REGENERON PHARMACEUTICALS INC
Form 10-Q
May 03, 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 March 31, 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 (Do not check if a smaller reporting company)	Smaller reporting company

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

Yes No X

Number of shares outstanding of each of the registrant's classes of common stock as of April 13, 2011:

Class of Common Stock	Number of Shares
Class A Stock, $0.001 par value	2,151,854
Common Stock, $0.001 par value	88,739,294

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PART I. FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS

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

ASSETS	March 31, 2011	December 31, 2010
Current assets		
Cash and cash equivalents	$ 135,376	$ 112,572
Marketable securities	91,065	136,796
Accounts receivable from the sanofi-aventis Group	84,391	79,603
Accounts receivable - other	3,765	13,509
Prepaid expenses and other current assets	10,904	15,142
Total current assets	325,501	357,622
Restricted cash and marketable securities	7,520	7,518
Marketable securities	373,621	370,053
Property, plant, and equipment, at cost, net of accumulated depreciation and amortization	357,423	347,450
Other assets	10,228	6,789
Total assets	$ 1,074,293	$ 1,089,432
LIABILITIES and STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 58,602	$ 53,658
Deferred revenue from sanofi-aventis, current portion	19,561	19,506
Deferred revenue - other, current portion	33,291	35,217
Facility lease obligations, current portion	798	675
Total current liabilities	112,252	109,056
Deferred revenue from sanofi-aventis	94,398	97,081
Deferred revenue - other	183,019	188,775
Facility lease obligations	159,353	159,355
Other long term liabilities	7,180	7,350
Total liabilities	556,202	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 - 2,182,036 in 2011 and 2010	2	2
Common Stock, $.001 par value; 160,000,000 shares authorized; shares issued and outstanding - 88,548,041 in 2011 and 87,238,301 in 2010	89	87
Additional paid-in capital	1,609,185	1,575,780
Accumulated deficit	(1,089,010)	(1,045,563)
Accumulated other comprehensive loss	(2,175)	(2,491)
Total stockholders' equity	518,091	527,815
Total liabilities and stockholders' equity	$ 1,074,293	$ 1,089,432

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

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

	Three months ended March 31,	
	2011	2010
Revenues		
Sanofi-aventis collaboration revenue	$ 85,329	$ 68,671
Other collaboration revenue	12,481	13,087
Technology licensing	7,845	10,038
Net product sales	4,427	9,852
Contract research and other	2,122	1,886
	112,204	103,534
Expenses		
Research and development	129,392	117,471
Selling, general, and administrative	23,411	14,223
Cost of goods sold	382	717
	153,185	132,411
Loss from operations	(40,981)	(28,877)
Other income (expense)		
Investment income	1,037	439
Interest expense	(3,719)	(2,084)
	(2,682)	(1,645)
Net loss before income tax benefit	(43,663)	(30,522)
Income tax benefit	(216)	
Net loss	$ (43,447)	$ (30,522)
Net loss per share, basic and diluted	$ (0.49)	$ (0.38)
Weighted average shares outstanding, basic and diluted	89,162	81,169

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

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY (Unaudited)
For the three months ended March 31, 2011 and 2010
(In thousands)

	Class A Stock		Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive
	Shares	Amount	Shares	Amount	Capital	Deficit	Income (Loss)
Balance, December 31, 2010	2,182	$ 2	87,238	$ 87	$ 1,575,780	$ (1,045,563)	$ (2,491)
Issuance of Common Stock in connection with exercise of stock options, net of shares tendered			1,218	2	15,102		
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			92		3,405		
Stock-based compensation charges					14,898		
Net loss						(43,447)	
Change in net unrealized gain (loss) on marketable securities, net of tax effect of $0.2 million							316
Balance, March 31, 2011	2,182	$ 2	88,548	$ 89	$ 1,609,185	$ (1,089,010)	$ (2,175)
Balance, December 31, 2009	2,245	$ 2	78,861	$ 79	$ 1,336,732	$ (941,095)	$ 1,044
Issuance of Common Stock in connection with exercise of stock options, net of shares tendered			685	1	8,656		
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			111		2,867		
Conversion of Class A Stock to Common Stock	(33)		33				
Stock-based compensation charges					8,834		
Net loss						(30,522)	
Change in net unrealized gain (loss) on marketable securities							(327)
Balance, March 31, 2010	2,212	$ 2	79,690	$ 80	$ 1,357,089	$ (971,617)	$ 717

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

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

	Three months ended March 31,	
	2011	2010
Cash flows from operating activities		
Net loss	$ (43,447)	$ (30,522)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	6,978	4,183
Non-cash compensation expense	14,801	8,834
Other non-cash charges and expenses	582	544
Changes in assets and liabilities		
Decrease (increase) in accounts receivable	4,956	(6,290)
Decrease (increase) in prepaid expenses and other assets	2,286	(2,483)
(Decrease) increase in deferred revenue	(10,310)	3,513
Increase in accounts payable, accrued expenses, and other liabilities	13,574	12,643
Total adjustments	32,867	20,944
Net cash used in operating activities	(10,580)	(9,578)
Cash flows from investing activities		
Purchases of marketable securities	(15,638)	(177,594)
Sales or maturities of marketable securities	58,151	63,936
Capital expenditures	(22,166)	(22,743)
Net cash provided by (used in) investing activities	20,347	(136,401)
Cash flows from financing activities		
Proceeds in connection with facility lease obligations		47,544
Payments in connection with facility lease obligations	(89)	(555)
Net proceeds from the issuance of Common Stock	13,343	9,226
Payments in connection with capital lease obligation	(217)	
Net cash provided by financing activities	13,037	56,215
Net increase (decrease) in cash and cash equivalents	22,804	(89,764)
Cash and cash equivalents at beginning of period	112,572	207,075
Cash and cash equivalents at end of period	$ 135,376	$ 117,311

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 presentation 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 three months ended March 31, 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 three months ended March 31, 2010.

ARCALYST® net product sales totaled $4.4 million and $9.9 million for the three months ended March 31, 2011 and 2010, respectively. ARCALYST® net product sales during the first three months of 2010 included $5.1 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 March 31, 2011 or 2010.

Cost of goods sold related to ARCALYST® sales, which consisted primarily of royalties, totaled $0.4 million and $0.7 million for the three months ended March 31, 2011 and 2010, respectively. ARCALYST® shipments to the Company's customers primarily consisted of supplies of inventory manufactured and expensed as research and development costs prior to 2008; therefore, the costs of these supplies were not included in costs of goods sold.

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 months ended March 31, 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:

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

	Three Months Ended March 31,	
	2011	2010
Net loss (Numerator)	$ (43,447)	$ (30,522)
Weighted-average shares, in thousands (Denominator)	89,162	81,169
Basic and diluted net loss per share	$ (0.49)	$ (0.38)

Shares issuable upon the exercise of stock options and vesting of restricted stock awards, which have been excluded from the March 31, 2011 and 2010 diluted per share amounts because their effect would have been antidilutive, include the following:

	Three months ended March 31,	
	2011	2010
Stock Options:		
Weighted average number, in thousands	22,378	21,400
Weighted average exercise price	$ 20.26	$ 18.59
Restricted Stock:		
Weighted average number, in thousands	845	501

4. Statement of Cash Flows

Supplemental disclosure of noncash investing and financing activities:

Included in accounts payable and accrued expenses at March 31, 2011 and December 31, 2010 were $5.7 million and $10.7 million, respectively, of accrued capital expenditures. Included in accounts payable and accrued expenses at March 31, 2010 and December 31, 2009 were $5.4 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 March 31, 2010 was $0.8 million of capitalized and deferred interest for the quarter ended March 31, 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.

Included in other assets at March 31, 2011 and December 31, 2010 was $1.9 million and $0.2 million, respectively, due to the Company in connection with employee exercises of stock options.

Included in marketable securities at March 31, 2011 and December 31, 2010 were $2.0 million and $1.4 million, respectively, of accrued interest income. Included in marketable securities at March 31, 2010 and December 31, 2009 were $1.3 million and $0.6 million, respectively, of accrued interest income.

5. Marketable Securities

Marketable securities at March 31, 2011 and December 31, 2010 consisted of debt securities, as detailed below, and equity securities, the aggregate fair value of which was $4.6 million and $3.6 million at March 31, 2011 and December 31, 2010, respectively, and the aggregate cost

basis of which was $4.0 million at both March 31, 2011 and December 31, 2010. The Company also held restricted marketable securities at both March 31, 2011 and December 31, 2010, which consisted of debt securities, as detailed below, that collateralize (i) a letter of credit in connection with the Company's lease of facilities in Tarrytown, New York and (ii) capital lease obligations.

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

The following tables summarize the amortized cost basis of debt securities included in marketable securities, the aggregate fair value of those securities, and gross unrealized gains and losses on those securities at March 31, 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 March 31, 2011	Amortized Cost Basis	Fair Value	Unrealized Gains	(Losses)	Net
Unrestricted					
Maturities within one year					
U.S. government obligations	$ 38,551	$ 38,593	$ 42		$ 42
U.S. government guaranteed corporate bonds	39,670	39,939	269		269
U.S. government guaranteed collateralized mortgage obligations	1,588	1,590	2		2
Municipal bonds	10,786	10,799	13		13
Mortgage-backed securities	146	144		$ (2)	(2)
	90,741	91,065	326	(2)	324
Maturities between one and five years					
U.S. government obligations	348,753	346,784	10	(1,979)	(1,969)
U.S. government guaranteed corporate bonds	15,546	15,503		(43)	(43)
Municipal bonds	6,546	6,552	6		6
	370,845	368,839	16	(2,022)	(2,006)
Maturities between five and six years					
Mortgage-backed securities	281	144		(137)	(137)
	461,867	460,048	342	(2,161)	(1,819)
Restricted					
Maturities within one year					
U.S. government obligations	2,924	2,926	2		2
Maturities between one and three years					
U.S. government obligations	4,138	4,115		(23)	(23)
	7,062	7,041	2	(23)	(21)
	$ 468,929	$ 467,089	$ 344	$ (2,184)	$ (1,840)
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

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

At December 31, 2010 (continued)	Amortized Cost Basis	Fair Value	Unrealized Gains	Unrealized (Losses)	Net
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 March 31, 2011 and December 31, 2010, marketable securities included an additional unrealized gain of $0.6 million and an unrealized loss of $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 March 31, 2011 and December 31, 2010. The debt securities listed at March 31, 2011, excluding mortgage-backed securities, mature at various dates through December 2013. The mortgage-backed securities listed at March 31, 2011 mature at various dates through February 2017.

	Less than 12 Months		12 Months or Greater		Total	
At March 31, 2011	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
Unrestricted						
U.S. government obligations	$ 331,731	$ (1,979)			$ 331,731	$ (1,979)
U.S. government guaranteed corporate bonds	15,503	(43)			15,503	(43)
Mortgage-backed securities			$ 288	$ (139)	288	(139)
	347,234	(2,022)	288	(139)	347,522	(2,161)
Restricted						
U.S. government obligations	4,115	(23)			4,115	(23)
	4,115	(23)			4,115	(23)

$ 351,349	$ (2,045)	$ 288	$ (139)	$ 351,637	$ (2,184)

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 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 months ended March 31, 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.

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

		Fair Value Measurements at Reporting Date Using		
		Quoted Prices in Active Markets for Identical Assets	Significant Other Observable Inputs	Significant Unobservable Inputs
At March 31, 2011	Fair Value	(Level 1)	(Level 2)	(Level 3)
Unrestricted				
Available-for-sale marketable securities				
U.S. government obligations	$ 385,377		$ 385,377	
U.S. government guaranteed corporate bonds	55,442		55,442	
U.S. government guaranteed collateralized mortgage obligations	1,590		1,590	
Municipal bonds	17,351		17,351	
Mortgage-backed securities	288		288	
Equity securities	4,638	$ 4,638		
	464,686	4,638	460,048	
Restricted				
Available-for-sale marketable securities				

U.S. government obligations	7,041		7,041
	$ 471,727	$ 4,638	$ 467,089

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

At December 31, 2010	Fair Value	Fair Value Measurements at Reporting Date Using Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	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	

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 three months ended March 31, 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 $1.1 million 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. The Company did not record any charges for other-than-temporary impairment of its Level 2 marketable securities during the three months ended March 31, 2011.

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

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

	March 31, 2011	December 31, 2010
Raw materials	$ 162	$ 592
Work in process	3,634	699
Finished goods	85	132
	$ 3,881	$ 1,423

At March 31, 2011, $0.1 million of inventories were included in prepaid expenses and other current assets and $3.8 million of inventories were included in other assets. At December 31, 2010, inventories were included in prepaid expenses and other current assets.

7. Accounts Payable and Accrued Expenses

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

	March 31, 2011	December 31, 2010
Accounts payable	$ 16,146	$ 15,589
Accrued payroll and related costs	20,039	12,025
Accrued clinical trial expense	8,606	9,727
Accrued property, plant, and equipment costs	3,940	7,622
Other accrued expenses and liabilities	7,112	6,441
Payable to Bayer HealthCare	2,759	2,254
	$ 58,602	$ 53,658

8. Income Taxes

For the three months ended March 31, 2011 and 2010, the Company incurred net losses for tax purposes and recognized a full valuation allowance against deferred tax assets. For the three months ended March 31, 2011, the Company recognized a $0.2 million income tax benefit in connection with the net tax effect of the decrease in the Company's unrealized loss on "available-for-sale" marketable securities, which is included in other comprehensive loss. For the three months ended March 31, 2010, no provision or benefit for income taxes was recorded.

9. 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. Legal costs associated with the Company's resolution of legal proceedings are expensed as incurred.

