REGENERON PHARMACEUTICALS INC
Form 10-Q
October 27, 2011

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2011

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) 347-7000
(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	Smaller reporting company

(Do not check if a smaller reporting company)

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

Yes No X

Number of shares outstanding of each of the registrant's classes of common stock as of October 19, 2011:

Class of Common Stock	Number of Shares
Class A Stock, $0.001 par value	2,109,512
Common Stock, $0.001 par value	90,466,178

REGENERON PHARMACEUTICALS, INC.
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PART I. FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS

REGENERON PHARMACEUTICALS, INC.
CONDENSED BALANCE SHEETS AT SEPTEMBER 30, 2011 AND DECEMBER 31, 2010 (Unaudited)
(In thousands, except share data)

	September 30, 2011	December 31, 2010
ASSETS		
Current assets		
Cash and cash equivalents	$ 206,395	$ 112,572
Marketable securities	39,103	136,796
Accounts receivable from Sanofi	74,788	79,603
Accounts receivable - other	3,659	13,509
Prepaid expenses and other current assets	15,927	15,142
Total current assets	339,872	357,622
Restricted cash and marketable securities	8,150	7,518
Marketable securities	258,073	370,053
Property, plant, and equipment, at cost, net of accumulated depreciation and amortization	363,913	347,450
Other assets	13,023	6,789
Total assets	$ 983,031	$ 1,089,432
LIABILITIES and STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 78,890	$ 53,658
Deferred revenue from Sanofi, current portion	19,819	19,506
Deferred revenue - other, current portion	33,606	35,217
Facility lease obligations, current portion	920	675
Total current liabilities	133,235	109,056
Deferred revenue from Sanofi	88,033	97,081
Deferred revenue - other	166,623	188,775
Facility lease obligations	159,482	159,355
Other long term liabilities	7,405	7,350
Total liabilities	554,778	561,617
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 - 2,109,512 in 2011 and 2,182,036 in 2010	2	2
Common Stock, $.001 par value; 160,000,000 shares authorized; shares issued and outstanding - 90,418,871 in 2011 and 87,238,301 in 2010	90	87
Additional paid-in capital	1,643,772	1,575,780
Accumulated deficit	(1,213,880)	(1,045,563)

Accumulated other comprehensive loss		(1,731)		(2,491)
Total stockholders' equity		428,253		527,815
Total liabilities and stockholders' equity	$	983,031	$	1,089,432

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

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

	Three months ended September 30,		Nine months ended September 30,	
	2011	2010	2011	2010
Revenues				
Sanofi collaboration revenue	$ 79,802	$ 75,583	$ 249,577	$ 229,195
Other collaboration revenue	10,094	13,761	33,698	40,483
Technology licensing	5,893	10,037	18,966	30,112
Net product sales	5,468	4,936	14,934	19,985
Contract research and other	1,576	1,662	5,672	5,624
	102,833	105,979	322,847	325,399
Expenses				
Research and development	127,924	122,043	400,465	364,040
Selling, general, and administrative	32,916	15,658	80,912	44,560
Cost of goods sold	450	372	1,227	1,494
	161,290	138,073	482,604	410,094
Loss from operations	(58,457)	(32,094)	(159,757)	(84,695)
Other income (expense)				
Investment income	715	453	2,750	1,484
Interest expense	(4,061)	(2,234)	(11,827)	(6,660)
	(3,346)	(1,781)	(9,077)	(5,176)
Net loss before income tax expense (benefit)	(61,803)	(33,875)	(168,834)	(89,871)
Income tax expense (benefit)	562		(517)	
Net loss	$ (62,365)	$ (33,875)	$ (168,317)	$ (89,871)
Net loss per share, basic and diluted	$ (0.68)	$ (0.41)	$ (1.87)	$ (1.10)
Weighted average shares outstanding, basic and diluted	91,046	81,638	90,215	81,433

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

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY (Unaudited)
For the nine months ended September 30, 2011 and 2010
(In thousands)

	Class A Stock		Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Total Stockholders'	Comprehensive
	Shares	Amount	Shares	Amount	Capital	Deficit	Income (Loss)	Equity	Loss
Balance, December 31, 2010	2,182	$ 2	87,238	$ 87	$ 1,575,780	$ (1,045,563)	$ (2,491)	$ 527,815	
Issuance of Common Stock in connection with exercise of stock options, net of shares tendered			3,000	3	23,819			23,822	
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			92		3,405			3,405	
Issuance of restricted Common Stock under Long-Term Incentive Plan			16						
Conversion of Class A Stock to Common Stock	(73)		73						
Stock-based compensation charges					40,768			40,768	
Net loss						(168,317)		(168,317)	$ (168,317)
Change in net unrealized gain (loss) on marketable securities, net of tax effect of $0.5 million							760	760	760
Balance, September 30, 2011	2,109	$ 2	90,419	$ 90	$ 1,643,772	$ (1,213,880)	$ (1,731)	$ 428,253	$ (167,557)
Balance, December 31, 2009	2,245	$ 2	78,861	$ 79	$ 1,336,732	$ (941,095)	$ 1,044	$ 396,762	
Issuance of Common Stock in connection with exercise of stock options, net of shares tendered			993	1	13,193			13,194	
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			111		2,867			2,867	
Issuance of restricted Common Stock under Long-Term Incentive Plan			15						
Conversion of Class A Stock to Common Stock	(63)		63						
Stock-based compensation charges					26,331			26,331	
Net loss						(89,871)		(89,871)	$ (89,871)
Change in net unrealized gain (loss) on marketable securities							(1,219)	(1,219)	(1,219)
Balance, September 30, 2010	2,182	$ 2	80,043	$ 80	$ 1,379,123	$ (1,030,966)	$ (175)	$ 348,064	$ (91,090)

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

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

	Nine months ended September 30,	
	2011	2010
Cash flows from operating activities		
Net loss	$ (168,317)	$ (89,871)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities		
Depreciation and amortization	23,156	13,601
Non-cash compensation expense	40,561	26,331
Other non-cash charges and expenses, net	2,121	2,627
Changes in assets and liabilities		
Decrease (increase) in accounts receivable	14,665	(16,719)
(Increase) decrease in prepaid expenses and other assets	(6,307)	3,446
(Decrease) increase in deferred revenue	(32,498)	172,660
Increase in accounts payable, accrued expenses, and other liabilities	35,254	27,998
Total adjustments	76,952	229,944
Net cash (used in) provided by operating activities	(91,365)	140,073
Cash flows from investing activities		
Purchases of marketable securities	(115,538)	(241,665)
Sales or maturities of marketable securities	324,530	228,483
Capital expenditures	(45,928)	(67,427)
Increase in restricted cash	(685)	(1,800)
Net cash provided by (used in) investing activities	162,379	(82,409)
Cash flows from financing activities		
Proceeds in connection with facility lease obligations		47,544
Payments in connection with facility lease obligations	(468)	(757)
Net proceeds from the issuance of Common Stock	23,989	13,760
Payments in connection with capital lease obligations	(712)	
Net cash provided by financing activities	22,809	60,547
Net increase in cash and cash equivalents	93,823	118,211
Cash and cash equivalents at beginning of period	112,572	207,075
Cash and cash equivalents at end of period	$ 206,395	$ 325,286

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 adjustments, consisting only of normal recurring 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, 2010 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, 2010.

Certain reclassifications have been made to the financial statements for the nine months ended September 30, 2010 to conform with the current period's presentation.

2. ARCALYST® (rilonacept) Product Revenue

In February 2008, the Company received marketing approval from the U.S. Food and Drug Administration ("FDA") for ARCALYST® Injection for Subcutaneous Use for the treatment of Cryopyrin-Associated Periodic Syndromes ("CAPS"). The Company had limited historical return experience for ARCALYST® beginning with initial sales in 2008 through the end of 2009; therefore, ARCALYST® net product sales were deferred until the right of return no longer existed and rebates could be reasonably estimated. Effective in the first quarter of 2010, the Company determined that it had accumulated sufficient historical data to reasonably estimate both product returns and rebates of ARCALYST®. As a result, $4.8 million of previously deferred ARCALYST® net product sales were recognized as revenue in the first quarter of 2010. The effect of this change in estimate related to ARCALYST® net product sales revenue was to lower the Company's net loss per share by $0.06 for the nine months ended September 30, 2010.

ARCALYST® net product sales totaled $5.5 million and $4.9 million for the three months ended September 30, 2011 and 2010, respectively, and $14.9 million and $20.0 million for the nine months ended September 30, 2011 and 2010, respectively. ARCALYST® net product sales during the first nine months of 2010 included $15.2 million of net product sales made during this period and $4.8 million of previously deferred net product sales, as described above. There was no deferred ARCALYST® net product sales revenue at September 30, 2011 or 2010.

Cost of goods sold related to ARCALYST® sales, which consisted primarily of royalties, totaled $0.5 million and $0.4 million for the three months ended September 30, 2011 and 2010, respectively, and $1.2 million and $1.5 million for the nine months ended September 30, 2011 and 2010, respectively.

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 and diluted net loss per share amounts have been computed by dividing net loss by the weighted average number of shares of Common Stock and Class A Stock outstanding. Net 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. For the three and nine months ended September 30, 2011 and 2010, the Company reported net losses; therefore, no common stock equivalents were included in the computation of diluted net loss per share for these periods, since such inclusion would have been antidilutive. The calculations of basic and diluted net loss per share are as follows:

	Three Months Ended September 30,	
	2011	2010
Net loss (Numerator)	$ (62,365)	$ (33,875)
Weighted-average shares, in thousands (Denominator)	91,046	81,638
Basic and diluted net loss per share	$ (0.68)	$ (0.41)

	Nine Months Ended September 30,	
	2011	2010
Net loss (Numerator)	$ (168,317)	$ (89,871)
Weighted-average shares, in thousands (Denominator)	90,215	81,433
Basic and diluted net loss per share	$ (1.87)	$ (1.10)

Shares issuable upon the exercise of stock options and vesting of restricted stock awards, which have been excluded from the September 30, 2011 and 2010 diluted per share amounts because their effect would have been antidilutive, include the following:

	Three months ended September 30,	
	2011	2010
Stock Options:		
Weighted average number, in thousands	20,395	21,265
Weighted average exercise price	$ 21.24	$ 18.76
Restricted Stock:		
Weighted average number, in thousands	854	511

	Nine months ended September 30,	
	2011	2010
Stock Options:		
Weighted average number, in thousands	21,239	21,317
Weighted average exercise price	$ 20.72	$ 18.67
Restricted Stock:		
Weighted average number, in thousands	848	507

4. Statement of Cash Flows

Supplemental disclosure of noncash investing and financing activities:

Included in accounts payable and accrued expenses at September 30, 2011 and December 31, 2010 were $4.9 million and $10.7 million, respectively, of accrued capital expenditures. Included in accounts payable and accrued expenses at September 30, 2010 and December 31, 2009 were $12.0 million and $9.8 million, respectively, of accrued capital expenditures.

Included in accounts payable and accrued expenses at December 31, 2010 and 2009 were $2.9 million and $2.6 million, respectively, of accrued Company 401(k) Savings Plan contribution expense. In the first quarter of 2011 and 2010, the Company contributed 91,761 and 111,419 shares, respectively, of Common Stock to the 401(k) Savings Plan in satisfaction of these obligations.

Included in facility lease obligations and property, plant, and equipment at September 30, 2010 was $2.6 million of capitalized and deferred interest for the nine months ended September 30, 2010, as the related facilities being leased by the Company were under construction and lease payments on these facilities did not commence until January 2011.

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

The Company incurred capital lease obligations of $0.7 million during the nine months ended September 30, 2011 in connection with acquisitions of equipment.

Included in marketable securities at September 30, 2011 and December 31, 2010 were $1.1 million and $1.4 million, respectively, of accrued interest income. Included in marketable securities at September 30, 2010 and December 31, 2009 were $1.3 million and $0.6 million, respectively, of accrued interest income.

5. Marketable Securities

Marketable securities at September 30, 2011 and December 31, 2010 consisted of debt securities, as detailed below, and equity securities. The aggregate fair value of the equity securities was $3.1 million and $3.6 million at September 30, 2011 and December 31, 2010, respectively, and the aggregate cost basis was $4.0 million at both September 30, 2011 and December 31, 2010. The Company also held restricted marketable securities at both September 30, 2011 and December 31, 2010, which consisted of debt securities, as detailed below, that collateralize letters of credit and lease obligations.

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 September 30, 2011 and December 31, 2010. 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.

At September 30, 2011	Amortized Cost Basis	Fair Value	Unrealized Gains	Unrealized (Losses)	Unrealized Net
Unrestricted					
Maturities within one year					
U.S. government obligations	$ 2,028	$ 2,033	$ 5		$ 5
U.S. government guaranteed corporate bonds	21,249	21,309	60		60
U.S. government guaranteed collateralized mortgage obligations	986	986			
Municipal bonds	14,722	14,749	27		27
Mortgage-backed securities	26	26			
	39,011	39,103	92		92
Maturities between one and five years					
U.S. government obligations	238,958	239,418	519	$ (59)	460
U.S. government guaranteed corporate bonds	15,415	15,457	42		42
	254,373	254,875	561	(59)	502
Maturities between five and six years					
Mortgage-backed securities	270	123		(147)	(147)
	293,654	294,101	653	(206)	447

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

At September 30, 2011 (continued)	Amortized Cost Basis	Fair Value	Unrealized Gains	Unrealized (Losses)	Net
Restricted					
Maturities within one year					
U.S. government obligations	2,946	2,947	1		1
Maturities between one and three years					
U.S. government obligations	4,261	4,280	19		19
	7,207	7,227	20		20
	$ 300,861	$ 301,328	$ 673	$ (206)	$ 467
At December 31, 2010					
Unrestricted					
Maturities within one year					
U.S. government obligations	$ 83,635	$ 83,684	$ 54	$ (5)	$ 49
U.S. government guaranteed corporate bonds	48,173	48,531	358		358
U.S. government guaranteed collateralized mortgage obligations	2,027	2,131	104		104
Municipal bonds	1,597	1,603	6		6
Mortgage-backed securities	875	847		(28)	(28)
	136,307	136,796	522	(33)	489
Maturities between one and five years					
U.S. government obligations	352,345	350,683	64	(1,726)	(1,662)
U.S. government guaranteed corporate bonds	15,522	15,477		(45)	(45)
Mortgage-backed securities	110	38		(72)	(72)
	367,977	366,198	64	(1,843)	(1,779)
Maturities between five and seven years					
Mortgage-backed securities	284	243		(41)	(41)
	504,568	503,237	586	(1,917)	(1,331)
Restricted					
Maturities within one year					
U.S. government obligations	2,922	2,921		(1)	(1)
Maturities between one and three years					
U.S. government obligations	4,135	4,118		(17)	(17)
	7,057	7,039		(18)	(18)
	$ 511,625	$ 510,276	$ 586	$ (1,935)	$ (1,349)

At September 30, 2011 and December 31, 2010, marketable securities included an additional unrealized loss of $0.9 million and $0.4 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 September 30, 2011 and December 31, 2010. The debt securities held at September 30, 2011, excluding mortgage-backed securities, mature at various dates through June 2014. The mortgage-backed securities held at September 30, 2011 have various estimated maturity dates through August 2017.

