 should marketing approval be achieved. In conjunction with this agreement, we and Bayer HealthCare amended our existing global license and collaboration agreement for EYLEA to convert the 50/50 profit share for Japan into a royalty agreement under which we are entitled to receive a tiered royalty of between 33.5% and 40.0% of EYLEA annual net sales in Japan. In certain specified circumstances, the Japan royalty may revert to a profit share arrangement.

Commencing on the first commercial sale of EYLEA in a major market country outside the United States, we will be 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. 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. Within the United States, we retain exclusive commercialization rights to EYLEA and are entitled to all profits from any such sales. We have received $60 million in development milestone payments and can earn up to $50 million in future milestone payments related to marketing approvals of EYLEA in major market countries outside the United States. We can also earn up to $135 million in sales milestone payments if total annual sales of EYLEA outside the United States achieve certain specified levels starting at $200 million.

2. ZALTRAP (aflibercept) also known as VEGF Trap 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 the growth of new blood vessels (a process known as angiogenesis) that are needed for tumors to grow.

ZALTRAP is being developed globally in cancer indications in collaboration with Sanofi. In April 2011, we and Sanofi announced that the Phase 3 VELOUR trial evaluating ZALTRAP in combination with the FOLFIRI chemotherapy regimen [folinic acid (leucovorin), 5-fluorouracil, and irinotecan] versus a regimen of FOLFIRI plus placebo met its primary endpoint of improving overall survival (OS) in previously treated metastatic colorectal cancer (mCRC) patients. Based upon the positive VELOUR data, Sanofi submitted regulatory applications for marketing approval of ZALTRAP for the treatment of previously-treated mCRC patients to the European Medicines Agency (EMA) in December 2011 and to the FDA in February 2012. Under PDUFA, we were granted Priority Review of the BLA for ZALTRAP with a target date for an FDA decision of August 4, 2012.

Another randomized, double-blind Phase 3 trial (VENICE), evaluated ZALTRAP as a first-line treatment for metastatic androgen-independent prostate cancer in combination with docetaxel/prednisone. In April 2012, we and Sanofi announced that the results from the Phase 3 VENICE trial did not meet the pre-specified criterion of improvement in overall survival. The safety profile was generally consistent with previous studies of ZALTRAP in combination with docetaxel.

ZALTRAP Collaboration with Sanofi

We and Sanofi globally collaborate on the development and commercialization of ZALTRAP. Under the terms of our September 2003 collaboration agreement, as amended, we and Sanofi will share co-promotion rights and profits on sales, if any, of ZALTRAP outside of Japan for disease indications included in our collaboration. In Japan, we are entitled to a royalty of approximately 35% on annual sales of ZALTRAP, subject to certain potential adjustments. We may also receive up to $400 million in milestone payments upon receipt of specified marketing approvals, including up to $360 million related to the receipt of marketing approvals for up to eight ZALTRAP oncology and other indications in the United States or the European Union and up to $40 million related to the receipt of marketing approvals for up to five oncology indications in Japan.

Under the ZALTRAP collaboration agreement, as amended, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be 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, if ZALTRAP receives regulatory approval for patients previously treated for mCRC, we expect that, initially, our share of any ZALTRAP profits will be diverted to reimburse Sanofi for this repayment obligation.

3. ARCALYST (rilonacept) Inflammatory Diseases

ARCALYST is being developed for the prevention of gout flares in patients initiating uric acid-lowering therapy. Gout, a disease in which IL-1 may play an important role in pain and inflammation, is a very painful and common form of arthritis that results from high levels of uric acid, a bodily waste product normally excreted by the kidneys. The elevated uric acid can lead to formation of urate crystals in the joints of the toes, ankles, knees, wrists, fingers, and elbows. Uric acid-lowering therapy, most commonly allopurinol, is prescribed to eliminate the urate crystals and prevent them from reforming. Paradoxically, the initiation of uric acid-lowering therapy often triggers an increase in the frequency of gout attacks in the first several months of treatment, which may lead to discontinuation of therapy. The break-up of urate crystals can result in stimulation of inflammatory mediators, including IL-1, resulting in acute flares of joint pain and inflammation. These painful flares generally persist for at least five days.

We conducted a Phase 3 clinical development program with ARCALYST in gout patients initiating uric acid-lowering therapy. The program consisted of three studies: PRE-SURGE 1, PRE-SURGE 2, and RE-SURGE, as well as an ongoing long-term safety study (UPSURGE). Based on the positive results of these studies, we submitted a supplemental BLA for U.S. regulatory approval of ARCALYST for the prevention of gout flares in patients initiating uric acid-lowering therapy. In November 2011, the FDA accepted for review our supplemental BLA. Under PDUFA, we were granted a target date for an FDA decision on the ARCALYST supplemental BLA of July 30, 2012. On May 8, 2012, the Arthritis Advisory Committee of the FDA voted against approval of ARCALYST for the prevention of gout flares in patients initiating uric acid-lowering therapy.

We own worldwide rights to ARCALYST.

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

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

Sarilumab is a fully human monoclonal antibody to IL-6R generated using our *VelocImmune* technology. In July 2011, we and Sanofi announced that in the Phase 2b stage of the MOBILITY trial in rheumatoid arthritis, patients treated with sarilumab in combination with a standard RA treatment, methotrexate (MTX), achieved a significant and clinically meaningful improvement in signs and symptoms of moderate-to-severe RA compared to patients treated with MTX alone. The primary endpoint of the study was the proportion of patients achieving at least a 20% improvement in RA symptoms (ACR20) after 12 weeks. During the third quarter of 2011, we and Sanofi initiated the Phase 3 stage of the Phase 2/3 MOBILITY study in patients with rheumatoid arthritis. In addition, we and Sanofi plan to initiate additional Phase 3 studies of sarilumab in the second half of 2012.

5. REGN727 (PCSK9 Antibody) for LDL cholesterol reduction

Elevated LDL cholesterol (bad cholesterol) level is a validated risk factor leading to cardiovascular disease. Statins are a class of drugs that lower LDL cholesterol by up regulating the expression of the LDL receptor (LDLR), which removes LDL from circulation. PCSK9 is a naturally occurring secreted protein that also modulates LDL cholesterol levels through its interaction with the LDL receptor. In a landmark study published in the *New England Journal of Medicine* in March 2006, patients with lower than normal PCSK9 levels due to a genetic abnormality not only had significantly lower levels of LDL cholesterol, but also a significant reduction in the risk of coronary heart disease. We used our *VelocImmune* technology to generate a fully human monoclonal antibody inhibitor of PCSK9, called REGN727, that is intended to lower LDL cholesterol.

In March 2012, data from the Phase 1 program were published in the *New England Journal of Medicine*. In addition, data from two Phase 2 trials were presented at the American College of Cardiology (ACC) Annual Meeting, one of which was also published in the Journal of the American College of Cardiology. Study DFI11565, presented at a late-breaking clinical trials session, was a Phase 2 dose-finding clinical trial, and enrolled 183 patients with elevated LDL-C (greater than or equal to 100 mg/dL) despite being on a stable dose of atorvastatin. The objective of the study was to evaluate the effect of adding REGN727 to existing statin therapy. Across the five different dose regimens tested, patients receiving REGN727 for 12 weeks achieved and sustained a mean LDL-C reduction from baseline of 40% to 72%, compared to 5% in patients receiving placebo ($p<0.0001$). Patients in the study were followed for a total of 20 weeks for safety. The most common adverse events (AEs) with REGN727 were injection site reactions. Serious AEs occurred in one patient receiving placebo and three patients in the active treatment arms, including a patient on active treatment who experienced a skin rash diagnosed as leukocytoclastic vasculitis. Six patients, all on active treatment, prematurely discontinued therapy due to AEs. Muscle complaints were infrequent and similar across all treatment groups. There were no significant elevations in liver enzymes or other lab values in patients on active treatment.

Data from a second trial, Study DFI11566, were also presented at an oral session of the ACC meeting. The study enrolled patients with primary hypercholesterolemia (heFH) with elevated LDL cholesterol (greater than or equal to 100 mg/dL) who were on a stable low dose of atorvastatin (10 mg). The primary objective of the study was to compare the effect on LDL cholesterol lowering of switching to a high dose of atorvastatin alone (80 mg) versus a high dose of atorvastatin combined with REGN727. Patients who received REGN727 plus atorvastatin 80 mg achieved a mean reduction of 73% in LDL cholesterol, compared to a mean reduction of 17% for patients who switched to atorvastatin 80 mg alone ($p<0.001$) after eight weeks. The study also included a third arm in which REGN727 was added to the stable low dose of atorvastatin. Patients in this arm achieved a 66% reduction in mean LDL cholesterol. Patients in the study were followed for a total of 16 weeks for safety. In this trial, the most common AE with REGN727 was infection. There was one serious adverse event in the REGN727 plus atorvastatin 80 mg group (dehydration) that was deemed not to be treatment-related.

Data from a third Phase 2 trial were published online in *The Lancet* and also presented at the European Atherosclerosis Society Congress (EAS) in May 2012. The trial randomized 77 patients with heFH whose LDL-cholesterol levels remained uncontrolled on statin therapy with or without ezetimibe. Across the four different dosing regimens tested, patients receiving REGN727 for 12 weeks achieved a mean LDL-cholesterol reduction from baseline of 28.9% to 67.9%, compared to 10.7% in patients receiving placebo ($p < 0.05$). In addition, in the most intense dose regimen tested where the greatest LDL-cholesterol reduction was observed (150 mg every two weeks), 93.8% of patients achieved LDL-cholesterol levels lower than 100 mg/dL (2.59 mmol/L), compared to 13.3% of patients on placebo, and 81.3% reached LDL-cholesterol levels lower than 70 mg/dL (1.81 mmol/L), compared to none on placebo. There were no serious adverse events on active treatment, while a single serious adverse event was recorded for a patient in the placebo group. There were no elevations in liver function tests (LFT) > 3 times the upper limit of normal (ULN) and no cases of elevated creatinine kinase (CK) were reported. The most common adverse event reported was injection-site reaction.

We, along with Sanofi, initiated a global Phase 3 program (ODYSSEY) for REGN727 in June 2012. This was the first Phase 3 program of an investigational drug targeting PCSK9. The ODYSSEY program will enroll more than 22,000 patients. This includes over ten clinical trials evaluating the effect of REGN727 on lowering LDL cholesterol and an 18,000 patient cardiovascular outcomes (e.g., heart attacks, stroke) study. LDL cholesterol is expected to be the primary efficacy endpoint for regulatory filings. The studies will be conducted in clinical centers around the world including the United States, Canada, Western and Eastern Europe, South America, Australia and Asia. A Phase 3, long-term safety and tolerability study of REGN727 is ongoing in patients with hypercholesterolemia who are not adequately controlled with their current lipid-modifying therapy.

6. REGN668 (IL-4R Antibody) for allergic and immune conditions

IL-4R is required for signaling by the cytokines IL-4 and IL-13. Both of these cytokines are critical mediators of immune response, which, in turn, drives the formation of Immunoglobulin E (IgE) antibodies and the development of allergic responses, as well as the atopic state that underlies asthma and atopic dermatitis.

REGN668 is a fully human monoclonal antibody generated using our *VelocImmune* technology that is designed to bind to IL-4R. REGN668 is in Phase 2 studies in patients with atopic dermatitis and eosinophilic asthma.

7. REGN421 (Dll4 Antibody) for advanced malignancies

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

REGN421 is a fully human monoclonal antibody to Dll4 generated using our *VelocImmune* technology, and is in Phase 1 clinical development.

8. 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, angiopoietin 2 (ANG2) is strongly upregulated by endothelial cells at sites of angiogenesis and vascular remodeling, including tumors.

REGN910 is a fully human monoclonal antibody generated using our *VelocImmune* technology that is designed to block ANG2. REGN910 is in Phase 1 clinical development in oncology.

9. REGN728

REGN728, a fully human monoclonal antibody generated using our VelocImmune technology against an undisclosed target, has completed a Phase 1 study.

10. REGN1033

In January 2012, we initiated a Phase 1 clinical study for REGN1033, a fully human monoclonal antibody generated using our *VelocImmune* technology, against an undisclosed target.

11. REGN475 (NGF Antibody) for pain

REGN475 is a fully human monoclonal antibody to NGF, generated using our *VelocImmune* technology, which is designed to block pain sensitization in neurons. Preclinical experiments indicate that REGN475 specifically binds to and blocks NGF activity and does not bind to or block cell signaling for closely related neurotrophins such as NT-3, NT-4, or BDNF.

In May 2010, we announced positive results from an interim analysis of a randomized, double-blind, four-arm, placebo-controlled Phase 2 trial in 217 patients with osteoarthritis of the knee. In July 2010, we presented additional results from this trial through 16 weeks.

In December 2010, the FDA placed REGN475 and other investigational agents targeting NGF on clinical hold after a case of rapidly progressive osteoarthritis leading to joint replacement was seen in another company s anti-NGF program. At that time, the FDA expressed concern that this case, which followed previously-reported cases of joint replacements in patients on an anti-NGF drug candidate being developed by a different pharmaceutical company, provided evidence to suggest a class effect.

An FDA Arthritis Advisory Committee met on March 12, 2012 to discuss possible safety issues related to anti-NGF compounds and voted unanimously in favor of continued development of anti-NGF agents in osteoarthritis. The Arthritis Advisory Committee also voted twenty to one in favor for continued development of anti-NGF agents to manage the pain associated with conditions for which there are no agents with demonstrated analgesic efficacy. While the committee's recommendation will be considered by the FDA, it is not binding on the FDA.

There are currently no ongoing trials with REGN475 that are either enrolling or treating patients, but we are finalizing plans to initiate new trials, subject to FDA approval.

In February 2012, Sanofi elected not to continue co-development of REGN475, and Regeneron now has sole global rights to REGN475. Under the terms of our agreement, Sanofi remains obligated to fund agreed-upon REGN475 development costs through the end of 2012 and is entitled to receive a mid-single digit royalty on any future sales of REGN475.

12. REGN846

REGN846 is a fully human monoclonal antibody generated using our *VelocImmune* technology, against an undisclosed target, and is being evaluated in a Phase 2a study in patients with atopic dermatitis. In July 2011, Sanofi elected not to continue co-development of REGN846, and Regeneron now has sole global rights to REGN846. Under the terms of our agreement, Sanofi remains obligated to fund agreed-upon REGN846 clinical costs through conclusion of a planned proof-of-concept trial and is entitled to receive a mid-single digit royalty on any future sales of REGN846.

13. REGN1154

REGN1154 is a fully human monoclonal antibody generated using our *VelocImmune* technology, against an undisclosed target. In March 2012, we initiated a Phase 1 clinical study in Australia. Sanofi decided not to opt-in to the REGN1154 program and we have sole global rights. Under the terms of our agreement, Sanofi is entitled to receive a mid-single digit royalty on any future sales of REGN1154.

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 two approved products, ARCALYST and EYLEA, as well as ZALTRAP, for which regulatory applications for marketing approval have been submitted. 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.

Antibody Collaboration and License Agreements

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

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

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

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

Under the amended discovery agreement, Sanofi agreed to fund up to $160 million per year of our antibody discovery activities over the period from 2010-2017, subject to a one-time option for Sanofi to adjust the maximum reimbursement amount down to $120 million per year commencing in 2014 if over the prior two years certain specified criteria were not satisfied. Sanofi has an option to extend the discovery program for up to an additional three years after 2017 for further antibody development and preclinical activities. Pursuant to the collaboration, Sanofi funded up to $30 million of agreed-upon costs we incur to expand our manufacturing capacity at our Rensselaer, New York facilities.