As previously reported, on November 19, 2010, the Company filed a complaint against Genentech, Inc. in the U.S. District Court for the Southern District of New York seeking a declaratory judgment that no activities relating to VEGF Trap infringe any valid claim of certain Genentech patents referred to as the Davis-Smyth patents. 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 VEGF Trap-Eye for the treatment of 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 it, 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. The Company believes Genentech's counterclaims are without merit and intends to defend against them vigorously. As this matter is at a very 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.

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

10. 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 three months ended March 31, 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 FASB codifying the milestone method of revenue recognition as an acceptable revenue recognition model when a milestone is deemed to be substantive. The Company has historically accounted for milestones under the milestone method; as such 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 the sanofi-aventis Group and Bayer HealthCare LLC. 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-aventis to jointly develop and commercialize ZALTRAPTM (aflibercept), 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 ZALTRAPTM 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 ZALTRAPTM oncology indications in Japan. Under the Company's global, strategic collaboration with sanofi-aventis to discover, develop, and commercialize fully human monoclonal antibodies, for each drug candidate identified under the collaboration's Discovery and Preclinical Development Agreement, sanofi-aventis 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-aventis must make a $10.0 million substantive milestone payment to the Company. Under the Company's license and collaboration agreement with Bayer HealthCare LLC to globally develop, and commercialize outside the U.S., the Company's VEGF Trap for the treatment of eye disease by local administration ("VEGF Trap-Eye"), the Company is eligible to receive up to $50 million in future substantive milestone payments related to marketing approvals of VEGF Trap-Eye in major market countries outside the U.S..

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 and therapeutic applications of 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 its 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 the sanofi-aventis Group 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, 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 for 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, including three that are in late-stage (Phase 3) studies. All of these product candidates were discovered in our research laboratories. Our late-stage programs are VEGF Trap-Eye (aflibercept ophthalmic solution), which is being developed using intraocular delivery for the treatment of serious eye diseases; ZALTRAPTM (aflibercept), also known as VEGF Trap, which is being developed in oncology in collaboration with sanofi-aventis; and ARCALYST®, which is being developed for the prevention of gout flares in patients initiating uric acid-lowering treatment. Our earlier stage clinical programs include the following fully human antibodies, which are being developed in collaboration with sanofi-aventis:

- REGN727, an antibody to Proprotein Convertase Substilisin/Kexin type 9 (PCSK9), which is being developed for low-density lipoprotein (LDL) cholesterol reduction;
- REGN88, an antibody to the interleukin-6 receptor (IL-6R), which is being developed in rheumatoid arthritis and ankylosing spondylitis;
- 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); and
- REGN728 and REGN846, two antibodies in clinical development against undisclosed targets.

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-aventis, which was expanded during 2009, we plan to advance an average of four to five new antibody product candidates into clinical development each year, for an anticipated total of 30-40 candidates from 2010 through 2017. 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 first quarter of 2011 were $4.4 million. In the same quarter of 2010, net product sales of ARCALYST® were $9.9 million, which included $5.1 million of ARCALYST® net product sales made in the first quarter of 2010 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 for 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. VEGF Trap-Eye – Ophthalmologic Diseases

VEGF Trap-Eye (aflibercept ophthalmic solution) is a specially purified and formulated form of VEGF Trap, which is being developed for use in intraocular applications. We, together with our ex-U.S. collaborator Bayer HealthCare, are evaluating VEGF Trap-Eye 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 VEGF Trap-Eye and Lucentis® (ranibizumab injection), a registered trademark of Genentech, Inc. Lucentis® is an anti-angiogenic 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 VEGF Trap-Eye 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.

The primary endpoint of these non-inferiority studies was the proportion of patients treated with VEGF Trap-Eye 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 VEGF Trap-Eye, including VEGF Trap-Eye 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 VEGF Trap-Eye 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 VEGF Trap-Eye in wet AMD in the U.S. In April 2011, the FDA accepted the BLA for filing and granted our request for Priority Review. Under Priority Review, the target date for an FDA decision on the VEGF Trap-Eye BLA is August 20, 2011. Bayer HealthCare intends to submit regulatory applications in the first half of 2011 for marketing approval of VEGF Trap-Eye in wet AMD in Europe and other countries.

VEGF Trap-Eye is also in Phase 3 development 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 VEGF Trap-Eye 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.

We and Bayer HealthCare announced in December 2010 that in the COPERNICUS study, VEGF Trap-Eye met the primary endpoint of a statistically significant improvement in visual acuity at six months compared to sham injections. In the study, VEGF Trap-Eye 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 VEGF Trap-Eye 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 VEGF Trap-Eye 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, VEGF Trap-Eye also met the primary endpoint of a statistically significant improvement in visual acuity at six months compared to sham injections. In this trial, 60.2% of patients receiving 2.0 mg of VEGF Trap-Eye 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 VEGF Trap-Eye 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, VEGF Trap-Eye 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 VEGF Trap-Eye group were 2.9% and were more frequent in the control group (8.8%). The most frequently reported adverse events overall in the VEGF Trap-Eye 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 reduction of 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 VEGF Trap-Eye in CRVO in the U.S. in the second half of 2011, and Bayer HealthCare is planning to submit regulatory applications in this indication in Europe in 2012.

In April 2011, we and Bayer Healthcare announced that Bayer Healthcare initiated a Phase 3 study outside the U.S. to evaluate the safety and efficacy of VEGF Trap-Eye in DME. The study, named VIVID-DME (VEGF Trap-Eye In Vision Impairment Due to DME), has three study arms. In the first arm, patients will be treated every month with 2.0 mg of VEGF Trap-Eye. In the second arm, patients will be treated with 2.0 mg of VEGF Trap-Eye 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 intend to commence a second Phase 3 study in DME, the VISTA-DME study (VEGF Trap-Eye: Investigation of Safety, Treatment effect, and Anatomic outcomes in DME), in the U.S., Canada, and other countries, later in 2011.

In January 2011, Regeneron 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 VEGF Trap-Eye 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 VEGF Trap-Eye. Under the agreement, we and Bayer HealthCare collaborate on, and share the costs of, the development of VEGF Trap-Eye through an integrated global plan. Bayer HealthCare will market VEGF Trap-Eye outside the U.S., where the companies will share equally in profits from any future sales of VEGF Trap-Eye. Commencing on the first commercial sale of VEGF Trap-Eye 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 VEGF Trap-Eye 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 VEGF Trap-Eye 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 VEGF Trap-Eye outside the U.S. achieve certain specified levels starting at $200 million.

2. ZALTRAPTM (also known as aflibercept or VEGF Trap) – Oncology

ZALTRAPTM (aflibercept) is a protein-based product candidate designed to bind all forms of Vascular Endothelial Growth Factor-A (called VEGF-A), VEGF-B, and the related Placental Growth Factor (called 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.

ZALTRAPTM is being developed globally in cancer indications in collaboration with sanofi-aventis. In April 2011, we and sanofi-aventis 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 the second-line treatment of metastatic colorectal cancer (mCRC). Full results will be presented at an upcoming medical meeting. The most frequent adverse events reported with ZALTRAP™ in combination with FOLFIRI were diarrhea, asthenia/fatigue, stomatitis and ulceration, nausea, infection, hypertension, gastrointestinal and abdominal pains, vomiting, decreased appetite, decreased weight, epistaxis, alopecia, and dysphonia.

Based upon these positive findings, we and sanofi-aventis plan to submit regulatory applications for marketing approval of ZALTRAP™ for the second-line treatment of mCRC to the FDA and the European Medicines Agency (EMA) in the second half of 2011.

In March 2011, we and sanofi-aventis announced results from the Phase 3 VITAL trial evaluating ZALTRAPTM for the second-line treatment of non-small cell lung cancer (NSCLC). The data showed that adding ZALTRAPTM to the chemotherapy drug docetaxel did not meet the pre-specified criteria for the primary endpoint of improvement in overall survival compared with a regimen of docetaxel plus placebo (HR=1.01, CI: 0.868 to 1.174). The addition of ZALTRAPTM to docetaxel demonstrated activity as measured by key secondary endpoints of the study: progression free survival (PFS) (HR=0.82, CI: 0.716 to 0.937) and an overall objective response rate (ORR) of 23.3% in the ZALTRAPTM arm compared to 8.9% in the placebo arm. Consistent with published literature reporting on combined cytotoxic and anti-VEGF therapy, the incidence of adverse events was higher in the ZALTRAPTM arm compared to placebo. The most frequent Grade 3/4 adverse events included fatigue, stomatitis, disease progression, and hypertension.

Another randomized, double-blind Phase 3 trial (VENICE), which is fully enrolled, is evaluating ZALTRAPTM 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. Both interim and final analyses will be conducted when a pre-specified number of events have occurred in this trial. Based on projected event rates, an interim analysis of the VENICE trial is expected to be conducted by an IDMC in mid-2011, with final results anticipated in 2012.

In addition, a randomized Phase 2 study (AFFIRM) of ZALTRAPTM 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 in the second half of 2011.

ZALTRAPTM Collaboration with sanofi-aventis

We and sanofi-aventis globally collaborate on the development and commercialization of ZALTRAPTM. Under the terms of our September 2003 collaboration agreement, as amended, we and sanofi-aventis will share co-promotion rights and profits on sales, if any, of ZALTRAPTM 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 ZALTRAPTM, 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 ZALTRAPTM 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 ZALTRAPTM collaboration agreement, as amended, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis out of our share of ZALTRAPTM 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 ZALTRAPTM profits in the quarter unless we elect to reimburse sanofi-aventis at a faster rate.

3. ARCALYST®– Inflammatory Diseases

ARCALYST® (rilonacept) 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 the 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 have been conducting a Phase 3 clinical development program with ARCALYST® in gout patients initiating uric acid-lowering therapy. The program consists 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. Patients initiating uric acid-lowering therapy who received ARCALYST® at a weekly, self-administered, subcutaneous dose of 160 mg had an 80% decrease in mean number of gout flares compared to the placebo group over the 16 week treatment period (0.21 flares vs. 1.06 flares, $p<0.0001$). Patients who received ARCALYST® at a weekly dose of 80 mg had a 73% decrease compared to the placebo group (0.29 flares vs. 1.06 flares, $p<0.0001$).

All secondary endpoints of the study were highly 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% (3.8% with ARCALYST® 160 mg, 5.0% with ARCALYST® 80 mg, and 31.6% with placebo, $p<0.001$). In addition, treatment with ARCALYST® reduced the proportion of patients who experienced at least one gout flare during the study period by up to 65% (16.3% with ARCALYST® 160 mg, 18.8% with ARCALYST® 80 mg, and 46.8% with placebo, $p<0.001$).

A total of 241 patients were randomized in PRE-SURGE 1. ARCALYST® was generally well tolerated with no reported drug-related serious adverse events. Adverse events that occurred at a frequency of at least 5% in any study group were injection site reaction (19.8% with ARCALYST® 160 mg, 8.8% with ARCALYST® 80 mg, and 1.3% with placebo), upper respiratory tract infection (9.9% with ARCALYST® 160 mg, 8.8% with ARCALYST® 80 mg, and 7.6% with placebo), lower respiratory tract infection (0% with ARCALYST® 160 mg, 5.0% with ARCALYST® 80 mg, and 2.5% with placebo), musculoskeletal pain/discomfort (6.2% with ARCALYST® 160 mg, 7.5% with ARCALYST® 80 mg, and 8.9% with placebo), and headache, (3.7% with ARCALYST® 160 mg, 6.3% with ARCALYST® 80 mg, and 1.3% with placebo).

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% (6.0% with ARCALYST® 160 mg, 8.5% with ARCALYST® 80 mg, and 32.9% with placebo, $p\leq0.001$). 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% (20.5% with ARCALYST® 160 mg, 25.6% with ARCALYST® 80 mg, and 56.1% with placebo, $p\leq0.001$).

ARCALYST® was generally well tolerated with no reported drug-related serious adverse events. The most frequently reported adverse event was upper respiratory tract infection (15.5% with ARCALYST® 160 mg, 12.2% with ARCALYST® 80 mg, and 12.2% with placebo). Overall, the cumulative rate of infections was 27.4% in patients treated with ARCALYST® 160 mg, 28.0% in patients treated with ARCALYST® 80 mg, and 25.6% in patients treated with placebo. Injection site reactions were more commonly reported in patients treated with ARCALYST® (17.9% with ARCALYST® 160 mg, 12.2% with ARCALYST® 80 mg, and 1.2% with placebo). These results were consistent with those in PRE-SURGE 1.

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. RE-SURGE evaluated 1,315 patients who were at risk for gout flares while initiating or continuing uric acid-lowering drug treatment. Other than injection site reactions, the incidence of treatment-emergent adverse events was generally well-balanced among the 985 patients who received ARCALYST® at a weekly, self-administered, subcutaneous dose of 160 mg and the 330 patients who received placebo. Injection site reactions, usually considered mild, were reported more commonly with ARCALYST® (15.2%) than with placebo (3.3%). Overall, the cumulative rate of infections was 20.1% in patients treated with ARCALYST® and 19.1% in placebo patients. Serious infections were reported in 0.5% of patients treated with ARCALYST® and 0.9% of placebo patients. Deaths were reported for 0.3% of patients treated with ARCALYST® and 0.9% of placebo patients.

In the RE-SURGE study, ARCALYST® 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 plan to submit in mid-2011 a supplemental BLA for U.S. regulatory approval of ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering therapy. We own worldwide rights to ARCALYST®.

4. 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 robustly 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. No serious adverse events and no dose limiting toxicities have been reported.

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.