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 September 30, 2011	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
Unrestricted						
U.S. government obligations	$ 67,234	$ (59)			$ 67,234	$ (59)
Equity securities	3,075	(969)			3,075	(969)
Mortgage-backed securities			$ 149	$ (147)	149	(147)
	70,309	(1,028)	149	(147)	70,458	(1,175)

	Less than 12 Months		12 Months or Greater		Total	
At December 31, 2010	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
Unrestricted						
U.S. government obligations	$ 340,444	$ (1,731)			$ 340,444	$ (1,731)
U.S. government guaranteed corporate bonds	19,005	(45)			19,005	(45)
Equity securities	3,612	(433)			3,612	(433)
Mortgage-backed securities			$ 1,128	$ (141)	1,128	(141)
	363,061	(2,209)	1,128	(141)	364,189	(2,350)
Restricted						
U.S. government obligations	6,154	(18)			6,154	(18)
	6,154	(18)			6,154	(18)
	$ 369,215	$ (2,227)	$ 1,128	$ (141)	$ 370,343	$ (2,368)

Realized gains and losses are included as a component of investment income. For the three and nine months ended September 30, 2011 and 2010, realized gains and losses on sales of marketable securities were not significant. In computing realized gains and losses, the Company computes the cost of its investments on a specific identification basis. Such cost includes the direct costs to acquire the security, adjusted for the amortization of any discount or premium.

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

The Company's assets that are measured at fair value on a recurring basis, at September 30, 2011 and December 31, 2010, were as follows:

		Fair Value Measurements at Reporting Date Using		
At September 30, 2011	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	$ 241,451		$ 241,451	
U.S. government guaranteed corporate bonds	36,766		36,766	
U.S. government guaranteed collateralized mortgage obligations	986		986	
Municipal bonds	14,749		14,749	
Mortgage-backed securities	149		149	
Equity securities	3,075	$ 3,075		
	297,176	3,075	294,101	
Restricted				
Available-for-sale marketable securities				
U.S. government obligations	7,227		7,227	
	$ 304,403	$ 3,075	$ 301,328	

		Fair Value Measurements at Reporting Date Using		
At December 31, 2010	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	$ 434,367		$ 434,367	
U.S. government guaranteed corporate bonds	64,008		64,008	
U.S. government guaranteed collateralized mortgage obligations	2,131		2,131	
Municipal bonds	1,603		1,603	

Mortgage-backed securities	1,128		1,128
Equity securities	3,612	$ 3,612	
	506,849	3,612	503,237
Restricted			
Available-for-sale marketable securities			
U.S. government obligations	7,039		7,039
	$ 513,888	$ 3,612	$ 510,276

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

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. During the nine months ended September 30, 2010, deterioration in the credit quality of a marketable security from one issuer subjected the Company to the risk of not being able to recover a portion of the security's carrying value. As a result, the Company recognized a $0.1 million impairment charge related to this Level 2 marketable security, which the Company considered to be other-than-temporarily impaired. During the three and nine months ended September 30, 2011, and the three months ended September 30, 2010, the Company did not record any charges for other-than-temporary impairment of its Level 2 marketable securities.

The Company holds one Level 3 marketable security, which had no fair value at September 30, 2011 and December 31, 2010. 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 and nine months ended September 30, 2011 and 2010. There were no transfers of marketable securities between Levels 1, 2, or 3 classifications during the three and nine months ended September 30, 2011 and 2010.

On a quarterly basis, the Company reviews its portfolio of marketable securities, using both quantitative and qualitative factors, to determine if declines in fair value below cost are other-than-temporary. With respect to debt securities, this review process also includes an evaluation of the Company's (a) intent to sell an individual debt security or (b) need to sell the debt security before its anticipated recovery or maturity. With respect to equity securities, this review process includes an evaluation of the Company's ability and intent to hold the securities until their full value can be recovered.

6. Inventory

Inventories as of September 30, 2011 and December 31, 2010 consist of the following:

	September 30, 2011	December 31, 2010
Raw materials	$ 223	$ 592
Work in process	7,728	699
Finished goods	83	132
	$ 8,034	$ 1,423

At September 30, 2011, $1.0 million of inventories were included in prepaid expenses and other current assets and $7.0 million of inventories were included in other assets. At December 31, 2010, inventories were included in prepaid expenses and other current assets.

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7. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses as of September 30, 2011 and December 31, 2010 consist of the following:

	September 30, 2011	December 31, 2010
Accounts payable	$ 17,309	$ 15,589
Accrued payroll and related costs	37,616	12,025
Accrued clinical trial expense	10,018	9,727
Accrued property, plant, and equipment costs	2,333	7,622
Other accrued expenses and liabilities	8,208	6,441
Payable to Bayer HealthCare LLC	3,406	2,254
	$ 78,890	$ 53,658

8. Comprehensive Loss

Comprehensive loss of the Company includes net loss adjusted for the change in net unrealized gain (loss) on marketable securities, net of any tax effect. For the three and nine months ended September 30, 2011 and 2010, the components of comprehensive loss are:

	Three months ended September 30, 2011	2010
Net loss	$ (62,365)	$ (33,875)
Change in net unrealized gain (loss) on marketable securities, net of tax effect of $0.6 million in 2011	(827)	131
Total comprehensive loss	$ (63,192)	$ (33,744)

	Nine months ended September 30, 2011	2010
Net loss	$ (168,317)	$ (89,871)
Change in net unrealized gain (loss) on marketable securities, net of tax effect of $0.5 million in 2011	760	(1,219)
Total comprehensive loss	$ (167,557)	$ (91,090)

9. Income Taxes

For the three and nine months ended September 30, 2011 and 2010, the Company incurred net losses for tax purposes and recognized a full valuation allowance against deferred tax assets. For the three and nine months ended September 30, 2011, the Company recognized income tax expense of $0.6 million and an income tax benefit of $0.5 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 loss. For the three and nine months ended September 30, 2010, no provision or benefit for income taxes was recorded.

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.

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As previously reported, on November 19, 2010, the Company filed a complaint against Genentech in the U.S. District Court for the Southern District of New York seeking a declaratory judgment that no activities relating to the Company's VEGF Trap (aflibercept) infringe any valid claim of certain Genentech patents referred to as the Davis-Smyth patents. On January 12, 2011, Genentech filed a motion to dismiss the complaint, arguing that the lawsuit was premature and thus the Court lacked subject matter jurisdiction. Upon the Company's submission to the FDA of a Biologics License Application (BLA) for EYLEATM (aflibercept injection) for the treatment of age-related macular degeneration (wet AMD), the Company filed a second complaint against Genentech in the same court seeking the same declaratory relief. On April 7, 2011, the Company and Genentech entered into a Joint Stipulation, which was approved and executed by the Court on April 11, 2011. Pursuant to the Joint Stipulation, the Company voluntarily dismissed its original complaint in favor of proceeding with its second complaint, and Genentech agreed that it would not seek to transfer the case to another judicial district or move to dismiss the second complaint for lack of subject matter jurisdiction or otherwise under Rule 12(b) of the Federal Rules of Civil Procedure. On April 25, 2011, Genentech filed an answer to the second complaint, denying that the Company is entitled to the declaratory relief being sought by the Company, and asserting counterclaims that the Company's prior or planned activities relating to VEGF Trap have infringed or will infringe one or more claims of the Davis-Smyth patents. In its answer, Genentech requests a judgment against the Company for damages, including for willful infringement, and other relief as the Court deems appropriate. On May 11, 2011, Genentech filed an amended answer and counterclaim, again denying that the Company is entitled to the declaratory relief being sought by the Company, and asserting 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. In its amended answer and counterclaim, Genentech requests a judgment against the Company for damages, including for willful infringement, and other relief as the Court deems appropriate. On May 25, 2011, the Company replied to Genentech's amended answer and counterclaim, denying Genentech's counterclaims, and denying that any of the Company's prior or planned activities relating to VEGF Trap infringe any valid claim of the Davis-Smyth patents.The Company believes Genentech's counterclaims are without merit and intends to continue to defend against them 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 this matter.

The Company has initiated patent-related actions against Genentech in Germany, the United Kingdom, and Italy, and may initiate other actions in other countries outside the U.S.

11. Subsequent Event – Offering of Senior Convertible Notes

On October 17, 2011, the Company announced an offering of $400 million aggregate principal amount of 1.875% convertible senior notes (the "Notes") due October 1, 2016. The offering closed on October 21, 2011. The initial purchaser of the Notes has a 13-day option to purchase up to an additional $60 million aggregate principal amount of Notes on the same terms and conditions.

The Notes will pay interest semi-annually on April 1 and October 1 at an annual rate of 1.875%, and will mature on October 1, 2016, unless earlier converted or repurchased. The Notes will be convertible, subject to certain conditions, into cash, shares of the Company's Common Stock, or a combination of cash and shares of Common Stock, at the Company's option. The initial conversion rate for the Notes will be 11.9021 shares of Common Stock (subject to adjustment in certain circumstances) per $1,000 principal amount of the Notes, which is equal to an initial conversion price of approximately $84.02 per share.

In connection with the offering of the Notes, the Company entered into convertible note hedge and warrant transactions with multiple counterparties, including an affiliate of the initial purchaser. The convertible note hedge transactions cover, subject to customary anti-dilution adjustments, the number of shares of the Company's Common Stock that initially underlie the Notes, and are intended to reduce the dilutive impact of the conversion feature of the Notes. The warrant transactions will have an initial strike price of approximately $103.41 per share, and may be settled in cash or shares of the Company's Common Stock, at the Company's option.

The net proceeds from the Notes offering were approximately $391.3 million after deducting the initial purchaser's discount and estimated offering expenses (and will be approximately $450.1 million if the initial purchaser exercises in full its option to purchase additional Notes). In addition, the cost of the initial convertible note hedge, after taking into account the proceeds received by the Company from the warrant transactions, was $23.7 million. If the initial purchaser exercises its option to purchase additional Notes, the Company may use net proceeds from the sale of the additional Notes to enter into additional convertible note hedge and warrant transactions.

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12. Recently Issued Accounting Standards

Multiple-deliverable revenue arrangements

During the first quarter of 2011 the Company adopted amended authoritative guidance issued by the Financial Accounting Standards Board ("FASB") on multiple-deliverable revenue arrangements. The amended guidance provides greater ability to separate and allocate consideration to be received in a multiple-deliverable revenue arrangement by requiring the use of estimated selling prices to allocate the consideration, thereby eliminating the use of the residual method of allocation. The amended guidance also requires expanded qualitative and quantitative disclosures surrounding multiple-deliverable revenue arrangements. The Company is applying this amended guidance prospectively for new or materially modified arrangements, of which there were none during the nine months ended September 30, 2011. The adoption of this guidance did not have a material impact on the Company's financial statements.

Milestone method of revenue recognition

During the first quarter of 2011, the Company adopted amended authoritative guidance issued by the FASB codifying the milestone method of revenue recognition as an acceptable revenue recognition model when a milestone is deemed to be substantive. Since the Company has historically accounted for milestones under the milestone method, the adoption of this guidance did not have a material impact on the Company's financial statements.

In accordance with the Company's accounting policy for recognition of revenue in connection with collaboration agreements, as previously disclosed in the Company's financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2010, payments which are based on achieving a specific performance milestone, involving a degree of risk, are recognized as revenue when the milestone is achieved and the related payment is due and non-refundable, provided there is no future service obligation associated with that milestone. Substantive performance milestones typically consist of significant achievements in the development life-cycle of the related product candidate, such as completion of clinical trials, filing for approval with regulatory agencies, and receipt of approvals by regulatory agencies. In determining whether a payment is deemed to be a substantive performance milestone, the Company takes into consideration (i) the nature, timing, and value of significant achievements in the development life-cycle of the related development product candidate, (ii) the relative level of effort required to achieve the milestone, and (iii) the relative level of risk in achieving the milestone, taking into account the high degree of uncertainty in successfully advancing product candidates in a drug development program and in ultimately attaining an approved drug product. Payments for achieving milestones which are not considered substantive are accounted for as license payments and recognized over the related performance period.

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The Company earns substantive performance milestone payments in connection with its collaboration agreements to develop and commercialize product candidates with Sanofi and Bayer HealthCare. Descriptions of these collaboration agreements, including various financial terms and conditions, were provided in the Company's financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2010. Under the Company's collaboration agreement with Sanofi to jointly develop and commercialize ZALTRAP® (aflibercept, also known as VEGF Trap), the Company may receive up to $400 million in substantive milestone payments upon receipt of specified marketing approvals, including up to $360 million in milestone payments related to the receipt of marketing approvals for up to eight ZALTRAP® oncology and other indications in the U.S. or the European Union and up to $40 million related to the receipt of marketing approvals for up to five ZALTRAP® oncology indications in Japan. Under the Company's global, strategic collaboration with Sanofi to discover, develop, and commercialize fully human monoclonal antibodies, for each drug candidate identified under the collaboration's Discovery and Preclinical Development Agreement, Sanofi has the option to license rights to the candidate under the collaboration's License and Collaboration Agreement and co-develop the drug candidate with the Company through product approval. Under certain defined circumstances, upon exercising its option to license rights to particular candidates, Sanofi must make a $10 million substantive milestone payment to the Company. Under the Company's license and collaboration agreement with Bayer HealthCare to globally develop, and commercialize outside the U.S., EYLEATM, the Company is eligible to receive up to $50 million in future substantive milestone payments related to marketing approvals of EYLEATM in major market countries outside the U.S.

Fees paid to the federal government by pharmaceutical manufacturers

In December 2010, the FASB provided authoritative guidance on how pharmaceutical manufacturers should recognize and classify in their income statement annual fees mandated by the Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act. This guidance became effective for calendar years beginning after December 31, 2010. The adoption of this guidance did not have an impact on the Company's financial statements as the fee does not currently apply to the Company. The Company's marketed product, ARCALYST® for the treatment of CAPS, has been approved as an orphan drug and orphan drugs are not subject to this annual fee.

Presentation of comprehensive income

In June 2011, the FASB amended its authoritative guidance on the presentation of comprehensive income. Under the amendment, an entity will have the option to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. This amendment, therefore, eliminates the currently available option to present the components of other comprehensive income as part of the statement of changes in stockholders' equity. The amendment does 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 will adopt this amended guidance for the fiscal year beginning January 1, 2012. As this guidance relates to presentation only, the adoption of this guidance will 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 other things, the nature, timing, and possible success of and therapeutic applications for our product candidates and research programs now underway or planned, the likelihood and timing of possible regulatory approval and commercial launch of our late-stage product candidates, determinations by regulatory and administrative governmental authorities which may delay or restrict our ability to continue to develop or commercialize our product and drug candidates, competing drugs that may be superior to our product and drug candidates, uncertainty of market acceptance of our product and drug candidates, unanticipated expenses, the availability and cost of capital, the costs of developing, producing, and selling products, the potential for any 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 biopharmaceutical company that discovers, develops, manufactures, and commercializes pharmaceutical products for the treatment of serious medical conditions. We currently have one marketed product: 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.