From the collaboration's inception in November 2007 through June 30, 2012, Sanofi has funded a total of $565.7 million of our costs under the discovery agreement and a total of $477.9 million of our development costs under the license agreement, or a total of $1.0 billion in funding for our antibody research and development activities during this period.

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

Astellas Pharma Inc. In March 2007, we entered into a six-year, non-exclusive license agreement with Astellas Pharma Inc. to allow Astellas to utilize our *VelocImmune* technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, Astellas made a $20.0 million annual, non-refundable payment to us in each of the second quarters of 2007, 2008, 2009, and 2010. In July 2010, the license agreement with Astellas was amended and extended through June 2023. Under the terms of the amended agreement, Astellas made a $165.0 million up-front payment to us in August 2010. In addition, Astellas will make a $130.0 million second payment to us in June 2018 unless the license agreement has been terminated prior to that date. Astellas has the right to terminate the agreement at any time by providing 90 days advance written notice. Under certain limited circumstances, such as our material breach of the agreement, Astellas may terminate the agreement and receive a refund of a portion of its up-front payment or, if such termination occurs after June 2018, a portion of its second payment, to us under the July 2010 amendment to the agreement. We are entitled to receive a mid-single digit royalty on any future sales of antibody products discovered by Astellas using our *VelocImmune* technology.

Royalty Agreement with Novartis Pharma AG

Under a June 2009 agreement with Novartis (that replaced a previous collaboration and license agreement), we receive royalties on worldwide sales of Novartis canakinumab, a fully human anti-interleukin-IL1ß antibody. The royalty rates in the agreement start at 4% and reach 15% when annual sales exceed $1.5 billion. Canakinumab is marketed for the treatment of CAPS, has completed Phase 3 development for gout, and is in earlier stage development for atherosclerosis and other inflammatory diseases. We are unable to predict whether canakinumab will be approved for gout or any other indication in addition to CAPS, or whether, even if approved, canakinumab for such indication(s) will be successfully commercialized. Accordingly, we are unable to predict whether these royalties will ever contribute materially to our results of operations or financial condition. To date these royalties have been minimal.

Research Programs

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

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.

We expect to incur substantial costs to prepare for potential commercialization of ZALTRAP for the treatment of previously-treated mCRC patients and other late-stage product candidates and, if one or more of these product candidates receive regulatory approval, to fund the launch of the product(s).

From our inception in 1988 through 2011, we generally incurred net losses. In addition, since our inception in 1988, we have generally incurred negative cash flows from operations. Beginning in the first quarter of 2012, we reported profitability. Our ability to continue to generate profits and to generate positive cash flow from operations over the next several years depends significantly on our success in commercializing EYLEA. We expect to continue to incur substantial expenses related to our research and development activities, a significant portion of which we expect to be reimbursed by our collaborators. Also, our research and development activities outside our collaborations, the costs of which are not reimbursed, will expand and require additional resources. Our operating results may fluctuate from quarter to quarter and will depend on, among other factors, the net sales of our marketed products, as well as the scope and progress of our research and development efforts, the timing of certain expenses, the continuation of our collaborations with Sanofi and Bayer HealthCare, and the amount of reimbursement that we receive from collaborators. We cannot predict whether or when ZALTRAP or new indications for our marketed products will receive regulatory approval or, if any such approval is received, whether we will be able to successfully commercialize such product(s) and whether or when they may become profitable.

The planning, execution, and results of our clinical programs are significant factors that can affect our operating and financial results. In our clinical programs, key events in 2012 to date were, and plans for the next 12 months are, as follows:

Trap-based Clinical Programs:

2012 Events to Date	**2012-13 Plans (next 12 months)**
EYLEA	
• Bayer HealthCare received approval for EYLEA from Australia and Colombia for the treatment of patients with wet AMD • Bayer HealthCare continued to pursue regulatory applications for marketing approval for EYLEA for the treatment of wet AMD in various countries • Initiated Phase 3 study in BRVO • Completed enrollment of VISTA-DME and VIVID-DME studies	• EMA decision on regulatory applications for the treatment of wet AMD • Japan authority decision on regulatory application for the treatment of wet AMD • Target date for FDA decision on supplemental BLA for the treatment of CRVO is September 23, 2012
ZALTRAP	
• FDA granted Priority Review for the BLA for the treatment of mCRC • Reported final results in the Phase 3 VENICE trial in prostate cancer	• Target date for FDA decision on BLA for the treatment of mCRC is August 4, 2012 • EMA decision on regulatory applications in mCRC
ARCALYST	
• FDA Advisory Committee recommended against approval of ARCALYST for the prevention of gout flares in patients initiating uric acid-lowering treatment	• Target date for FDA decision on ARCALYST supplemental BLA for gout is July 30, 2012

Antibody-based Clinical Programs:

	2012 Events to Date	**2012-13 Plans (next 12 months)**
Sarilumab (IL-6R Antibody)	• Continued patient enrollment in Phase 3 MOBILITY study	• Initiate additional Phase 3 studies
REGN727 (PCSK9 Antibody)	• Initiated long-term safety study • Phase 1 data published in *New England Journal of Medicine* • Reported positive final data from three Phase 2 studies for LDL cholesterol reduction • Initiated Phase 3 ODYSSEY program for LDL cholesterol reduction. Phase 3 studies began enrolling patients with familial hypercholesterolemia or elevated cardiovascular risk, as well as patients unable to tolerate statin therapy	• Initiate Phase 3 ODYSSEY cardiovascular outcomes trial
REGN668 (IL-4R Antibody)	• Initiated Phase 2 studies in atopic dermatitis	• Report initial results for Phase 1b study in atopic dermatitis • Report initial results for Phase 2 study in eosinophilic asthma
REGN421 (Dll4 Antibody)	• Continued patient enrollment in Phase 1 program	• Initiate expansion of the Phase 1 program
REGN910 (ANG2 Antibody)	• Continued patient enrollment in Phase 1 program	• Initiate a Phase 1b program in advanced malignancies

REGN1033 ***(target not disclosed)***	• Initiated Phase 1 program	
REGN475 ***(NGF Antibody)***	• Anti-NGF class of antibodies is on clinical hold • FDA Advisory Committee voted unanimously in favor of a role for the ongoing development of anti-NGF agents in osteoarthritis • Sanofi elected not to co-develop REGN475	• Determine future development plan
REGN846 ***(target not disclosed)***	• Continued patient enrollment in Phase 2a program in atopic dermatitis	
REGN1154 ***(target not disclosed)***	• Initiated Phase 1 program	

Results of Operations

Three Months Ended June 30, 2012 and 2011

Net Income (Loss)

We reported net income of $76.7 million, or $0.70 per diluted share, for the second quarter of 2012, compared to a net loss of $62.5 million, or $0.69 per diluted share, for the second quarter of 2011. Our net income in the second quarter of 2012 resulted from net product sales of EYLEA, which we launched in November 2011.

Revenues

Revenues for the three months ended June 30, 2012 and 2011 consist of the following:

(In millions)	2012	2011
Net product sales	$ 199.5	$ 5.0
Collaboration revenue:		
Sanofi	89.0	84.5
Bayer HealthCare	9.1	11.1
Total collaboration revenue	98.1	95.6
Technology licensing revenue	5.9	5.2
Contract research and other revenue	0.9	2.0
Total revenue	$ 304.4	$ 107.8

Net Product Sales

Net product sales consist of U.S. sales of our two marketed products, 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. For the three months ended June 30, 2012, we recognized $194.0 million of EYLEA net product sales. For the three months ended June 30, 2012 and 2011, we also recognized ARCALYST net product sales of $5.5 million and $5.0 million, respectively.

We sell EYLEA in the United States to three distributors and several specialty pharmacies. We sell ARCALYST in the United States to two specialty pharmacies. Under these distribution models, the distributors and specialty pharmacies (collectively, our customers) generally take physical delivery of product. For EYLEA, the distributors and specialty pharmacies generally sell the product directly to healthcare providers; whereas for ARCALYST, the specialty pharmacies sell the product directly to patients. We record revenue from product sales upon delivery to our customers. For the three months ended June 30, 2012, we recorded 79% of our gross product revenue from sales to our distributor, Besse Medical, a subsidiary of AmerisourceBergen Corporation.

We record product sales net of allowances and accruals for prompt pay discounts, rebates and chargebacks under governmental programs (including Medicaid), product returns, and distribution-related fees. The following table summarizes the provisions, and credits/payments, for government rebates and chargebacks, distribution-related fees, and other sales-related deductions; such amounts were not material for the three months ended June 30, 2011.

(In millions)	Rebates & Chargebacks	Distribution-Related Fees	Other Sales-Related Deductions	Total
Balance as of March 31, 2012	$ 2.8	$ 5.5	$ 0.5	$ 8.8
Provision related to current period sales	3.8	11.0	1.6	16.4
Credits/payments	(1.8)	(5.4)	(0.6)	(7.8)
Balance as of June 30, 2012	$ 4.8	$ 11.1	$ 1.5	$ 17.4

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 and recognition of revenue related to non-refundable up-front payments of $105.0 million related to the ZALTRAP collaboration and $85.0 million related to the antibody collaboration. We subtract from Sanofi collaboration revenue amounts that we are obligated to pay Sanofi to reimburse them for commercialization expenses that they incur.

Sanofi Collaboration Revenue	**Three months ended June 30,**	
(In millions)	**2012**	**2011**
ZALTRAP:		
Regeneron expense reimbursement	$ 4.2	$ 4.2
Recognition of deferred revenue related to up-front payments	2.9	2.5
Regeneron share of ZALTRAP commercialization expenses	(8.4)	(1.3)
Total ZALTRAP	(1.3)	5.4
Antibody:		
Regeneron expense reimbursement	87.8	76.6
Recognition of deferred revenue related to up-front and other payments	2.1	2.1
Recognition of revenue related to *VelociGene* agreement	0.4	0.4
Total antibody	90.3	79.1
Total Sanofi collaboration revenue	$ 89.0	$ 84.5

Sanofi s reimbursement of our ZALTRAP expenses primarily consists of reimbursements for manufacturing ZALTRAP supplies and research and development activities. We and Sanofi equally share pre-launch commercialization expenses related to ZALTRAP in accordance with the companies collaboration agreement. These expenses have increased in the second quarter of 2012, compared to the same period in 2011, due to an increase in commercialization activities in preparation for potential regulatory approvals. In connection with recognition of deferred revenue related to ZALTRAP, as of June 30, 2012, $17.3 million of the original $105.0 million of up-front payments was deferred and will be recognized as revenue in future periods.

In the second quarter of 2012, Sanofi s reimbursement of our antibody expenses consisted of $46.5 million under the discovery agreement and $41.3 million of development costs under the license agreement, compared to $40.7 million and $35.9 million, respectively, in the second quarter of 2011. The higher reimbursement amount under the discovery agreement in the second quarter of 2012, compared to the same period in 2011, was primarily due to an increase in our antibody discovery activities. The higher reimbursement of development costs in the second quarter of 2012, compared to the same period in 2011, was primarily due to an increase in development activities related to REGN727.

In connection with recognition of deferred revenue related to our antibody collaboration, as of June 30, 2012, $73.4 million of the original $85.0 million up-front payment and other payments was deferred and will be recognized as revenue in future periods. In connection with the November 2009 amendment of the discovery agreement, Sanofi is funding up to $30 mi*l*lion of agreed-upon costs incurred by us to expand our manufacturing capacity at our Rensselaer, New York facilities, of which $29.6 million was received or receivable as of June 30, 2012. Revenue related to such funding from Sanofi is deferred and recognized as collaboration revenue prospectively over the related performance period in conjunction with the recognition of the original $85.0 million up-front payment.

Bayer HealthCare Collaboration Revenue

The collaboration revenue we earned from Bayer HealthCare, as detailed below, consisted of cost sharing of Regeneron EYLEA development expenses and recognition of revenue related to a non-refundable $75.0 million up-front payment received in October 2006 and a $20.0 million milestone payment received in August 2007 (which, for the purpose of revenue recognition, was not considered substantive).

Bayer HealthCare Collaboration Revenue	**Three months ended June 30,**	
(In millions)	**2012**	**2011**
Cost-sharing of Regeneron EYLEA development expenses	$ 7.1	$ 8.6
Recognition of deferred revenue related to up-front and other milestone payments	2.0	2.5
Total Bayer HealthCare collaboration revenue	$ 9.1	$ 11.1

Cost-sharing of our global EYLEA development expenses with Bayer HealthCare decreased in the second quarter of 2012 compared to the same period in 2011 due primarily to lower costs in connection with our Phase 3 VIEW 1 study in wet AMD, which has concluded. Recognition of deferred revenue related to the up-front and August 2007 milestone payments from Bayer HealthCare decreased in the second quarter of 2012 from the same quarter in 2011 due to an extension in the estimated performance period over which this deferred revenue is being recognized, effective in the fourth quarter of 2011. As of June 30, 2012, $40.6 million of these up-front and milestone payments was deferred and will be recognized as revenue in future periods.

Technology Licensing Revenue

In connection with our *VelocImmune* license agreement with Astellas, the $20.0 million non-refundable payment received in the second quarter of 2010 was deferred upon receipt and recognized as revenue ratably over the ensuing year. In addition, in connection with the amendment and extension of our license agreement with Astellas, in August 2010, we received a $165.0 million up-front payment, which was deferred upon receipt and is being recognized as revenue ratably over a seven-year period beginning in June 2011. In the second quarter of 2012 and 2011, we recognized $5.9 million and $5.2 million, respectively, of technology licensing revenue related to this agreement. As of June 30, 2012, $139.9 million of the August 2010 technology licensing payment received from Astellas was deferred and will be recognized as revenue in future periods.

Contract Research and Other Revenue

Contract research and other revenue for the three months ended June 30, 2011 included $1.2 million recognized in connection with our five-year grant from the National Institutes of Health (NIH), which we were awarded in September 2006 as part of the NIH s Knockout Mouse Project. As of the end of 2011, no further revenue has been recognized by us in connection with this NIH Grant. In addition, under a June 2009 agreement with Novartis, we receive royalties on worldwide sales of Novartis canakinumab. For the three months ended June 30, 2012 and 2011, contract research and other revenue included $0.8 million and $0.5 million, respectively, of royalties from Novartis.

Expenses

Total operating expenses increased to $216.9 million in the second quarter of 2012 from $168.1 million in the second quarter of 2011. Our average headcount in the second quarter of 2012 increased to 1,783 from 1,497 in the same period of 2011 principally in connection with commercializing EYLEA in wet AMD, and as a result of our expanding research and development activities, which were primarily attributable to our antibody collaboration with Sanofi.

Operating expenses in the second quarter of 2012 and 2011 included a total of $19.6 million and $12.4 million, respectively, of non-cash compensation expense related to employee stock option and restricted stock awards (Non-cash Compensation Expense). The increase in total Non-cash Compensation Expense in the second quarter of 2012 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 2011 compared to recent prior years.

Research and Development Expenses

Research and development expenses increased to $147.4 million in the second quarter of 2012 from $143.1 million in the same period of 2011. The following table summarizes the major categories of our research and development expenses for the three months ended June 30, 2012 and 2011:

Research and Development Expenses* *(In millions)*	**For the three months ended June 30, 2012**	**2011**	**Increase (Decrease)**
Payroll and benefits (1)	$ 50.8	$ 41.5	$ 9.3
Clinical trial expenses	19.3	19.5	(0.2)
Clinical manufacturing costs (2)	39.3	34.0	5.3
Research and other development costs	13.0	15.8	(2.8)
Occupancy and other operating costs	20.4	15.0	5.4
Cost-sharing of Bayer HealthCare EYLEA development expenses (3)	4.6	17.3	(12.7)
Total research and development expenses	$ 147.4	$ 143.1	$ 4.3

* Certain prior year amounts have been reclassified to conform to the current year s presentation.