In early 2011, we initiated Phase 2 studies of REGN727 in patients with hypercholesterolemia in combination with statin therapy. REGN727 is being developed in collaboration with sanofi-aventis.

5. 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 Genentech, has been approved for the treatment of rheumatoid arthritis.

REGN88 is a fully human monoclonal antibody to IL-6R generated using our VelocImmune® technology that has completed Phase 1 studies, the results of which were presented at the annual meetings of the European League Against Rheumatism (EULAR) in June 2010 and the American College of Rheumatology in October 2010. REGN88 was well tolerated by patients with rheumatoid arthritis, and no dose-limiting toxicities were reported. Treatment with REGN88 resulted in dose-related reductions in biomarkers of inflammation. REGN88 is currently in a Phase 2/3 double-blind, placebo-controlled, dose-ranging study in patients with active rheumatoid arthritis and a Phase 2 double-blind, placebo-controlled, dose-ranging study in ankylosing spondylitis, a form of arthritis that primarily affects the spine. Both studies are enrolling patients, and initial Phase 2 results are expected in mid-2011. REGN88 is being developed in collaboration with sanofi-aventis.

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. A Phase 1 trial of REGN668 in healthy volunteers has been completed. A Phase 1b study in patients with atopic dermatitis and a Phase 2 study in eosinophilic asthma are underway. REGN668 is being developed in collaboration with sanofi-aventis.

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. REGN421, which is being developed in collaboration with sanofi-aventis, is in Phase 1 clinical development.

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 in collaboration with sanofi-aventis.

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, the Company was 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. There are currently no ongoing trials with REGN475 that are either enrolling or treating patients. REGN475 is being developed in collaboration with sanofi-aventis.

10. REGN728 and REGN846

In the fourth quarter of 2010, clinical trials began with two additional fully human monoclonal antibodies generated using our VelocImmune® technology that are part of the sanofi-aventis collaboration, REGN728 and REGN846. The targets of these antibodies have not been disclosed.

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 ZALTRAPTM and VEGF Trap-Eye, 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-aventis. In November 2007, we and sanofi-aventis 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-aventis. Pursuant to the collaboration, sanofi-aventis 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-aventis has the option to license rights to the candidate under the license agreement. If it elects to do so, sanofi-aventis will co-develop the drug candidate with us through product approval. Development costs for the drug candidate are shared between the companies, with sanofi-aventis 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-aventis and 20% by us. We are generally responsible for reimbursing sanofi-aventis 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-aventis for these development costs.

Sanofi-aventis 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-aventis)/35% (us) and ending at 55% (sanofi-aventis)/45% (us), and will share losses outside the U.S. at 55% (sanofi-aventis)/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-aventis amended these agreements to expand and extend our antibody collaboration. The goal of the expanded collaboration is to advance an average of four to five new antibody product candidates into clinical development each year, for an anticipated total of 30-40 candidates from 2010 through 2017.

Under the amended discovery agreement, sanofi-aventis 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-aventis 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-aventis 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-aventis 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-aventis 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 March 31, 2011, sanofi-aventis has funded a total of $354.8 million of our costs under the discovery agreement and a total of $294.1 million of our development costs under the license agreement, or a total of $648.9 million in funding for our antibody research and development activities during this period.

In August 2008, we entered into an agreement with sanofi-aventis to use our VelociGene® platform to supply sanofi-aventis with genetically modified mammalian models of gene function and disease. Under this agreement, sanofi-aventis 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-aventis. Sanofi-aventis 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.

AstraZeneca UK Limited. In February 2007, we entered into a six-year, non-exclusive license agreement with AstraZeneca UK Limited to allow AstraZeneca to utilize our VelocImmune® technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, AstraZeneca made a $20.0 million annual, non-refundable payment to us in each of the first quarters of 2007, 2008, 2009, and 2010. In November 2010, as permitted by the agreement, MedImmune Limited (as successor by novation from AstraZeneca) gave written notice of voluntary termination of the agreement, effective in February 2011, thereby canceling its obligation to make either of the final two annual payments. We remain entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by MedImmune 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. 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, we have received $22.6 million from the grant's inception through March 31, 2011 and are entitled to receive an additional $2.7 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 March 31, 2011, we had a cumulative loss of $1.1 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 VEGF Trap-Eye in wet AMD in the U.S. In April 2011, the FDA accepted the BLA for filing and granted our request for Priority Review. Under Priority Review, the target date for an FDA decision on the VEGF Trap-Eye BLA is August 20, 2011. Bayer HealthCare intends to submit regulatory applications in the first half of 2011 for marketing approval of VEGF Trap-Eye in wet AMD in Europe and other countries. We plan to submit a BLA to the FDA in the second half of 2011 for marketing approval of VEGF Trap-Eye in CRVO in the U.S., and Bayer HealthCare is planning to submit regulatory applications for marketing approval of VEGF Trap-Eye in CRVO in Europe in 2012. We also plan to submit a supplemental BLA to the FDA in mid-2011 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-aventis plan to submit regulatory applications for marketing approval of ZALTRAP™ for the second-line treatment of mCRC to the FDA and the EMA in the second half 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 VEGF Trap-Eye 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)
VEGF Trap–Eye	• 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 • Reported positive six-month results in the Phase 3 GALILEO trial in CRVO • Bayer Healthcare initiated a Phase 3 trial in DME outside the U.S. • Initiated a Phase 3 trial in Asia in CNV of the retina as a result of pathologic myopia	• Target date for FDA decision on VEGF Trap-Eye BLA is August 20, 2011 • Report two-year data from VIEW 1 and VIEW 2 in wet AMD, and one-year data from COPERNICUS and GALILEO in CRVO in the second half of 2011 • Submit a BLA to the FDA for the treatment of CRVO in the second half of 2011 • Initiate a second DME Phase 3 trial in the U.S. in the second half of 2011

Clinical Program	2011 Events to Date	2011-12 Plans (next 12 months)
ZALTRAP™	• Reported positive results in the Phase 3 VELOUR trial in mCRC • Reported results for the VITAL trial in NSCLC	• Submit a BLA to the FDA for the treatment of mCRC in the second half of 2011 • IDMC review of interim results for the Phase 3 VENICE trial in prostate cancer in mid-2011 • Report initial results in the Phase 2 AFFIRM trial in colorectal cancer in the second half of 2011
ARCALYST®	• Reported positive results from two Phase 3 studies for the prevention of gout flares (PRE-SURGE 2 and RESURGE)	• Submit a supplemental BLA to the FDA for the prevention of gout flares in mid-2011
REGN727 (PCSK9 Antibody)	• Initiated Phase 2 studies for LDL cholesterol reduction	• Report initial data from the Phase 2 program for LDL cholesterol reduction
REGN88 (IL-6R Antibody)	• Continued patient enrollment in studies in rheumatoid arthritis and ankylosing spondylitis	• Report initial Phase 2 data in rheumatoid arthritis and ankylosing spondylitis
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

Results of Operations

Three Months Ended March 31, 2011 and 2010

Net Loss

Regeneron reported a net loss of $43.4 million, or $0.49 per share (basic and diluted), for the first quarter of 2011, compared to a net loss of $30.5 million, or $0.38 per share (basic and diluted) for the first quarter 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, partly offset by higher collaboration revenue in connection with our antibody collaboration with sanofi-aventis.

Revenues

Revenues for the three months ended March 31, 2011 and 2010 consist of the following:

(In millions)	2011	2010
Collaboration revenue		
Sanofi-aventis	$ 85.3	$ 68.7
Bayer HealthCare	12.5	13.1
Total collaboration revenue	97.8	81.8
Technology licensing revenue	7.9	10.0
Net product sales	4.4	9.9
Contract research and other revenue	2.1	1.8
Total revenue	$ 112.2	$ 103.5

Sanofi-aventis Collaboration Revenue

The collaboration revenue we earned from sanofi-aventis, 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 ZALTRAPTM collaboration and $85.0 million related to the antibody collaboration.

Sanofi-aventis Collaboration Revenue (In millions)	Three months ended March 31, 2011	2010
ZALTRAPTM:		
Regeneron expense reimbursement	$ 7.2	$ 4.9
Recognition of deferred revenue related to up-front payments	2.5	2.5
Total ZALTRAPTM	9.7	7.4
Antibody:		
Regeneron expense reimbursement	73.2	59.3
Recognition of deferred revenue related to up-front and other payments	2.0	1.6
Recognition of revenue related to VelociGene® agreement	0.4	0.4
Total antibody	75.6	61.3
Total sanofi-aventis collaboration revenue	$ 85.3	$ 68.7

Sanofi-aventis' reimbursement of our ZALTRAPTM expenses increased in the first quarter of 2011 compared to same period in 2010, primarily due to higher costs related to manufacturing ZALTRAPTM clinical supplies. As of March 31, 2011, $30.1 million of the original $105.0 million of up-front payments related to ZALTRAPTM was deferred and will be recognized as revenue in future periods.

In the first quarter of 2011, sanofi-aventis' reimbursement of our antibody expenses consisted of $42.1 million under the discovery agreement and $31.1 million of development costs under the license agreement, compared to $26.7 million and $32.6 million, respectively, in the first quarter of 2010. The higher reimbursement amount under the discovery agreement in the first quarter of 2011, compared to the same period in 2010, was primarily due to an increase in our antibody discovery activities.

Recognition of deferred revenue related to sanofi-aventis' $85.0 million up-front payment and other payments increased in the first quarter of 2011 compared to the same period in 2010. In connection with the November 2009 amendment of the discovery agreement, sanofi-aventis is funding up to $30 million of agreed-upon costs incurred by us to expand our manufacturing capacity at our Rensselaer, New York facilities. Revenue related to these payments for such funding from sanofi-aventis is deferred and recognized as collaboration revenue prospectively over the related performance period in conjunction with the recognition of the original $85.0 million up-front payment. As of March 31, 2011, $23.9 million of such funding from sanofi-aventis was received or receivable, compared to $5.1 million as of March 31, 2010; as a result, we recognized more deferred revenue in the first quarter of 2011 than in the same quarter of 2010. As of March 31, 2011, $78.3 million of the sanofi-aventis payments was deferred and will be recognized as revenue in future periods.

In August 2008, we entered into a separate VelociGene® agreement with sanofi-aventis. In both the three months ended March 31, 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 VEGF Trap-Eye 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 March 31, 2011	2010
Cost-sharing of Regeneron VEGF Trap-Eye development expenses	$ 10.0	$ 10.6
Recognition of deferred revenue related to up-front and other milestone payments	2.5	2.5
Total Bayer HealthCare collaboration revenue	$ 12.5	$ 13.1

Cost-sharing of our VEGF Trap-Eye development expenses with Bayer HealthCare decreased slightly in the first quarter of 2011 compared to the same period in 2010. In the first quarter of 2011, we incurred lower clinical development costs in connection with our Phase 3 VIEW 1 trial in wet AMD and our Phase 2 DA VINCI trial in DME, partly offset by higher internal costs in connection with regulatory filings 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 March 31, 2011, $44.5 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 is being 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 will be recognized as revenue ratably over a seven-year period beginning in mid-2011. In connection with our VelocImmune® license agreement with AstraZeneca, the $20.0 million non-refundable payment received in the first quarter of 2010 was deferred upon receipt and recognized as revenue ratably over the final year of the agreement. In the first quarter of 2011 and 2010, we recognized $7.9 million and $10.0 million, respectively, of technology licensing revenue related to these agreements. As of March 31, 2011, $168.7 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 March 31, 2011 and 2010, we recognized as revenue $4.4 million and $9.9 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, $4.8 million of previously deferred ARCALYST® net product sales were recognized as revenue in the first quarter of 2010. At March 31, 2011 and 2010, there was no deferred revenue related to ARCALYST® net product sales.

Contract Research and Other Revenue

Contract research and other revenue for the three months ended March 31, 2011 and 2010 included $1.0 million and $1.1 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 $153.2 million in the first quarter of 2011 from $132.4 million in the first quarter of 2010. Our average headcount in the first quarter of 2011 increased to 1,432 from 1,087 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-aventis.

Operating expenses in the first quarter of 2011 and 2010 included a total of $14.8 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 March 31, 2011		
Expenses (In millions)	Expenses before inclusion of Non-cash Compensation Expense	Non-cash Compensation Expense	Expenses as Reported
Research and development	$ 121.6	$ 7.8	$ 129.4
Selling, general, and administrative	16.4	7.0	23.4
Cost of goods sold	0.4		0.4
Total operating expenses	$ 138.4	$ 14.8	$ 153.2

	For the three months ended March 31, 2010		
Expenses (In millions)	Expenses before inclusion of Non-cash Compensation Expense	Non-cash Compensation Expense	Expenses as Reported
Research and development	$ 112.5	$ 5.0	$ 117.5
Selling, general, and administrative	10.4	3.8	14.2
Cost of goods sold	0.7		0.7
Total operating expenses	$ 123.6	$ 8.8	$ 132.4

The increase in total Non-cash Compensation Expense in the first quarter of 2011 was primarily attributable to (i) the recognition of higher expense in the first 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 $129.4 million in the first quarter of 2011 from $117.5 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 March 31, 2011 and 2010:

Research and Development Expenses (In millions)	For the three months ended March 31, 2011	2010	Increase (Decrease)
Payroll and benefits (1)	$ 42.6	$ 27.7	$ 14.9
Clinical trial expenses	19.0	32.2	(13.2)
Clinical manufacturing costs (2)	22.2	20.0	2.2
Research and other development costs	15.3	12.8	2.5
Occupancy and other operating costs	14.0	12.0	2.0
Cost-sharing of Bayer HealthCare VEGF Trap-Eye development expenses (3)	16.3	12.8	3.5
Total research and development expenses	$ 129.4	$ 117.5	$ 11.9

(1) Includes $6.9 million and $4.3 million of Non-cash Compensation Expense for the three months ended March 31, 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 $0.9 million and $0.7 million of Non-cash Compensation Expense for the three months ended March 31, 2011 and 2010, respectively.