We have 11 product candidates in clinical development, all of which were discovered in our research laboratories. Our Trap-based, late-stage (Phase 3) programs are:

- EYLEATM (aflibercept injection), also known as VEGF Trap-Eye, which is being developed using intraocular delivery for the treatment of serious eye diseases;
- ZALTRAP® (aflibercept), also known 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 the following fully human monoclonal antibodies:

- Sarilumab (REGN88), an antibody to the interleukin-6 receptor (IL-6R), which is being developed in rheumatoid arthritis;
- REGN727, an antibody to Proprotein Convertase Substilisin/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;
- REGN475, an antibody to Nerve Growth Factor (NGF), which is being developed for the treatment of pain (currently on clinical hold);
- REGN728, an antibody in clinical development against an undisclosed target; and
- REGN846, an antibody against an undisclosed target, which is being developed in atopic dermatitis.

With the exception of REGN846, which we are developing independently, all of these antibodies are being developed in collaboration with Sanofi.

Our core business strategy is to maintain a strong foundation in basic scientific research and discovery-enabling technologies, to combine that foundation with our clinical development and manufacturing capabilities, and to continue to expand our commercialization capabilities in anticipation of possible regulatory approval and launch of one or more of our late-stage product candidates. 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 approximately 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 Product:

ARCALYST® – CAPS

Net product sales of ARCALYST® (rilonacept) in the third quarter of 2011 were $5.5 million, compared to $4.9 million during the same quarter of 2010. ARCALYST® net product sales for the nine months ended September 30, 2011 and 2010, respectively, totaled $14.9 million and $20.0 million. ARCALYST® net product sales during the first nine months of 2010 included $15.2 million of net product sales made during this period and $4.8 million of previously deferred net product sales, as described below under “Results of Operations.”

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 U.S. 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. EYLEATM (aflibercept injection) also known as VEGF Trap-Eye – Ophthalmologic Diseases

EYLEATM (aflibercept injection) 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. We, together with our ex-U.S. collaborator Bayer HealthCare, are evaluating EYLEATM in Phase 3 programs in patients with the neovascular form of age-related macular degeneration (wet AMD), central retinal vein occlusion (CRVO), 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.

The Phase 3 trials in wet AMD, known as VIEW 1 and VIEW 2 (VEGF Trap: Investigation of Efficacy and Safety in Wet age-related macular degeneration), compared EYLEATM and Lucentis® (ranibizumab injection), a registered trademark of Genentech, Inc. Lucentis® is an anti-VEGF agent approved for use and the current standard of care in wet AMD. VIEW 1 was conducted in North America and VIEW 2 was conducted in Europe, Asia Pacific, Japan, and Latin America. The VIEW 1 and VIEW 2 trials both evaluated EYLEATM doses of 0.5 milligrams (mg) and 2.0 mg at dosing intervals of four weeks and 2.0 mg at a dosing interval of eight weeks (following three initial monthly doses), compared with Lucentis® dosed according to its U.S. label, which specifies doses of 0.5 mg administered every four weeks over the first year. As-needed dosing (PRN) with both agents is being evaluated in the second year of the studies, although patients will be dosed no less frequently than every 12 weeks.

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The primary endpoint of these non-inferiority studies was the proportion of patients treated with EYLEATM who maintain visual acuity at the end of one year compared to patients dosed monthly with Lucentis®. Visual acuity is defined as the total number of letters read correctly on the Early Treatment Diabetic Retinopathy Study (ETDRS) chart, a standard research tool for measuring visual acuity. Maintenance of vision is defined as losing fewer than three lines (equivalent to 15 letters) on the ETDRS chart. Secondary endpoints included the mean change from baseline in visual acuity as measured by ETDRS, the proportion of patients who gained at least 15 letters of vision at week 52, and the amount of fluid under the retina.

We and Bayer HealthCare announced week 52 results from the VIEW 1 and VIEW 2 studies in November 2010. In these studies, all regimens of EYLEATM, including EYLEATM dosed every two months, successfully met the primary endpoint of statistical non-inferiority compared to Lucentis® dosed every month.

A generally favorable safety profile was observed for both EYLEATM and Lucentis®. The incidence of ocular treatment emergent adverse events was balanced across all four treatment groups in both studies, with the most frequent events associated with the injection procedure, the underlying disease, and/or the aging process. The most frequent ocular adverse events were conjunctival hemorrhage, macular degeneration, eye pain, retinal hemorrhage, and vitreous floaters. The most frequent serious non-ocular adverse events were typical of those reported in this elderly population who receive intravitreal treatment for wet AMD; the most frequently reported events were falls, pneumonia, myocardial infarction, atrial fibrillation, breast cancer, and acute coronary syndrome. There were no notable differences among the study arms.

Based on these positive results, we submitted a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) in February 2011 for marketing approval of EYLEATM in wet AMD in the U.S. In April 2011, the FDA accepted the BLA for filing and granted our request for Priority Review. In June 2011, the Dermatologic and Ophthalmic Drugs Advisory Committee of the FDA unanimously recommended that the FDA approve our BLA. Also in June 2011, Bayer HealthCare submitted regulatory applications for marketing approval of EYLEATM in wet AMD in the European Union and Japan. In August 2011, we announced that we received notification from the FDA that the agency had extended its target date to complete the priority review of the EYLEATM BLA to November 18, 2011, which is a three month extension from the original Prescription Drug User Fee Act (PDUFA) action date. The extension is a result of the agency classifying our responses to questions regarding the chemistry, manufacturing, and controls (CMC) section of the BLA as a major amendment to the BLA. The new action date provides the agency additional time to review the information submitted.

EYLEATM is also in Phase 3 clinical studies for the treatment of CRVO, another cause of visual impairment. We are leading the COPERNICUS (COntrolled Phase 3 Evaluation of Repeated iNtravitreal administration of VEGF Trap-Eye In Central retinal vein occlusion: Utility and Safety) study, and Bayer HealthCare is leading the GALILEO (General Assessment Limiting InfiLtration of Exudates in central retinal vein Occlusion with VEGF Trap-Eye) study. Patients in both studies receive six monthly intravitreal injections of either EYLEATM at a dose of 2.0 mg or sham control injections. The primary endpoint of both studies is improvement in visual acuity versus baseline after six months of treatment as measured by the ETDRS eye chart. At the end of the initial six months, patients are dosed on a PRN basis for another six months. All patients are eligible for rescue laser treatment.

In December 2010, we and Bayer HealthCare announced that in the COPERNICUS study, EYLEATM demonstrated a statistically significant improvement in visual acuity at six months compared to sham injections, the primary endpoint of the study. In the study, EYLEATM was generally well tolerated. The most common adverse events were those typically associated with intravitreal injections or the underlying disease. Serious ocular adverse events in the EYLEATM group were uncommon (3.5%), consisting of individual reports of corneal abrasion, endophalmitis, retinal vein occlusion, and reduced visual acuity, and were more frequent in the control group (13.5%). The incidence of non-ocular serious adverse events was generally well-balanced between the treatment arms. There were no deaths among the 114 patients treated with EYLEATM and two (2.7%) in the 73 patients treated with sham injections.

In April 2011, we and Bayer HealthCare announced that in the GALILEO study, EYLEATM also demonstrated a statistically significant improvement in visual acuity at six months compared to sham injections, the primary endpoint of the study. In this trial, 60.2% of patients receiving 2.0 mg of EYLEATM monthly gained at least 15 letters of vision from baseline, compared to 22.1% of patients receiving sham injections ($p<0.0001$). Patients receiving 2.0 mg of EYLEATM monthly gained, on average, 18 letters of vision compared to a mean gain of 3.3 letters with sham injections ($p<0.0001$), a secondary endpoint.

As in the COPERNICUS trial, EYLEATM was generally well tolerated in the GALILEO study and the most common adverse events were those typically associated with intravitreal injections or the underlying disease. Serious ocular adverse events in the EYLEATM group were 2.9% and were more frequent in the control group (8.8%). The most frequently reported adverse events overall in the EYLEATM arm were eye pain, conjunctival hemorrhage, and elevated intraocular pressure. The most frequently reported adverse events in the control group were macular edema, eye irritation, and reduced visual acuity. The incidence of non-ocular serious adverse events was generally well-balanced between the treatment arms. The most frequent non-ocular adverse events were headache and nasopharyngitis. There were no deaths in the study.

Based on these positive results, we intend to submit a regulatory application for marketing approval for EYLEATM in CRVO in the U.S. by the end of 2011, and Bayer HealthCare plans to submit regulatory applications in this indication in Europe in 2012.

In the second quarter of 2011, we and Bayer HealthCare initiated Phase 3 studies to evaluate the safety and efficacy of EYLEATM in DME. These clinical trials have three study arms. In the first arm, patients will be treated every month with 2.0 mg of EYLEATM. In the second arm, patients will be treated with 2.0 mg of EYLEATM every two months after an initial phase of monthly injections. In the third arm, the comparator arm, patients will be treated with macular laser photocoagulation. The primary endpoint of the study is mean change in visual acuity from baseline as measured by the ETDRS eye chart. All patients will be followed for three years. We are conducting one of these studies, called VISTA-DME (VEGF Trap-Eye: Investigation of Safety, Treatment effect, and Anatomic outcomes in DME), with study centers in the U.S. and other countries. Bayer HealthCare is conducting the second study, named VIVID-DME (VEGF Trap-Eye In Vision Impairment Due to DME), with study centers in Europe, Japan, and Australia.

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 EYLEATM in patients with CNV of the retina as a result of pathologic myopia. The study, which will enroll approximately 250 patients, has started in Japan and is scheduled to run until June 2013.

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 U.S. of EYLEATM. Under the agreement, we and Bayer HealthCare collaborate on, and share the costs of, the development of EYLEATM through an integrated global plan. Bayer HealthCare will market EYLEATM outside the U.S., where the companies will share equally in profits from any future sales of EYLEATM. Commencing on the first commercial sale of EYLEATM in a major market country outside the U.S., 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 U.S., we retain exclusive commercialization rights to EYLEATM 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 EYLEATM in major market countries outside the U.S. We can also earn up to $135 million in sales milestone payments if total annual sales of EYLEATM outside the U.S. achieve certain specified levels starting at $200 million.

2. ZALTRAP® (aflibercept) also known as VEGF Trap – Oncology

ZALTRAP® (aflibercept) 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. The VELOUR data were presented in June 2011 at the European Society of Medical Oncology World Congress on Gastrointestinal Cancer. In this study, the addition of ZALTRAP® to the FOLFIRI chemotherapy regimen significantly improved both overall survival (HR=0.817; p=0.0032) and progression-free survival (HR=0.758; p=0.00007) compared to FOLFIRI plus placebo. A similar effect was seen with ZALTRAP® therapy whether or not patients had received prior bevacizumab therapy.

In the VELOUR study, grade 3 or 4 adverse events that occurred with a more than two percent greater incidence in the ZALTRAP® arm than in the placebo arm included diarrhea, asthenia/fatigue, stomatitis/ulceration, infections, hypertension, GI/abdominal pains, neutropenia, neutropenic complications and proteinuria. Deaths on study treatment due to adverse events occurred in 2.4 percent of patients in the ZALTRAP® arm and in 1.0 percent of patients in the placebo arm.

Based upon these positive findings, we and Sanofi plan to submit regulatory applications for marketing approval of ZALTRAP® for the treatment of previously-treated mCRC patients to the FDA and the European Medicines Agency (EMA) by the end of 2011.

Another randomized, double-blind Phase 3 trial (VENICE), which is fully enrolled, is evaluating ZALTRAP® as a first-line treatment for hormone-refractory metastatic prostate cancer in combination with docetaxel/prednisone. The VENICE trial is being monitored by an Independent Data Monitoring Committee (IDMC), a body of independent clinical and statistical experts. The IDMCs meet periodically to evaluate data from the trial and may recommend changes in study design or study discontinuation. In July 2011, the study's IDMC met for a scheduled interim analysis and recommended that the trial continue to completion. A final analysis will be conducted when a pre-specified number of events have occurred in this trial, which is anticipated in the first half of 2012.

In addition, a randomized Phase 2 study (AFFIRM) of ZALTRAP® in first-line mCRC in combination with FOLFOX [folinic acid (leucovorin), 5-fluorouracil, and oxaliplatin] is fully enrolled. Initial data from this study are anticipated by the end of 2011.

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 U.S. 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.

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 (PREvention Study against URate-lowering drug-induced Gout Exacerbations), PRE-SURGE 2, and RE-SURGE (REview of Safety Utilizing Rilonacept in Gout Exacerbations).

In June 2010, we announced that results from PRE-SURGE 1, a North America-based double-blind, placebo-controlled study, showed that ARCALYST® prevented gout attacks, as measured by the primary study endpoint of the number of gout flares per patient over the 16 week treatment period.

In addition, all secondary endpoints of the study were positive ($p<0.001$ vs. placebo). Among these endpoints, treatment with ARCALYST® reduced the proportion of patients who experienced two or more flares during the study period by up to 88%. Treatment with ARCALYST® also reduced the proportion of patients who experienced at least one gout flare during the study period by up to 65%.

In February 2011, we reported the results of PRE-SURGE 2 and RE-SURGE. In the PRE-SURGE 2 efficacy study in gout patients initiating allopurinol therapy, which was identical to PRE-SURGE 1 in design and analysis, 248 patients were randomized. ARCALYST® met the primary and all secondary study endpoints. The primary endpoint was the number of gout flares per patient over the 16-week treatment period. Patients who received ARCALYST® at a weekly, self-administered, subcutaneous dose of either 160 mg or 80 mg had a 72% decrease in mean number of gout flares compared to the placebo group ($p<0.0001$). Among secondary endpoints, treatment with ARCALYST® reduced the proportion of patients who experienced two or more flares during the study period by up to 82%. In addition, treatment with ARCALYST® reduced the proportion of patients who experienced at least one gout flare during the study period by up to 63%.

We also announced that in the RE-SURGE study, which evaluated the safety of ARCALYST® versus placebo over 16 weeks, ARCALYST® was generally well tolerated, and the safety profile was consistent with that reported in the PRE-SURGE 1 and PRE-SURGE 2 studies. In the overall gout program, the most frequently reported adverse events were injection site reaction and headache.

In the RE-SURGE study, ARCALYST® also met all secondary endpoints, which evaluated efficacy, over the 16 week treatment period ($p<0.0001$). These included the number of gout flares per patient, the proportion of patients who experienced two or more flares, and the proportion of patients who experienced at least one gout flare during the study period.

Based on the results of the three Phase 3 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 addition, we plan to initiate a long-term safety study in this setting, known as UPSURGE (Understanding long-term safety in a Preventative Study against URate-lowering drug-induced Gout Exacerbations). 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 Phase 2b stage of the MOBILITY study was a 306-patient, dose-ranging, multi-national, randomized, multi-arm, double-blind, placebo-controlled study, that compared five different dose regimens of sarilumab in combination with MTX to placebo plus MTX. The primary endpoint of the study was the proportion of patients achieving at least a 20% improvement in RA symptoms (ACR20) after 12 weeks.

In the Phase 2b stage of the MOBILITY trial, there was a dose response observed in patients receiving sarilumab in combination with MTX. An ACR20 response after 12 weeks was seen in 49.0% of patients receiving the lowest sarilumab dose regimen and 72.0% of patients receiving the highest dose regimen compared to 46.2% of patients receiving placebo and MTX (p=0.02, corrected for multiplicity, for the highest sarilumab dose regimen). The most common adverse events (>5%) reported more frequently in active treatment arms included infections (non-serious), neutropenia, and liver function test abnormalities. The types and frequencies of adverse events were consistent with those previously reported with IL-6 inhibition. The incidence of serious adverse events among the five sarilumab treatment groups and the placebo group was comparable.