(1) Includes Non-cash Compensation Expense of $10.3 million for the three months ended June 30, 2012 and $6.7 million for the three months ended June 30, 2011.

(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 $1.2 million for the three months ended June 30, 2012 and $1.0 million for the three months ended June 30, 2011.

(3) Under our collaboration with Bayer HealthCare, in periods when Bayer HealthCare incurs EYLEA development expenses, we also recognize, as additional research and development expense, the portion of Bayer HealthCare s EYLEA development expenses that we are obligated to reimburse. Bayer HealthCare provides us with estimated EYLEA development expenses for the most recent fiscal quarter. Bayer HealthCare s estimate is reconciled to its actual expenses for such quarter in the subsequent fiscal quarter and our portion of its EYLEA development expenses that we are obligated to reimburse is adjusted accordingly.

Payroll and benefits increased principally due to the increase in employee headcount and Non-cash Compensation Expense, as described above. Clinical trial expenses decreased due primarily to lower costs related to our Phase 3 VIEW 1 trial of EYLEA in wet AMD, which has concluded, partly offset by higher costs related to our Phase 3 studies of EYLEA in DME and BRVO, and higher costs for clinical studies of our antibody candidates. Clinical manufacturing costs increased primarily due to higher costs related to manufacturing REGN727 and ARCALYST supplies. Research and other development costs decreased primarily due to lower preclinical development costs associated with our antibody programs. Occupancy and other operating costs increased principally in connection with our higher headcount and expanded research and development activities. Cost-sharing of Bayer HealthCare s EYLEA development expenses decreased primarily due to lower costs in connection with Bayer HealthCare s wet AMD development activities, including the VIEW 2 trial, which has concluded.

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

Project Costs *(In millions)*	**For the three months ended June 30, 2012**	**2011**	**Increase (Decrease)**
ARCALYST	$ 15.0	$ 8.0	$ 7.0
EYLEA	27.3	44.1	(16.8)
ZALTRAP	5.7	4.0	1.7
Sarilumab	5.9	7.3	(1.4)
REGN727	18.0	9.7	8.3
Other antibody candidates in clinical development	15.2	15.4	(0.2)
Other research programs & unallocated costs	60.3	54.6	5.7
Total research and development expenses	$ 147.4	$ 143.1	$ 4.3

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 $47.7 million in the second quarter of 2012 from $24.6 million in the same period of 2011 due to higher selling expenses in connection with commercialization of EYLEA in wet AMD, higher headcount, and higher Non-cash Compensation Expense principally for the reason described above. Selling, general, and administrative expenses included $7.8 million and $4.7 million of Non-cash Compensation Expense for the three months ended June 30, 2012 and 2011, respectively.

Cost of Goods Sold

Cost of goods sold increased to $21.8 million in the second quarter of 2012 from $0.4 million in the same period of 2011 due primarily to our launch of EYLEA for the treatment of wet AMD in November 2011. 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 second quarter of 2012, cost of goods sold included inventory write-downs and reserves totaling $6.5 million. 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 may be expected to expire prior to sale.

Other Income and Expense

Investment income decreased to $0.5 million in the second quarter of 2012 from $1.0 million in the same period of 2011 due primarily to lower yields on cash and marketable securities.

Interest expense increased to $11.2 million in the second quarter of 2012 from $4.0 million in the same period of 2011. In October 2011, we issued $400.0 million aggregate principal amount of 1.875% convertible senior notes. Total interest expense in the second quarter of 2012 associated with these notes, including amortization of the note discount and debt issuance costs, was $7.2 million.

Income Taxes

Despite achieving profitability in the first quarter of 2012, we continue to recognize a full valuation allowance against our net operating loss carry-forward and other deferred tax assets since we have an extended history of losses. For the three months ended June 30, 2011, we recognized an income tax benefit of $0.9 million in connection with the net tax effect of the change in our unrealized gain/(loss) on available-for-sale marketable securities, which is included in other comprehensive income (loss).

Six Months Ended June 30, 2012 and 2011

Net Income (Loss)

We reported net income of $88.4 million, or $0.81 per diluted share, for the first half of 2012, compared to a net loss of $106.0 million, or $1.18 per diluted share, for the first half of 2011. Our net income in the first half of 2012 resulted from net product sales of EYLEA, which we launched in November 2011.

Revenues

Revenues for the six months ended June 30, 2012 and 2011 consist of the following:

(In millions)	**2012**	**2011**
Net product sales	$327.4	$ 9.5
Collaboration revenue:		
Sanofi	174.0	169.8
Bayer HealthCare	21.6	23.6
Total collaboration revenue	195.6	193.4
Technology licensing revenue	11.8	13.0
Contract research and other revenue	1.4	4.1
Total revenue	$536.2	$220.0

Net Product Sales

Net product sales consist of U.S. sales of our two marketed products, 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. For the six months ended June 30, 2012, we recognized $317.5 million of EYLEA net product sales. For the six months ended June 30, 2012 and 2011, we also recognized ARCALYST net product sales of $9.9 million and $9.5 million, respectively.

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We sell EYLEA in the United States to three distributors and several specialty pharmacies. We sell ARCALYST in the United States to two specialty pharmacies. Under these distribution models, the distributors and specialty pharmacies (collectively, our customers) generally take physical delivery of product. For EYLEA, the distributors and specialty pharmacies generally sell the product directly to healthcare providers; whereas for ARCALYST, the specialty pharmacies sell the product directly to patients. We record revenue from product sales upon delivery to our customers. For the six months ended June 30, 2012, we recorded 79% of our gross product revenue from sales to Besse Medical, a subsidiary of AmerisourceBergen Corporation.

We record product sales net of allowances and accruals for prompt pay discounts, rebates and chargebacks under governmental programs (including Medicaid), product returns, and distribution-related fees. The following table summarizes the provisions, and credits/payments, for government rebates and chargebacks, distribution-related fees, and other sales-related deductions; such amounts were not material as of and for the six months ended June 30, 2011.

(In millions)	Rebates & Chargebacks	Distribution-Related Fees	Other Sales-Related Deductions	Total
Balance as of December 31, 2011	$ 0.6	$ 1.5	$ 0.2	$ 2.3
Provision related to current period sales	6.2	17.9	2.4	26.5
Credits/payments	(2.0)	(8.3)	(1.1)	(11.4)
Balance as of June 30, 2012	$ 4.8	$ 11.1	$ 1.5	$ 17.4

Sanofi Collaboration Revenue

The collaboration revenue we earned from Sanofi, as detailed below, consisted primarily of reimbursement for research and development expenses and recognition of revenue related to non-refundable up-front payments of $105.0 million related to the ZALTRAP collaboration and $85.0 million related to the antibody collaboration. We subtract from Sanofi collaboration revenue amounts that we are obligated to pay Sanofi to reimburse them for commercialization expenses that they incur.

Sanofi Collaboration Revenue	**Six months ended June 30,**	
(In millions)	**2012**	**2011**
ZALTRAP:		
Regeneron expense reimbursement	$ 7.0	$ 11.4
Recognition of deferred revenue related to up-front payments	5.4	5.0
Regeneron share of ZALTRAP commercialization expenses	(12.1)	(1.3)
Total ZALTRAP	0.3	15.1
Antibody:		
Regeneron expense reimbursement	168.6	149.8
Recognition of deferred revenue related to up-front and other payments	4.3	4.1
Recognition of revenue related to *VelociGene* agreement	0.8	0.8
Total antibody	173.7	154.7
Total Sanofi collaboration revenue	$ 174.0	$ 169.8

Sanofi s reimbursement of our ZALTRAP expenses decreased in the first half of 2012 compared to same period in 2011, primarily due to lower costs related to manufacturing ZALTRAP supplies and a decrease in other research and development activities. Effective in the second quarter of 2011, we and Sanofi began equally sharing pre-launch commercialization expenses related to ZALTRAP in accordance with the companies collaboration agreement. These expenses have increased in the first half of 2012, compared to the same period in 2011, due to an increase in commercialization activities in preparation for potential regulatory approvals.

In the first half of 2012, Sanofi s reimbursement of our antibody expenses consisted of $91.1 million under the discovery agreement and $77.5 million of development costs under the license agreement, compared to $82.8 million and $67.0 million, respectively, in the first half of 2011. The higher reimbursement amount under the discovery agreement in the first half of 2012, compared to the same period in 2011, was

primarily due to an increase in our antibody discovery activities. The higher reimbursement of development costs in the first half of 2012, compared to the same period in 2011, was primarily due to an increase in development activities related to REGN727 and REGN1033.

As it relates to recognition of deferred revenue, in connection with the November 2009 amendment of the discovery agreement, Sanofi is funding up to $30 million of agreed-upon costs incurred by us to expand our manufacturing capacity at our Rensselaer, New York facilities, of which $29.6 million was received or receivable as of June 30, 2012. Revenue related to such funding from Sanofi is deferred and recognized as collaboration revenue prospectively over the related performance period in conjunction with the recognition of the original $85.0 million up-front payment.

Bayer HealthCare Collaboration Revenue

The collaboration revenue we earned from Bayer HealthCare, as detailed below, consisted of cost sharing of Regeneron EYLEA development expenses and recognition of revenue related to a non-refundable $75.0 million up-front payment received in October 2006 and a $20.0 million milestone payment received in August 2007 (which, for the purpose of revenue recognition, was not considered substantive).

Bayer HealthCare Collaboration Revenue	**Six months ended June 30,**	
(In millions)	**2012**	**2011**
Cost-sharing of Regeneron EYLEA development expenses	$ 17.6	$ 18.7
Recognition of deferred revenue related to up-front and other milestone payments	4.0	4.9
Total Bayer HealthCare collaboration revenue	$ 21.6	$ 23.6

Cost-sharing of our global EYLEA development expenses with Bayer HealthCare decreased slightly in the first half of 2012 compared to the same period in 2011. In the first half of 2012, we incurred lower costs in connection with our Phase 3 VIEW 1 study in wet AMD, which has concluded, partly offset by higher costs in connection with regulatory and other development activities. Recognition of deferred revenue related to the up-front and August 2007 milestone payments from Bayer HealthCare decreased in the first half of 2012 from the same quarter in 2011 due to an extension in the estimated performance period over which this deferred revenue is being recognized, effective in the fourth quarter of 2011.

Technology Licensing Revenue

In connection with our *VelocImmune* license agreement with Astellas, the $20.0 million non-refundable payment received in the second quarter of 2010 was deferred upon receipt and recognized as revenue ratably over the ensuing year. In addition, in connection with the amendment and extension of our 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 connection with our *VelocImmune* license agreement with AstraZeneca, which terminated effective as of February 2011, the $20.0 million non-refundable payment received in the first quarter of 2010 was deferred upon receipt and recognized as revenue ratably through February 2011. In the first half of 2012 and 2011, we recognized $11.8 million and $13.0 million, respectively, of technology licensing revenue related to these agreements.

Contract Research and Other Revenue

Contract research and other revenue for the six months ended June 30, 2011 included $2.2 million recognized in connection with our five-year grant from the NIH, which we were awarded in September 2006 as part of the NIH s Knockout Mouse Project. As of the end of 2011, no further revenue has been recognized by us in connection with this NIH Grant. In addition, under a June 2009 agreement with Novartis, we receive royalties on worldwide sales of Novartis canakinumab. For the six months ended June 30, 2012 and 2011, contract research and other revenue included $1.3 million and $1.2 million, respectively, of royalties from Novartis.

Expenses

Total operating expenses increased to $426.5 million in the first half of 2012 from $321.3 million for the same period of 2011. Our average headcount in the first half of 2012 increased to 1,756 from 1,464 in the same period of 2011 principally in connection with commercializing EYLEA in wet AMD, and as a result of our expanding research and development activities, which were primarily attributable to our antibody collaboration with Sanofi.

Operating expenses in the first half of 2012 and 2011 included a total of $42.9 million and $27.2 million, respectively, of Non-cash Compensation Expense. The increase in total Non-cash Compensation Expense in the first half of 2012 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 2011 compared to recent prior years.

Research and Development Expenses

Research and development expenses increased to $286.2 million in the first half of 2012 from $272.5 million in the same period of 2011. The following table summarizes the major categories of our research and development expenses for the six months ended June 30, 2012 and 2011:

Research and Development Expenses* ***(In millions)***	**For the six months ended June 30, 2012**	**2011**	**Increase (Decrease)**
Payroll and benefits (1)	$ 102.2	$ 84.1	$ 18.1
Clinical trial expenses	42.6	35.6	7.0
Clinical manufacturing costs (2)	66.3	59.1	7.2
Research and other development costs	25.8	31.1	(5.3)
Occupancy and other operating costs	39.2	29.0	10.2
Cost-sharing of Bayer HealthCare EYLEA development expenses (3)	10.1	33.6	(23.5)
Total research and development expenses	$ 286.2	$ 272.5	$ 13.7

* Certain prior year amounts have been reclassified to conform to the current year s presentation.

(1) Includes Non-cash Compensation Expense of $19.8 million for the six months ended June 30, 2012 and $13.6 million for the six months ended June 30, 2011.

(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 $2.2 million for the six months ended June 30, 2012 and $1.9 million for the six months ended June 30, 2011.

(3) Under our collaboration with Bayer HealthCare, in periods when Bayer HealthCare incurs EYLEA development expenses, we also recognize, as additional research and development expense, the portion of Bayer HealthCare s EYLEA development expenses that we are obligated to reimburse. Bayer HealthCare provides us with estimated EYLEA development expenses for the most recent fiscal quarter. Bayer HealthCare s estimate is reconciled to its actual expenses for such quarter in the subsequent fiscal quarter and our portion of its EYLEA development expenses that we are obligated to reimburse is adjusted accordingly.

Payroll and benefits increased principally due to the increase in employee headcount and Non-cash Compensation Expense, as described above. Clinical trial expenses increased due primarily to higher costs related to our Phase 3 studies of EYLEA in DME and BRVO, as well as and higher costs for clinical studies of our antibody candidates, partly offset by lower costs related to our Phase 3 VIEW 1 trial of EYLEA in wet AMD, which has concluded. Clinical manufacturing costs increased primarily due to higher costs related to manufacturing REGN727 and ARCALYST supplies. Research and other development costs decreased primarily due lower preclinical development costs associated with our antibody programs. Occupancy and other operating costs increased principally in connection with our higher headcount and expanded research and development activities. Cost-sharing of Bayer HealthCare s EYLEA development expenses decreased primarily due to lower costs in connection with Bayer HealthCare s wet AMD development activities, including the VIEW 2 trial, which has concluded.

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

Project Costs	**For the six months ended June 30,**		**Increase**
(In millions)	**2012**	**2011**	**(Decrease)**
ARCALYST	$ 25.8	$ 16.6	$ 9.2
EYLEA	62.2	83.7	(21.5)
ZALTRAP	8.5	10.4	(1.9)
Sarilumab	17.2	14.0	3.2
REGN727	25.1	16.8	8.3
Other antibody candidates in clinical development	29.9	28.0	1.9
Other research programs & unallocated costs	117.5	103.0	14.5
Total research and development expenses	$ 286.2	$ 272.5	$ 13.7

For the reasons described above under Research and Development Expenses for the three months ended June 30, 2012 and 2011, 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 will generate material product revenues and net cash inflows.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased to $106.1 million in the first half of 2012 from $48.0 million in the same period of 2011 due to higher selling expenses in connection with commercialization of EYLEA in wet AMD, higher headcount, and higher Non-cash Compensation Expense principally for the reason described above. Selling, general, and administrative expenses includes $20.4 million and $11.7 million of Non-cash Compensation Expense for the six months ended June 30, 2012 and 2011, respectively.