(3) Under our collaboration with Bayer HealthCare, in periods when Bayer HealthCare incurs VEGF Trap-Eye development expenses, we also recognize, as additional research and development expense, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. Bayer HealthCare provides us with estimated VEGF Trap-Eye 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 VEGF Trap-Eye 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 Phase 3 VIEW 1 trial of VEGF Trap-Eye in wet AMD and our Phase 2 DA VINCI trial in DME, and our clinical development program for NGF, which is currently on clinical hold. Clinical manufacturing costs increased due to higher facility-related costs in connection with the expansion of our manufacturing capacity at our Rensselaer facility and higher costs related to manufacturing ZALTRAPTM clinical supplies, partly offset by lower costs related to manufacturing ARCALYST® clinical supplies. Research and other development costs increased primarily due to higher costs associated with filing our BLA for VEGF Trap-Eye in wet AMD. Occupancy and other operating costs increased principally in connection with our higher headcount, expanded research and development activities, and new and expanded leased laboratory and office facilities in Tarrytown, New York. Cost-sharing of Bayer HealthCare's VEGF Trap-Eye development expenses increased primarily due to higher costs in connection with Bayer HealthCare's Phase 3 trial in DME, which was initiated in the first quarter of 2011.

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 VEGF Trap-Eye 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 March 31, 2011	2010	Increase (Decrease)
ARCALYST®	$ 8.9	$ 20.1	$ (11.2)
VEGF Trap-Eye	39.6	33.6	6.0
ZALTRAPTM	6.4	3.9	2.5
REGN88	6.7	4.9	1.8
REGN727	7.1	5.2	1.9
Other antibody candidates in clinical development	12.6	18.9	(6.3)
Other research programs & unallocated costs	48.1	30.9	17.2
Total research and development expenses	$ 129.4	$ 117.5	$ 11.9

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®, ZALTRAPTM, and VEGF Trap-Eye 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 $23.4 million in the first quarter of 2011 from $14.2 million in the same period of 2010 due primarily to increases in compensation expense principally in connection with higher headcount in the first quarter of 2011, higher market research costs primarily in connection with VEGF Trap-Eye, higher legal expenses in connection with patent-related litigation with Genentech, and an increase in Non-cash Compensation Expense for the reasons described above.

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Cost of Goods Sold

Cost of goods sold in the first quarter of 2011 and 2010 was $0.4 million and $0.7 million, respectively, and consisted primarily of royalties and other period costs related to ARCALYST® commercial supplies.

Other Income and Expense

Investment income increased to $1.0 million in the first quarter of 2011 from $0.4 million in the same period of 2010, due primarily to higher yields on, and higher average balances of, cash and marketable securities.

Interest expense increased to $3.7 million in the first quarter of 2011 from $2.1 million in the same period of 2010. Interest expense is primarily attributable to the imputed interest portion of payments to our landlord, commencing in the third quarter of 2009, to lease newly constructed laboratory and office facilities in Tarrytown, New York. In February 2011, we began occupying an additional new building in Tarrytown and, therefore, began recognizing interest expense on the related payments to our landlord.

Liquidity and Capital Resources

Since our inception in 1988, we have financed our operations primarily through offerings of our equity securities, a private placement of convertible debt (which was repurchased or repaid in 2008), purchases of our equity securities by our collaborators, including sanofi-aventis, revenue earned under our past and present research and development agreements, including our agreements with sanofi-aventis and Bayer HealthCare, our past contract manufacturing agreements, our technology licensing agreements, ARCALYST® product revenue, and investment income.

Three months ended March 31, 2011 and 2010

At March 31, 2011, we had $607.6 million in cash, cash equivalents, and marketable securities (including $7.5 million of restricted cash and marketable securities) compared with $626.9 million at December 31, 2010 (including $7.5 million of restricted cash and marketable securities). In January 2011, we received, from Bayer HealthCare, a $10.0 million milestone payment, which was earned in 2010, in connection with the COPERNICUS study of VEGF Trap-Eye in CRVO.

Cash Used in Operating Activities

Net cash used in operating activities was $10.6 million in the first quarter of 2011 and $9.6 million in the first quarter of 2010. Our net losses of $43.4 million in the first quarter of 2011 and $30.5 million in the first quarter of 2010 included $14.8 million and $8.8 million, respectively, of Non-cash Compensation Expense. Our net losses also included depreciation and amortization of $7.0 million and $4.2 million in the first quarter of 2011 and 2010, respectively.

At March 31, 2011, accounts receivable decreased by $5.0 million, compared to end-of-year 2010, primarily due to the receipt of the $10.0 million milestone payment in January 2011 from Bayer HealthCare, as discussed above. Our deferred revenue at March 31, 2011 decreased by $10.3 million, compared to end-of-year 2010, primarily due to the amortization of previously received and deferred $20.0 million payments under our license agreements with AstraZeneca and Astellas. Accounts payable, accrued expenses, and other liabilities increased by $13.6 million at March 31, 2011, compared to end-of-year 2010, primarily in connection with higher liabilities for payroll-related expenses.

At March 31, 2010, accounts receivable increased by $6.3 million, compared to end-of-year 2009, primarily due to a higher receivable balance related to our antibody collaboration with sanofi-aventis. At March 31, 2010, accounts payable, accrued expenses, and other liabilities increased by $12.6 million, compared to end-of-year 2009, primarily in connection with our expanded levels of activities and expenditures, including higher liabilities for clinical-related expenses and payroll and related costs.

Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities was $20.3 million in the first quarter of 2011, compared with net cash used in investing activities of $136.4 million in the first quarter of 2010. In the first quarter of 2011, sales or maturities of marketable securities exceeded purchases by $42.5 million, whereas in the first quarter of 2010, purchases of marketable securities exceeded sales or maturities by $113.7 million. Capital expenditures in the first quarter of 2011 and 2010 included costs in connection with expanding our manufacturing capacity at our Rensselaer, New York facilities and tenant improvements and related costs in connection with our December 2006 Tarrytown, New York lease.

Cash Provided by Financing Activities

Net cash provided by financing activities was $13.0 million in the first quarter of 2011 and $56.2 million in the first quarter of 2010. In the first quarter of 2010, we received $47.5 million from our landlord in connection with tenant improvement costs for our new Tarrytown facilities, which we recognized as additional facility lease obligations since we are deemed to own these facilities in accordance with FASB authoritative guidance. In addition, proceeds from issuances of Common Stock in connection with exercises of employee stock options were $13.3 million in the first quarter of 2011 and $9.2 million in the first quarter of 2010.

Fair Value of Marketable Securities

At March 31, 2011 and December 31 2010, we held marketable securities whose aggregate fair value totaled $471.7 million and $513.9 million, respectively. The composition of our portfolio of marketable securities on these dates was as follows:

	March 31, 2011		December 31, 2010	
Investment type	Fair Value	Percent	Fair Value	Percent
Unrestricted				
U.S. government agency securities	$ 385.4	82%	$ 434.4	85%
U.S. government-guaranteed corporate bonds	55.4	12%	64.0	13%
Municipal bonds	17.4	4%		
Equity securities	4.6	1%	3.6	1%
U.S. government guaranteed collateralized mortgage obligations	1.6		2.1	
Other			1.6	
Mortgage-backed securities	0.3		1.1	
Total unrestricted marketable securities	464.7	99%	506.8	99%
Restricted				
U.S. government agency securities	7.0	1%	7.1	1%
Total marketable securities	$ 471.7	100%	$ 513.9	100%

In addition, at March 31, 2011 and December 31, 2010, we had $135.9 million and $113.0 million, respectively, of cash, cash equivalents, and restricted cash, primarily held in money market funds that invest in U.S. government securities.

Capital Expenditures:

Our cash expenditures for property, plant, and equipment totaled $22.2 million and $22.7 million for the first three months of 2011 and 2010, respectively. In February 2010, we received $47.5 million from our landlord in connection with tenant improvement costs in Tarrytown. In addition, sanofi-aventis has funded $0.5 million and $4.6 million, respectively, of agreed-upon capital expenditures incurred by us during the first quarters of 2011 and 2010 to expand our manufacturing capacity at our Rensselaer facilities, which was either received or receivable at March 31, 2011 and 2010.

We expect to incur capital expenditures of approximately $50 to $65 million during the remainder of 2011 primarily in connection with tenant improvements at our leased Tarrytown facilities, capital improvements at our Rensselaer, New York manufacturing facilities, and purchases of equipment. We expect to be reimbursed for a portion of these capital expenditures for our Rensselaer facilities by sanofi-aventis, with the remaining amount to be funded by our existing capital resources.

Funding Requirements:

We expect to continue to incur substantial funding requirements for research and development activities (including preclinical and clinical testing). As described above, expenses that we incur in connection with our ZALTRAPTM and antibodies collaborations are, generally, fully funded by sanofi-aventis. In addition, as described above, we and Bayer HealthCare share agreed-upon development expenses that both companies incur in connection with our VEGF Trap-Eye collaboration. After taking into account anticipated reimbursements from our collaborators, we currently estimate that approximately 30-40% of our funding requirements for 2011 will be directed toward technology development, basic research and early preclinical activities, and the preclinical and clinical development of our product candidates (principally, for ARCALYST® and VEGF Trap-Eye). For 2011, we also currently estimate that approximately 15-25% of our funding requirements will be directed toward the planned commercialization of our late-stage product candidates; approximately 20-30% of our funding requirements will be applied to capital expenditures (as described above); and the remainder of our funding requirements will be used for general corporate purposes.

The amount we need to fund operations will depend on various factors, including the potential regulatory approval and commercialization of our product candidates and the timing thereof, the status of competitive products, the success of our research and development programs, the potential future need to expand our professional and support staff and facilities, the status of patents and other intellectual property rights (and pending or future litigation related thereto), the delay or failure of a clinical trial of any of our potential drug candidates, and the continuation, extent, and success of our collaborations with sanofi-aventis and Bayer HealthCare. Clinical trial costs are dependent, among other things, on the size and duration of trials, fees charged for services provided by clinical trial investigators and other third parties, the costs for manufacturing the product candidate for use in the trials, and for supplies, laboratory tests, and other expenses. The amount of funding that will be required for our clinical programs depends upon the results of our research and preclinical programs and early-stage clinical trials, regulatory requirements, the duration and results of clinical trials underway and of additional clinical trials that we decide to initiate, and the various factors that affect the cost of each trial as described above. Our commercialization costs over approximately the next few years will depend on, among other things, whether or not our late-stage product candidates receive regulatory approval, the market potential for such product candidates, and the commercialization terms of our collaboration agreements, if applicable (whereby some or all commercialization costs may be shared with our collaborators). Currently, we are required to pay royalties on product sales of ARCALYST® for the treatment of CAPS. In the future, if we are able to successfully develop, market, and sell ARCALYST® for other indications or certain of our product candidates, we may be required to pay royalties or share the profits from such sales pursuant to our license or collaboration agreements.

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

We believe that our existing capital resources, including funding we are entitled to receive under our collaboration agreements, will enable us to meet operating needs through at least 2013. However, this is a forward-looking statement based on our current operating plan, and there may be a change in projected revenues or expenses that would lead to our capital being consumed significantly before such time. For example, in connection with preparing to commercialize and launch potential products that are not licensed to a third party, we could incur substantial pre-marketing and commercialization expenses that could lead us to consume our cash at a faster rate. If there is insufficient capital to fund all of our planned operations and activities, we anticipate that we would (i) seek sources of additional capital through collaborative arrangements and/or additional public or private financing, including debt and equity financing and/or (ii) prioritize available capital to fund selected preclinical and clinical development programs and/or preparations for the potential commercialization of our late-stage product candidates, or license selected products.

Other than letters of credits totaling $3.8 million, including the $3.4 million letter of credit issued in connection with our lease for facilities in Tarrytown, New York, we have no off-balance sheet arrangements. In addition, we do not guarantee the obligations of any other entity. As of March 31, 2011, we had $0.7 million of financing available under a capital equipment lease line. Aside from this lease line, we had no other established banking arrangements through which we could obtain short-term financing or a line of credit. In October 2010, we filed a shelf registration statement on Form S-3 registering the sale, in one or more offerings, of an indeterminate amount of equity or debt securities, together or separately. Our October 2010 public offering of approximately 6.3 million shares of Common Stock was completed under this shelf registration statement; however, there is no assurance that we will be able to complete any additional offerings of securities. Factors influencing the availability of additional financing include our progress in product development and commercialization, investor perception of our prospects, and the general condition of the financial markets. We may not be able to secure the necessary funding through new collaborative arrangements or additional public or private offerings. If we cannot raise adequate funds to satisfy our capital requirements, we may have to delay, scale-back, or eliminate certain of our research and development activities or future operations. This could materially harm our business.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

Our earnings and cash flows are subject to fluctuations due to changes in interest rates, principally in connection with our investments in marketable securities, which consist primarily of direct obligations of the U.S. government and its agencies, other debt securities guaranteed by the U.S. government, and money market funds that invest in U.S. Government securities. We do not believe we are materially exposed to changes in interest rates. Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes. We estimate that a one percent unfavorable change in interest rates would have resulted in approximately a $5.5 million and $1.6 million decrease in the fair value of our investment portfolio at March 31, 2011 and 2010, respectively. The increase in interest rate risk year over year is due primarily to higher balances of marketable debt securities with maturities in excess of one year that we held at March 31, 2011 compared to the same period of 2010.