Sarilumab also demonstrated significant benefit compared to placebo in secondary endpoints, including ACR 50, ACR 70, and Disease Activity Score (DAS) 28 scores, additional measures of clinical activity used in RA trials.

In July 2011, we and Sanofi announced that in the phase 2b ALIGN trial in ankylosing spondylitis, sarilumab did not demonstrate significant improvements in the signs and symptoms of active AS compared to placebo in patients who had inadequate response to Non-Steroidal Anti-Inflammatory Drugs (NSAIDs). Sarilumab was generally well tolerated. The most common adverse events reported more frequently in active treatment arms included infections and neutropenia.

During the third quarter of 2011, we and Sanofi initiated the Phase 3 stage of the Phase 2/3 MOBILITY study.

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 upregulating 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 May 2010, we announced that in an interim efficacy analysis of a dose-escalating, randomized, double-blind, placebo-controlled, Phase 1 trial in healthy volunteers, REGN727 achieved substantial, dose dependent decreases of LDL cholesterol. Each dosing cohort consisted of six treated and two placebo patients. In July 2010, we presented additional data from this Phase 1 program. At the highest intravenous dose tested, a single dose of REGN727 achieved a greater than 60% maximum mean reduction of LDL cholesterol from baseline that lasted for more than one month. At the highest subcutaneous dose tested, a single dose of REGN727 achieved a greater than 60% maximum mean reduction of LDL cholesterol from baseline that lasted for more than two weeks. In these early trials, REGN727 was generally safe and well tolerated with no trend in drug-related adverse events and no evidence of hepato- or myo-toxicity. Injection site reactions were minimal.

In July 2010, we also presented the results of an interim efficacy analysis of a dose escalating, randomized, double-blind, placebo-controlled Phase 1 trial of subcutaneously delivered REGN727 in hyperlipidemic patients (familial hypercholesterolemia and non-familial hypercholesterolemia) on stable doses of statins whose LDL levels were greater than 100 milligrams per deciliter (mg/dL). At the highest dose tested at that time, in eleven patients, a single dose of REGN727 achieved an approximately 40% maximum mean additional reduction of LDL cholesterol from baseline. No serious adverse events and no dose limiting toxicities were reported.

During 2011, three Phase 2 studies with subcutaneous regimens of REGN727 have been initiated: (1) a randomized, double-blind, multi-dose, placebo controlled, 75-patient trial in patients with heterozygous familial hypercholesterolemia (heFH), (2) a randomized, double-blind, multi-dose, placebo controlled, 90-patient trial in combination with atorvastatin in patients with primary hypercholesterolemia, and (3) a randomized, double-blind, multi-dose, placebo controlled, 180-patient trial in combination with atorvastatin in patients with primary hypercholesterolemia and on stable doses of atorvastatin. The primary endpoint of each Phase 2 study is the change in LDL cholesterol from baseline compared to placebo over the study period. Initial data from these Phase 2 studies will be available by the end of 2011 and the first half of 2012.

REGN727 is being developed in collaboration with Sanofi.

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 a Phase 1b study in patients with atopic dermatitis and a Phase 2 study in eosinophilic asthma. REGN668 is being developed in collaboration with Sanofi.

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. REGN421 is being developed in collaboration with Sanofi.

8. REGN910 (ANG2 Antibody) for oncology

In the fourth quarter of 2010, we initiated a Phase 1 study in an oncology setting of REGN910, an antibody that specifically blocks ANG2. The angiopoietins, which were discovered at Regeneron, are ligands for the endothelial cell receptor Tie2 and are essential for vascular development and angiogenesis. Unlike other family members, ANG2 is strongly upregulated by endothelial cells at sites of angiogenesis and vascular remodeling, including tumors. REGN910 is a fully human monoclonal antibody generated using our VelocImmune® technology, which is being developed for cancer indications. REGN910 is being developed in collaboration with Sanofi.

9. 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, we were informed by the FDA that a case confirmed as avascular necrosis of a joint was seen in another company's anti-NGF program. The FDA believes this case, which follows previously-reported cases of joint replacements in patients on an anti-NGF drug candidate being developed by another pharmaceutical company, provides evidence to suggest a class-effect and has placed REGN475 on clinical hold. The FDA Arthritis Advisory Committee meeting scheduled for September 13, 2011 to discuss possible safety issues related to anti-NGF compounds has been postponed. There are currently no ongoing trials with REGN475 that are either enrolling or treating patients. REGN475 is being developed in collaboration with Sanofi.

10. REGN728

In the fourth quarter of 2010, clinical trials began with REGN728, a fully human monoclonal antibody generated using our VelocImmune® technology, against an undisclosed target. REGN728 is being developed in collaboration with Sanofi.

11. 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 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.

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 first approved product, ARCALYST®, as well as ZALTRAP® and EYLEATM, all of which are in Phase 3 clinical trials. 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. VelociSuiteTM 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.

VelociSuiteTM

VelociSuiteTM 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 VelociSuiteTM 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 U.S. The parties will share profits outside the U.S. 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 U.S. 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 U.S. 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 approximately 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 is also obligated to fund up to $30 million of agreed-upon costs we incur to expand our manufacturing capacity at our Rensselaer, New York facilities.

In 2010, as we scaled up our capacity to conduct antibody discovery activities, Sanofi funded $137.7 million of our preclinical research under the expanded collaboration. The balance between that amount and $160 million, or $22.3 million, has been added to the funding otherwise available to us in 2011-2012 under the amended discovery agreement.

From the collaboration's inception in November 2007 through September 30, 2011, Sanofi has funded a total of $435.3 million of our costs under the discovery agreement and a total of $364.9 million of our development costs under the license agreement, or a total of $800.2 million 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. While our royalties under this agreement could be significant if canakinumab is approved and successfully commercialized for additional disease indications, to date these royalties have been minimal. 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.

National Institutes of Health Grant

In September 2006, we were awarded a five-year grant from the National Institutes of Health (NIH) as part of the NIH's Knockout Mouse Project. The goal of the Knockout Mouse Project is to build a comprehensive and broadly available resource of knockout mice to accelerate the understanding of gene function and human diseases. Under the NIH grant, as amended, $24.6 million has been received or is receivable from the grant's inception as of September 30, 2011 and we are entitled to receive an additional $0.7 million through the remaining term of the grant.

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. Since inception we have not generated any significant sales or profits from the commercialization of ARCALYST® or any of our other product candidates. Before significant revenues from the commercialization of ARCALYST® or our other product candidates 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.

From inception on January 8, 1988 through September 30, 2011, we had a cumulative loss of $1.2 billion, principally related to our research and development activities. 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. We submitted a BLA to the FDA in February 2011 for marketing approval of EYLEATM in wet AMD in the U.S. In April 2011, the FDA accepted the BLA for filing and granted our request for Priority Review. In August 2011, Regeneron announced that we received notification from the FDA that the agency had extended its target date to complete the priority review of our BLA for EYLEATM to November 18, 2011, which is a three month extension from the original PDUFA action date. The extension is a result of the agency classifying our responses to questions regarding the CMC section of the BLA as a major amendment to the BLA. The new action date provides the agency additional time to review the information submitted. In June 2011, Bayer HealthCare submitted regulatory applications for marketing approval of EYLEATM in wet AMD in the European Union and in Japan. We intend to submit a BLA to the FDA by the end of 2011 for marketing approval of EYLEATM in CRVO in the U.S., and Bayer HealthCare is planning to submit regulatory applications for marketing approval of EYLEATM in CRVO in Europe in 2012. We have also submitted a supplemental BLA for marketing approval in the U.S. of ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering therapy. We and Sanofi plan to submit regulatory applications for marketing approval of ZALTRAP® for the treatment of patients with previously treated mCRC to the FDA and the EMA by the end of 2011.

We expect to incur substantial costs to prepare for potential commercialization of these late-stage product candidates and, if one or more of these product candidates receive regulatory approval, to fund the launch of the product(s). Thus, we expect to continue to incur substantial operating losses over at least the next few years related primarily to our research and development and commercialization activities. Also, our research and development activities outside our collaborations, the costs of which are not reimbursed, may expand and require additional resources. Our losses may fluctuate from quarter to quarter and will depend on, among other factors, the scope and progress of our research and development efforts, the progress of our efforts to commercialize our late-stage product candidates, the timing of certain expenses, and the amount of reimbursement that we receive from collaborators. We cannot predict whether or when our late-stage product candidates, including EYLEATM in wet AMD, will receive regulatory approval or, if such approval is received, whether we will be able to successfully commercialize such product(s), or if we do commercialize such product(s), 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 2011 to date were, and plans for the next 12 months are, as follows:

Clinical Program	2011 Events to Date	2011-12 Plans (next 12 months)
EYLEATM	• Submitted a BLA to the U.S. FDA for the treatment of wet AMD • FDA accepted BLA for wet AMD and granted our request for Priority Review • FDA Advisory Committee unanimously recommended FDA approval of BLA for the treatment of wet AMD • FDA extended the target date for a decision on the BLA for the treatment of wet AMD to November 18, 2011 • Bayer HealthCare submitted regulatory applications for marketing approval for EYLEATM for the treatment of wet AMD in the European Union and Japan • Reported positive six-month results in the Phase 3 GALILEO trial in CRVO • Reported positive one-year data from the Phase 3 COPERICUS trial in CRVO • Initiated Phase 3 trials in DME in the U.S. and outside the U.S. • Bayer HealthCare initiated a Phase 3 trial in Asia in CNV of the retina as a result of pathologic myopia	• Report two-year data from VIEW 1 and VIEW 2 trials in wet AMD by the end of 2011 • Report one-year data from GALILEO trial in CRVO by the end of 2011 • Submit a BLA to the FDA for the treatment of CRVO by the end of 2011 • Target date for FDA decision on BLA for the treatment of wet AMD is November 18, 2011
ZALTRAP®	• Presented positive results from the Phase 3 VELOUR trial in previously treated mCRC patients • IDMC reviewed interim results for the Phase 3 VENICE trial in prostate cancer and recommended study continue to completion • Reported results for the VITAL trial in non-small cell lung cancer. ZALTRAP® did not meet primary study endpoint.	• Submit a BLA to the FDA for the treatment of mCRC by the end of 2011 • Report initial results in the Phase 2 AFFIRM trial in first-line mCRC by the end of 2011 • Report final results in the Phase 3 VENICE trial in prostate cancer in the first half of 2012

Clinical Program	2011 Events to Date	2011-12 Plans (next 12 months)
ARCALYST®	• Reported positive results from two Phase 3 studies for the prevention of gout flares (PRE-SURGE 2 and RE-SURGE) • Submitted a supplemental BLA for U.S. regulatory approval for the prevention of gout flares	• Initiate a long-term safety study for the prevention of gout flares (UPSURGE)
Sarilumab (IL-6R Antibody)	• Reported positive Phase 2b data from the MOBILITY trial in rheumatoid arthritis • Reported that the Phase 2b trial in ankylosing spondylitis did not meet its primary endpoint • Initiated the Phase 3 stage of the Phase 2/3 MOBILITY trial	
REGN727 (PCSK9 Antibody)	• Initiated Phase 2 studies for LDL cholesterol reduction	• Report initial data from the Phase 2 program for LDL cholesterol reduction • Initiate Phase 3 program for LDL cholesterol reduction
REGN668 (IL-4R Antibody)	• Initiated Phase 1b study in atopic dermatitis and Phase 2 proof of concept study in eosinophilic asthma	• Initiate Phase 2 program in atopic dermatitis
REGN421 (Dll4 Antibody)	• Continued patient enrollment in Phase 1 program	• Initiate a Phase 1b program in advanced malignancies
REGN910 (ANG2 Antibody)	• Continued patient enrollment in Phase 1 program	
REGN475 (NGF Antibody)	• On clinical hold	
REGN728 (target not disclosed)	• Continued patient enrollment in Phase 1 program	
REGN846 (target not disclosed)	• Continued patient enrollment in Phase 1 program • Sanofi elected not to co-develop REGN846 • Initiated Phase 2a program in atopic dermatitis	

Results of Operations

Three Months Ended September 30, 2011 and 2010

Net Loss

Regeneron reported a net loss of $62.4 million, or $0.68 per share (basic and diluted), for the third quarter of 2011, compared to a net loss of $33.9 million, or $0.41 per share (basic and diluted), for the third quarter of 2010. The increase in our net loss in 2011 was principally due to higher selling, general, and administrative expenses, partly in connection with preparing to commercialize EYLEATM in wet AMD, and higher research and development expenses.

Revenues

Revenues for the three months ended September 30, 2011 and 2010 consist of the following:

(In millions)	2011	2010
Collaboration revenue		
Sanofi	$ 79.8	$ 75.6
Bayer HealthCare	10.1	13.8
Total collaboration revenue	89.9	89.4
Technology licensing revenue	5.9	10.0
Net product sales	5.5	4.9
Contract research and other revenue	1.5	1.7
Total revenue	$ 102.8	$ 106.0

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.

Sanofi Collaboration Revenue	Three months ended September 30,	
(In millions)	2011	2010
ZALTRAP®:		
Regeneron expense reimbursement	$ 2.9	$ 3.9
Regeneron share of ZALTRAP® commercialization expenses	(2.7)	
Recognition of deferred revenue related to up-front payments	2.5	2.5
Total ZALTRAP®	2.7	6.4
Antibody:		
Regeneron expense reimbursement	74.7	66.8
Recognition of deferred revenue related to up-front and other payments	2.0	2.0
Recognition of revenue related to VelociGene® agreement	0.4	0.4
Total antibody	77.1	69.2
Total Sanofi collaboration revenue	$ 79.8	$ 75.6

Sanofi's reimbursement of our ZALTRAP® expenses decreased in the third quarter of 2011 compared to the same quarter in 2010, primarily due to a decrease in internal research 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. Our share of these expenses was $2.7 million in the third quarter of 2011, which reduced our Sanofi collaboration revenue. In connection with recognition of deferred revenue

related to ZALTRAP®, as of September 30, 2011, $25.1 million of the original $105.0 million of up-front payments was deferred and will be recognized as revenue in future periods.

In the third quarter of 2011, Sanofi's reimbursement of our antibody expenses consisted of $39.8 million under the discovery agreement and $34.9 million of development costs under the license agreement, compared to $36.9 million and $29.9 million, respectively, in the third quarter of 2010. The higher reimbursement amounts in the third quarter of 2011, compared to the same quarter in 2010, were due to an increase in our research activities conducted under the discovery agreement and increases in our development activities for antibody candidates under the license agreement.

Recognition of deferred revenue related to Sanofi's $85.0 million up-front payment and other payments was $2.0 million for both three months ended September 30, 2011 and 2010. In connection with the November 2009 amendment of the discovery agreement, Sanofi is funding up to $30 million of agreed-upon costs to expand our manufacturing capacity at our Rensselaer, New York facilities, of which $26.4 million was received or receivable as of September 30, 2011. Revenue related to such funding from Sanofi is deferred and recognized as collaboration revenue prospectively over the performance period applicable to recognition of the original $85.0 million up-front payment. As of September 30, 2011, $76.7 million of the Sanofi up-front and other payments was deferred and will be recognized as revenue in future periods.