Cost of Goods Sold

Cost of goods sold increased to $34.1 million in the first half of 2012 from $0.8 million in the same period of 2011 due primarily to our launch of EYLEA for the treatment of wet AMD in November 2011. 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 half of 2012, cost of goods sold included inventory write-downs and reserves totaling $8.4 million. 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 may be expected to expire prior to sale.

Other Income and Expense

Investment income decreased to $1.1 million in the first half of 2012 from $2.0 million in the same period of 2011 due primarily to lower yields on cash and marketable securities.

Interest expense increased to $22.4 million in the first half of 2012 from $7.8 million in the same period of 2011. In October 2011, we issued $400.0 million aggregate principal amount of 1.875% convertible senior notes. Total interest expense in the first half of 2012 associated with these notes, including amortization of the note discount and debt issuance costs, was $14.3 million.

Income Taxes

Despite achieving profitability in the first half of 2012, we continue to recognize a full valuation allowance against our net operating loss carry-forward and other deferred tax assets since we have an extended history of losses. For the six months ended June 30, 2011, we recognized an income tax benefit of $1.1 million in connection with the net tax effect of the change in our unrealized gain/(loss) on available-for-sale marketable securities, which is included in other comprehensive income (loss).

Liquidity and Capital Resources

Since our inception in 1988, we have financed our operations primarily through offerings of our equity securities, private placements of convertible debt, purchases of our equity securities by our collaborators, including Sanofi, revenue earned under our past and present research and development agreements, including our agreements with Sanofi and Bayer HealthCare, EYLEA and ARCALYST product revenue, our technology licensing agreements, our past contract manufacturing agreements, and investment income.

Six months ended June 30, 2012 and 2011

At June 30, 2012, we had $597.5 million in cash, cash equivalents, and marketable securities (including $8.1 million of restricted cash and marketable securities) compared with $810.6 million at December 31, 2011 (including $7.7 million of restricted cash and marketable securities). In connection with our product launch of EYLEA in November 2011, we have offered extended payment terms to our EYLEA customers. As a result, only a small portion of the proceeds from our EYLEA product sales to date have been collected and our net trade accounts receivable increased to $349.6 million at June 30, 2012 from $28.3 million at December 31, 2011. We expect collections of EYLEA trade receivables to increase effective in the third quarter.

Cash Used in Operating Activities

Net cash used in operating activities was $165.4 million in the first six months of 2012 and $44.6 million in the first six months of 2011. Our net income of $88.4 million in the first half of 2012, and our net loss of $106.0 million in the first half of 2011, included $42.9 million and $27.2 million, respectively, of Non-cash Compensation Expense, and $17.8 million and $14.9 million, respectively, of depreciation and amortization. Our net income in the first half of 2012 also included non-cash interest expense of $10.5 million resulting from the amortization of the discount and debt issuance costs in connection with our convertible senior notes, which were issued in October 2011.

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

At June 30, 2011, deferred revenue decreased by $20.6 million, compared to end-of-year 2010, primarily due to the amortization of previously received and deferred $20.0 million payments under our license agreements with AstraZeneca and Astellas, as well as amortization of previously deferred payments under our Sanofi and Bayer HealthCare collaborations. Accounts payable, accrued expenses, and other liabilities increased by $38.6 million at June 30, 2011, compared to end-of-year 2010, primarily in connection with our expanded levels of activities and expenditures, including higher liabilities for pre-launch commercialization activities, higher payroll-related liabilities, and an $8.8 million increase in cost-sharing payments due to Bayer HealthCare in connection with our EYLEA collaboration.

Cash (Used in) Provided by Investing Activities

Net cash used in investing activities was $123.4 million in the first six months of 2012, compared with cash provided by investing activities of $163.3 million in the first six months of 2011. In the first half of 2012, purchases of marketable securities exceeded sales or maturities by $99.0 million. In the first half of 2011, sales or maturities of marketable securities exceeded purchases by $201.0 million. Capital expenditures in the first half of 2012 and 2011 included costs in connection with expanding our manufacturing capacity at our Rensselaer, New York facilities and tenant improvement and associated costs related to our leased facilities in Tarrytown, New York.

Cash (Used in) Provided by Financing Activities

Net cash used in financing activities was $22.8 million in the first six months of 2012, compared with net cash provided by financing activities of $23.1 million in the first six months of 2011. There was an increase in exercises of employee stock options in the first six months of 2012 compared to the same period of 2011. As a result, net proceeds from issuances of Common Stock were $39.6 million in the first six months of 2012 as compared to $28.5 million in the first six months of 2011, and payments for employee tax obligations in connection with Common Stock tendered for stock option exercises were $61.4 million in the first six months of 2012 and $4.7 million in the first six months of 2011.

Fair Value of Marketable Securities

At June 30, 2012 and December 31 2011, we held marketable securities whose aggregate fair value totaled $425.4 million and $325.2 million, respectively. The composition of our portfolio of marketable securities on these dates was as follows:

	June 30, 2012		December 31, 2011	
Investment type	**Fair Value**	**Percent**	**Fair Value**	**Percent**
Unrestricted				
U.S. government obligations	$ 351.8	83%	$ 284.9	87%
U.S. government guaranteed corporate bonds	50.6	12%	15.3	5%
Municipal bonds	12.4	3%	15.3	5%
Equity securities	2.5		3.0	1%
U.S. government guaranteed collateralized mortgage obligations			0.6	
Mortgage-backed securities	0.1		0.1	
Total unrestricted marketable securities	417.4	98 %	319.2	98 %
Restricted				
U.S. government obligations	8.0	2%	6.0	2%
Total marketable securities	$ 425.4	100%	$ 325.2	100%

In addition, at June 30, 2012 and December 31, 2011, we had $172.0 million and $485.4 million, respectively, of cash, cash equivalents, and restricted cash, primarily held in money market funds that invest in U.S. government securities.

Capital Expenditures

Our cash expenditures for property, plant, and equipment totaled $23.9 million for the first six months of 2012 and $37.0 million for the first six months of 2011. In addition, in connection with our antibody collaboration with Sanofi, Sanofi funded $1.4 million and $2.1 million, respectively, of agreed-upon capital expenditures incurred by us during the first half of 2012 and 2011 to expand our manufacturing capacity at our Rensselaer facilities, of which $0.2 million was receivable at June 30, 2012.

We expect to incur capital expenditures of approximately $80 to $100 million during the remainder of 2012 and 2013 primarily in connection with expanding our manufacturing facilities for the production of antibodies, tenant improvements at our leased Tarrytown facilities, and purchases of equipment.

Funding Requirements

We expect to continue to incur substantial funding requirements for our research and development activities (including preclinical and clinical testing). As described above, research and development expenses that we incur in connection with our ZALTRAP and antibodies collaborations are generally funded by Sanofi. In addition, as described above, we and Bayer HealthCare share agreed-upon development expenses that both companies incur in connection with our EYLEA collaboration. After taking into account anticipated reimbursements from our collaborators, we currently estimate that approximately 50-60% of our funding requirements for 2012 will be directed toward technology development, basic research and early preclinical activities, and the preclinical and clinical development of our product candidates. For 2012, we also currently estimate that approximately 10-15% of our funding requirements will be directed toward the planned commercialization of new indications for our marketed products and ZALTRAP; approximately 15-20% of our funding requirements will be applied to capital expenditures (as described above); and the remainder of our funding requirements will be used for general corporate purposes.

Under our collaboration with Bayer HealthCare, over the next several years we and Bayer HealthCare will share agreed-upon EYLEA development expenses incurred by both companies, under a global development plan, as described above. In addition, under our collaboration agreements with Sanofi and Bayer HealthCare, if the applicable collaboration becomes profitable, we have contingent contractual obligations to reimburse Sanofi and Bayer HealthCare for a defined percentage (generally 50%) of agreed-upon development expenses incurred by Sanofi and Bayer HealthCare, respectively. Profitability under each collaboration will be measured by calculating net sales less agreed-upon expenses. These reimbursements would be deducted from our share of the collaboration profits (and, for our ZALTRAP collaboration with Sanofi and our Bayer HealthCare collaboration, royalties on product sales in Japan) otherwise payable to us, unless, in some cases, we elect to reimburse these expenses at a faster rate. Given the uncertainties related to drug development (including the development of ZALTRAP and co-developed antibody candidates in collaboration with Sanofi and EYLEA in collaboration with Bayer HealthCare), such as the variability in the length of time necessary to develop a product candidate and the ultimate ability to obtain governmental approval for commercialization, we are currently unable to reliably estimate if our collaborations with Sanofi and Bayer HealthCare will become profitable. In particular, for ZALTRAP, as of December 31, 2011, our reimbursement obligation to Sanofi was $394.2 million. Therefore, we expect that, initially, our share of any profits from sales of ZALTRAP will be diverted to reimburse Sanofi for this obligation.

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 pending or 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 approximately the next few years will depend on, among other things, whether or not new indications for our marketed products or our late-stage product candidates 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 product sales of EYLEA for the treatment of wet AMD and ARCALYST for the treatment of CAPS. Pursuant to our Non-Exclusive License and Partial Settlement Agreement with Genentech, we expect to make a lump-sum payment of $60 million to Genentech in the third quarter of 2012 once cumulative U.S. sales of EYLEA reach $400 million. In the future, if we are able to successfully develop, market, and sell EYLEA or ARCALYST for other indications, or certain of our product candidates, we may be required to pay royalties or share the profits from such sales pursuant to our license or collaboration agreements.

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

Due to the amounts of our net operating loss and tax credit carry-forwards available for tax purposes, which totaled $800.2 million and $67.7 million, respectively, at December 31, 2011, we do not anticipate incurring substantive obligations for federal and state corporate income taxes over the next several years.

Under the terms of our collaboration agreement with Sanofi, we are entitled to receive milestone payments upon receipt of specified ZALTRAP marketing approvals. In connection with our collaboration with Bayer HealthCare, we are entitled to receive milestone payments related to marketing approvals of EYLEA in major market countries outside the United States, as well as sales milestones based on total annual sales of EYLEA outside the United States achieving certain specified levels.

We believe that our existing capital resources, funds generated by anticipated EYLEA net product sales, and funding for reimbursement of development costs that we are entitled to receive under our collaboration agreements, will enable us to meet our projected operating needs for the foreseeable future. Other than letters of credits totaling $4.6 million as of June 30, 2012, including a $3.4 million letter of credit issued in connection with our lease for facilities in Tarrytown, New York, we have no off-balance sheet arrangements. In addition, we do not guarantee the obligations of any other entity. As of June 30, 2012, we had no other established banking arrangements through which we could obtain short-term financing or a line of credit. In October 2011, we completed a private placement of convertible senior notes. In addition, in October 2010, we filed a shelf registration statement on Form S-3 registering the sale, in one or more offerings, of an indeterminate amount of equity or debt securities, together or separately, and our October 2010 public offering of approximately 6.3 million shares of Common Stock was completed under this shelf registration statement. There is no assurance, however, that we will be able to complete any additional offerings of securities. Factors influencing the availability of additional financing include our progress in product development and commercialization, investor perception of our prospects, and the general condition of the financial markets. We may not be able to secure additional funding through new collaborative arrangements or additional public or private offerings. If we require additional funding, and cannot raise adequate funds to satisfy our capital requirements, we may have to delay, scale-back, or eliminate certain of our research and development activities or future operations. This could materially harm our business.

Impact of Recently Issued Accounting Standards

Presentation of comprehensive income

In June and December 2011, the Financial Accounting Standards Board (FASB) amended its authoritative guidance on the presentation of comprehensive income. Under the amendments, an entity has the option to present comprehensive income and net income either in a single continuous statement or in two separate but consecutive statements. This amendment, therefore, eliminated the option to present the components of other comprehensive income as part of the statement of changes in stockholders' equity. The amendment did not change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income. We have adopted this amended guidance for the fiscal year beginning January 1, 2012. As this guidance relates to presentation only, the adoption of this guidance did not have any other effect on our financial statements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

Our earnings and cash flows are subject to fluctuations due to changes in interest rates, principally in connection with our investments in marketable securities, which consist primarily of direct obligations of the U.S. government and its agencies, other debt securities guaranteed by the U.S. government, and money market funds that invest in U.S. government securities. We do not believe we are materially exposed to changes in interest rates. Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes. We estimate that a one percent unfavorable change in interest rates would have resulted in approximately a $3.4 million and $1.4 million decrease in the fair value of our investment portfolio at June 30, 2012 and 2011, respectively. The increase in interest rate risk year over year is due primarily to higher balances of marketable debt securities with maturities in excess of one year that we held at June 30, 2012 compared to the same period of 2011.

Credit Quality Risk

We have an investment policy that includes guidelines on acceptable investment securities, minimum credit quality, maturity parameters, and concentration and diversification. Nonetheless, deterioration of the credit quality of an investment security subsequent to purchase may subject us to the risk of not being able to recover the full principal value of the security. During the first six months of 2012 and 2011, we did not recognize any other-than-temporary impairment charges.

We are also subject to credit risk in connection with accounts receivable from our product sales of EYLEA and ARCALYST. Our marketed products are sold in the United States, and related accounts receivable are due from three distributors and several specialty pharmacies, who are our customers. We have contractual payment terms with each of our customers. We monitor our customers financial performance and credit worthiness so that we can properly assess and respond to any changes in their credit profile. During the first six months of 2012 and 2011, we did not recognize any charges for write-offs of accounts receivable related to our marketed products. At June 30, 2012 and December 31, 2011, one individual customer accounted for 82% and 71%, respectively, of our net trade accounts receivable balances.

ITEM 4. CONTROLS AND PROCEDURES

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

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended June 30, 2012 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 ordinary course legal proceedings to have a material adverse effect on our business or financial condition.

Genentech Patent Litigation

We are aware of issued patents and pending patent applications owned by Genentech that claim certain chimeric VEGF receptors. We do not believe that ZALTRAP or EYLEA infringe any valid claim in these patents or patent applications. We are involved in five patent litigations with Genentech, two in the United States and three in Europe. In November 2010, we commenced a lawsuit against Genentech in the U.S. District Court for the Southern District of New York (the Court), seeking a declaratory judgment that no activities relating to our VEGF Trap infringe any valid claim of certain Genentech patents referred to as the Davis-Smyth patents (the First Davis-Smyth Case). Genentech answered the complaint and asserted counterclaims that our prior or planned activities relating to VEGF Trap have infringed or will infringe claims of four of the five Davis-Smyth patents and requested a judgment against us for damages, including for willful infringement, and other relief as the Court deems appropriate.

On December 31, 2011, we entered into a Non-Exclusive License and Partial Settlement Agreement with Genentech (the Genentech Agreement) that covers 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 ends the litigation relating to those matters. Under the Genentech Agreement, we received a non-exclusive license to the Davis-Smyth patents, and certain other technology patents owned or co-owned by Genentech. The Genentech Agreement does not cover any non-U.S. patent rights or non-U.S. patent disputes, and does not cover any use of aflibercept other than for prevention and treatment of human eye diseases and disorders in the United States. The First Davis-Smyth Case is continuing with respect to matters not covered by the Genentech Agreement. The Genentech Agreement provides 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. We will make a lump-sum payment of $60 million once cumulative U.S. sales of EYLEA reach $400 million. We will also pay royalties of 4.75% on cumulative U.S. sales of EYLEA between $400 million and $3 billion and 5.5% on any cumulative U.S. sales of EYLEA over $3 billion. As a result of the Genentech Agreement, on January 17, 2012 Genentech filed a second amended answer and counterclaim in the First Davis-Smyth Case, in which it amended its counterclaims alleging infringement of four of the five Davis-Smyth patents. On December 23, 2011, Genentech initiated a related case in the Court against Regeneron and Sanofi alleging infringement of four of the five Davis-Smyth Patents by activities relating to VEGF Trap (but excluding EYLEA) (the Second Davis-Smyth Case). As in the First Davis-Smyth Case, in the new complaint Genentech requests a judgment against us for damages, including for willful infringement, and other relief as the Court deems appropriate.