Credit Quality Risk

We have an investment policy that includes guidelines on acceptable investment securities, minimum credit quality, maturity parameters, and concentration and diversification. Nonetheless, deterioration of the credit quality of an investment security subsequent to purchase may subject us to the risk of not being able to recover the full principal value of the security. We recognized an other-than-temporary impairment charge related to a marketable security of $0.1 million in the first quarter of 2010. During the first quarter of 2011, we did not recognize any other-than-temporary impairment charges.

ITEM 4. CONTROLS AND PROCEDURES

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

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended March 31, 2011 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

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

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

ITEM 1A. RISK FACTORS

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

Risks Related to Our Financial Results and Need for Additional Financing

We have had a history of operating losses and we may never achieve profitability. If we continue to incur operating losses, we may be unable to continue our operations.

From inception on January 8, 1988 through March 31, 2011, we had a cumulative loss of $1.1 billion. If we continue to incur operating losses and fail to become a profitable company, we may be unable to continue our operations. In the absence of substantial revenue from the sale of products or other sources, the amount, timing, nature or source of which cannot be predicted, our losses will continue as we conduct our research and development activities.

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

We will need to expend substantial resources for research and development, including costs associated with clinical testing of our product candidates, and to prepare for potential commercialization of our late-stage product candidates and, if one or more of those product candidates receive(s) regulatory approval, to fund the launch of those product(s). We believe our existing capital resources, together with funding we are entitled to receive under our collaboration agreements, will enable us to meet operating needs through at least 2013; however, one or more of our collaboration agreements may terminate, our projected revenue may decrease, or our expenses may increase, which could result in our capital being consumed significantly before that time. Our expenses may increase for many reasons, including expenses in connection with the potential commercial launch of our late-stage product candidates, expenses related to clinical trials testing ARCALYST® or VEGF Trap-Eye, and expenses related to the potential requirement for us to fund 20% of Phase 3 clinical trial costs for any of our antibody product candidates pursuant to the terms of our collaboration with sanofi-aventis.

We may require additional financing in the future and we may not be able to raise additional funds. If we are able to obtain additional financing through the sale of equity or convertible debt securities, such sales may be dilutive to our shareholders. Debt financing arrangements may require us to pledge certain assets or enter into covenants that would restrict our business activities or our ability to incur further indebtedness and may contain other terms that are not favorable to our shareholders. In October 2010, we filed a shelf registration statement on Form S-3 registering the sale, in one or more offerings, of an indeterminate amount of equity or debt securities, together or separately. Our October 2010 public offering of approximately 6.3 million shares of Common Stock was completed under this shelf registration statement; however, there is no assurance that we will be able to complete any additional offerings of securities. Should we require and be unable to raise sufficient funds to complete the development of our product candidates and also to successfully commercialize our late-stage product candidates if they obtain regulatory approval, we may face delay, reduction, or elimination of our research and development or preclinical or clinical programs, and even if regulatory approval is obtained for such product candidates, they may never be successfully launched or become profitable, in which case our business, financial condition, or results of operations may be materially harmed.

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

As of March 31, 2011, our cash, cash equivalents, and marketable securities totaled $607.6 million (including $7.5 million of restricted cash and marketable securities) and represented 57% of our total assets. We have invested our excess cash primarily in direct obligations of the U.S. government and its agencies, other debt securities guaranteed by the U.S. government, and money market funds that invest in U.S. government securities. We consider assets classified as marketable securities to be “available-for-sale,” as defined by FASB authoritative guidance. Marketable securities totaled $464.7 million at March 31, 2011, are carried at fair value, and the unrealized gains and losses are included in other accumulated comprehensive income (loss) as a separate component of stockholders’ equity. If the decline in the value of a security in our investment portfolio is deemed to be other-than-temporary, we write down the security to its current fair value and recognize a loss which may be fully charged against income. For example, we recognized an other-than-temporary impairment charge related to a marketable security of $0.1 million in 2010. The current economic environment and the volatility of securities markets increase the risk that we may not recover the principal we invested and/or there may be further declines in the market value of securities in our investment portfolio. As a result, we may incur additional charges against income in future periods for other-than-temporary impairments or realized losses upon a security’s sale or maturity, and such amounts may be material.

Risks Related to the Development and Approval of Our Product Candidates

We believe that a significant portion of the value attributed to our company by investors is based on the commercial potential of VEGF Trap-Eye for the treatment of wet AMD and other ophthalmologic diseases, which has not yet been approved by the FDA or by regulatory authorities in countries outside the U.S. If there are material delays in obtaining marketing approval for VEGF Trap-Eye, or such approval is not obtained, our business, results of operations, and financial condition will be materially harmed.

The FDA has substantial discretion in deciding whether or not VEGF Trap-Eye should be granted approval in the U.S. based on the benefits and risks of VEGF Trap-Eye in treating the particular ophthalmologic diseases in which it is being studied in clinical trials. Analogous regulatory authorities in countries outside the U.S. have similar discretion as to approval of VEGF Trap-Eye in those countries. In February 2011, we submitted a BLA for VEGF Trap-Eye for the treatment of wet AMD to the FDA. In April 2011, the FDA accepted the BLA for filing and granted our request for Priority Review. Under Priority Review, the target date for an FDA decision on the BLA is August 20, 2011. However, the FDA is not under any legal obligation to complete its review of the BLA or to render a decision within this timeframe, and it is not unusual for the FDA's review of and/or rendering a decision with respect to a BLA that has been granted Priority Review to extend beyond the initial target date. For instance, the FDA may request additional clinical or other data or information, including by issuing a complete response letter which may require that we submit additional clinical or other data or impose other conditions that must be met in order to secure final approval of our BLA. Even if such data and information are submitted, the FDA may ultimately decide that the BLA does not satisfy the criteria for approval. The granting of Priority Review designation for our BLA does not change the standards for approval and does not ensure that VEGF Trap-Eye for the treatment of wet AMD will be approved.

Whether VEGF Trap-Eye is approved by the FDA for the treatment of wet AMD, and the timing thereof, will depend on many factors, including the following:

- whether or not the FDA determines that the evidence gathered in well-controlled clinical trials, other clinical trials and nonclinical studies of VEGF Trap-Eye demonstrates that it is safe and effective as a treatment for wet AMD;
- whether or not the FDA is satisfied that the manufacturing facilities, processes, and controls for VEGF Trap-Eye are adequate, that the labeling is satisfactory and that plans for post-marketing studies, safety monitoring, and risk evaluation and management are sufficient; and
- the timing and nature of the FDA's comments and questions, or those of any advisers to the FDA if the FDA seeks external advice, regarding our BLA for VEGF Trap-Eye for the treatment of wet AMD, the time required to respond to any such comments and questions and to obtain final labeling, and any other delays that may be associated with the BLA review process.

If we experience material delays in obtaining marketing approval for VEGF Trap-Eye for wet AMD in the U.S., we will not receive product revenues during the delay, which would negatively affect our business, results of operations, and financial condition. Such delays may also increase the challenge of competitive products as doctors and patients continue to use existing therapies. If we do not obtain approval to market VEGF Trap-Eye for wet AMD in the U.S., or if there are material delays in obtaining such approval, our business and financial position will be materially harmed.

If we do not obtain regulatory approval for our product candidates, we will not be able to market or sell them, which would materially and negatively impact our business and prospects.

We cannot sell or market products without regulatory approval. If we do not obtain and maintain regulatory approval for our product candidates, including ARCALYST® for the treatment of diseases other than CAPS, VEGF Trap-Eye for the treatment of ophthalmologic diseases, and/or ZALTRAPTM for one or more oncology indications, the value of our company and our results of operations will be materially harmed. As with our BLA for VEGF Trap-Eye for the treatment of wet AMD, we cannot predict as to whether or when our other product candidates, including ZALTRAPTM for second-line treatment of mCRC, VEGF Trap-Eye for CRVO and DME, and ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering therapy, will receive regulatory approval. If we are unable to obtain such approval(s), or if we are materially delayed in doing so, our business and prospects would be materially harmed.

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

In the U.S., we must obtain and maintain approval from the FDA for each drug we intend to sell. Obtaining FDA approval is typically a lengthy and expensive process, and approval is highly uncertain. Foreign governments also regulate drugs distributed in their country and approval in any country is likely to be a lengthy and expensive process, and approval is highly uncertain. Except for FDA approval of ARCALYST®, and the EMA approval of rilonacept, for the treatment of CAPS, none of our product candidates has ever received regulatory approval to be marketed and sold in the U.S. or any other country. We may never receive regulatory approval for any of our current or future product candidates.

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

Before approving a new drug or biologic product, the FDA requires that the facilities at which the product will be manufactured be in compliance with current Good Manufacturing Practices, or cGMP, requirements. Manufacturing product candidates in compliance with these regulatory requirements is complex, time-consuming, and expensive. To be successful, our products must be manufactured for development, and following approval in commercial quantities, in compliance with regulatory requirements, and at competitive costs. If we or any of our product collaborators or third-party manufacturers, product packagers, or labelers are unable to maintain regulatory compliance, the FDA can impose regulatory sanctions, including, among other things, refusal to approve a pending application for a new drug or biologic product, or revocation of a pre-existing approval. As a result, our business, financial condition, and results of operations may be materially harmed.

In addition to the FDA and other regulatory agency regulations in the U.S., we are subject to a variety of foreign regulatory requirements governing human clinical trials, manufacturing, marketing and approval of drugs, and commercial sale and distribution of drugs in foreign countries. The foreign regulatory approval process includes all of the risks associated with FDA approval as well as country specific regulations. Whether or not we obtain FDA approval for a product in the U.S., we must obtain approval of the product by the comparable regulatory authorities in foreign countries before we can conduct clinical trials of or market that product or any other product in those countries.

Clinical trials required for our product candidates are expensive and time-consuming, and their outcome is highly uncertain. If any of our drug trials are delayed or yield unfavorable results, regulatory approval for our product candidates may be delayed or become unobtainable.

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

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

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

Only a small minority of all research and development programs ultimately result in commercially successful drugs. We are testing ZALTRAPTM and VEGF Trap-Eye in a number of late-stage clinical trials. Clinical trials may not demonstrate statistically sufficient effectiveness and safety to obtain the requisite regulatory approvals for these product candidates. In a number of instances, we have terminated the development of product candidates due to a lack of or only modest effectiveness. Moreover, even if we obtain positive results from preclinical or clinical trials, we may not achieve the same success in future trials. Many companies in the biopharmaceutical industry, including Regeneron, have suffered significant setbacks in clinical trials, even after promising results have been obtained in earlier trials.

In April 2011 we announced that our Phase 3 VELOUR trial of ZALTRAPTM met its primary endpoint of improving overall survival in the second-line treatment of mCRC, and that based upon these positive results, we and sanofi-aventis plan to submit regulatory applications for marketing approval to the FDA and EMA in the second half of 2011. However, we can give no assurance as to whether or when such applications, if submitted, will be approved. ZALTRAPTM is also in a Phase 3 clinical trial in combination with a standard chemotherapy regimen for the treatment of first-line androgen independent prostate cancer. We do not have proof of concept data from early-stage, double-blind, controlled clinical trials that ZALTRAPTM will be safe or effective in this cancer setting. In March 2010, Genentech announced that a Phase 3 trial of its VEGF antagonist, Avastin® (Bevacizumab Injection), in combination with chemotherapy in men with prostate cancer, did not meet its primary endpoint. This trial had a very similar design to our ongoing Phase 3 trial of ZALTRAPTM in prostate cancer.

We are testing VEGF Trap-Eye in Phase 3 trials for the treatment of wet AMD, the treatment of CRVO, and the treatment of DME. As described above, in February 2011, we submitted a BLA to the FDA for marketing approval of VEGF Trap-Eye in wet AMD in the U.S. In April 2011, the FDA accepted the BLA for filing and granted our request for Priority Review. Although we reported positive Phase 3 trial results with VEGF Trap-Eye in wet AMD after one year of treatment, the Phase 3 trials will continue for an additional year and there is a risk that the results from the second year of the studies could differ from the previously reported results; such difference could delay or preclude regulatory approval or, if regulatory approval has been granted, result in the revocation of such approval. We also reported positive Phase 3 trial results with VEGF Trap-Eye in CRVO after six months of treatment. The trials are continuing and there is a risk that the one-year results from the studies could differ from the previously reported results, and such final results could delay or preclude regulatory approval. We also reported positive results of a Phase 2 trial in the treatment of DME and that we have initiated a Phase 3 program in that indication. A number of other potential new drugs and biologics which showed promising results in Phase 1 and 2 clinical trials subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals, and this could occur with respect to subsequent clinical trials of VEGF Trap-Eye for the treatment of DME.

Based on the results of three Phase 3 studies, we plan to submit a supplemental BLA to the FDA seeking approval of ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering drug therapy. However, there can be no assurance as to if or when the FDA will grant such approval.

Many of our clinical trials are conducted under the oversight of IDMCs. These independent oversight bodies are made up of external experts who review the progress of ongoing clinical trials, including available safety and efficacy data, and make recommendations concerning a trial's continuation, modification, or termination based on interim, unblinded data. Any of our ongoing clinical trials may be discontinued or amended in response to recommendations made by responsible IDMCs based on their review of such interim trial results. For example, in September 2009, a Phase 3 trial that was evaluating ZALTRAPTM as a first-line treatment for metastic pancreatic cancer in combination with gemcitabine was discontinued at the recommendation of an IDMC after a planned analysis of interim efficacy data determined that the trial would not meet its efficacy endpoint. The recommended termination of any of our ongoing late-stage clinical trials by an IDMC could negatively impact the future development of our product candidate(s), and our business may be materially harmed.