In August 2008, we entered into a separate VelociGene® agreement with Sanofi. For both three month periods ended September 30, 2011 and 2010, we recognized $0.4 million in revenue related to this agreement.

Bayer HealthCare Collaboration Revenue

The collaboration revenue we earned from Bayer HealthCare, as detailed below, consisted of cost sharing of Regeneron's global EYLEATM 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 (In millions)	Three months ended September 30, 2011	2010
Cost-sharing of Regeneron EYLEATM development expenses	$ 7.6	$ 11.3
Recognition of deferred revenue related to up-front and other milestone payments	2.5	2.5
Total Bayer HealthCare collaboration revenue	$ 10.1	$ 13.8

Cost-sharing of our global EYLEATM development expenses with Bayer HealthCare decreased in the third quarter of 2011 compared to the same period in 2010. In the third quarter of 2011, we incurred lower clinical development costs primarily in connection with our Phase 3 VIEW 1 trial in wet AMD. In connection with the recognition of deferred revenue related to the $75.0 million up-front payment and $20.0 million milestone payment received in August 2007, as of September 30, 2011, $39.5 million of these 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 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 third quarter of 2011, we recognized $5.9 million of technology licensing revenue related to the Astellas agreement. In the third quarter of 2010, we recognized a total of $10.0 million of technology licensing revenue related to both the Astellas and AstraZeneca agreements. As of September 30, 2011, $157.6 million of technology licensing payments received from Astellas was deferred and will be recognized as revenue in future periods.

Net Product Sales

For the three months ended September 30, 2011 and 2010, we recognized as revenue $5.5 million and $4.9 million, respectively, of ARCALYST® net product sales.

Contract Research and Other Revenue

Contract research and other revenue for the three months ended September 30, 2011 and 2010 included $1.0 million and $1.2 million, respectively, 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.

Expenses

Total operating expenses increased to $161.3 million in the third quarter of 2011 from $138.1 million in the third quarter of 2010. Our average headcount in the third quarter of 2011 increased to 1,646 from 1,317 in the same quarter of 2010, principally as a result of our expanding research and development activities, which were primarily attributable to our antibody collaboration with Sanofi, and 2011 activities in connection with preparing to commercialize EYLEATM in wet AMD.

Operating expenses in the third quarter of 2011 and 2010 included a total of $13.4 million and $8.8 million, respectively, of non-cash compensation expense related to employee stock option and restricted stock awards (Non-cash Compensation Expense), as detailed below:

	For the three months ended September 30, 2011		
Expenses (In millions)	Expenses before inclusion of Non-cash Compensation Expense	Non-cash Compensation Expense	Expenses as Reported
Research and development	$ 119.8	$ 8.1	$ 127.9
Selling, general, and administrative	27.6	5.3	32.9
Cost of goods sold	0.5		0.5
Total operating expenses	$ 147.9	$ 13.4	$ 161.3

	For the three months ended September 30, 2010		
Expenses (In millions)	Expenses before inclusion of Non-cash Compensation Expense	Non-cash Compensation Expense	Expenses as Reported
Research and development	$ 116.7	$ 5.3	$ 122.0
Selling, general, and administrative	12.2	3.5	15.7
Cost of goods sold	0.4		0.4
Total operating expenses	$ 129.3	$ 8.8	$ 138.1

The increase in total Non-cash Compensation Expense in the third quarter of 2011 was primarily attributable to (i) the recognition of higher expense in the third quarter of 2011 in connection with previously granted performance-based stock options that we estimate will vest, (ii) the higher fair market value of our Common Stock on the date of our annual employee option grants made in December 2010 compared to recent prior years, and (iii) the recognition of higher expense related to grants of restricted stock in December 2010.

Research and Development Expenses

Research and development expenses increased to $127.9 million in the third quarter of 2011 from $122.0 million in the same period of 2010. The following table summarizes the major categories of our research and development expenses for the three months ended September 30, 2011 and 2010:

Research and Development Expenses (In millions)	For the three months ended September 30, 2011	2010	Increase (Decrease)
Payroll and benefits (1)	$ 42.2	$ 34.7	$ 7.5
Clinical trial expenses	18.0	23.1	(5.1)
Clinical manufacturing costs (2)	28.4	25.1	3.3
Research and other development costs	13.8	13.8	-
Occupancy and other operating costs	16.3	13.5	2.8
Cost-sharing of Bayer HealthCare EYLEATM development expenses (3)	9.2	11.8	(2.6)
Total research and development expenses	$ 127.9	$ 122.0	$ 5.9

(1) Includes $7.1 million and $4.6 million of Non-cash Compensation Expense for the three months ended September 30, 2011 and 2010, respectively.

(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, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes $1.0 million and $0.7 million of Non-cash Compensation Expense for the three months ended September 30, 2011 and 2010, respectively.

(3) Under our collaboration with Bayer HealthCare, in periods when Bayer HealthCare incurs global EYLEATM development expenses, we also recognize, as additional research and development expense, the portion of Bayer HealthCare's global EYLEATM development expenses that we are obligated to reimburse. Bayer HealthCare provides us with estimated global EYLEATM 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 global EYLEATM development expenses that we are obligated to reimburse is adjusted accordingly.

Payroll and benefits increased principally due to the increase in employee headcount, as described above. Clinical trial expenses decreased due primarily to lower costs related to our Phase 3 clinical development program for ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering therapy, our VIEW 1 trial for EYLEATM in wet AMD, and our clinical development program for REGN475, which is currently on clinical hold. These decreases were partly offset by higher expenses related to our Phase 3 trial for EYLEATM in DME. Clinical manufacturing costs increased primarily due to higher costs related to manufacturing supplies of antibody candidates. Occupancy and other operating costs increased principally in connection with our higher headcount, expanded research and development activities, and expanded leased facilities in Tarrytown, New York. Cost-sharing of Bayer HealthCare's global EYLEATM development expenses decreased primarily due to lower costs in connection with Bayer HealthCare's VIEW 2 trial in wet AMD, partly offset by higher costs in connection with Bayer HealthCare's Phase 3 trial in DME.

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 EYLEATM 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 September 30, 2011	2010	Increase (Decrease)
ARCALYST®	$ 13.7	$ 16.5	$ (2.8)
EYLEATM	31.7	33.2	(1.5)
ZALTRAP®	3.2	2.8	0.4

Sarilumab	3.9	6.0	(2.1)
REGN727	7.6	5.9	1.7
Other antibody candidates in clinical development	19.7	12.5	7.2
Other research programs & unallocated costs	48.1	45.1	3.0
Total research and development expenses	$ 127.9	$ 122.0	$ 5.9

Drug development and approval in the U.S. 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. For example, we, and our collaborators where applicable, continue to explore further development of ARCALYST®, ZALTRAP®, and EYLEATM in different disease indications.

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” under “Risks Related to the Development and Approval of Our Product Candidates,” “Risks Related to Commercialization of Products,” and “Regulatory and Litigation Risks.” 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 will generate material product revenues and net cash inflows. In 2008, we received FDA approval for ARCALYST® for the treatment of CAPS, a group of rare, inherited auto-inflammatory diseases that affect a very small group of people. We currently do not expect to generate material product revenues and net cash inflows from the sale of ARCALYST® for the treatment of CAPS.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased to $32.9 million in the third quarter of 2011 from $15.7 million in the same period of 2010 due primarily to increases in compensation expense and recruitment costs principally in connection with higher headcount in the third quarter of 2011, higher commercialization-related costs, primarily in connection with preparing to commercialize EYLEATM in wet AMD, higher legal expenses in connection with patent-related litigation with Genentech, and an increase in Non-cash Compensation Expense for the reasons previously described above.

Cost of Goods Sold

Cost of goods sold in the third quarter of 2011 and 2010 was $0.5 million and $0.4 million, respectively, and consisted primarily of royalties and other period costs related to ARCALYST® commercial supplies.

Other Income and Expense

Investment income increased to $0.7 million in the third quarter of 2011 from $0.5 million in the same period of 2010, due primarily to higher average balances of cash and marketable securities.

Interest expense increased to $4.1 million in the third quarter of 2011 from $2.2 million in the same period of 2010. Interest expense is primarily attributable to the imputed interest portion of payments to our landlord, commencing in the third quarter of 2009, to lease newly constructed laboratory and office facilities in Tarrytown, New York. In February 2011, we began occupying an additional new building in Tarrytown and, therefore, began recognizing interest expense on the related payments to our landlord.

Nine Months Ended September 30, 2011 and 2010

Net Loss

Regeneron reported a net loss of $168.3 million, or $1.87 per share (basic and diluted), for the first nine months of 2011, compared to a net loss of $89.9 million, or $1.10 per share (basic and diluted) for the first nine months of 2010. The increase in our net loss in 2011 was principally due to higher research and development expenses and higher selling, general, and administrative expenses.

Revenues

Revenues for the nine months ended September 30, 2011 and 2010 consist of the following:

(In millions)	2011	2010
Collaboration revenue		
Sanofi	$ 249.6	$ 229.2
Bayer HealthCare	33.7	40.5
Total collaboration revenue	283.3	269.7
Technology licensing revenue	18.9	30.1
Net product sales	14.9	20.0
Contract research and other revenue	5.7	5.6
Total revenue	$ 322.8	$ 325.4

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.

Sanofi Collaboration Revenue (In millions)	Nine months ended September 30, 2011	2010
ZALTRAP®:		
Regeneron expense reimbursement	$ 14.4	$ 12.6
Regeneron share of ZALTRAP® commercialization expenses	(4.0)	
Recognition of deferred revenue related to up-front payments	7.4	7.4
Total ZALTRAP®	17.8	20.0
Antibody:		
Regeneron expense reimbursement	224.5	202.7
Recognition of deferred revenue related to up-front and other payments	6.1	5.3
Recognition of revenue related to VelociGene® agreement	1.2	1.2
Total antibody	231.8	209.2
Total Sanofi collaboration revenue	$ 249.6	$ 229.2

Sanofi's reimbursement of our ZALTRAP® expenses increased in the first nine months of 2011 compared to the same period in 2010, primarily due to higher costs related to manufacturing ZALTRAP® clinical supplies. 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. Our share of these expenses was $4.0 million in the first nine months of 2011, which reduced our Sanofi collaboration revenue.

In the first nine months of 2011, Sanofi's reimbursement of our antibody expenses consisted of $122.6 million under the discovery agreement and $101.9 million of development costs under the license agreement, compared to $100.3 million and $102.4 million, respectively, in the first nine months of 2010. The higher reimbursement amount under the discovery agreement in the first nine months of 2011, compared to the same period in 2010, was primarily due to an increase in our antibody discovery activities. The slightly lower reimbursement of development costs in the first nine months of 2011, compared to the same period in 2010, was primarily due to a decrease in development activities related to REGN475, which is currently on clinical hold, offset by increases in development activities for other antibody candidates.

Recognition of deferred revenue related to Sanofi's $85.0 million up-front payment and other payments increased in the first nine months of 2011 compared to the same period in 2010. In connection with the November 2009 amendment of the discovery agreement, Sanofi is funding up to $30 million of agreed-upon costs to expand our manufacturing capacity at our Rensselaer, New York facilities, of which $26.4 million was received or receivable as of September 30, 2011. Revenue related to such funding from Sanofi is deferred and recognized as collaboration revenue prospectively over the performance period applicable to recognition of the original $85.0 million up-front payment.

In August 2008, we entered into a separate VelociGene® agreement with Sanofi. For both nine month periods ended September 30, 2011 and 2010, we recognized $1.2 million in revenue related to this agreement.

Bayer HealthCare Collaboration Revenue

The collaboration revenue we earned from Bayer HealthCare, as detailed below, consisted of cost sharing of Regeneron's global EYLEATM 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 (In millions)	Nine months ended September 30, 2011	2010
Cost-sharing of Regeneron EYLEATM development expenses	$ 26.3	$ 33.1
Recognition of deferred revenue related to up-front and other milestone payments	7.4	7.4
Total Bayer HealthCare collaboration revenue	$ 33.7	$ 40.5

Cost-sharing of our global EYLEATM development expenses with Bayer HealthCare decreased in the first nine months of 2011 compared to the same period in 2010. In the first nine months of 2011, we incurred lower clinical development costs primarily in connection with our Phase 3 VIEW 1 trial in wet AMD and our Phase 2 trial in DME, partly offset by higher internal costs in connection with regulatory filings in wet AMD.

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 nine months of 2011 and 2010, we recognized $18.9 million and $30.0 million, respectively, of technology licensing revenue related to these agreements.

Net Product Sales

For the nine months ended September 30, 2011 and 2010, we recognized as revenue $14.9 million and $20.0 million, respectively, of ARCALYST® net product sales. We had limited historical return experience for ARCALYST® beginning with initial sales in 2008 through the end of 2009; therefore, ARCALYST® net product sales were deferred until the right of return no longer existed and rebates could be reasonably estimated. Effective in the first quarter of 2010, we determined that we had accumulated sufficient historical data to reasonably estimate both product returns and rebates of ARCALYST®. As a result, for the nine months ended September 30, 2010, we recognized as revenue $20.0 million of ARCALYST® net product sales, which included $15.2 million of ARCALYST® net product sales made during the period and $4.8 million of previously deferred net product sales.

Contract Research and Other Revenue

Contract research and other revenue for the first nine months of 2011 and 2010 included $3.2 million and $3.5 million, respectively, 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.

Expenses

Total operating expenses increased to $482.6 million in the first nine months of 2011 from $410.1 million for the same period of 2010. Our average headcount in the first nine months of 2011 increased to 1,525 from 1,206 in the same period of 2010 principally as a result of our expanding research and development activities, which were primarily attributable to our antibody collaboration with Sanofi, and 2011 activities in connection with preparing to commercialize EYLEATM in wet AMD.

Operating expenses in the first nine months of 2011 and 2010 included a total of $40.6 million and $26.3 million, respectively, of Non-cash Compensation Expense, as detailed below:

	For the nine months ended September 30, 2011		
Expenses (In millions)	Expenses before inclusion of Non-cash Compensation Expense	Non-cash Compensation Expense	Expenses as Reported
Research and development	$ 376.9	$ 23.6	$ 400.5
Selling, general, and administrative	63.9	17.0	80.9
Cost of goods sold	1.2		1.2
Total operating expenses	$ 442.0	$ 40.6	$ 482.6

	For the nine months ended September 30, 2010		
Expenses (In millions)	Expenses before inclusion of Non-cash Compensation Expense	Non-cash Compensation Expense	Expenses as Reported
Research and development	$ 348.7	$ 15.3	$ 364.0
Selling, general, and administrative	33.6	11.0	44.6
Cost of goods sold	1.5		1.5
Total operating expenses	$ 383.8	$ 26.3	$ 410.1

The increase in total Non-cash Compensation Expense in the first nine months of 2011 was primarily attributable to (i) the recognition of higher expense in the first nine months of 2011 in connection with previously granted performance-based stock options that we estimate will vest, (ii) the higher fair market value of our Common Stock on the date of our annual employee option grants made in December 2010 compared to recent prior years, and (iii) the recognition of higher expense related to grants of restricted stock in December 2010.