We believe Genentech's remaining claims in the First Davis Smyth Case and the Second Davis Smyth Case are without merit and intend to continue to defend against all of Genentech s remaining claims vigorously.

We have initiated patent-related actions against Genentech in Germany, the United Kingdom, and Italy relating in each case to a patent that expires on October 28, 2012. We may initiate other actions in other countries outside the United States, which could have similar or other adverse outcomes that would materially harm our business and which, irrespective of the outcomes, may also entail significant costs and expenses. In the United Kingdom, an adverse decision dated March 22, 2012 is under appeal. This decision found the designation of European patent EP 1 238 986 in the United Kingdom to be valid and potential acts relating to VEGF Trap Eye in the United Kingdom before expiration of the patent on October 28, 2012 to infringe this patent.

ITEM 1A. RISK FACTORS

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

Risks Related to Our Financial Results and Need for Additional Financing

We have a history of operating losses. If we cannot sustain profitability and continue to incur operating losses, we may be unable to continue our operations.

From inception on January 8, 1988 through June 30, 2012, we had a cumulative loss of $1.2 billion. If we cannot sustain profitability and continue to incur operating losses, we may be unable to continue our operations. In the absence of substantial revenue from the sale of products on an ongoing basis, including our current sales of EYLEA, and ARCALYST or from other sources, the amount, timing, nature or source of which cannot be predicted, our substantial losses will continue 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 will need to expend substantial resources for research and development, including costs associated with clinical testing of our product candidates and new indications of our marketed products, continued commercialization of EYLEA in the United States, to prepare for potential commercialization of our late-stage product candidates and new indications for our marketed products and, if one or more of those product candidates or additional indications receive(s) regulatory approval, to fund the launch of those product(s) or new indications. 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, which could result in our capital being consumed significantly faster than anticipated. Our expenses may increase for many reasons, including expenses in connection with the ongoing launch and marketing of EYLEA and the potential commercial launches of our late-stage product candidates and new indications for our marketed products, manufacturing scale-up, expenses related to clinical trials testing ARCALYST, EYLEA, REGN475, REGN846, or REGN1154, and expenses related to the potential requirement for us to fund 20% of Phase 3 clinical trial costs for any of our antibody product candidates being developed in collaboration with Sanofi.

We may require additional financing in the future and we may not be able to raise additional funds. If necessary and we are able to obtain additional financing through the sale of equity or convertible debt securities, such sales will likely be dilutive to our shareholders. Debt financing arrangements, if available given the current uncertainties in the global credit and financial markets, 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 (i) raise sufficient funds to complete the development of our product candidates, (ii) successfully commercialize our late-stage product candidates or new indications for our marketed products if they obtain regulatory approval, and (iii) continue our manufacturing and marketing of EYLEA for the treatment of wet AMD, 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. We cannot be certain how profitable our current marketing of EYLEA for the treatment of wet AMD will be and, even if we obtain regulatory approval for our product candidates or new indications for our marketed products, they may never be successfully launched or become profitable, in which case our business, prospects, operating results, and financial condition may be materially harmed.

The value of our investment portfolio is influenced by varying economic and market conditions and may experience losses.

As of June 30, 2012, our cash, cash equivalents, and marketable securities totaled $597.5 million (including $8.1 million of restricted cash and marketable securities). We have invested our excess cash primarily in direct obligations of the U.S. government and its agencies, other debt securities guaranteed by the U.S. government, and money market funds that invest in U.S. government securities. We consider assets classified as marketable securities to be available-for-sale, as defined by FASB authoritative guidance. Unrestricted and restricted marketable securities totaled $425.4 million at June 30, 2012, are carried at fair value, and the unrealized gains and losses are included in other accumulated comprehensive income (loss) as a separate component of stockholders equity. If the decline in the value of a security in our investment portfolio is deemed to be other-than-temporary, we write down the security to its current fair value and recognize a loss which may be fully charged against income. The current economic environment and the volatility of securities markets increase the risk that we may not recover the principal we invested and/or there may be further declines in the market value of securities in our investment portfolio. As a result, we may incur additional charges against income in future periods for other-than-temporary impairments or realized losses upon a security s sale or maturity, and such amounts may be material.

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

We believe that a significant portion of the value attributed to our company by investors is based on the commercial potential of EYLEA. If marketing approval for EYLEA is not obtained in countries outside the United States, or approval is not obtained for other indications, or if we fail to maintain regulatory compliance and lose the marketing approval we have in the United States, or if the product is withdrawn for any reason, our business, prospects, operating results, and financial condition will be materially harmed.

Whether EYLEA is approved by regulatory authorities outside the United States or approved by the FDA for new indications, and the timing thereof, will depend on many factors, including the following:

- whether or not the FDA determines that the evidence gathered in well-controlled clinical trials, other clinical trials and nonclinical studies of EYLEA demonstrates that it is safe and effective as a treatment for the indication under review; and
- whether or not the FDA is satisfied that the manufacturing facilities, processes, and controls for EYLEA are adequate, that the labeling is satisfactory, and that plans for post-marketing studies, safety monitoring, and risk evaluation and management are sufficient.

Bayer HealthCare has submitted regulatory applications for marketing approval of EYLEA in wet AMD in the European Union, Japan, and other countries. Analogous regulatory authorities in these countries outside the United States have similar discretion to the FDA as to approval of EYLEA in those countries.

If Bayer HealthCare does not obtain approval to market EYLEA in the European Union, Japan, or other countries, or if there are material delays in obtaining such approvals, our business, prospects, operating results, and financial condition will be materially harmed.

If we do not obtain and maintain regulatory approval for our products and product candidates or new indications for our marketed products, or maintain regulatory approval for EYLEA in the United States, we will not be able to market or sell them, which would materially and negatively impact our business, results of operations, and prospects.

We cannot sell or market products without regulatory approval. If we do not obtain and maintain regulatory approval for our products and product candidates, including ARCALYST for the treatment of diseases other than CAPS, EYLEA for the treatment of ophthalmologic diseases other than wet AMD and/or ZALTRAP for one or more oncology indications, the value of our company, our results of operations, and our prospects will be materially harmed. Our product candidates, including ZALTRAP for the treatment of previously treated mCRC patients and EYLEA for CRVO and DME, and ARCALYST for the prevention of gout flares in patients initiating uric acid-lowering therapy, may not receive regulatory approval. If we are unable to obtain such approval(s), or if we are materially delayed in doing so, our business, prospects, results of operations, and financial condition will be materially harmed. In addition, if we fail to maintain regulatory approval for EYLEA for the treatment of wet AMD, we may lose marketing approval and the ability to generate EYLEA product sales revenue, which would materially and negatively impact our business, prospects, results of operations, and financial condition.

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

In the United States, we must obtain and maintain approval from the FDA for each drug we intend to sell. Obtaining FDA approval is typically a lengthy and expensive process, and approval is highly uncertain. Foreign governments also regulate drugs distributed in their country and approval in any country is likely to be a lengthy and expensive process, and approval is highly uncertain.

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

Before approving a new drug or biologic product, the FDA requires that the facilities at which the product will be manufactured or advanced through the supply chain be in compliance with current Good Manufacturing Practices, or cGMP, requirements and regulations governing the 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 for development, and following approval in commercial quantities, in compliance with regulatory requirements, and at competitive costs. If we or any of our product collaborators, or third-party manufacturers, product packagers, labelers, or other parties performing steps in the supply chain are unable to maintain regulatory compliance, the FDA can impose regulatory sanctions, including, among other things, refusal to approve a pending application for a new drug or biologic product, or revocation of a pre-existing approval. As a result, our business, prospects, operating results, and financial condition may be materially harmed.

In addition to the FDA and other regulatory agency regulations in the United States, we are subject to a variety of foreign regulatory requirements governing human clinical trials, manufacturing, marketing and approval of drugs, and commercial sale and distribution of drugs in foreign countries. The foreign regulatory approval process and requirements include all of the risks associated with FDA approval as well as country specific regulations, and actions by a regulatory agency in a country or region with respect to a product candidate may have an impact on the approval process for that product candidate in another country or region. Whether or not we obtain FDA approval for a product in the United States, we must obtain approval of the product by the comparable regulatory authorities in foreign countries before we can conduct clinical trials of or market that product or any other product in those countries.

Clinical trials 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 of our drug trials 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 these trials 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 the 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 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 trials, which are expensive and time consuming, or abandon that drug development program. The failure of clinical trials to demonstrate the safety and effectiveness of our clinical candidates for the desired indication(s) would preclude the successful development of those candidates for such indication(s), in which event our business, prospects, operating results, and financial condition may be materially harmed.

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

Only a small minority of all research and development programs ultimately result in commercially successful drugs. We are testing EYLEA in a number of late-stage clinical trials in various indications and ARCALYST for the prevention of gout flares in patients initiating uric acid-lowering drug therapy. Clinical trials may not demonstrate statistically sufficient effectiveness and safety to obtain the requisite regulatory approvals for these product candidates in these indications. In a number of instances, we have terminated the development of product candidates due to a lack of or only modest effectiveness. Moreover, even if we obtain positive results from preclinical testing or clinical trials, we may not achieve the same success in future trials. Many companies in the biopharmaceutical industry, including our company, have suffered significant setbacks in clinical trials, even after promising results have been obtained in earlier trials.

In April 2011, we announced that our Phase 3 VELOUR trial of ZALTRAP met its primary endpoint of improving overall survival in the treatment of patients with previously treated mCRC. Based upon these positive results, we and Sanofi submitted regulatory applications for marketing approval to the FDA and EMA. Under PDUFA, we and Sanofi were granted a target date for an FDA decision on the ZALTRAP in mCRC BLA of August 4, 2012. However, this expected timing for an FDA decision may not be met, and the FDA may not grant such approval or such approval may be substantially delayed. The FDA could also require us to provide additional clinical data in connection with this application. There can be no assurance that we will receive regulatory approval for ZALTRAP in mCRC. Also in April 2011, we and Sanofi announced that the results from another randomized, double-blind Phase 3 trial (VENICE), evaluated ZALTRAP as a first-line treatment for metastatic androgen-independent prostate cancer in combination with docetaxel/prednisone. The VENICE trial did not meet the pre-specified criterion of improvement in overall survival. The safety profile was generally consistent with previous studies of ZALTRAP in combination with docetaxel.

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.

We also reported positive Phase 3 trial results with EYLEA in CRVO after six months of treatment and, based on these results, have submitted a supplemental BLA filing to the FDA for marketing approval in the United States of EYLEA in CRVO. Under PDUFA, we were granted a target date for an FDA decision on our EYLEA in CRVO supplemental BLA of September 23, 2012. However, this expected timing for an FDA decision may not be met, and the FDA may not grant such approval or such approval may be substantially delayed. The FDA could also require us to provide additional clinical data in connection with this application. There can be no assurance that we will receive regulatory approval for EYLEA in CRVO.

We also reported positive results of a Phase 2 trial of EYLEA for the treatment of DME and that we have initiated a Phase 3 program in that indication. A number of other potential new drugs and biologics which showed promising results in Phase 1 and 2 clinical trials subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals, and this could occur with respect to subsequent clinical trials of EYLEA for the treatment of DME.

Based on the results of three Phase 3 studies, we have 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 and, under PDUFA, we were granted a target date for an FDA decision on our ARCALYST supplemental BLA of July 30, 2012. 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. The Committee s recommendation is not binding on the FDA, but it will be considered by the FDA in its review of our ARCALYST supplemental BLA. For example, in June 2011, following two positive Phase 3 trials, the Arthritis Advisory Committee, voted to recommend against approval in a gout indication for Ilaris® (canikinumab), Novartis IL-1 inhibitor which works through a similar mechanism as ARCALYST and, in August 2011, Novartis received a Complete Response letter from the FDA requesting additional information, including clinical data to evaluate the benefit-risk profile of Ilaris® in refractory patients. The expected timing for an FDA decision on our ARCALYST supplemental BLA may not be met, and the FDA may not grant approval of ARCALYST for the prevention of gout flares in patients initiating uric acid-lowering drug therapy, or such approval may be substantially delayed. The FDA could also require us to provide additional clinical data in connection with this application.

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 may be materially harmed.

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

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

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

ZALTRAP is being studied for the potential treatment of mCRC and EYLEA is being studied in diseases of the eye in addition to wet AMD. There are many potential safety concerns associated with significant blockade of VEGF that may limit our ability to successfully develop ZALTRAP and EYLEA in each of the indications for which we are studying these product candidates. These serious and potentially life-threatening risks, based on clinical and preclinical experience of VEGF inhibitors, include bleeding, intestinal perforation, hypertension, proteinuria, congestive heart failure, heart attack, and stroke. In addition, patients given infusions of any protein, including ZALTRAP delivered through intravenous administration, may develop severe hypersensitivity reactions or infusion reactions. Other VEGF blockers have reported side effects that became evident only after large scale trials or after marketing approval when large numbers of patients were treated. There are risks inherent in the intravitreal administration of drugs like EYLEA, which can cause injury to the eye and other complications. For example, in our Phase 3 trials of EYLEA in wet AMD, the most frequent ocular adverse events were conjunctival hemorrhage, macular degeneration, eye pain, retinal hemorrhage, and vitreous floaters. These and other complications or side effects could harm the development and/or commercialization of ZALTRAP for the treatment of mCRC or EYLEA for the treatment of diseases of the eye.

As ARCALYST is studied for the prevention of gout flares in patients initiating uric acid-lowering therapy and, potentially in new disease settings, new risks and side effects associated with ARCALYST may be discovered, and risks previously viewed as inconsequential could be determined to be significant. Like cytokine antagonists such as Ilaris® (canakinumab), a registered trademark of Novartis, Kineret® (anakinra) and Enbrel® (etanercept), registered trademarks of Amgen, and Remicade® (infliximab) a registered trademark of Centocor Ortho Biotech, ARCALYST affects the immune defense system of the body by blocking some of its functions. Therefore, ARCALYST may interfere with the body s ability to fight infections. As noted above, in June 2011, following two positive Phase 3 trials, the Arthritis Advisory Committee of the FDA voted to recommend against approval in a gout indication for Ilaris®, Novartis IL-1 inhibitor which works through a similar mechanism as ARCALYST and, in August 2011, Novartis received a Complete Response letter from the FDA requesting additional information, including clinical data to evaluate the benefit-risk profile of Ilaris® in refractory patients.

Treatment with Kineret®, a medication that works through the inhibition of IL-1, has been associated with an increased risk of serious infections, and serious, life threatening infections have been reported in patients taking ARCALYST. These or other complications or side effects could cause regulatory authorities to revoke approvals of ARCALYST for the treatment of CAPS or deny the approval of ARCALYST for the prevention of gout flares in patients initiating uric acid-lowering treatment or other disease settings. Alternatively, we may be required to conduct additional clinical trials, make changes in the labeling of our product, or limit or abandon our efforts to develop ARCALYST in new disease settings. Any such side effects may also result in a reduction, or even the elimination, of sales of ARCALYST in the current or future approved indications.

We are studying REGN475, a fully human monoclonal antibody to NGF, in a variety of pain indications, including osteoarthritis of the knee. In December 2010, the FDA placed REGN475 and other investigational agents targeting NGF on clinical hold after a case of rapidly progressive osteoarthritis leading to joint replacement was seen in another company s anti-NGF program. At that time, the FDA expressed concern that this case, which followed previously-reported cases of joint replacements in patients on an anti-NGF drug candidate being developed by a different pharmaceutical company, provided evidence to suggest a class effect. An FDA Arthritis Advisory Committee met on March 12, 2012 to discuss possible safety issues related to anti-NGF compounds and voted unanimously in favor of a role for the ongoing development of anti-NGF agents in osteoarthritis. The Arthritis Advisory Committee also voted twenty to one in favor of a role for development of anti-NGF agents to manage the pain associated with conditions for which there are no agents with demonstrated analgesic efficacy. The committee's recommendation will be considered by the FDA, but is not binding on the FDA. There are currently no ongoing trials with REGN475 that are either enrolling or treating patients. Discussions with the FDA about REGN475 are ongoing.