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

Serious complications or side effects have occurred, and may continue to occur, in connection with the use of our approved product and in clinical trials of some of our product candidates which could cause our regulatory approval to be revoked or otherwise negatively affected or lead to delay or discontinuation of development of our product candidates which could severely harm our business.

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

ZALTRAPTM is being studied for the potential treatment of certain types of cancer and our VEGF Trap-Eye candidate is being studied in diseases of the eye. There are many potential safety concerns associated with significant blockade of VEGF that may limit our ability to successfully develop ZALTRAPTM and VEGF Trap-Eye. These serious and potentially life-threatening risks, based on clinical and preclinical experience of VEGF inhibitors, include bleeding, intestinal perforation, hypertension, proteinuria, congestive heart failure, heart attack, and stroke. In addition, patients given infusions of any protein, including VEGF Trap delivered through intravenous administration, may develop severe hypersensitivity reactions or infusion reactions. Other VEGF blockers have reported side effects that became evident only after large scale trials or after marketing approval when large numbers of patients were treated. There are risks inherent in the intravitreal administration of drugs like VEGF Trap-Eye, which can cause injury to the eye and other complications. These and other complications or side effects could harm the development of ZALTRAPTM for the treatment of cancer or VEGF Trap-Eye for the treatment of diseases of the eye.

As more patients begin to use ARCALYST® if it receives approval for the prevention of gout flares in patients initiating uric acid-lowering therapy, and to the extent it is tested in new disease settings, new risks and side effects associated with ARCALYST® may be discovered, and risks previously viewed as inconsequential could be determined to be significant. Like cytokine antagonists such as Ilaris® (canakinumab), a registered trademark of Novartis, Kineret® (anakinra), a registered trademark of Biovitrum AB, Enbrel® (etanercept), a registered trademark of Amgen, Inc. and Pfizer Inc., and Remicade® (infliximab) a registered trademark of Centocor Ortho Biotech, ARCALYST® affects the immune defense system of the body by blocking some of its functions. Therefore, ARCALYST® may interfere with the body's ability to fight infections. Treatment with Kineret®, a medication that works through the inhibition of IL-1, has been associated with an increased risk of serious infections, and serious, life threatening infections have been reported in patients taking ARCALYST®. These or other complications or side effects could cause regulatory authorities to revoke approvals of ARCALYST® for the treatment of CAPS or deny the approval of ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering treatment or other disease settings. Alternatively, we may be required to conduct additional clinical trials, make changes in the labeling of our product, or limit or abandon our efforts to develop ARCALYST® in new disease settings. Any such side effects may also result in a reduction, or even the elimination, of sales of ARCALYST® in approved indications.

We are studying REGN475, a fully human monoclonal antibody to NGF, in a variety of pain indications, including osteoarthritis of the knee. In December 2010, we were informed by the FDA that a case confirmed as avascular necrosis of a joint was seen in another company's anti-NGF program. The FDA believes this case, which follows previously-reported cases of joint replacements in patients on an anti-NGF drug candidate being developed by another pharmaceutical company, provides evidence to suggest a class-effect and placed REGN475 on clinical hold. There are currently no ongoing trials with REGN475 that are either enrolling or treating patients.

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

In addition to the safety, efficacy, manufacturing, and regulatory hurdles faced by our product candidates, the administration of recombinant proteins frequently causes an immune response, resulting in the creation of antibodies against the therapeutic protein. The antibodies can have no effect or can totally neutralize the effectiveness of the protein, or require that higher doses be used to obtain a therapeutic effect. In some cases, the antibody can cross react with the patient's own proteins, resulting in an "auto-immune" type disease. Whether antibodies will be created can often not be predicted from preclinical or clinical experiments, and their detection or appearance is often delayed, so that there can be no assurance that neutralizing antibodies will not be detected at a later date, in some cases even after pivotal clinical trials have been completed. Antibodies directed against the receptor domains of ARCALYST® were detected in patients with CAPS after treatment with ARCALYST®. Nineteen of 55 subjects (35%) who received ARCALYST® for at least 6 weeks tested positive for treatment-emerging binding antibodies on at least one occasion. To date, no side effects related to antibodies were observed in these subjects and there were no observed effects on drug efficacy or drug levels. It is possible that as we continue to test ZALTRAPTM and VEGF Trap-Eye with more sensitive assays in different patient populations, we will find that subjects given ZALTRAPTM and VEGF Trap-Eye develop antibodies to these product candidates, and may also experience side effects related to the antibodies, which could adversely impact the development of such candidates.

We may be unable to formulate or manufacture our product candidates in a way that is suitable for clinical or commercial use.

Changes in product formulations and manufacturing processes may be required as product candidates progress in clinical development and are ultimately commercialized. If we are unable to continue to develop suitable product formulations or manufacturing processes to support large scale clinical testing of our product candidates, including our antibody candidates, we may be unable to supply necessary materials for our clinical trials, which would delay the development of our product candidates. Similarly, if we are unable to supply sufficient quantities of our product or develop product formulations suitable for commercial use, we will not be able to successfully commercialize our product candidates.

Risks Related to Intellectual Property

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

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

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

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

We are aware of patents and pending applications owned by Genentech that claim certain chimeric VEGF receptors. We do not believe that ZALTRAPTM or VEGF Trap-Eye infringes any valid claim in these patents or patent applications. As described above under Item 1 (“Legal Proceedings”), in November 2010, we commenced a lawsuit against Genentech in the U.S. District Court for the Southern District of New York, seeking a declaratory judgment that no activities relating to the Regeneron VEGF Trap infringe any valid claim of certain Genentech patents referred to as the Davis-Smyth patents. In April 2011, we and Genentech entered into a Joint Stipulation whereby Genentech agreed that it would not seek to transfer the case to another judicial district or move to dismiss the case for lack of subject matter jurisdiction. On April 25, 2011, Genentech filed an answer to our complaint, denying that we are entitled to the declaratory relief being sought by us, and asserting counterclaims that our prior or planned activities relating to VEGF Trap have infringed or will infringe one or more claims of the Davis-Smyth patents. In its answer, Genentech requests a judgment against us for damages, including for willful infringement, and other relief as the Court deems appropriate. We believe Genentech's counterclaims are without merit and intend to defend against them vigorously. However, it is possible that there could be an adverse determination or judgment in this litigation that would materially harm our business by requiring us to seek a license, which may not be available, or precluding the manufacture, further development, or sale of ZALTRAPTM or VEGF Trap-Eye, or resulting in a damage award. In addition, irrespective of the outcome of this litigation, we have incurred and will likely continue to incur significant costs and expenses associated with this matter, which has negatively affected, and will likely continue to negatively affect, our results of operations. We have initiated patent-related actions against Genentech in Germany and the United Kingdom, and may initiate other actions in other countries outside the U.S., which could have similar or other adverse outcomes that would materially harm our business and which, irrespective of the outcomes, may also entail significant costs and expenses.

We are aware of patents and pending applications owned by Roche that claim antibodies to IL-6R and methods of treating rheumatoid arthritis with such antibodies. We are developing REGN88, an antibody to IL-6R, for the treatment of rheumatoid arthritis. Although we do not believe that REGN88 infringes any valid claim in these patents or patent applications, Roche could initiate a lawsuit for patent infringement and assert its patents are valid and cover REGN88.

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

Further, we are aware of a number of other third-party patent applications that, if granted with claims as currently drafted, may cover our current or planned activities. We cannot assure you that our products and/or actions in manufacturing and selling our product candidates will not infringe such patents.

Any patent holders could sue us for damages and seek to prevent us from manufacturing, selling, or developing our drug candidates, and a court may find that we are infringing validly issued patents of third parties. In the event that the manufacture, use, or sale of any of our clinical candidates infringes on the patents or violates other proprietary rights of third parties, we may be prevented from pursuing product development, manufacturing, and commercialization of our drugs and may be required to pay costly damages. Such a result may materially harm our business, financial condition, and results of operations. Legal disputes are likely to be costly and time consuming to defend.

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

Risks Related to Manufacturing and Supply

We have limited manufacturing capacity, and we rely on contract manufacturers for fill and finish, which could result in our being unable to successfully commercialize our products if they receive regulatory approval and to continue to develop our clinical candidates.

Our manufacturing facility is likely to be inadequate to produce sufficient commercial quantities of all of our late-stage products if they receive regulatory approval. We intend to rely on our corporate collaborators, as well as contract manufacturers, to produce commercial quantities of drug material needed for commercialization of our products to the extent such quantities are not manufactured at our own facility. We rely entirely on third-party manufacturers for filling and finishing services. Generally, in order for third parties to perform any step in the manufacturing and supply chain, we must transfer technology to the third party which can be time consuming and may not be successfully accomplished without considerable cost and expense, or at all. We will have to depend on these third parties to perform effectively on a timely basis and to comply with regulatory requirements. If for any reason they are unable to do so, and as a result we are unable to manufacture and supply sufficient commercial quantities of our products on acceptable terms, or if we should encounter delays or other difficulties in our relationships with our corporate collaborators or third-party manufacturers or other vendors in our supply chain which adversely affect the timely manufacture and supply of our products, our business, financial condition, and results of operations may be materially harmed.

We also must expand our own manufacturing capacity to support the planned growth of our clinical pipeline. Moreover, we will need to expand our manufacturing capacity to supply commercial quantities of the active pharmaceutical ingredients for our product candidates if they are approved for marketing. This will require substantial additional expenditures, and we will need to hire and train significant numbers of employees and managerial personnel to staff our facility. Start-up costs can be large and scale-up entails significant risks related to process development and manufacturing yields. The FDA and analogous foreign regulatory authorities must determine that our manufacturing facilities comply, or continue to comply, with cGMP requirements for both clinical and commercial production and license them, or continue to license them, accordingly. We may not successfully expand or establish sufficient manufacturing capabilities or manufacture our products economically or in compliance with cGMPs and other regulatory requirements, and we and our collaborators may not be able to build or procure additional capacity in the required timeframe to meet commercial demand for VEGF-Trap-Eye, ZALTRAPTM, or our other late-stage product candidates if they receive regulatory approval, and to continue to meet the requirements of our clinical programs. This would interfere with our efforts to successfully commercialize VEGF Trap-Eye, ZALTRAPTM, and our other late-stage product candidates if they receive regulatory approval and could also delay our clinical development programs. As a result, our business, financial condition, and results of operations may be materially harmed.

We may also be unable to obtain key raw materials and supplies for the manufacture of ARCALYST® and our product candidates. In addition, we may face difficulties in developing or acquiring production technology and managerial personnel to manufacture sufficient quantities of our product candidates at reasonable costs and in compliance with applicable quality assurance and environmental regulations and governmental permitting requirements.

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

Our ability to manufacture ARCALYST®, and our late-stage product candidates, including VEGF Trap-Eye and ZALTRAPTM in our Rensselaer, New York facilities, or to utilize third-party contract manufacturers to produce our products or perform fill/finish services, depends on our and their ability to operate without infringing the patents or other intellectual property rights of third parties. Other parties may allege that our manufacturing activities, or the activities of third parties involved in our manufacture and supply chain, infringe patents or other intellectual property rights. A judicial decision in favor of one or more parties making such allegations could preclude the manufacture of our products which could materially harm our business, operations and prospects.

If any of our clinical programs are delayed or discontinued, we may face costs related to the unused capacity at our manufacturing facilities and those of our third-party contract manufacturers performing fill/finish services.

We have large-scale manufacturing operations in Rensselaer, New York. We use our facilities to produce bulk product for clinical and preclinical candidates for ourselves and our collaborations. If our clinical candidates are discontinued, or their clinical development is delayed, we may have to absorb one hundred percent of related overhead costs and inefficiencies, as well as similar costs of third-party contract manufacturers performing fill/finish services for us.

Third-party supply or other failures, business interruptions, or natural disasters affecting our manufacturing facilities in Rensselaer, New York could adversely affect our ability to supply our products.

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

Certain raw materials necessary for the manufacture and formulation of ARCALYST® and of our product candidates, including VEGF Trap-Eye and ZALTRAPTM, are provided by single-source unaffiliated third-party suppliers. In addition, we rely on certain third parties to perform filling, finishing, distribution, laboratory testing, and other services related to the manufacture of ARCALYST® and our product candidates. We would be unable to obtain these raw materials or services for an indeterminate period of time if any of these third parties were to cease or interrupt production or otherwise fail to supply these materials, products, or services to us for any reason, including due to regulatory requirements or action, adverse financial developments at or affecting the supplier, failure by the supplier to comply with GMPs, business interruptions, or labor shortages or disputes. This, in turn, could materially and adversely affect our ability to manufacture or supply ARCALYST® or our product candidates for use in clinical trials or commercial supply, which could materially and adversely affect our business and future prospects.

Also, certain of the raw materials required in the manufacture and the formulation of our product candidates may be derived from biological sources, including mammalian tissues, bovine serum, and human serum albumin. There are certain European regulatory restrictions on using these biological source materials. If we are required to substitute for these sources to comply with European regulatory requirements, our clinical development activities may be delayed or interrupted.

Risks Related to Commercialization of Products

Even if we receive regulatory approval to market our products, we may be unsuccessful in commercializing them, which would materially harm our business, results of operations, and financial condition.

Even if clinical trials demonstrate the safety and effectiveness of any of our product candidates for a specific disease and the necessary regulatory approvals are obtained, the commercial success of any of our product candidates will depend upon, among other things, their acceptance by patients, the medical community, and third-party payers and on our and our collaborators' ability to successfully manufacture and commercialize those products. Even if we obtain regulatory approval for our product candidates, if they are not successfully commercialized, we will not be able to recover the significant investment we have made in developing such products and our business, results of operations, and financial condition would be severely harmed.