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Research and Development Expenses

Research and development expenses increased to $400.5 million in the first nine months of 2011 from $364.0 million for the same period of 2010. The following table summarizes the major categories of our research and development expenses for the nine months ended September 30, 2011 and 2010:

Research and Development Expenses (In millions)	For the nine months ended September 30, 2011	2010	Increase (Decrease)
Payroll and benefits (1)	$ 126.3	$ 94.3	$ 32.0
Clinical trial expenses	60.5	83.8	(23.3)
Clinical manufacturing costs (2)	80.6	72.6	8.0
Research and other development costs	44.9	40.4	4.5
Occupancy and other operating costs	45.3	38.3	7.0
Cost-sharing of Bayer HealthCare EYLEATM development expenses (3)	42.9	34.6	8.3
Total research and development expenses	$ 400.5	$ 364.0	$ 36.5

(1) Includes $20.7 million and $13.1 million of Non-cash Compensation Expense for the nine months ended September 30, 2011 and 2010, respectively.

(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, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes $2.9 million and $2.2 million of Non-cash Compensation Expense for the nine months ended September 30, 2011 and 2010, respectively.

(3) Under our collaboration with Bayer HealthCare, in periods when Bayer HealthCare incurs global EYLEATM development expenses, we also recognize, as additional research and development expense, the portion of Bayer HealthCare's global EYLEATM development expenses that we are obligated to reimburse. Bayer HealthCare provides us with estimated global EYLEATM 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 global EYLEATM development expenses that we are obligated to reimburse is adjusted accordingly.

Payroll and benefits increased principally due to the increase in employee headcount, as described above. Clinical trial expenses decreased due primarily to lower costs related to our Phase 3 clinical development program for ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering therapy, our VIEW 1 trial for EYLEATM in wet AMD, our Phase 2 trial for EYLEATM in DME, and our clinical development program for REGN475, which is currently on clinical hold. Clinical manufacturing costs increased primarily due to higher costs related to manufacturing supplies of antibody candidates and EYLEATM, partly offset by lower costs related to manufacturing clinical supplies of ARCALYST®. Research and other development costs increased primarily due to higher costs associated with our antibody programs and filing our BLA for EYLEATM in wet AMD. Occupancy and other operating costs increased principally in connection with our higher headcount, expanded research and development activities, and expanded leased facilities in Tarrytown, New York. Cost-sharing of Bayer HealthCare's global EYLEATM development expenses increased primarily due to higher costs in connection with Bayer HealthCare's Phase 3 trial in DME, which was initiated in the second quarter of 2011, and costs associated with ex-U.S. regulatory approval filings for EYLEATM in wet AMD.

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 EYLEATM 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 nine months ended September 30, 2011	2010	Increase (Decrease)
ARCALYST®	$ 31.1	$ 48.2	$ (17.1)
EYLEATM	115.4	98.0	17.4
ZALTRAP®	13.6	9.8	3.8
Sarilumab	17.9	20.7	(2.8)
REGN727	24.4	17.1	7.3
Other antibody candidates in clinical development	47.7	51.6	(3.9)
Other research programs & unallocated costs	150.4	118.6	31.8
Total research and development expenses	$ 400.5	$ 364.0	$ 36.5

For the reasons described above under "Research and Development Expenses" for the three months ended September 30, 2011 and 2010, 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. In 2008, we received FDA approval for ARCALYST® for the treatment of CAPS, a group of rare, inherited auto-inflammatory diseases that affect a very small group of people. We currently do not expect to generate material product revenues and net cash inflows from the sale of ARCALYST® for the treatment of CAPS.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased to $80.9 million in the first nine months of 2011 from $44.6 million for the same period of 2010 due primarily to increases in compensation expense and recruitment costs principally in connection with higher headcount in the first nine months of 2011, higher commercialization-related costs, primarily in connection with EYLEATM, higher legal expenses in connection with patent-related litigation with Genentech, and an increase in Non-cash Compensation Expense for the reasons previously described above.

Cost of Goods Sold

Cost of goods sold in the first nine months of 2011 and 2010 was $1.2 million and $1.5 million, respectively, and consisted primarily of royalties and other period costs related to ARCALYST® commercial supplies.

Other Income and Expense

Investment income increased to $2.8 million in the first nine months of 2011 from $1.5 million in the same period of 2010, due primarily to higher average balances of cash and marketable securities.

Interest expense increased to $11.8 million in the first nine months of 2011 from $6.7 million in the same period of 2010. Interest expense is primarily attributable to the imputed interest portion of payments to our landlord, commencing in the third quarter of 2009, to lease newly constructed laboratory and office facilities in Tarrytown, New York. In February 2011, we began occupying an additional new building in Tarrytown and, therefore, began recognizing interest expense on the related payments to our landlord.

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, our past contract manufacturing agreements, our

technology licensing agreements, ARCALYST® product revenue, and investment income.

Nine months ended September 30, 2011 and 2010

At September 30, 2011, we had $511.7 million in cash, cash equivalents, and marketable securities (including $8.2 million of restricted cash and marketable securities) compared with $626.9 million at December 31, 2010 (including $7.5 million of restricted cash and marketable securities). In addition, as described below, in October 2011, we completed an offering of $400 million aggregate principal amount of convertible senior notes.

Cash (Used in) Provided by Operating Activities

Net cash used in operating activities was $91.4 million in the first nine months of 2011 and net cash provided by operating activities was $140.1 million in the first nine months of 2010. Our net losses of $168.3 million in the first nine months of 2011 and $89.9 million in the first nine months of 2010 included $40.6 million and $26.3 million, respectively, of Non-cash Compensation Expense. Our net losses also included depreciation and amortization of $23.2 million and $13.6 million in the first nine months of 2011 and 2010, respectively.

At September 30, 2011, accounts receivable decreased by $14.7 million, compared to end-of-year 2010, primarily due to the receipt of the $10.0 million milestone payment in January 2011 from Bayer HealthCare, which was earned in 2010 in connection with the COPERNICUS study of EYLEATM in CRVO. Prepaid expenses and other assets increased by $6.3 million, compared to end-of-year 2010, primarily due to an increase in capitalized inventories. Our deferred revenue at September 30, 2011 decreased by $32.5 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 received deferred payments under our Sanofi and Bayer HealthCare collaborations. Accounts payable, accrued expenses, and other liabilities increased by $35.3 million at September 30, 2011, compared to end-of-year 2010, due primarily to higher payroll-related liabilities.

At September 30, 2010, accounts receivable increased by $16.7 million, compared to end-of-year 2009, primarily due to a higher receivable balance related to our antibody collaboration with Sanofi. Also, our deferred revenue balances at September 30, 2010 increased by $172.7 million, compared to end-of-year 2009, primarily due to (i) the receipt of the $165.0 million up-front payment from Astellas, as described above, which was deferred and will be recognized ratably over the seven-year period that commenced in mid-2011, (ii) the receipt of the $20.0 million annual payments from AstraZeneca and Astellas in the first half of 2010, which were deferred and recognized ratably over the ensuing year, and (iii) Sanofi's funding of $21.1 million of agreed-upon costs incurred by us during the first nine months of 2010 to expand our manufacturing capacity at our Rensselaer facilities, which was deferred and is being recognized as collaboration revenue prospectively over the related performance period in conjunction with the original $85.0 million up-front payment received from Sanofi. These increases were partially offset by amortization of previously received deferred payments under our Sanofi and Bayer HealthCare collaborations. At September 30, 2010, accounts payable, accrued expenses, and other liabilities increased by $28.0 million, compared to end-of-year 2009, primarily in connection with our expanded levels of activities and expenditures, including higher liabilities for payroll and related costs and clinical trial expenses.

Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities was $162.4 million in the first nine months of 2011, compared with net cash used in investing activities of $82.4 million in the first nine months of 2010. In the first nine months of 2011, sales or maturities of marketable securities exceeded purchases by $209.0 million, whereas in the first nine months of 2010, purchases of marketable securities exceeded sales or maturities by $13.2 million. Capital expenditures in the first nine months of 2011 and 2010 included costs in connection with expanding our manufacturing capacity at our Rensselaer, New York facilities and tenant improvements and related costs in connection with our leased facilities in Tarrytown, New York.

Cash Provided by Financing Activities

Net cash provided by financing activities was $22.8 million in the first nine months of 2011 and $60.5 million in the first nine months of 2010. In the first nine months of 2010, we received $47.5 million from our landlord in connection with tenant improvement costs for our new Tarrytown facilities, which we recognized as additional facility lease obligations since we are deemed to own these facilities in accordance with Financial Accounting Standards Board (FASB) authoritative guidance. In addition, proceeds from issuances of Common Stock in connection with exercises of employee stock options were $24.0 million in the first nine months of 2011 and $13.8 million in the first nine months of 2010.

Fair Value of Marketable Securities

At September 30, 2011 and December 31, 2010, we held marketable securities whose aggregate fair value totaled $304.4 million and $513.9 million, respectively. The composition of our portfolio of marketable securities on these dates was as follows:

Investment type	September 30, 2011 Fair Value	Percent	December 31, 2010 Fair Value	Percent
Unrestricted				
U.S. government obligations	$ 241.5	79%	$ 434.4	85%
U.S. government guaranteed corporate bonds	36.8	12%	64.0	13%
Municipal bonds	14.7	5%	1.6	
Equity securities	3.1	1%	3.6	1%
U.S. government guaranteed collateralized mortgage obligations	1.0	1%	2.1	
Mortgage-backed securities	0.1		1.1	
Total unrestricted marketable securities	297.2	98%	506.8	99%
Restricted				
U.S. government obligations	7.2	2%	7.1	1%
Total marketable securities	$ 304.4	100%	$ 513.9	100%

In addition, at September 30, 2011 and December 31, 2010, we had $207.3 million and $113.0 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 $45.9 million and $67.4 million for the first nine months of 2011 and 2010, respectively. In February 2010, we received $47.5 million from our landlord in connection with tenant improvement costs in Tarrytown. In addition, Sanofi has funded $3.0 million and $21.1 million, respectively, of agreed-upon capital expenditures incurred by us during the first nine months of 2011 and 2010 to expand our manufacturing capacity at our Rensselaer facilities, which was either received or receivable at September 30, 2011 and 2010.

We expect to incur capital expenditures of approximately $10 to $20 million during the remainder of 2011 primarily in connection with tenant improvements at our leased Tarrytown facilities, capital improvements at our Rensselaer, New York manufacturing facilities, and purchases of equipment. We expect to be reimbursed for a portion of these capital expenditures for our Rensselaer facilities by Sanofi, with the remaining amount to be funded by our existing capital resources.

Offering of Convertible Senior Notes

On October 17, 2011, we announced an offering of $400 million aggregate principal amount of 1.875% convertible senior notes due October 1, 2016. The offering closed on October 21, 2011. The initial purchaser of the notes has a 13-day option to purchase up to an additional $60 million aggregate principal amount of notes on the same terms and conditions. The notes were offered by the initial purchaser only to qualified

institutional buyers pursuant to Rule 144A under the Securities Act of 1933.

The notes will pay interest semi-annually on April 1 and October 1 at an annual rate of 1.875%, and will mature on October 1, 2016, unless earlier converted or repurchased. The notes will be convertible, subject to certain conditions, into cash, shares of our Common Stock, or a combination of cash and shares of Common Stock, at our option. The initial conversion rate for the notes will be 11.9021 shares of Common Stock (subject to adjustment in certain circumstances) per $1,000 principal amount of the notes, which is equal to an initial conversion price of approximately $84.02 per share.

In connection with the offering of the notes, we entered into convertible note hedge and warrant transactions with multiple counterparties, including an affiliate of the initial purchaser. The convertible note hedge transactions cover, subject to customary anti-dilution adjustments, the number of shares of our Common Stock that initially underlie the notes, and are intended to reduce the dilutive impact of the conversion feature of the notes. The warrant transactions will have an initial strike price of approximately $103.41 per share, and may be settled in cash or shares of our Common Stock, at our option.

The net proceeds from the notes offering were approximately $391.3 million after deducting the initial purchaser's discount and estimated offering expenses (and will be approximately $450.1 million if the initial purchaser exercises in full its option to purchase additional notes). In addition, the cost of the initial convertible note hedge, after taking into account the proceeds received by us from the warrant transactions, was $23.7 million. If the initial purchaser exercises its option to purchase additional notes, we may use net proceeds from the sale of the additional notes to enter into additional convertible note hedge and warrant transactions. We intend to use the remaining net proceeds for general corporate purposes.

Funding Requirements

We expect to continue to incur substantial funding requirements for research and development activities (including preclinical and clinical testing). As described above, expenses that we incur in connection with our ZALTRAP® and antibodies collaborations are, generally, fully 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 EYLEATM collaboration. After taking into account anticipated reimbursements from our collaborators, we currently estimate that approximately 40-50% of our funding requirements for 2011 will be directed toward technology development, basic research and early preclinical activities, and the preclinical and clinical development of our product candidates (principally, for ARCALYST® and EYLEATM). For 2011, we also currently estimate that approximately 10-15% of our funding requirements will be directed toward the planned commercialization of our late-stage product candidates; approximately 20-25% 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.

The amount we need to fund operations will depend on various factors, including the potential regulatory approval and commercialization of our product candidates and the timing thereof, the status of competitive products, the success of our research and development programs, the potential future need to expand our professional and support staff and facilities, the status of patents and other intellectual property rights (and 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 our late-stage product candidates receive regulatory approval, the market potential for such 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 ARCALYST® for the treatment of CAPS. In the future, if we are able to successfully develop, market, and sell 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.

We believe that our existing capital resources, together with the net proceeds of our offering of convertible senior notes, as described above, and funding we are entitled to receive under our collaboration agreements, will enable us to meet operating needs for at least the next several years. However, this is a forward-looking statement based on our current operating plan, and there may be a change in projected revenues or expenses that would lead to our capital being consumed significantly before such time. For example, in connection with preparing to commercialize and launch potential products that are not licensed to a third party, we could incur substantial pre-marketing and commercialization expenses that could lead us to consume our cash at a faster rate. If there is insufficient capital to fund all of our planned operations and activities, we anticipate that we would (i) seek sources of additional capital through collaborative arrangements and/or additional public or private financing, including debt and equity financing and/or (ii) prioritize available capital to fund selected preclinical and clinical development programs and/or preparations for the potential commercialization of our late-stage product candidates, or license selected products.

Other than letters of credit totaling $4.2 million, 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 September 30, 2011, we had no other established banking arrangements through which we could obtain short-term financing or a line of credit. In October 2011, we announced our offering of convertible senior notes, as described above. 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 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.

Future Impact of Recently Issued Accounting Standards

In December 2010, the FASB provided authoritative guidance on how pharmaceutical manufacturers should recognize and classify in their income statement annual fees mandated by the Patient Protection and Affordable Care Act (PPACA) as amended by the Health Care and Education Reconciliation Act. This guidance became effective for calendar years beginning after December 31, 2010. The adoption of this guidance did not have an impact on our financial statements as the fee does not currently apply to us. Our one marketed product, ARCALYST® for the treatment of CAPS, has been approved as an orphan drug and orphan drugs are not subject to this annual fee.

