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

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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.

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

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		