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

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

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

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

Risks Related to Commercialization of EYLEA for the Treatment of Wet AMD

We are subject to significant ongoing regulatory obligations and oversight with respect to EYLEA for the treatment of wet AMD. 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 approved for treatment of wet AMD in the United States and Bayer HealthCare is seeking approval in other countries. We are subject to significant ongoing regulatory obligations with respect to EYLEA for the treatment of wet AMD in the United States, and, if approved outside the United States, commercialization of EYLEA will be subject to significant ongoing regulatory obligations and oversight in those countries where approval is obtained as well. If we fail to maintain regulatory compliance for EYLEA for the treatment of wet AMD, we may lose marketing approval, which would materially harm our business, prospects, operating results, and financial condition. Failure to comply may also subject us to sanctions, product recalls, or withdrawals of previously approved marketing applications. See also *If we fail to meet the stringent requirements of governmental regulation in the manufacture of drug products or product candidates, we could incur substantial remedial costs, delays in the development or approval of our product candidates or new indications for our marketed products and/or in their commercial launch if they obtain regulatory approval, and a reduction in sales.*

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

There are risks inherent in intravitreal injections, including 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 is limited to sales in the United States. 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 have received regulatory approval for sale of EYLEA for the treatment of wet AMD only in the United States. 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, results of operations, and financial condition would be materially impacted.

Our sales of EYLEA for the treatment of wet AMD are dependent on the availability and extent of reimbursement from third party payers, and changes to such reimbursement may materially harm our sales and potential revenue and harm our business, prospects, operating results, and financial condition.

Our current sales in the United States of EYLEA for the treatment of wet AMD are dependent, in part, on the availability and extent of reimbursement from third-party payers, including government programs such as Medicare and Medicaid and private payer healthcare and insurance programs. If approved for sale in other countries, such sales will be dependent, in part, on similar programs in these 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 for the treatment of wet AMD is too expensive for most patients to afford without health insurance coverage, if adequate coverage and reimbursement by third-party payers, including Medicare and Medicaid in the United States, is not available, our ability to successfully commercialize EYLEA will be materially adversely impacted. Our sales and potential profits and our business, prospects, operating results, and financial condition would be materially harmed. See also "*The successful commercialization of EYLEA for the treatment of wet AMD as well as our late-stage product candidates or new indications for our marketed products, if approved, will depend on obtaining coverage and reimbursement for use of these products from third-party payers, including Medicare and Medicaid in the United States, and these payers may not agree to cover or adequately reimburse for use of our products or may do so at levels that make our products uncompetitive and/or unprofitable, which would materially harm our business, prospects, operating results, and financial condition*."

The status of a J-Code for EYLEA could also affect reimbursement. J-Codes are permanent reimbursement codes maintained by Centers for Medicare and Medicaid Services (CMS) that are a component of the Healthcare Common Procedure Coding System (HCPCS), and are typically used to report injectable drugs that ordinarily cannot be self-administered. We do not currently have a J-Code for EYLEA, although we anticipate assignment of a J-Code for EYLEA in January 2013. Since our product launch of EYLEA in November 2011, EYLEA has been billed using a non-specific miscellaneous J-code. Since such codes may be used for a wide variety of products, health plans may have more difficulty determining the actual product used and billed for the patient. As a result, these claims must often be submitted with additional information and manually processed, which can create delays in claims processing times as well as increasing the likelihood for claim errors. Effective July 1, 2012, CMS issued a Q-Code, which is a temporary code to facilitate reimbursement for physician-administered EYLEA in wet AMD pending the issuance of the J-Code expected in January 2013.

The commercial success of EYLEA currently being marketed for the treatment of wet AMD 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, CRVO, DME, and other eye indications. Lucentis® was approved by the FDA in June 2006 for the treatment of wet AMD and in June 2010 for the treatment of macular edema following retinal vein occlusion (RVO), CRVO, and BRVO. Lucentis® was also approved by the EMA for wet AMD in January 2007 and for DME in January 2011. Many other companies are working on the development of product candidates for the potential treatment of wet AMD and DME including those that act by blocking VEGF and VEGF receptors, as well as small interfering ribonucleic acids (siRNAs) that modulate gene expression. Ophthotech Corporation is developing Fovista™, an aptamer directed against platelet-derived growth factor subunit B (PDGF-B), as a product candidate intended to be used in combination with an anti-VEGF therapy in wet AMD. In June 2012, Ophthotech announced results of a Phase 2b study in wet AMD that it claimed demonstrated that Fovista™ administered in combination with Lucentis® resulted in increased visual outcomes compared to Lucentis® monotherapy. In addition, ophthalmologists are using off-label, third-party repackaged versions of Genentech s approved VEGF antagonist, Avastin® with success 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.

The National Eye Institute (NEI) and others are conducting long-term, controlled clinical trials comparing Lucentis® to Avastin® in the treatment of wet AMD. 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. It may be difficult for EYLEA in this or other eye indications for which it may be approved to compete against Lucentis® and off-label use of Avastin® because doctors and patients have had significant experience using these medicines. Moreover, the reported results of the CATT study, combined with the relatively low cost of Avastin® in treating patients with wet AMD, may well exacerbate the competitive challenge which EYLEA will face in this or other eye indications for which it may be approved. In addition, 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, if ZALTRAP is approved for the treatment of certain cancers, there is a risk that third parties will attempt to repackage ZALTRAP for off-label use and sale for the treatment of wet AMD and other diseases of the eye, which would present a potential low-cost competitive threat to EYLEA for wet AMD or other eye indications. See also *The commercial success of EYLEA currently being marketed for the treatment of wet AMD, and for our other product candidates or new indications for our marketed products, if any are approved for marketing, is highly uncertain given their method of administration, and because our competitors have received approval for and may be marketing products with a similar mechanism of action or may enter the marketplace with better or lower cost drugs.*

Risks Related to Intellectual Property and Market Exclusivity

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

Our business requires using sensitive and proprietary technology and other information that we protect as trade secrets. We seek to prevent improper disclosure of these trade secrets through confidentiality agreements. If our trade secrets are improperly disclosed, by our own employees, our collaborators or otherwise, it would help our competitors and adversely affect our business. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of biotechnology companies, including our company, involves complex legal and factual questions and, therefore, enforceability cannot be predicted with certainty. Our patents may be challenged, invalidated, or circumvented. Patent applications filed outside the United States may be challenged by third parties who file an opposition. Such opposition proceedings are increasingly common in the European Union and are costly to defend. We have pending patent applications in the European Patent Office and it is likely that we will need to defend patent applications from third-party challengers from time to time in the future. Patent applications filed in the United States may also be challenged by third parties who file a request for post-grant review under the America Invents Act of 2011, beginning on September 16, 2012. We expect that post-grant review proceedings will become common in the United States and will be costly to defend. We have pending patent applications in the United States Patent and Trademark Office and it is likely that we will need to defend patent applications from third-party challengers from time to time in the future. Our patent rights may not provide us with a proprietary position or competitive advantages against competitors. Furthermore, even if the outcome is favorable to us, the enforcement of our intellectual property rights can be extremely expensive and time consuming.

We may be restricted in our development, manufacturing, and/or commercialization activities by, and could be subject to damage awards if we are found to have infringed, third-party patents or other proprietary rights, and the costs and expenses of ongoing patent litigation have been and will likely continue to be significant.

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

We are aware of issued patents and pending patent applications owned by Genentech that claim certain chimeric VEGF receptors. We do not believe that ZALTRAP or EYLEA infringe any valid claim in these patents or patent applications. We are involved in five patent litigations with Genentech, two in the United States and three in Europe. In November 2010, we commenced a lawsuit against Genentech in the U.S. District Court for the Southern District of New York (the Court), seeking a declaratory judgment that no activities relating to our VEGF Trap infringe any valid claim of certain Genentech patents referred to as the Davis-Smyth patents (the First Davis-Smyth Case). Genentech answered the complaint and asserted counterclaims that our prior or planned activities relating to VEGF Trap have infringed or will infringe claims of four of the five Davis-Smyth patents and requested a judgment against us for damages, including for willful infringement, and other relief as the Court deems appropriate.

On December 31, 2011, we entered into the Genentech Agreement that covers 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 ends the litigation relating to those matters. Under the Genentech Agreement, we received a non-exclusive license to the Davis-Smyth patents, and certain other technology patents owned or co-owned by Genentech. The Genentech Agreement does not cover any non-U.S. patent rights or non-U.S. patent disputes, and does not cover any use of aflibercept other than for prevention and treatment of human eye diseases and disorders in the United States. The First Davis-Smyth Case is continuing with respect to matters not covered by the Genentech Agreement. The Genentech Agreement provides 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. We will make a lump-sum payment of $60 million once cumulative U.S. sales of EYLEA reach $400 million. We will also pay royalties of 4.75% on cumulative U.S. sales of EYLEA between $400 million and $3 billion and 5.5% on any cumulative U.S. sales of EYLEA over $3 billion. As a result of the Genentech Agreement, on January 17, 2012 Genentech filed a second amended answer and counterclaim in the First Davis-Smyth Case, in which it amended its counterclaims alleging infringement of four of the five Davis-Smyth patents. On December 23, 2011, Genentech initiated a related case in the Court against Regeneron and Sanofi alleging infringement of four of the five Davis-Smyth Patents by activities relating to VEGF Trap (but excluding EYLEA) (the Second Davis-Smyth Case). As in the First Davis-Smyth Case, in the new complaint Genentech requests a judgment against us for damages, including for willful infringement, and other relief as the Court deems appropriate.

We believe Genentech's remaining claims in the First Davis Smyth Case and the Second Davis Smyth Case are without merit and intend to continue to defend against all of Genentech s remaining claims vigorously. However, it is possible that there could be an adverse determination or judgment in either or both cases that would materially harm our business by requiring us to seek a license for matters not covered by the Agreement, which may not be available at all or on reasonable terms, or precluding the manufacture, further development, or sale of EYLEA outside the United States or ZALTRAP, or resulting in a damage award. In addition, irrespective of the outcome of the Davis-Smyth cases, we have incurred and will likely continue to incur significant costs and expenses associated with them, which have negatively affected, and will likely continue to negatively affect, our results of operations. An adverse determination in any of the proceedings described herein may have a material adverse effect on our business, prospects, results of operations, and financial condition.

We have initiated patent-related actions against Genentech in Germany, the United Kingdom, and Italy relating in each case to a patent that expires on October 28, 2012. We may initiate other actions in other countries outside the United States, which could have similar or other adverse outcomes that would materially harm our business and which, irrespective of the outcomes, may also entail significant costs and expenses. In the United Kingdom, an adverse decision dated March 22, 2012 is under appeal. This decision found the designation of European patent EP 1 238 986 in the United Kingdom to be valid and potential acts relating to VEGF Trap Eye in the United Kingdom before expiration of the patent on October 28, 2012 to infringe this patent.

We are aware of patents and pending applications owned by Roche that claim antibodies to IL-6R and methods of treating rheumatoid arthritis with such antibodies. We are developing sarilumab, an antibody to IL-6R, for the treatment of rheumatoid arthritis. Although we do not believe that sarilumab infringes any valid claim in these patents or patent applications, Roche could initiate a lawsuit for patent infringement and assert its patents are valid and cover sarilumab.

We are aware of a U.S. patent jointly owned by Genentech and City of Hope relating to the production of recombinant antibodies in host cells. We currently produce our antibody product candidates using recombinant antibodies from host cells and may choose to produce additional antibody product candidates in this manner. Neither ARCALYST, ZALTRAP, nor EYLEA are recombinant antibodies. If any of our antibody product candidates are produced in a manner subject to valid claims in the Genentech patent, then we may need to obtain a license from Genentech, should one be available. Genentech has licensed this patent to several different companies under confidential license agreements. If we desire a license for any of our antibody product candidates and are unable to obtain a license on commercially reasonable terms or at all, we may be restricted in our ability to use Genentech s techniques to make recombinant antibodies in or to import them into the United States.

Further, we are aware of a number of other third-party patent applications that, if granted with claims as currently drafted, may cover our current or planned activities. It could be determined that our products and/or actions in manufacturing or selling our product candidates infringe such patents.

Patent holders in addition to Genentech could assert claims against us for damages and seek to prevent us from manufacturing, selling, or developing our drug candidates, and a court may find that we are infringing validly issued patents of third parties. In the event that the manufacture, use, or sale of any of our drug candidates, including EYLEA or our other late-stage product candidates, infringes on the patents or violates other proprietary rights of third parties, we may be prevented from pursuing product development, manufacturing, and commercialization of those drugs and may be required to pay costly damages. Such a result may materially harm our business, prospects, operating results, and financial condition. In any event, legal disputes are likely to be costly and time consuming to defend.

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

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

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

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

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

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

Risks Related to Manufacturing and Supply

We rely on limited internal and contracted manufacturing and supply chain capacity, which could result in our being unable to continue to successfully commercialize EYLEA and to commercialize our other product candidates or other indications for our marketed products if they receive regulatory approval and are unable to continue to develop our clinical candidates.

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

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

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 we will need to hire and train significant numbers of employees and managerial personnel to staff our 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 and, if they receive regulatory approval, ZALTRAP and ARCALYST for the prevention of gout flares in patients initiating uric acid-lowering treatment, and could also delay or require us to discontinue one or more of our clinical development programs. As a result, our business, prospects, operating results, and financial condition could be materially harmed.

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

Our ability to continue to manufacture ARCALYST, EYLEA, and ZALTRAP in our Rensselaer, New York facilities, or to utilize third parties to produce our products or perform fill/finish services or other steps in our manufacture and supply chain, depends on our and their ability to operate without infringing the patents or other intellectual property rights of third parties. Other parties may allege that our manufacturing activities, or the activities of third parties involved in our manufacture and supply chain, infringe patents or other intellectual property rights. A judicial decision in favor of one or more parties making such allegations could preclude the manufacture of our products where those intellectual property rights apply which could materially harm our business, results of operations, and prospects.

If sales of EYLEA for the treatment of wet AMD do not meet the levels currently expected, or if the launch of our late-stage product candidates or new indications of our marketed products, or any of our clinical programs, are delayed or discontinued, we may face costs related to unused capacity at our manufacturing facilities and at the facilities of third parties.

We have large-scale manufacturing operations in Rensselaer, New York. We use our facilities to produce bulk product of ARCALYST for the treatment of CAPS, bulk product of EYLEA for the treatment of wet AMD and clinical and preclinical candidates for ourselves and our collaborations, and plan to use such facilities to produce bulk product for commercial supply of our late-stage product candidates or new indications of our marketed products if they are approved for marketing. If our clinical candidates are discontinued or their clinical development is delayed, if the launch of any of our late-stage product candidates or new indications for our marketed products is delayed or does not occur, or if such products are launched and subsequently recalled or marketing approval is rescinded, we may have to absorb one hundred percent of related overhead costs and inefficiencies, as well as similar costs of third-party contract manufacturers performing services for us.