In June 2011, the FASB amended its authoritative guidance on the presentation of comprehensive income. Under the amendment, an entity will have the option to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. This amendment, therefore, eliminates the currently available option to present the components of other comprehensive income as part of the statement of changes in stockholders' equity. The amendment does 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 will adopt this amended guidance for the fiscal year beginning January 1, 2012. As this guidance relates to presentation only, the adoption of this guidance will 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 $1.7 million and $0.4 million decrease in the fair value of our unrestricted investment portfolio at September 30, 2011 and 2010, 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 September 30, 2011 compared to the same period of 2010.

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. We recognized an other-than-temporary impairment charge related to a marketable security of $0.1 million in the first nine months of 2010. During the first nine months of 2011, we did not recognize any other-than-temporary impairment charges.

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 September 30, 2011 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.

As previously reported, on November 19, 2010, we filed a complaint against Genentech in the U.S. District Court for the Southern District of New York seeking a declaratory judgment that no activities relating to our VEGF Trap (aflibercept) infringe any valid claim of certain Genentech patents referred to as the Davis-Smyth patents. On January 12, 2011, Genentech filed a motion to dismiss the complaint, arguing that the lawsuit was premature and thus the Court lacked subject matter jurisdiction. Upon our submission to the FDA of a BLA for EYLEATM (aflibercept injection) for the treatment of wet AMD, we filed a second complaint against Genentech in the same court seeking the same declaratory relief. On April 7, 2011, we and Genentech entered into a Joint Stipulation, which was approved and executed by the Court on April 11, 2011. Pursuant to the Joint Stipulation, we voluntarily dismissed our original complaint in favor of proceeding with our second complaint, and Genentech agreed that it would not seek to transfer the case to another judicial district or move to dismiss the second complaint for lack of subject matter jurisdiction or otherwise under Rule 12(b) of the Federal Rules of Civil Procedure. On April 25, 2011, Genentech filed an answer to the second complaint, denying that we are entitled to the declaratory relief being sought by us, and asserting counterclaims that our prior or planned activities relating to VEGF Trap have infringed or will infringe one or more claims of the Davis-Smyth patents. In its answer, Genentech requests a judgment against us for damages, including for willful infringement, and other relief as the Court deems appropriate. On May 11, 2011, Genentech filed an amended answer and counterclaim, again denying that we are entitled to the declaratory relief being sought by us, and asserting 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. In its amended answer and counterclaim, Genentech requests a judgment against us for damages, including for willful infringement, and other relief as the Court deems appropriate. On May 25, 2011, we replied to Genentech's amended answer and counterclaim, denying Genentech's counterclaims, and denying that any of our prior or planned activities relating to VEGF Trap infringe any valid claim of the Davis-Smyth patents. We believe Genentech's counterclaims are without merit and intend to continue to defend against them vigorously.

We have initiated patent-related actions against Genentech in Germany, the United Kingdom, and Italy, and may initiate other actions in other countries outside the U.S.

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, operating results, financial condition, and cash flows. 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 operations. 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 had a history of operating losses and we may never achieve profitability. If we continue to incur operating losses, we may be unable to continue our operations.

From inception on January 8, 1988 through September 30, 2011, we had a cumulative loss of $1.2 billion. If we continue to incur operating losses and fail to become a profitable company, we may be unable to continue our operations. In the absence of substantial revenue from the sale of products or 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 and prepare for possible commercialization of our product candidates.

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 to prepare for potential commercialization of our late-stage product candidates and, if one or more of those product candidates receive(s) regulatory approval, to fund the launch of those product(s). We believe our existing capital resources, together with the net proceeds of our October 2011 offering of convertible senior notes and funding we are entitled to receive under our collaboration agreements, will enable us to meet anticipated operating needs for at least the next several years; however, one or more of our collaboration agreements may terminate, our projected revenue may decrease or be delayed, or our expenses may increase, which could result in our capital being consumed significantly before that time. Our expenses may increase for many reasons, including expenses in connection with the potential commercial launch of our late-stage product candidates, manufacturing scale-up, expenses related to clinical trials testing ARCALYST®, EYLEATM, or REGN846, 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 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 even 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 raise sufficient funds to complete the development of our product candidates and also to successfully commercialize our late-stage product candidates if they obtain regulatory approval, we may face delay, reduction, or elimination of our research and development or preclinical or clinical programs. Even if we obtain regulatory approval for our product candidates, they may never be successfully launched or become profitable, in which case our business, financial condition, or results of operations may be materially harmed.

The value of our investment portfolio, which includes cash, cash equivalents, and marketable securities, is influenced by varying economic and market conditions. A decrease in the value of an asset in our investment portfolio or a default by the issuer may result in our inability to recover the principal we invested and/or a recognition of a loss charged against income.

As of September 30, 2011, our cash, cash equivalents, and marketable securities totaled $511.7 million (including $8.2 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 $304.4 million at September 30, 2011, 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

We believe that a significant portion of the value attributed to our company by investors is based on the commercial potential of EYLEATM for the treatment of wet AMD and other ophthalmologic diseases, which has not yet been approved by the FDA or by regulatory authorities in countries outside the U.S. The FDA recently extended its target action date for the EYLEATM BLA by three months to November 18, 2011. If there are additional material delays in obtaining marketing approval for EYLEATM, or such approval is not obtained in the U.S. or in countries outside the U.S., our business, results of operations, and financial condition will be materially harmed.

The FDA has substantial discretion in deciding whether or not EYLEATM should be granted approval in the U.S. based on the benefits and risks of EYLEATM in treating the particular ophthalmologic diseases in which it is being studied in clinical trials. In February 2011, we submitted a BLA for EYLEATM for the treatment of wet AMD to the FDA. In April 2011, the FDA accepted the BLA for filing and granted our request for Priority Review. Under Priority Review, the target date for an FDA decision on the BLA was August 20, 2011. On August 16, 2011, FDA notified us that it had extended its target date to complete the priority review of the EYLEATM BLA for the treatment of wet AMD to November 18, 2011, which is a three month extension from the original action date. The extension is a result of the agency classifying responses to questions regarding the CMC section of the BLA as a major amendment to the BLA. The new action date gives the agency additional time to review the additional information. However, the FDA is not under any legal obligation to complete its review of the BLA or to render a decision within this extended timeframe. It is not unusual for the FDA’s review of and/or rendering a decision with respect to a BLA that has been granted Priority Review to extend the action date. For instance, the FDA may request additional clinical or other data or information, including by issuing a complete response letter which may require that we submit additional clinical or other data or impose other conditions that must be met in order to secure final approval of our BLA. Even if such data and information are submitted, the FDA may ultimately decide that the BLA does not satisfy the criteria for approval. The granting of Priority Review designation for our BLA does not change the standards for approval and does not ensure that EYLEATM for the treatment of wet AMD will be approved by November 18, 2011 or ever. In June 2011, the Dermatologic and Ophthalmic Drugs Advisory Committee of the FDA voted unanimously to recommend that the FDA approve EYLEATM for the treatment of wet AMD at a dose of 2 mg every eight weeks following three initial doses given every four weeks. The FDA will consider the committee's recommendation in its review of our BLA, but it is not bound by the committee's recommendation and the FDA may not follow the committee's recommendation.

Whether EYLEATM is approved by the FDA for the treatment of wet AMD, 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 EYLEATM demonstrates that it is safe and effective as a treatment for wet AMD;
- whether or not the FDA is satisfied that the manufacturing facilities, processes, and controls for EYLEATM are adequate, that the labeling is satisfactory, and that plans for post-marketing studies, safety monitoring, and risk evaluation and management are sufficient;
- whether or not FDA is satisfied with our responses to its inquiries in connection with the three month extension of the action date on the EYLEATM BLA for the treatment of wet AMD, the timing and nature of additional or follow-up comments and questions, or those of any advisers to the FDA if the FDA seeks external advice, regarding our BLA and the FDA's satisfaction with our responses to its inquiries, the time required to respond to any such additional or follow-up comments and questions, and to obtain final labeling, and any other or additional delays that may be associated with the BLA review process in addition to the three month delay already incurred.

In June 2011, Bayer HealthCare submitted regulatory applications for marketing approval of ELYEATM in wet AMD in the European Union and Japan. Analogous regulatory authorities in these and other countries outside the U.S. have similar discretion to the FDA as to approval of EYLEATM in those countries.

If we experience material delays in obtaining marketing approval for EYLEATM for wet AMD, we will not receive product revenues during the delay, which would negatively affect our business, results of operations, financial condition, and cash flow. Such delays may also increase the challenge of competitive products as doctors and patients continue to use existing therapies. If we do not obtain approval to market EYLEATM for wet AMD in the United States, our business, results of operations, financial condition, and cash flows will be materially harmed. Similarly, but independently, if Bayer HealthCare does not obtain approval to market EYLEATM in the European Union or Japan, or if there are material delays in obtaining such approvals, our business, results of operations, financial condition, and cash flow will be harmed.

If we do not obtain regulatory approval for our product candidates, 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 product candidates, including ARCALYST® for the treatment of diseases other than CAPS, EYLEATM for the treatment of ophthalmologic diseases, 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. As with our BLA for EYLEATM for the treatment of wet AMD, our other product candidates, including ZALTRAP® for previously treated mCRC, EYLEATM 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, results of operations, and prospects will be materially harmed.

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

In the U.S., 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. Except for FDA approval of ARCALYST®, and the EMA approval of rilonacept, for the treatment of CAPS, none of our product candidates has ever received regulatory approval to be marketed and sold in the U.S. or any other country. We may never receive regulatory approval for any of our current or future product candidates.

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, financial condition, and results of operations may be materially harmed.

In addition to the FDA and other regulatory agency regulations in the U.S., 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 U.S., 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 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 may be delayed or become unobtainable.

As described above, we must conduct extensive testing of our product candidates 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, financial condition, results of operations, and prospects 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 ZALTRAP® and EYLEATM 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 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 previously treated mCRC, and that based upon these positive results, we and Sanofi plan to submit regulatory applications for marketing approval to the FDA and EMA by the end of 2011. However, the expected timing for this submission may not be met and even if submitted such applications may not be accepted for filing or ultimately approved. ZALTRAP® is also in a Phase 3 clinical trial in combination with a standard chemotherapy regimen for the treatment of first-line androgen independent prostate cancer. We do not have proof of concept data from early-stage, double-blind, controlled clinical trials that ZALTRAP® will be safe or effective in this cancer setting. In March 2010, Genentech announced that a Phase 3 trial of its VEGF antagonist, Avastin® (Bevacizumab Injection), in combination with chemotherapy in men with prostate cancer, did not meet its primary endpoint. This trial had a very similar design to our ongoing Phase 3 trial of ZALTRAP® in prostate cancer.

We are testing EYLEATM in Phase 3 trials for the treatment of wet AMD, the treatment of CRVO, and the treatment of DME. As described above, in February 2011, we submitted a BLA to the FDA for marketing approval of EYLEATM in wet AMD in the U.S. In April 2011, the FDA accepted the BLA for filing and granted our request for Priority Review. On August 16, 2011, FDA notified us that it had extended its target date to complete the priority review of the EYLEATM BLA for the treatment of wet AMD to November 18, 2011, which is a three month extension from the original action date. Although we reported positive Phase 3 trial results with EYLEATM in wet AMD after one year of treatment, the Phase 3 trials will continue for an additional year and there is a risk that the results from the second year of the studies could differ from the previously reported results; such difference could delay or preclude regulatory approval or, if regulatory approval has been granted, result in the revocation of such approval.

We also reported positive Phase 3 trial results with EYLEATM in CRVO after six months of treatment and, based on these results, intend to submit a regulatory application to the FDA for marketing approval in the U.S. of EYLEATM in CRVO by the end of 2011. However, these trials are not all completed, and there is a risk that one-year results could differ from six-month results, and such final results could delay or preclude regulatory approval or, if regulatory approval has been granted, result in the revocation of such approval. There can be no assurance that we will meet our expected timing for this submission, the submission will be accepted for filing, or if or when we will receive regulatory approval for EYLEATM in CRVO.

We also reported positive results of a Phase 2 trial of EYLEATM 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 EYLEATM 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. However, the expected timing may not be met, the application may not be accepted for filing, 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. For example, 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® (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.

Many of our clinical trials are conducted under the oversight of 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 metastic 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 early stage 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 early stage 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 have occurred, and may continue to occur, in connection with the use of ARCALYST® for the treatment of CAPS and in clinical trials of some of our product candidates, and may also occur with the more widespread use of ZALTRAP®, EYLEATM, and/or ARCALYST® for the prevention of gout flares if they receive regulatory approval, which could cause our regulatory approval(s) to be revoked or otherwise negatively affected or lead to delay or discontinuation of development of our product candidates 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. It is possible that as we test our drug candidates 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 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 certain types of cancer and our EYLEATM candidate is being studied in diseases of the eye. There are many potential safety concerns associated with significant blockade of VEGF that may limit our ability to successfully develop ZALTRAP® and EYLEATM 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 EYLEATM, which can cause injury to the eye and other complications. These and other complications or side effects could harm the development and/or commercialization of ZALTRAP® for the treatment of cancer or EYLEATM for the treatment of diseases of the eye.

As more patients begin to use ARCALYST® if it receives regulatory approval for the prevention of gout flares in patients initiating uric acid-lowering therapy, and to the extent it is tested 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, we were informed by the FDA that a case confirmed as avascular necrosis of a joint was seen in another company's anti-NGF program. The FDA believes this case, which follows previously-reported cases of joint replacements in patients on an anti-NGF drug candidate being developed by another pharmaceutical company, provides evidence to suggest a class-effect and placed REGN475 on clinical hold. The FDA Arthritis Advisory Committee scheduled for September 13, 2011 to discuss possible safety issues related to anti-NGF compounds has been postponed. There are currently no ongoing trials with REGN475 that are either enrolling or treating patients.

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

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

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

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

Risks Related to Intellectual Property and Market Exclusivity

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

Our business requires using sensitive and proprietary technology and other information that we protect as trade secrets. We seek to prevent improper disclosure of these trade secrets through confidentiality agreements. If our trade secrets are improperly disclosed, by our own employees, our collaborators or otherwise, it would help our competitors and adversely affect our business. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of biotechnology companies, including our company, involves complex legal and factual questions and, therefore, enforceability cannot be predicted with certainty. Our patents may be challenged, invalidated, or circumvented. Patent applications filed outside the U.S. 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 U.S. 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 U.S. and will be costly to defend. We have pending patent applications in the U.S. 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 EYLEATM infringe any valid claim in these patents or patent applications. As described above under Part II, Item 1 (“Legal Proceedings”), in November 2010, we commenced a lawsuit against Genentech in the U.S. District Court for the Southern District of New York, seeking a declaratory judgment that no activities relating to VEGF Trap infringe any valid claim of certain Genentech patents referred to as the Davis-Smyth patents. In April 2011, we and Genentech entered into a Joint Stipulation whereby Genentech agreed that it would not seek to transfer the case to another judicial district or move to dismiss the case for lack of subject matter jurisdiction. On April 25, 2011, Genentech filed an answer to our complaint, denying that we are entitled to the declaratory relief being sought by us, and asserting counterclaims that our prior or planned activities relating to VEGF Trap have infringed or will infringe one or more claims of the Davis-Smyth patents. In its answer, Genentech requests a judgment against us for damages, including for willful infringement, and other relief as the Court deems appropriate. On May 11, 2011, Genentech filed an amended answer and counterclaim, again denying that we are entitled to the declaratory relief being sought by us, and asserting counterclaims that our prior or planned activities relating to our VEGF Trap have infringed or will infringe claims of four of the five Davis-Smyth patents. In its amended answer and counterclaim, Genentech requests a judgment against us for damages, including for willful infringement, and other relief as the Court deems appropriate. On May 25, 2011, we replied to Genentech's amended answer and counterclaim, denying Genentech's counterclaims, and denying that any of our prior or planned activities relating to VEGF Trap infringe any valid claim of the Davis-Smyth patents. We believe Genentech's counterclaims are without merit and intend to continue to defend against them vigorously. However, it is possible that there could be an adverse determination or judgment in this litigation that would materially harm our business by requiring us to seek a license, which may not be available, or precluding the manufacture, further development, or sale of ZALTRAP® or EYLEATM, or resulting in a damage award. In addition, irrespective of the outcome of this litigation, we have incurred and will likely continue to incur significant costs and expenses associated with this matter, which has negatively affected, and will likely continue to negatively affect, our results of operations. We have initiated patent-related actions against Genentech in Germany, the United Kingdom, and Italy, and may initiate other actions in other countries outside the U.S., 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.