If we are unable to establish sales, marketing, and distribution capabilities, or to enter into agreements with third parties to do so, we will be unable to successfully market and sell our products.

We are selling ARCALYST® for the treatment of CAPS ourselves in the U.S., primarily through third-party service providers. We have no sales or distribution personnel in the U.S. and have only a small staff with commercial capabilities. If we are unable to obtain those capabilities, either by developing our own organizations or entering into agreements with service providers, even if our current or future product candidates receive marketing approval, we will not be able to successfully sell those products. In that event, we will not be able to generate significant revenue, even if our product candidates receive regulatory approval. We cannot guarantee that we will be able to hire the qualified sales and marketing personnel we need or that we will be able to enter into marketing or distribution agreements with third-party providers on acceptable terms, if at all.

We currently have no sales, marketing, commercial, or distribution capabilities outside the U.S. Under the terms of our collaboration agreement with sanofi-aventis, we will rely on sanofi-aventis for sales, marketing, and distribution of ZALTRAPTM in cancer indications, should it be approved in the future by regulatory authorities for marketing. Under the terms of our license and collaboration agreement with Bayer HealthCare, we will rely on Bayer HealthCare for sales, marketing, and distribution of VEGF Trap-Eye in countries outside the U.S. should it be approved for marketing in such countries.

We will have to rely on a third party or devote significant resources to develop our own sales, marketing, and distribution capabilities for our other product candidates, including VEGF Trap-Eye in the U.S. and ARCALYST® for patients with gout initiating uric acid-lowering drug therapy if such products receive regulatory approval. Though we are currently actively pursuing establishing our own sales, marketing, and distribution organization in anticipation of receiving regulatory approval to market and sell in the U.S. VEGF Trap-Eye for the treatment of wet AMD, and in anticipation of filing for and receiving regulatory approval to market and sell in the U.S. VEGF Trap-Eye for the treatment of CRVO and ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering treatment, we may be unsuccessful in doing so.

We have no experience in sales, marketing, or distribution of products in substantial commercial quantities or in establishing and managing the required infrastructure to do so, including large-scale information technology systems and a large-scale distribution network, and we may be unable to establish such infrastructure on a timely basis. In building a sales force in anticipation of the possible approval and launch in the U.S. of VEGF Trap-Eye in wet AMD and other ophthalmologic indications for which it is currently in Phase 3 clinical trials and of ARCALYST® for the prevention of gout flares, we may be unable to successfully recruit and retain within the required time frame an adequate number of qualified sales representatives and may encounter difficulties in retaining third parties to provide sales, marketing, or distribution resources. Even if we hire the qualified sales and marketing personnel, and establish the required infrastructure we need to support our objectives, or enter into marketing and distribution agreements with third parties on acceptable terms, we may not do so in an efficient manner or on a timely basis. We may not be able to correctly judge the size and experience of the sales and marketing force and the scale of distribution capabilities necessary to successfully market and sell in the U.S. VEGF Trap-Eye, ARCALYST® for the prevention of gout flares, or any of our other product candidates, if they receive regulatory approval. Establishing and maintaining sales, marketing, and distribution capabilities are expensive and time-consuming. Our expenses associated with building up and maintaining the sales force and distribution capabilities may be disproportional, particularly in the near term, compared to the revenues we may be able to generate on sales in the U.S. of VEGF Trap-Eye or ARCALYST® for the prevention of gout flares. We cannot guarantee that we will be successful in commercializing VEGF Trap-Eye, ARCALYST® for the prevention of gout flares, or any of our other product candidates.

Even if our product candidates are approved for marketing, their commercial success is highly uncertain given their method of administration, and because our competitors have received approval for and may be marketing products with a similar mechanism of action or may enter the marketplace with better or lower cost drugs.

Our product candidates are delivered either by intravenous infusion or by intravitreal or subcutaneous injections, which are generally less well received by patients than tablet or capsule delivery and this could adversely affect the commercial success of those products if they receive marketing approval.

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

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

The market for eye disease products is also very competitive. Novartis and Genentech are collaborating on the commercialization and further development of a VEGF antibody fragment, Lucentis® for the treatment of wet AMD, DME, and other eye indications. Lucentis® was approved by the FDA in June 2006 for the treatment of wet AMD and in June 2010 for the treatment of macular edema following RVO. Lucentis® was also approved by the EMA for wet AMD in January 2007 and for DME in January 2011. Many other companies are working on the development of product candidates for the potential treatment of wet AMD and DME including those that act by blocking VEGF and VEGF receptors, as well as siRNAs that modulate gene expression. In addition, ophthalmologists are using off-label, with success for the treatment of wet AMD, DME, and RVO, a third-party repackaged version of Genentech's approved VEGF antagonist, Avastin®.

The NEI and others are conducting long-term, controlled clinical trials comparing Lucentis® to Avastin® in the treatment of wet AMD. One-year data from the Comparison of Age-Related Macular Degeneration Treatments Trial (CATT), were reported in April 2011 and indicated that Avastin® dosed monthly was non-inferior to Lucentis® dosed monthly in the primary efficacy endpoint of mean visual acuity gain at 52 weeks. Even if our BLA for VEGF Trap-Eye for the treatment of wet AMD which was filed in February 2011 is approved, it may be difficult for VEGF Trap-Eye in this or other eye indications for which it may be approved to compete against Lucentis®, because doctors and patients have had significant experience using this medicine. Moreover, the recently reported results of the CATT study, combined with the relatively low cost of Avastin® in treating patients with wet AMD, may well exacerbate the competitive challenge which VEGF Trap-Eye will face in this or other eye indications for which it may be approved. In addition, while we believe that ZALTRAPTM would not be well tolerated if administered directly to the eye, if ZALTRAPTM is approved for the treatment of certain cancers, there is a risk that third parties will attempt to repackage ZALTRAPTM for use and sale for the treatment of wet AMD and other diseases of the eye, which would present a potential low-cost competitive threat to VEGF Trap-Eye if it is ever approved for wet AMD or other eye indications.

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

There are both small molecules and antibodies in development by other companies that are designed to block the synthesis of IL-1 or inhibit the signaling of IL-1. For example, Eli Lilly, Xoma Ltd. (in collaboration with Servier), and Novartis are each developing antibodies to IL-1 and both Amgen and MedImmune are developing antibodies to the IL-1 receptor. In 2009, Novartis received regulatory approval in the U.S. and Europe for canakinumab, a fully human anti-interleukin-IL1ß antibody, for the treatment of CAPS. Canakinumab is also in development for atherosclerosis and a number of other inflammatory diseases. Novartis' IL-1 antibody and these other drug candidates could offer competitive advantages over ARCALYST®. For example, canakinumab is dosed once every eight weeks compared to the once-weekly dosing regimen for ARCALYST®. The successful development and/or commercialization of these competing molecules could adversely affect sales of ARCALYST® for CAPS and delay or impair our ability to commercialize ARCALYST® for indications other than CAPS.

We are developing ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering therapy and plan to submit a BLA for U.S. regulatory approval in mid-2011. In January 2011, Novartis announced that the results of two Phase 3 studies with canakinumab focused on reducing pain and preventing recurrent attacks or "flares" in patients with hard-to-treat gout were positive. Novartis has also reported that regulatory filings for the use of canakinumab in gouty arthritis have been completed in the European Union in 2010 and in the U.S. in the first quarter of 2011, based on the results of these two Phase 3 studies. Canakinumab is dosed less frequently for the treatment of CAPS and may be perceived as offering competitive advantages over ARCALYST® in gout by some physicians, which would make it difficult for us to successfully commercialize ARCALYST® in that disease.

Currently, inexpensive, oral therapies such as analgesics and other Nonsteroidal anti-inflammatory drugs (NSAIDS), are used as the standard of care to treat the symptoms of gout diseases. These established, inexpensive, orally delivered drugs will make it difficult for us to successfully commercialize ARCALYST® in these diseases.

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

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

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

The successful commercialization of our product candidates will depend on obtaining coverage and reimbursement for use of these products from third-party payers and these payers may not agree to cover or reimburse for use of our products, and we may be unable to profitably commercialize ARCALYST® for CAPS.

Our product candidates, if commercialized, may be significantly more expensive than traditional drug treatments. For example, we are developing ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering drug therapy. Patients suffering from this gout indication are currently treated with inexpensive therapies, including NSAIDS. These existing treatment options are likely to be considerably less expensive and may be preferable to a biologic medication for some patients. Our future revenues and profitability will be adversely affected if U.S. and foreign governmental, private third-party insurers and payers, and other third-party payers, including Medicare and Medicaid, do not agree to defray or reimburse the cost of our products to the patients. If these entities refuse to provide coverage and reimbursement with respect to our products or provide an insufficient level of coverage and reimbursement, our products may be too costly for many patients to afford them, and physicians may not prescribe them. Many third-party payers cover only selected drugs, making drugs that are not preferred by such payers more expensive for patients, and require prior authorization or failure on another type of treatment before covering a particular drug. In particular, payers may impose these obstacles to coverage on higher-priced drugs, as our product candidates are likely to be.

We market and sell ARCALYST® in the U.S. for the treatment of a group of rare genetic disorders called CAPS. We have received European Union marketing authorization for rilonacept for the treatment of CAPS. There may be too few patients with CAPS to profitably commercialize ARCALYST®. Physicians may not prescribe ARCALYST®, and CAPS patients may not be able to afford ARCALYST®, if third-party payers do not agree to reimburse the cost of ARCALYST® therapy and this would adversely affect our ability to commercialize ARCALYST® profitably.

In addition to potential restrictions on coverage, the amount of reimbursement for our products may also reduce our profitability. Government and other third-party payers are challenging the prices charged for healthcare products and increasingly limiting, and attempting to limit, both coverage and level of reimbursement for prescription drugs. In March 2010, the PPACA and a related reconciliation bill were enacted in the U.S. This legislation imposes cost containment measures that are likely to adversely affect the amount of reimbursement for our future products. The full effects of this legislation are unknown at this time and will not be known until regulations and guidance are issued by the Centers for Medicare and Medicaid Services and other federal and state agencies. Some states are also considering legislation that would control the prices of drugs, and state Medicaid programs are increasingly requesting manufacturers to pay supplemental rebates and requiring prior authorization by the state program for use of any drug for which supplemental rebates are not being paid. It is likely that federal and state legislatures and health agencies will continue to focus on additional health care reform in the future that will impose additional constraints on prices and reimbursements for our products.

Since ARCALYST® and our product candidates will likely be too expensive for most patients to afford without health insurance coverage, if our products are unable to obtain adequate coverage and reimbursement by third-party payers, our ability to successfully commercialize our product candidates may be adversely impacted. Any limitation on the use of our products or any decrease in the price of our products will have a material negative effect on our ability to achieve profitability.

In certain foreign countries, pricing, coverage, and level of reimbursement of prescription drugs are subject to governmental control, and we may be unable to negotiate coverage, pricing, and reimbursement on terms that are favorable to us. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Our results of operations may suffer if we are unable to market our products in foreign countries or if coverage and reimbursement for our products in foreign countries is limited or delayed.

Regulatory and Litigation Risks

If we fail to meet the stringent requirements of governmental regulation in the manufacture of drug products or product candidates, we could incur substantial remedial costs, delays in the development or approval of our product candidates and/or in their commercial launch if they obtain regulatory approval, and a reduction in sales.

We and our third-party providers are required to maintain compliance with cGMP, and are subject to inspections by the FDA or comparable agencies in other jurisdictions to confirm such compliance. Changes of suppliers or modifications of methods of manufacturing may require amending our application(s) to the FDA and acceptance of the change by the FDA prior to release of product(s). Because we produce multiple product candidates at our facility in Rensselaer, New York, including ARCALYST®, VEGF Trap-Eye, and ZALTRAPTM, there are increased risks associated with cGMP compliance. Our inability, or the inability of our third-party fill/finish or other service providers, to demonstrate ongoing cGMP compliance could require us to engage in lengthy and expensive remediation efforts, withdraw or recall product, halt or interrupt clinical trials, and/or interrupt commercial supply of any marketed products, and could also delay or prevent our obtaining regulatory approval for our late-stage product candidates. Any delay, interruption or other issues that arise in the manufacture, fill/finish, packaging, or storage of any drug products or product candidates as a result of a failure of our facilities or the facilities or operations of third parties to pass any regulatory agency inspection or maintain cGMP compliance could significantly impair our ability to develop, obtain approval for, and successfully commercialize our products, which would substantially harm our business and prospects. Any finding of non-compliance could also increase our costs, cause us to delay the development of our product candidates, and cause us to lose revenue from our marketed product, which could be seriously detrimental to our business and financial condition.

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

The testing, manufacturing, marketing, and sale of drugs for use in people expose us to product liability risk. Any informed consent or waivers obtained from people who enroll in our clinical trials may not protect us from liability or the cost of litigation. We may also be subject to claims by patients who use our approved product, ARCALYST® for the treatment of CAPS, that they have been injured by a side effect associated with the drug. We may face product liability claims and be found responsible even if injury arises from the acts or omissions of our third-party fill/finish or other providers. Our product liability insurance may not cover all potential liabilities or may not completely cover any liability arising from any such litigation. Moreover, in the future we may not have access to liability insurance or be able to maintain our insurance on acceptable terms.

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

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

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Pharmaceutical companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in promotion for uses that the FDA has not approved, known as off-label uses, that caused claims to be submitted to Medicaid for non-covered off-label uses, and submitting inflated best price information to the Medicaid Rebate program.