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

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

Also, certain raw materials necessary for the manufacture and formulation of ARCALYST and EYLEA and of our product candidates, including ZALTRAP, 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 ARCALYST, EYLEA, and our product candidates. We would be unable to obtain these raw materials 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 action, adverse financial developments at or affecting the supplier, failure by the supplier to comply with cGMPs, business interruptions, or labor shortages or disputes. This, in turn, could materially and adversely affect our ability to manufacture or supply ARCALYST for the treatment of CAPS and EYLEA for the treatment of wet AMD and to manufacture and supply commercial quantities of EYLEA for other ophthalmologic diseases, ZALTRAP for previously-treated mCRC, and ARCALYST for the prevention of gout flares in patients initiating uric-acid lowering therapy if they receive regulatory approval, 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 cGMP, 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 product candidates at our facility in Rensselaer, New York, including ARCALYST, EYLEA, and ZALTRAP, there are increased risks associated with cGMP compliance. Our inability, or the inability of our third-party fill/finish or other service providers, to demonstrate ongoing cGMP compliance could require us to engage in lengthy and expensive remediation efforts, withdraw or recall product, halt or interrupt clinical trials, and/or interrupt commercial supply of any marketed products, and could also delay or prevent our obtaining regulatory approval for our late-stage product candidates or new indications for our marketed products. Any delay, interruption, or other issue that arises in the manufacture, fill/finish, packaging, or storage of any drug product or product candidate as a result of a failure of our facilities or the facilities or operations of third parties to pass any regulatory agency inspection or maintain cGMP compliance could significantly impair our ability to develop, obtain approval for, and successfully commercialize our products, which would substantially harm our business and prospects. Any finding of non-compliance could also increase our costs, cause us to delay the development of our product candidates, result in delay in our obtaining, or our not obtaining, regulatory approval of product candidates or new indications for our marketed products, and cause us to lose revenue from any marketed products, which could be seriously detrimental to our business, prospects, operating results, and financial condition.

Risks Related to Commercialization of Products

We may be unsuccessful in continuing our commercialization of EYLEA for the treatment of wet AMD or commercializing our late stage product candidates or new indications for our marketed products, if approved, which would materially delay or prevent our achieving long-term profitability.

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 and commercialize those products or new indications. 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.

In particular, we are in the launch phase of commercialization of EYLEA for wet AMD and cannot be sure that EYLEA will be successful longer term. In addition to the challenges we face related to a company launching its first major commercial drug, as described in detail in the risk factor immediately below, we and Bayer HealthCare will face intense competition from Lucentis® and from off-label use of Avastin®, both of which have been on the market for a number of years. We expect that the continued commercial success of EYLEA for the treatment of wet AMD will depend on many factors, including the following:

- the effectiveness of our and Bayer HealthCare's commercial strategies for the launch and marketing of EYLEA in and outside the United States, respectively, including pricing strategy and the effectiveness of efforts to obtain, and the timing of obtaining, adequate third-party reimbursements;
- maintaining and successfully monitoring commercial manufacturing arrangements for EYLEA with third parties who perform fill/finish or other steps in the manufacture of EYLEA to ensure that they meet our standards and those of regulatory authorities, including the FDA, which extensively regulate and monitor pharmaceutical manufacturing facilities;
- our ability to meet the demand for commercial supplies of EYLEA;
- our ability to effectively communicate to the marketplace the benefits of the dosing regimen of EYLEA as compared to the dosing regimen of Lucentis®, and the willingness of retinal specialists and patients to switch from Lucentis® or off-label use of Avastin® to EYLEA for the treatment of wet AMD;
- 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; and
- the effect of new health care legislation currently being implemented in the United States.

While we believe that EYLEA for the treatment of wet AMD has a commercially competitive profile, we cannot predict whether ophthalmologists, particularly retinal specialists, and patients, will continue to accept and utilize EYLEA. Our and Bayer HealthCare's efforts to educate the relevant medical community and third-party payers regarding the benefits of EYLEA for the treatment of wet AMD will require significant resources and may not be successful in achieving our objectives. If EYLEA is approved for marketing but does not achieve significant market acceptance for the treatment of wet AMD, our ability to sustain profitability would be materially impaired.

If we are unable to establish, and effectively deploy and manage, sales, marketing, and distribution capabilities in the applicable markets or to enter into agreements with third parties to do so, we will not generate our expected sales of EYLEA for treatment of wet AMD or successfully launch and commercialize our late-stage product candidates or new indications for our marketed products if they receive regulatory approval, which would materially harm our business, prospects, operating results, and financial condition.

We currently sell EYLEA in the United States to three distributors and several specialty pharmacies. We currently sell ARCALYST for the treatment of CAPS in the United States to two specialty pharmacies. Under these distribution models, we enter into written contracts with our distributors and specialty pharmacies (collectively, our customers), and our customers generally take physical delivery of product. For EYLEA, the distributors and specialty pharmacies generally sell the product directly to healthcare providers, whereas for ARCALYST, the specialty pharmacies sell the product directly to patients.

We have established our own sales and marketing organization for EYLEA in the United States for the treatment of wet AMD, and in anticipation of filing for and receiving regulatory approval to market and sell EYLEA in the United States for the treatment of CRVO. However, we may be unsuccessful in achieving a successful commercialization of EYLEA in the United States, which would materially harm our business, prospects, operating results, and financial condition.

If ARCALYST receives regulatory approval, we will have to rely on a third party or devote significant resources to develop our own sales and marketing capabilities, and our distribution network, for patients with gout flares initiating uric acid-lowering drug therapy. If we are unable to obtain these capabilities, either by developing our own organizations or entering into agreements with others to provide these functions, even if ARCALYST for the prevention of gout flares for patients initiating uric-acid lowering therapy receives marketing approval, we will not be able to successfully launch and commercialize this product, which would also materially harm our business, prospects, operating results, and financial condition.

We have limited experience in sales, marketing, or distribution of products in substantial commercial quantities or in establishing and managing the required infrastructure to do so, including large-scale information technology systems and a large-scale distribution network, and we may be unable to establish such infrastructure on a timely basis. To the extent we determine to utilize third parties to provide sales, marketing, or distribution capabilities for ARCALYST if it is approved for the prevention of gout flares in patients initiating uric-acid lowering therapy or any of our other product candidates or new indications for marketed products if they receive regulatory approval, we may encounter difficulties in retaining such parties on acceptable terms. Even if we hire qualified sales and marketing personnel, and establish the required infrastructure we need to support our objectives, or enter into marketing and distribution agreements with third parties on acceptable terms, we may not do so in an efficient manner or on a timely basis. We may not be able to correctly judge the size and experience of the sales and marketing force and the scale of distribution capabilities necessary to successfully market and sell in the United States EYLEA, ARCALYST if approved for the prevention of gout flares in patients initiating uric-acid lowering therapy, or any of our other product candidates or new indications if they receive regulatory approval in the United States and as to which we retain sales and marketing responsibility in that market. Establishing and maintaining sales, marketing, and distribution capabilities are expensive and time-consuming. Our expenses associated with building up and maintaining a sales force and distribution capabilities may be disproportional, particularly in the near term, compared to the revenues we may be able to generate on sales in the United States of EYLEA or ARCALYST if approved for the prevention of gout flares in patients initiating uric-acid lowering therapy. Ultimately neither we nor our collaborators may be successful in commercializing EYLEA or, if they received regulatory approval, ZALTRAP, ARCALYST for the prevention of gout flares in patients initiating uric-acid lowering therapy, or any of our other product candidates.

Under the terms of our collaboration agreement, Sanofi has primary responsibility for sales, marketing, and distribution of ZALTRAP in cancer indications, should it be approved in the future by regulatory authorities for marketing.

We currently have no sales, marketing, commercial, or distribution capabilities outside the United States. Under the terms of our license and collaboration agreement with Bayer HealthCare, we will rely on Bayer HealthCare for sales, marketing, and distribution of EYLEA in countries outside the United States should it be approved for marketing in such countries.

The commercial success of EYLEA currently being marketed for the treatment of wet AMD, and for our other product candidates or new indications for our marketed products, if any are approved for marketing, is highly uncertain given their method of administration, and because our competitors have received approval for and may be marketing products with a similar mechanism of action or may enter the marketplace with better or lower cost drugs.

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.

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

As previously noted, Genentech has an approved VEGF antagonist, Avastin®, on the market for treating certain cancers and many different pharmaceutical and biotechnology companies are working to develop competing VEGF antagonists, including Novartis, Amgen, Imclone LLC/Eli Lilly, Pfizer, AstraZeneca, and GlaxoSmithKline. Some of these molecules are further along in development than ZALTRAP and may offer competitive advantages over our molecule. Each of Pfizer, Onyx (together with its partner Bayer HealthCare), and GlaxoSmithKline are marketing and selling oral medications that target tumor cell growth and new vasculature formation that fuels the growth of tumors. The marketing approvals for Genentech s VEGF antagonist, Avastin®, and their extensive, ongoing clinical development plan for Avastin® in other cancer indications, make it more difficult for us to enroll patients in clinical trials to support ZALTRAP for those indications and to obtain regulatory approval of ZALTRAP in those indications. This may delay or impair our ability to successfully develop and commercialize ZALTRAP for various cancer indications. In addition, even if ZALTRAP is approved for sale for the treatment of mCRC, it will be difficult for our drug to compete against Avastin® and the FDA approved kinase inhibitors, because doctors and patients will have significant experience using these medicines. In addition, an oral medication may be considerably less expensive for patients than a biologic medication, providing a competitive advantage to companies that market such products.

The market for eye disease products is also very competitive. Novartis and Genentech are collaborating on the commercialization and further development of a VEGF antibody fragment, Lucentis® for the treatment of wet AMD, CRVO, DME, and other eye indications. Lucentis® was approved by the FDA in June 2006 for the treatment of wet AMD and in June 2010 for the treatment of macular edema following retinal vein occlusion (RVO), CRVO, and BRVO. Lucentis® was also approved by the EMA for wet AMD in January 2007 and for DME in January 2011. Many other companies are working on the development of product candidates for the potential treatment of wet AMD and DME including those that act by blocking VEGF and VEGF receptors, as well as small interfering ribonucleic acids (siRNAs) that modulate gene expression. 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 June 2012, Ophthotech announced results of a Phase 2b study that it claimed demonstrated that Fovista™ administered in combination with Lucentis® resulted in increased visual outcomes compared to Lucentis® monotherapy. In addition, ophthalmologists are using off-label, with success for the treatment of wet AMD, DME, and RVO, third-party repackaged versions of Genentech s approved VEGF antagonist, Avastin®.

The National Eye Institute (NEI) and others are conducting long-term, controlled clinical trials comparing Lucentis® to Avastin® in the treatment of wet AMD. One-year data from the CATT study were reported in April 2011 and indicated that Avastin® dosed monthly was non-inferior to Lucentis® dosed monthly in the primary efficacy endpoint of mean visual acuity gain at 52 weeks. Two-year data from CATT were reported in April 2012 and indicated that Avastin® was non-inferior to Lucentis® in mean visual acuity gain; as-needed dosing was not non-inferior to monthly dosing. It may be difficult for EYLEA in this or other eye indications for which it may be approved to compete against Lucentis® and off-label use of Avastin® because doctors and patients have had significant experience using these medicines. Moreover, the reported results of the CATT study, combined with the relatively low cost of Avastin® in treating patients with wet AMD, may well exacerbate the competitive challenge which EYLEA will face in this or other eye indications for which it may be approved. In addition, while we believe that ZALTRAP would not be well tolerated if administered directly to the eye, if ZALTRAP is approved for the treatment of certain cancers, there is a risk that third parties will attempt to repackage ZALTRAP for off-label use and sale for the treatment of wet AMD and other diseases of the eye, which would present a potential low-cost competitive threat to EYLEA for wet AMD or other eye indications.

The availability of highly effective FDA approved Tumor Necrosis Factors-antagonists (TNF-antagonists) such as Enbrel®, Remicade®, Humira® (adalimumab), a registered trademark of Abbott Laboratories, Simponi® (golimumab), a registered trademark of Johnson & Johnson, the IL-1 receptor antagonist Kineret®, Ilaris® (canakinumab), and other marketed therapies makes it more difficult to successfully develop and commercialize ARCALYST in indications other than CAPS, and this is one of the reasons we discontinued the development of ARCALYST in adult rheumatoid arthritis. In addition, even if ARCALYST is ever approved for sale in indications where TNF-antagonists are approved, it will be difficult for our drug to compete against these FDA approved TNF-antagonists because doctors and patients have had significant experience using these effective medicines. Moreover, in such indications these approved therapeutics may offer competitive advantages over ARCALYST, such as requiring fewer injections.

There are both small molecules and antibodies in development by other companies that are designed to block the synthesis of IL-1 or inhibit the signaling of IL-1. For example, Eli Lilly, Xoma (in collaboration with Servier), and Novartis are each developing antibodies to IL-1 and both Amgen and MedImmune are developing antibodies to the IL-1 receptor. In 2009, Novartis received regulatory approval in the United States and Europe for Ilaris®, a fully human anti-interleukin-IL1 antibody, for the treatment of CAPS. Ilaris® is also in development for atherosclerosis and a number of other inflammatory diseases. Novartis IL-1 antibody and these other drug candidates could offer competitive advantages over ARCALYST. For example, Ilaris® is dosed once every eight weeks compared to the once-weekly dosing regimen for ARCALYST. The successful development and/or commercialization of these competing molecules could adversely affect sales of ARCALYST for the treatment of CAPS and delay or impair our ability to commercialize ARCALYST for indications other than CAPS.

We are developing ARCALYST for the prevention of gout flares in patients initiating uric acid-lowering therapy and have submitted a supplemental BLA filing for U.S. regulatory approval in this indication. 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. In January 2011, Novartis announced that the results of two Phase 3 studies with Ilaris® focused on reducing pain and preventing recurrent attacks or flares in patients with hard-to-treat gout were positive. In June 2011, the Arthritis Advisory Committee voted to recommend against approval in a gout indication for Ilaris® (canikinumab), Novartis IL-1 inhibitor which works through a similar mechanism as ARCALYST and, in August 2011, Novartis received a Complete Response letter from the FDA requesting additional information, including clinical data to evaluate the benefit-risk profile of Ilaris® in refractory patients. Novartis has also reported that regulatory filings for the use of Ilaris® in gouty arthritis have been completed in the European Union in 2010 and in the United States in the first quarter of 2011, based on the results of these two Phase 3 studies. Ilaris® is dosed less frequently for the treatment of CAPS, and if it is approved for the treatment of gout flares in patients initiating uric-acid lowering therapy, it may be perceived by some physicians as offering competitive advantages over ARCALYST, which would make it difficult for us to successfully commercialize ARCALYST in that disease if ARCALYST receives regulatory approval.

Currently, inexpensive, oral therapies such as analgesics and other Non-Steroidal Anti-Inflammatory Drugs (NSAIDS), are used as the standard of care to treat the symptoms of gout diseases. These established, inexpensive, orally delivered drugs may make it difficult for us to successfully commercialize ARCALYST in these diseases.

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

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

We are aware of several pharmaceutical and biotechnology companies actively engaged in the research and development of antibody products against targets that are also the targets of our early-stage product candidates. For example, Pfizer, Johnson & Johnson, and Abbott are developing antibody product candidates against NGF. Genentech/Roche is marketing an antibody against IL-6R (tocilizumab) for the treatment of rheumatoid arthritis, and several other companies, including Centocor/Johnson & Johnson, and Bristol-Myers Squibb, have antibodies against IL-6 in clinical development for this disease. GlaxoSmithKline, in partnership with OncoMed Pharmaceuticals, has a Dll4 antibody in clinical development for the treatment of solid tumors. Aerovance has two formulations of a biologic directed against IL-4 in clinical development. Amgen previously had an antibody against IL-4R in clinical development for the treatment of asthma. Several companies, including Amgen, Pfizer, and Roche, have development programs for antibodies against PCSK9. Amgen, Pfizer, and AstraZeneca have development programs underway for antibodies against ANG2. If any of these or other competitors announces a successful clinical study involving a product that may be competitive with one of our product candidates or the grant of marketing approval by a regulatory agency for a competitive product, such developments may have an adverse effect on our business or future prospects.