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 EYLEATM 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 U.S.

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 EYLEATM 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, financial condition, and results of operations. 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 U.S. 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 U.S 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 U.S. 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 PPACA, enacted in 2010, there is now a new, abbreviated path in the U.S. 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 U.S. 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 U.S. 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 have and rely on limited internal and contracted manufacturing and supply chain capacity, which could result in our being unable to successfully commercialize our product candidates if they receive regulatory approval and also to continue to develop our clinical candidates.

Our manufacturing facility would be inadequate to produce the active pharmaceutical ingredients of (a) EYLEATM, ZALTRAP®, and ARCALYST® for the treatment of gout flares 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, financial condition, results of operations, and prospects 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 late-stage product candidates 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 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 EYLEATM, ZALTRAP®, and ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering treatment if they receive regulatory approval, and could also delay or require us to discontinue one or more of our clinical development programs. As a result, our business, financial condition, and results of operations 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®, EYLEATM, 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 the launch of our late-stage product candidates, 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 performing fill/finish services or other steps in our manufacture and supply chain.

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 and of 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 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 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 fill/finish 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 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 of our product candidates, including EYLEATM and 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® 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 to manufacture and supply commercial quantities of EYLEATM, ZALTRAP®, and ARCALYST® for the prevention of gout flares 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 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®, EYLEATM, 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. 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, and cause us to lose revenue from any marketed products, which could be seriously detrimental to our business, financial condition, and prospects.

Risks Related to Commercialization of Products

Even if we receive regulatory approval to market EYLEATM or our other late-stage product candidates, we may be unsuccessful in commercializing them, which would materially delay or prevent our achieving 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 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. Even if we obtain regulatory approval for our product candidates, 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, results of operations, and financial condition would be severely harmed.

In particular, we cannot be sure that EYLEATM for the treatment of wet AMD will be commercially successful in the pharmaceutical market even if we obtain marketing approval for EYLEATM for such indication in a timely manner. 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 initial commercial success of EYLEATM for the treatment of wet AMD if it is approved for marketing will depend on many factors, including the following:

- the effectiveness of our and Bayer HealthCare's commercial strategies for the launch and marketing of EYLEATM in and outside the U.S., 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 EYLEATM with third parties who perform fill/finish or other steps in the manufacture of EYLEATM 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 EYLEATM;
- our ability to effectively communicate to the marketplace the benefits of the dosing regimen of EYLEATM of every 2 months as compared to the monthly dosing regimen of Lucentis®, and the willingness of retinal specialists and patients to switch from Lucentis® or off-label use of Avastin® to EYLEATM 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 payors, including Medicare and Medicaid in the U.S. and other government and private payors in the U.S. and foreign jurisdictions; and
- the effect of new health care legislation currently being implemented in the United States.

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

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, even if our late-stage product candidates receive regulatory approval we will be unable to successfully launch and commercialize those products in those markets, which would materially harm our business, operating results, and financial condition.

We are selling ARCALYST® ourselves in the U.S. for the treatment of CAPS, primarily through third-party service providers. We are establishing our own sales, marketing, and distribution organization in anticipation of receiving regulatory approval to market and sell EYLEATM in the U.S. for the treatment of wet AMD, and in anticipation of filing for and receiving regulatory approval to market and sell EYLEATM in the U.S. for the treatment of CRVO. However, even if we can fully establish this organization in a timely fashion, we may be unsuccessful in achieving a successful launch and commercialization of EYLEATM in the U.S., which would materially harm our business, operating results, financial condition, and prospects.

We will have to rely on a third party or devote significant resources to develop our own sales, marketing, and distribution capabilities for ARCALYST® for patients with gout initiating uric acid-lowering drug therapy if it receives regulatory approval. 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 receives marketing approval, we will not be able to successfully launch and commercialize this product, which would also materially harm our business, operating results, financial condition, and prospects.

We have no 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. In building a field force in anticipation of the possible approval and launch in the U.S. of EYLEATM in wet AMD and other ophthalmologic indications for which it is currently in Phase 3 clinical trials, we may be unable to successfully recruit and retain within the required time frame an adequate number of qualified sales representatives. To the extent we determine to utilize third parties to provide sales, marketing, or distribution capabilities for ARCALYST® for the prevention of gout flares or any of our other 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 U.S. EYLEATM, ARCALYST® for the prevention of gout flares, or any of our other product candidates if they receive regulatory approval in the U.S. 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 U.S. of EYLEATM or ARCALYST® for the prevention of gout flares. Ultimately neither we nor our collaborators may be successful in commercializing EYLEATM, ZALTRAP®, ARCALYST® for the prevention of gout flares, 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 U.S. Under the terms of our license and collaboration agreement with Bayer HealthCare, we will rely on Bayer HealthCare for sales, marketing, and distribution of EYLEATM in countries outside the U.S. should it be approved for marketing in such countries.

Even if our product candidates are approved for marketing, their commercial success 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 pharmaceutical, biotechnology, 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 product commercialization, 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 and Company, 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 Pharmaceuticals, Inc. (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 certain cancers, 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 branch retinal vein occlusion (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. 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 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. Even if our BLA for EYLEATM for the treatment of wet AMD is approved, it may be difficult for EYLEATM 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 recently 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 EYLEATM 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 EYLEATM if it is approved 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 Ltd. (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 U.S. and Europe for Ilaris®, a fully human anti-interleukin-IL1ß 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 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. 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 U.S. 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, 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.

Currently, inexpensive, oral therapies such as analgesics and other 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 early-stage clinical candidates in development are all fully human monoclonal antibodies, which were generated using our VelocImmune® technology. Our antibody generation technologies and early-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. We believe that several companies, including Amgen and Pfizer, 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 our late-stage product candidates will depend on obtaining coverage and reimbursement for use of these products from third-party payers, including Medicare and Medicaid in the U.S., 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, 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 U.S. 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 U.S. 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 the Centers for Medicare and Medicaid Services (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 EYLEATM for the treatment of wet AMD and other eye diseases, ZALTRAP® for oncology indications, and ARCALYST® for the prevention of gout flares will likely be too expensive for most patients to afford without health insurance coverage, if these products are approved for marketing but are unable to obtain adequate coverage and reimbursement by third-party payers, including Medicare and Medicaid in the U.S., our ability to successfully commercialize these products would be materially adversely impacted. Third-party payers, including Medicare and Medicaid in the U.S., 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, 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 achieve 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 product, ARCALYST® for the treatment of CAPS, or EYLEATM, ZALTRAP®, or ARCALYST® for the prevention of gout flares 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 fraud and abuse 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.

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, such as shareholder approval of executive compensation (so-called "say on pay") and proxy access. On January 25, 2011, the SEC adopted final rules concerning "say on pay". 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.

In future years, if we are unable to conclude that our internal control over financial reporting is effective, the market value of our Common Stock could be adversely affected.

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring public companies to include a report of management on the Company's internal control over financial reporting in their annual reports on Form 10-K that contains an assessment by management of the effectiveness of our internal control over financial reporting. In addition, the independent registered public accounting firm auditing our financial statements must attest to and report on the effectiveness of our internal control over financial reporting. Our independent registered public accounting firm provided us with an unqualified report as to the effectiveness of our internal control over financial reporting as of December 31, 2010, which report is included in our Annual Report on Form 10-K for the fiscal year ended on that date. However, management or our independent registered public accounting firm may not be able to provide such an unqualified report as of future year-ends. In this event, investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the market value of our Common Stock. In addition, if it is determined that deficiencies in the design or operation of internal controls exist and that they are reasonably likely to adversely affect our ability to record, process, summarize, and report financial information, we would likely incur additional costs to remediate these deficiencies and the costs of such remediation could be material.

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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 REGN727, sarilumab, REGN668, REGN421, REGN910, REGN475, and REGN728, we rely on Sanofi to lead much of the clinical development efforts and assist with obtaining regulatory approval, particularly outside the U.S. 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. If Sanofi terminates the antibody collaboration or fails to comply with its payment obligations thereunder, our business, financial condition, results of operations and prospects 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 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 U.S., 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 cancer indications 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 EYLEATM is terminated, or Bayer HealthCare materially breaches its obligations thereunder, our business operations and financial condition, and our ability to continue to develop EYLEATM and commercialize EYLEATM outside the U.S. 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 U.S., of EYLEATM. 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 EYLEATM development program. As the EYLEATM program continues, we will continue to rely on Bayer HealthCare to assist with funding the EYLEATM development program, continue to lead the development of EYLEATM outside the U.S., obtain regulatory approval outside the U.S., and provide all sales, marketing, and commercial support for the product outside the U.S. In particular, Bayer HealthCare has responsibility for selling EYLEATM outside the U.S. using its sales force. While we cannot assure you that EYLEATM will receive regulatory approval in or outside the U.S. or be successfully commercialized, if Bayer HealthCare does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize EYLEATM outside the U.S. 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 EYLEATM outside the U.S. 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 U.S. Termination of the Bayer HealthCare collaboration agreement would create substantial new and additional risks to the successful development and commercialization of EYLEATM, particularly outside the U.S.

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, and will also depend on some of these third parties in connection with the commercialization of our late-stage product candidates 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 ARCALYST® and many other related activities in connection with the commercialization of ARCALYST® for the treatment of CAPS. 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 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 prepare for commercialization in the U.S. of our late-stage product candidates 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, financial condition, and results of operations.

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 currently pending or future application(s) for regulatory approval of our late-stage product candidate(s);
- announcement of submission of an application for regulatory approval of one or more of our late-stage product candidates;
- progress, delays, or adverse results in clinical trials;
- announcement of technological innovations or product candidates by us or competitors;
- fluctuations in our operating results; in particular, if EYLEATM or any of our other late-stage product candidates is approved for marketing, and our revenues, market share, and/or market acceptance of EYLEATM or such other products do not meet 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 product candidates, including EYLEATM, 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 product candidates or competitive 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 September 30, 2011, our six largest shareholders plus Leonard S. Schleifer, M.D, Ph.D., our Chief Executive Officer, beneficially owned 62.6% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of September 30, 2011. 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 September 30, 2011, Sanofi beneficially owned 15,816,953 shares of our Common Stock, representing approximately 17.5% 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 September 30, 2011, holders of Class A Stock held 18.9% of the combined voting power of all shares of Common Stock and Class A Stock then outstanding. These shareholders, if acting together, would be in a position to significantly influence the election of our directors and the vote on certain corporate transactions that require majority or supermajority approval of the combined classes, including mergers and other business combinations. This may result in our taking corporate actions that other shareholders may not consider to be in their best interest and may affect the price of our Common Stock. As of September 30, 2011:

- our current executive officers and directors beneficially owned 11.0% of our outstanding shares of Common Stock, assuming conversion of their Class A Stock into Common Stock and the exercise of all options held by such persons which are exercisable within 60 days of September 30, 2011, and 24.6% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by such persons which are exercisable within 60 days of September 30, 2011; and
- our six largest shareholders plus Leonard S. Schleifer, M.D., Ph.D. our Chief Executive Officer, beneficially owned 62.6% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of September 30, 2011. In addition, these seven shareholders held 65.7% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by our Chief Executive Officer which are exercisable within 60 days of September 30, 2011.

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 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 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 transaction. 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 convertible 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.

We are subject to counterparty risk with respect to the convertible note hedge transactions.

The hedge counterparties for the convertible note hedge transactions are financial institutions, and we will be subject to the risk that any or all of them might default under the convertible note hedge transactions. Our exposure to the credit risk of the hedge counterparties will not be secured by any collateral. Recent global economic conditions have resulted in the actual or perceived failure or financial difficulties of many financial institutions, including the bankruptcy filing by Lehman Brothers Holdings Inc. and its various affiliates. If a hedge counterparty becomes subject to insolvency proceedings, we will become an unsecured creditor in those proceedings with a claim equal to our exposure at that time under our transactions with that hedge counterparty. Furthermore, if a hedge counterparty defaults, we will not be able to set off our obligations to the hedge counterparty under the warrant transactions against the obligations of such hedge counterparty to us under the convertible note hedge transactions, which may result in significant losses to us. Our exposure will depend on many factors but, generally, the increase in our exposure will be correlated to the increase in the market price and in the volatility of our Common Stock. In addition, upon a default by a hedge counterparty, we may suffer adverse tax consequences and more dilution than we currently anticipate with respect to our Common Stock. We can provide no assurances as to the financial stability or viability of the hedge counterparties.

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

On October 21, 2011, we issued and sold $400 million aggregate principal amount of 1.875% Convertible Senior Notes due October 1, 2016 to the initial purchaser in a private placement pursuant to exemptions from the registration requirements of the Securities Act. We offered and sold the notes in reliance on the exemption from registration provided by Section 4(2) of the Securities Act. The initial purchaser offered and sold the notes to “qualified institutional buyers” pursuant to the exemption from registration provided by Rule 144A under the Securities Act.

On October 18, 2011, we entered into warrant confirmation transactions with certain option counterparties relating to convertible note hedge and warrant transactions. Pursuant to the warrant confirmation transactions, up to 4,760,840 shares of our Common Stock (subject to adjustment from time to time as provided in the warrant confirmations) may be issuable upon the conversion of warrants. The strike price of the warrant transaction will initially be $103.41 per share. We offered and sold the warrants in reliance on the exemption from registration provided by Section 4(2) of the Securities Act. Neither the warrants nor the underlying shares of Common Stock issuable upon the conversion of the warrants have been registered under the Securities Act.

The net proceeds to us from the notes offering were approximately $391.3 million after deducting the initial purchaser’s discount and estimated offering expenses. Although the gross proceeds to us from the sale of the warrants were approximately $93.8 million, we paid an aggregate of $117.5 million to the option counterparties for the convertible note hedge transactions. As a result, there were no additional net proceeds to us from the warrant transactions and we used $23.7 million of the net proceeds of the notes offering to fund the convertible hedge transactions. We intend to use the remaining net proceeds of the notes offering for general corporate purposes.

ITEM 6. EXHIBITS

(a) Exhibits

Exhibit Number	Description
10.1	- Eighth Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of August 1, 2011.
10.2	- Ninth Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of September 30, 2011.
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

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SIGNATURE

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

REGENERON PHARMACEUTICALS, INC.

Date: October 27, 2011

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)