The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer’s products from reimbursement under government programs, criminal fines, and imprisonment.

Even if it is determined that we have not violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which would harm our business and financial results and condition. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be challenged under one or more of such laws.

In recent years, several states and localities, including California, the District of Columbia, Massachusetts, Maine, Minnesota, Nevada, New Mexico, Vermont, and West Virginia, have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, and file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Similar requirements are being considered in other states. In addition, as part of the federal Patient Protection and Affordable Care Act, or PPACA, pharmaceutical companies will be required to file reports with the federal government regarding payments made to healthcare professionals. Many of these requirements are new and uncertain, and the penalties for failure to comply with these requirements are unclear. Nonetheless, if we are found not to be in full compliance with these laws, we could face enforcement actions, fines, and other penalties, and could receive adverse publicity, which would harm our business and financial results and condition.

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

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

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

We are subject to changing rules and regulations of various federal and state governmental authorities as well as the stock exchange on which our Common Stock is listed. These entities, including the Public Company Accounting Oversight Board (PCAOB), the SEC and The NASDAQ Stock Market LLC, have issued a significant number of new and increasingly complex requirements and regulations over the course of the last several years and continue to develop additional requirements and regulations in response to laws enacted by Congress, including the Sarbanes-Oxley Act of 2002 and, most recently, the Dodd-Frank Wall Street Reform and Protection Act, or the Dodd-Frank Act. There are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Act that expressly authorized or required the SEC to adopt additional rules in these areas, such as shareholder approval of executive compensation (so-called “say on pay”) and proxy access. On January 25, 2011, the SEC adopted final rules concerning “say on pay”. Our efforts to comply with these requirements and regulations have resulted in, and are likely to continue to result in, an increase in expenses and a diversion of management’s time from other business activities.

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

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

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

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

- changes in the FDA and foreign regulatory processes for new therapeutics that may delay or prevent the approval of any of our current or future product candidates;
- new laws, regulations, or judicial decisions related to healthcare availability or the payment for healthcare products and services, including prescription drugs, that would make it more difficult for us to market and sell products once they are approved by the FDA or foreign regulatory agencies;

- changes in FDA and foreign regulations that may require additional safety monitoring prior to or after the introduction of new products to market, which could materially increase our costs of doing business; and
- changes in FDA and foreign cGMPs that make it more difficult for us to manufacture our marketed product and clinical candidates in accordance with cGMPs.

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

Risks Related to Our Reliance on Third Parties

If our antibody collaboration with sanofi-aventis is terminated, our business operations and financial condition, and our ability to discover, develop, manufacture, and commercialize our pipeline of product candidates in the time expected, or at all, would be materially harmed.

We rely heavily on funding from sanofi-aventis to support our target discovery and antibody research and development programs. Sanofi-aventis has committed to pay up to $1.28 billion between 2010 and 2017 to fund our efforts to identify and validate drug discovery targets and pre-clinically develop fully human monoclonal antibodies against such targets. In addition, sanofi-aventis funds almost all of the development expenses incurred by both companies in connection with the clinical development of antibodies that sanofi-aventis elects to co-develop with us. We rely on sanofi-aventis to fund these activities. In addition, with respect to those antibodies that sanofi-aventis elects to co-develop with us, such as REGN727, REGN88, REGN668, REGN421, REGN910, and REGN475, we rely on sanofi-aventis to lead much of the clinical development efforts and assist with obtaining regulatory approval, particularly outside the U.S. We also rely on sanofi-aventis to lead the commercialization efforts to support all of the antibody products that are co-developed by sanofi-aventis and us. If sanofi-aventis does not elect to co-develop the antibodies that we discover or opts-out of their development, we would be required to fund and oversee on our own the clinical trials, any regulatory responsibilities, and the ensuing commercialization efforts to support our antibody products. If sanofi-aventis terminates the antibody collaboration or fails to comply with its payment obligations thereunder, our business, financial condition, and results of operations would be materially harmed. We would be required to either expend substantially more resources than we have anticipated to support our research and development efforts, which could require us to seek additional funding that might not be available on favorable terms or at all, or materially cut back on such activities. While we cannot assure you that any of the antibodies from this collaboration will ever be successfully developed and commercialized, if sanofi-aventis does not perform its obligations with respect to antibodies that it elects to co-develop, our ability to develop, manufacture, and commercialize these antibody product candidates will be significantly adversely affected.

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

We rely heavily on sanofi-aventis to lead much of the development of ZALTRAPTM. Sanofi-aventis funds all of the development expenses incurred by both companies in connection with the ZALTRAPTM program. If the ZALTRAPTM program continues, we will rely on sanofi-aventis to assist with funding the ZALTRAPTM program, provide commercial manufacturing capacity, enroll and monitor clinical trials, obtain regulatory approval, particularly outside the U.S., and lead the commercialization of ZALTRAPTM. While we cannot assure you that ZALTRAPTM will ever be successfully developed and commercialized, if sanofi-aventis does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize ZALTRAPTM in cancer indications will be significantly adversely affected. Sanofi-aventis has the right to terminate its collaboration agreement with us at any time upon twelve months advance notice. If sanofi-aventis were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could require us to seek additional funding that might not be available on favorable terms or at all, and could cause significant delays in the development and/or manufacture of ZALTRAPTM and result in substantial additional costs to us. We have limited commercial capabilities and would have to develop or outsource these capabilities. Termination of the sanofi-aventis collaboration agreement for ZALTRAPTM would create substantial new and additional risks to the successful development and commercialization of ZALTRAPTM.

If our collaboration with Bayer HealthCare for VEGF Trap-Eye is terminated, or Bayer HealthCare materially breaches its obligations thereunder, our business operations and financial condition, and our ability to continue to develop VEGF Trap-Eye and commercialize VEGF Trap-Eye in the time expected, or at all, would be materially harmed.

We rely heavily on Bayer HealthCare to assist with the development of VEGF Trap-Eye. Under our agreement with them, Bayer HealthCare is required to fund approximately half of the development expenses incurred by both companies in connection with the global VEGF Trap-Eye development program. As the VEGF Trap-Eye program continues, we will continue to rely on Bayer HealthCare to assist with funding the VEGF Trap-Eye development program, lead the development of VEGF Trap-Eye outside the U.S., obtain regulatory approval outside the U.S., and provide all sales, marketing, and commercial support for the product outside the U.S. In particular, Bayer HealthCare has responsibility for selling VEGF Trap-Eye outside the U.S. using its sales force. While we cannot assure you that VEGF Trap-Eye will ever receive regulatory approval in or outside the U.S. or be successfully commercialized, if Bayer HealthCare does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize VEGF Trap-Eye outside the U.S. will be significantly adversely affected. Bayer HealthCare has the right to terminate its collaboration agreement with us at any time upon six or twelve months advance notice, depending on the circumstances giving rise to termination. If Bayer HealthCare were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could require us to seek additional funding that might not be available on favorable terms or at all, and could cause significant delays in the development and/or commercialization of VEGF Trap-Eye outside the U.S. and result in substantial additional costs to us. We currently have limited commercial capabilities and would have to develop or outsource these capabilities outside the U.S. Termination of the Bayer HealthCare collaboration agreement would create substantial new and additional risks to the successful development and commercialization of VEGF Trap-Eye.

Our collaborators and service providers may fail to perform adequately in their efforts to support the development, manufacture, and commercialization of our drug candidates and sales of ARCALYST® for CAPS.

We depend upon third-party collaborators, including sanofi-aventis, Bayer HealthCare, and service providers such as CROs, outside testing laboratories, clinical investigator sites, and third-party manufacturers and product packagers and labelers, to assist us in the manufacture and preclinical and clinical development of our product candidates. If any of our existing collaborators or service providers breaches or terminates its agreement with us or does not perform its development or manufacturing services under an agreement in a timely manner or in compliance with applicable GMPs, Good Laboratory Practices (GLPs), or GCP Standards, we could experience additional costs, delays, and difficulties in the manufacture or development of, or in obtaining approval by regulatory authorities for our, product candidates.

We rely on third-party service providers to support the distribution of ARCALYST® and many other related activities in connection with the commercialization of ARCALYST® for the treatment of CAPS. We cannot be certain that these third parties will perform adequately. If these service providers do not perform their services adequately, our sales of ARCALYST® for the treatment of CAPS will suffer and ARCALYST® for that indication may never become profitable.

Risk Related to Employees

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

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

Risks Related to Our Common Stock

Our stock price is extremely volatile.

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

- announcement of actions by the FDA or foreign regulatory authorities regarding our currently pending or future application(s) for regulatory approval of our late-stage product candidate(s);
- announcement of submission of an application for regulatory approval of one or more of our late-stage product candidates;
- progress, delays, or adverse results in clinical trials;
- announcement of technological innovations or product candidates by us or competitors;
- fluctuations in our operating results;
- third-party claims that our products or technologies infringe their patents;
- public concern as to the safety or effectiveness of ARCALYST® or any of our product candidates;
- developments in our relationship with collaborative partners;
- developments in the biotechnology industry or in government regulation of healthcare;
- large sales of our Common Stock by our executive officers, directors, or significant shareholders;
- arrivals and departures of key personnel; and
- general market conditions.

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

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

A small number of our shareholders beneficially own a substantial amount of our Common Stock. As of April 13, 2011, our five largest shareholders plus Leonard S. Schleifer, M.D, Ph.D., our Chief Executive Officer, beneficially owned 55.0% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of April 13, 2011. In September 2003, sanofi-aventis (then Aventis Pharmaceuticals Inc.) purchased 2,799,552 newly issued, unregistered shares of our Common Stock, and in December 2007 sanofi-aventis purchased an additional 12 million newly issued, unregistered shares of our Common Stock. Under our investor agreement, as amended, with sanofi-aventis, these shares may not be sold until December 20, 2017 except under limited circumstances and subject to earlier termination of these restrictions upon the occurrence of certain events. In addition, in October 2010, sanofi-aventis purchased an additional 1,017,401 shares of Common Stock in our underwritten public offering. As of April 13, 2011, sanofi-aventis beneficially owned 15,816,953 shares of our Common Stock, representing approximately 17.8% of the shares of Common Stock then outstanding. If sanofi-aventis, or our other significant shareholders or we, sell substantial amounts of our Common Stock in the public market, or the perception that such sales may occur exists, the market price of our Common Stock could fall. Sales of Common Stock by our significant shareholders, including sanofi-aventis, also might make it more difficult for us to raise funds by selling equity or equity-related securities in the future at a time and price that we deem appropriate.

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

Holders of Class A Stock, who are generally the shareholders who purchased their stock from us before our initial public offering, are entitled to ten votes per share, while holders of Common Stock are entitled to one vote per share. As of April 13, 2011, holders of Class A Stock held 19.5% of the combined voting power of all shares of Common Stock and Class A Stock then outstanding. These shareholders, if acting together, would be in a position to significantly influence the election of our directors and to effect or prevent certain corporate transactions that require majority or supermajority approval of the combined classes, including mergers and other business combinations. This may result in our taking corporate actions that other shareholders may not consider to be in their best interest and may affect the price of our Common Stock. As of April 13, 2011:

- our current executive officers and directors beneficially owned 12.1% of our outstanding shares of Common Stock, assuming conversion of their Class A Stock into Common Stock and the exercise of all options held by such persons which are exercisable within 60 days of April 13, 2011, and 25.8% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by such persons which are exercisable within 60 days of April 13, 2011; and
- our five largest shareholders plus Leonard S. Schleifer, M.D., Ph.D. our Chief Executive Officer, beneficially owned 55.0% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of April 13, 2011. In addition, these six shareholders held 59.2% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by our Chief Executive Officer which are exercisable within 60 days of April 13, 2011.

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

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

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

- authorization to issue "blank check" preferred stock, which is preferred stock that can be created and issued by the board of directors without prior shareholder approval, with rights senior to those of our common shareholders;
- a staggered board of directors, so that it would take three successive annual meetings to replace all of our directors;
- a requirement that removal of directors may only be effected for cause and only upon the affirmative vote of at least eighty percent (80%) of the outstanding shares entitled to vote for directors, as well as a requirement that any vacancy on the board of directors may be filled only by the remaining directors;
- any action required or permitted to be taken at any meeting of shareholders may be taken without a meeting, only if, prior to such action, all of our shareholders consent, the effect of which is to require that shareholder action may only be taken at a duly convened meeting;

- any shareholder seeking to bring business before an annual meeting of shareholders must provide timely notice of this intention in writing and meet various other requirements; and
- under the New York Business Corporation Law, in addition to certain restrictions which may apply to "business combinations" involving the Company and an "interested shareholder", a plan of merger or consolidation of the Company must be approved by two-thirds of the votes of all outstanding shares entitled to vote thereon. See the risk factor immediately above captioned "Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval."

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

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

ITEM 6. EXHIBITS

(a) Exhibits

Exhibit Number	Description	
31.1	-	Certification of CEO pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
31.2	-	Certification of CFO pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
32	-	Certification of CEO and CFO pursuant to 18 U.S.C. Section 1350.
101	-	Interactive Data File
101.INS	-	XBRL Instance Document
101.SCH	-	XBRL Taxonomy Extension Schema
101.CAL	-	XBRL Taxonomy Extension Calculation Linkbase
101.LAB	-	XBRL Taxonomy Extension Label Linkbase
101.PRE	-	XBRL Taxonomy Extension Presentation Linkbase
101.DEF	-	XBRL Taxonomy Extension Definition Document

SIGNATURE

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

REGENERON PHARMACEUTICALS, INC.

Date: May 3, 2011

By: /s/ MURRAY A. GOLDBERG

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