The successful commercialization of EYLEA for the treatment of wet AMD 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 product candidates, if commercialized, may be significantly more expensive than traditional drug treatments. For example, we are developing ARCALYST for the prevention of gout flares in patients initiating uric acid-lowering drug therapy. Patients suffering from this gout indication are currently treated with inexpensive therapies, including NSAIDS. These existing treatment options are likely to be considerably less expensive and may be preferable to a biologic medication for some patients. Our future revenues and profitability will be adversely affected in a material manner if United States and foreign governmental, private third-party insurers and payers, and other third-party payers, including Medicare and Medicaid, do not agree to 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 and other eye diseases, and if approval, ZALTRAP for oncology indications, and ARCALYST for the prevention of gout flares in patients initiating uric-acid lowering therapy, will likely be too expensive for most patients to afford without health insurance coverage, if these products are unable to obtain adequate coverage and reimbursement by third-party payers, including Medicare and Medicaid in the United States, our ability to successfully commercialize these products would be materially adversely impacted. The status of a J-Code for our marketed products could also affect reimbursement. J-Codes are permanent reimbursement codes maintained by CMS that are a component of HCPCS, and are typically used to report injectable drugs that ordinarily cannot be self-administered. Although we have a J-Code for ARCALYST, we do not currently have a J-Code for EYLEA, although we anticipate assignment of a J-Code for EYLEA in January 2013. Effective July 1, 2012, CMS issued a Q-Code which is a temporary code to facilitate reimbursement for physician-administered EYLEA in wet AMD pending the issuance of the J-Code expected in January 2013. Without a unique J-Code identifier and prior to the effective date of the Q-code, EYLEA has been billed using a non-specific miscellaneous J-Code. Since such codes may be used for a wide variety of products, health plans may have more difficulty determining the actual product used and billed for the patient. As a result, these claims must often be submitted with additional information and manually processed, which can create delays in claims processing times as well as increasing the likelihood for claim errors. Third-party payers, including Medicare and Medicaid in the United States, may not cover and/or reimburse for these products at levels required for us to successfully commercialize these products. Any limitation imposed by third-party payers on the use of our products if they are approved for marketing, or any action or decision by CMS or analogous foreign agencies or authorities which for any reason denies coverage or reimbursement for our products or provides coverage or reimbursement at levels that harm our products competitiveness or leads to lower prices for those products, will have a material negative effect on our ability to sustain profitability. In certain foreign countries, pricing, coverage, and level of reimbursement of prescription drugs are subject to governmental control, and we and our collaborators may be unable to obtain coverage, pricing, and/or reimbursement on terms that are favorable to us or necessary for us or our collaborators to successfully commercialize our products in those countries. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Our results of operations may suffer if we or our collaborators are unable to market our products in foreign countries or if coverage and reimbursement for our products in foreign countries is limited or delayed.

Regulatory and Litigation Risks

If the testing or use of our products harms people, we could be subject to costly and damaging product liability claims.

The testing, manufacturing, marketing, and sale of drugs for use in people expose us to product liability risk. Any informed consent or waivers obtained from people who enroll in our clinical trials may not protect us from liability or the cost of litigation. We may also be subject to claims by patients who use our approved products, ARCALYST for the treatment of CAPS, or EYLEA for the treatment of wet AMD, or EYLEA for other indications, ZALTRAP for previously-treated mCRC, or ARCALYST for the prevention of gout flares in patients initiating uric-acid lowering therapy if those product candidates receive regulatory approval and become commercially available, that they have been injured by a side effect associated with the drug. We may face product liability claims and be found responsible even if injury arises from the acts or omissions of our third-party fill/finish or other providers. 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 and financial results and condition. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be challenged under one or more of such laws.

In recent years, several states and localities, including California, the District of Columbia, Massachusetts, Minnesota, Nevada, New Mexico, Vermont, and West Virginia, have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, and 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, pharmaceutical companies will be required to file reports with the federal government regarding payments made to healthcare professionals. Many of these requirements are new and uncertain, and the penalties for failure to comply with these requirements are unclear. Nonetheless, if we are found not to be in full compliance with these laws, we could face enforcement actions, fines, and other penalties, and could receive adverse publicity, which would harm our business and financial results and condition.

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Reliance on Third Parties

If our antibody collaboration with Sanofi is terminated, our business operations 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 has a one-time option to adjust the maximum reimbursement amount down to $120 million per year commencing in 2014 if over the prior two years certain specified criteria are not satisfied. If this downward adjustment occurs, it will reduce our resources available for antibody discovery activities and negatively affect our clinical pipeline. 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, REGN727, REGN668, REGN421, REGN910, and REGN1033, we rely on Sanofi to lead much of the clinical development efforts and assist with obtaining regulatory approval, particularly outside the United States. We also rely on Sanofi to lead the commercialization efforts to support all of the antibody products that are co-developed by Sanofi and us if they receive regulatory approval. If Sanofi does not elect to co-develop the antibodies that we discover or opts-out of their development, we would be required to fund and oversee on our own the clinical trials, any regulatory responsibilities, and the ensuing commercialization efforts to support those antibody products. For example, during 2011 and 2012 to date, Sanofi elected not to continue co-development of REGN846 and REGN475, and decided not to opt-in to the REGN1154 program. If Sanofi terminates the antibody collaboration or fails to comply with its payment obligations thereunder, our business, prospects, operating results, and financial condition would be materially harmed. We would be required to either expend substantially more resources than we have anticipated to support our research and development efforts, which could require us to seek additional funding that might not be available on favorable terms or at all, or materially cut back on such activities. Even though none of the antibodies from this collaboration may ever be successfully developed and commercialized, if Sanofi does not perform its obligations with respect to antibodies that it elects to co-develop, our ability to develop, manufacture, and commercialize these antibody product candidates will be significantly adversely affected.

If our collaboration with Sanofi for ZALTRAP is terminated, or Sanofi materially breaches its obligations thereunder, our business operations, prospects, and financial condition, and our ability to develop, manufacture, and commercialize ZALTRAP in the time expected, or at all, would be materially harmed.

We rely heavily on Sanofi to lead much of the development of ZALTRAP. Sanofi initially funds all of the development expenses incurred by both companies in connection with the ZALTRAP program. If the ZALTRAP program continues, we will rely on Sanofi to assist with funding the ZALTRAP program, provide commercial manufacturing capacity, enroll and monitor clinical trials, obtain regulatory approval, particularly outside the United States, and lead the commercialization of ZALTRAP. While ZALTRAP may not ever be successfully developed and commercialized, if Sanofi fails to perform its obligations in a timely manner, or at all, our ability to develop, manufacture, 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 partner, which could require us to seek additional funding that might not be available on favorable terms or at all, and could cause significant delays in the development and/or manufacture of ZALTRAP and result in substantial additional costs to us. We have limited commercial capabilities 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 operations, prospects, 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 in countries other than Japan. In Japan, Santen Pharmaceuticals Co. Ltd. will sell EYLEA pursuant to a Co-Promotion and Distribution Agreement with Bayer HealthCare s Japanese affiliate. While we cannot assure you that EYLEA will receive regulatory approval in or outside the United States or be successfully commercialized, if Bayer HealthCare and, in Japan, Santen do not perform their obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize EYLEA outside the United States will be significantly adversely affected. Bayer HealthCare has the right to terminate its collaboration agreement with us at any time upon six or twelve months advance notice, depending on the circumstances giving rise to termination. If Bayer HealthCare were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could require us to seek additional funding or another collaboration that might not be available on favorable terms or at all, and could cause significant delays in the development and/or commercialization of EYLEA outside the United States and result in substantial additional costs to us. We currently have limited commercial capabilities and would have to develop or outsource these capabilities outside the United States. 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, 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, Good Laboratory Practices (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 and successfully commercializing, our product candidates.

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

Risk Related to Employees

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

We are highly dependent on certain of our executive officers, other key members of our senior management team, and our Chairman. If we are not able to retain any of these persons, our business may suffer. In particular, we depend on the services of P. Roy Vagelos, M.D., the Chairman of our board of directors, Leonard S. Schleifer, M.D., Ph.D., our President and Chief Executive Officer, George D. Yancopoulos, M.D., Ph.D., our Executive Vice President, Chief Scientific Officer and President, Regeneron Research Laboratories, and Neil Stahl, Ph.D., our Senior Vice President, Research and Development Sciences. As we commercialize EYLEA in the United States for the treatment of wet AMD and prepare for commercialization in the United States of EYLEA for the treatment of CRVO and ARCALYST for the treatment of gout flares in patients initiating uric acid-lowering therapy, should they receive regulatory approval, we will also be 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 have a material adverse effect on our business, prospects, operating results, and financial condition.

Risks Related to Our Common Stock

Our stock price is extremely volatile.

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

- announcement of actions by the FDA or foreign regulatory authorities or their respective advisory committees regarding our, or our collaborators currently pending or future application(s) for regulatory approval of our product candidate(s) or new indications for our marketed products;

- announcement of submission of an application for regulatory approval of one or more of our product candidates or new indications for our marketed products;
- progress, delays, or results in clinical trials of our or our competitors product candidates or new indications for marketed products;
- announcement of technological innovations or product candidates by us or competitors;
- fluctuations in our operating results; in particular, net product sales of, and profits from, EYLEA and, if any of our product candidates or our new indications for our marketed products receive regulatory approval, net product sales of, and profits from, these product candidates and new indications;
- market acceptance of, and fluctuations in market share for, our marketed products, especially EYLEA, and whether these factors, including our net products sales, underperform, meet, or exceed the expectations of investors or analysts;
- third-party claims that our products or technologies infringe their patents;
- third-party challenges to our patents in the European Patent Office and in the U.S. Patent and Trademark Office;
- public concern as to the safety or effectiveness of any of our marketed products or product candidates or new indications for our marketed products, including EYLEA or, if approved, ZALTRAP, or ARCALYST for the prevention of gout flares in patients initiating uric acid-lowering therapy;
- 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 relationship with collaborative partners;
- developments in the biotechnology industry or in government regulation of healthcare;
- large sales of our Common Stock by our executive officers, directors, or significant shareholders;
- arrivals and departures of key personnel; and
- general market conditions.

The trading price of our Common Stock has been, and could continue to be, subject to wide fluctuations in response to these and other factors, including the sale or attempted sale of a large amount of our Common Stock in the market. Broad market fluctuations may also adversely affect the market price of our Common Stock.

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

A small number of our shareholders beneficially own a substantial amount of our Common Stock. As of April 11, 2012, our seven largest shareholders plus Leonard S. Schleifer, M.D, Ph.D., our Chief Executive Officer, beneficially owned 67.4% 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 11, 2012. In September 2003, Sanofi (then Aventis Pharmaceuticals Inc.) purchased 2,799,552 newly issued, unregistered shares of our Common Stock, and in December 2007 Sanofi purchased an additional 12,000,000 newly issued, unregistered shares of our Common Stock. Under our investor agreement, as amended, with Sanofi, these shares may not be sold until December 20, 2017 except under limited circumstances and subject to earlier termination of these restrictions upon the occurrence of certain events. In addition, in October 2010, Sanofi purchased an additional 1,017,401 shares of Common Stock in our underwritten public offering. As of April 11, 2012, Sanofi beneficially owned 15,816,953 shares of our Common Stock, representing approximately 17.0% of the shares of Common Stock then outstanding. If Sanofi, or our other significant shareholders or we, sell substantial amounts of our Common Stock in the public market, or the perception that such sales may occur exists, the market price of our Common Stock could fall. Sales of Common Stock by our significant shareholders, including Sanofi, also might make it more difficult for us to raise funds by selling equity or equity-related securities in the future at a time and price that we deem appropriate.

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

Holders of Class A Stock, who are generally the shareholders who purchased their stock from us before our initial public offering, are entitled to ten votes per share, while holders of Common Stock are entitled to one vote per share. As of April 11, 2012, holders of Class A Stock held 18.3% 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 11, 2012:

- our current executive officers and directors beneficially owned 11.1% 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 11, 2012, and 24.0% 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 11, 2012; and
- our seven largest shareholders plus Leonard S. Schleifer, M.D., Ph.D. our Chief Executive Officer, beneficially owned 67.4% 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 11, 2012. In addition, these seven shareholders held 69.8% 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 11, 2012.

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

The anti-takeover effects of provisions of our charter, by-laws, and of New York corporate law and the contractual standstill provisions in our investor agreement with Sanofi, could deter, delay, or prevent an acquisition or other change in control of us and could adversely affect the price of our Common Stock.

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

- authorization to issue blank check preferred stock, which is preferred stock that can be created and issued by the board of directors without prior shareholder approval, with rights senior to those of our Common Stock and Class A Stock;
- a staggered board of directors, so that it would take three successive annual meetings to replace all of our directors;
- a requirement that removal of directors may only be effected for cause and only upon the affirmative vote of at least eighty percent (80%) of the outstanding shares entitled to vote for directors, as well as a requirement that any vacancy on the board of directors may be filled only by the remaining directors;
- a provision whereby any action required or permitted to be taken at any meeting of shareholders may be taken without a meeting, only if, prior to such action, all of our shareholders consent, the effect of which is to require that shareholder action may only be taken at a duly convened meeting;
- a requirement that any shareholder seeking to bring business before an annual meeting of shareholders must provide timely notice of this intention in writing and meet various other requirements; and

- under the New York Business Corporation Law, in addition to certain restrictions which may apply to business combinations involving our company and an interested shareholder, a plan of merger or consolidation of our company must be approved by two-thirds of the votes of all outstanding shares entitled to vote thereon. See the risk factor immediately above captioned *Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval.*

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

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

Risks Relating to Our Convertible Senior Notes and Related Hedge Transactions

The convertible note hedges and warrant transactions we entered into in connection with our 1.875% Convertible Senior Notes issuance may affect the trading price of our Common Stock.

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

In connection with hedging these transactions, the hedge counterparties and/or their affiliates may enter into various derivative transactions with respect to our Common Stock, and may enter into, or may unwind, various derivative transactions and/or purchase or sell our Common Stock or other securities of ours in secondary market transactions prior to maturity of the notes (and are likely to do so during any conversion period related to any conversion of the notes). These activities could have the effect of increasing or preventing a decline in, or could have a negative effect on, the value of our Common Stock and could have the effect of increasing or preventing a decline in the value of our Common Stock during any cash settlement averaging period related to a conversion of the notes.

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

The fundamental change provisions of our 1.875% Convertible Senior Notes and certain of the terms of the convertible note hedge and warrant transactions may delay or prevent an otherwise beneficial takeover attempt of us.

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

ITEM 6. EXHIBITS

(a) Exhibits

Exhibit Number		**Description**
10.1*	-	Amendment Agreement, dated May 7, 2012, by and between Bayer HealthCare LLC and the Registrant.
31.1	-	Certification of CEO pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
31.2	-	Certification of CFO pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
32	-	Certification of CEO and CFO pursuant to 18 U.S.C. Section 1350.
101	-	Interactive Data File
101.INS	-	XBRL Instance Document
101.SCH	-	XBRL Taxonomy Extension Schema
101.CAL	-	XBRL Taxonomy Extension Calculation Linkbase
101.LAB	-	XBRL Taxonomy Extension Label Linkbase
101.PRE	-	XBRL Taxonomy Extension Presentation Linkbase
101.DEF	-	XBRL Taxonomy Extension Definition Document

* The Company has requested confidential treatment of certain information contained in this exhibit. Such information has been filed separately with the Commission pursuant to the Company s application for confidential treatment.

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: July 25, 2012

By: /s/ MURRAY A. GOLDBERG

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