

REGENERON PHARMACEUTICALS INC  
Form 10-Q  
July 28, 2010

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2010

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  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  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

Accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company)

Smaller reporting company

## Edgar Filing: REGENERON PHARMACEUTICALS INC - Form 10-Q

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

Yes                      No    X

Number of shares outstanding of each of the registrant's classes of common stock as of July 15, 2010:

Class of Common Stock	Number of Shares
Class A Stock, \$0.001 par value	2,182,036
Common Stock, \$0.001 par value	79,931,305

---

REGENERON PHARMACEUTICALS, INC.

Table of Contents

June 30, 2010

	Page Numbers
<b>PART I</b>	<b>FINANCIAL INFORMATION</b>
<b>Item 1</b>	<b>Financial Statements</b>
	Condensed balance sheets (unaudited) at June 30, 2010 and December 31, 2009
	3
	Condensed statements of operations (unaudited) for the three and six months ended June 30, 2010 and 2009
	4
	Condensed statements of stockholders' equity (unaudited) for the six months ended June 30, 2010 and 2009
	5
	Condensed statements of cash flows (unaudited) for the six months ended June 30, 2010 and 2009
	6
	Notes to condensed financial statements (unaudited)
	7-13
<b>Item 2</b>	<b>Management's Discussion and Analysis of Financial Condition and Results of Operations</b>
	14-37
<b>Item 3</b>	<b>Quantitative and Qualitative Disclosures About Market Risk</b>
	37
<b>Item 4</b>	<b>Controls and Procedures</b>
	37-38
<b>PART II</b>	<b>OTHER INFORMATION</b>
<b>Item 1</b>	<b>Legal Proceedings</b>
	38
<b>Item 1A</b>	<b>Risk Factors</b>
	38-54
<b>Item 6</b>	<b>Exhibits</b>
	54
<b>SIGNATURE PAGE</b>	<b>55</b>

Edgar Filing: REGENERON PHARMACEUTICALS INC - Form 10-Q

PART I. FINANCIAL INFORMATION  
ITEM 1. FINANCIAL STATEMENTS

REGENERON PHARMACEUTICALS, INC.  
CONDENSED BALANCE SHEETS AT JUNE 30, 2010 AND DECEMBER 31, 2009 (Unaudited)  
(In thousands, except share data)

	June 30, 2010	December 31, 2009
<b>ASSETS</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 112,000	\$ 207,075
Marketable securities	194,337	134,255
Accounts receivable from the sanofi-aventis Group	91,126	62,703
Accounts receivable - other	4,070	2,865
Prepaid expenses and other current assets	16,217	18,610
<b>Total current assets</b>	<b>417,750</b>	<b>425,508</b>
Restricted cash	3,400	1,600
Marketable securities	70,465	47,080
Property, plant, and equipment, at cost, net of accumulated depreciation and amortization	292,329	259,676
Other assets	6,697	7,338
<b>Total assets</b>	<b>\$ 790,641</b>	<b>\$ 741,202</b>
<b>LIABILITIES and STOCKHOLDERS' EQUITY</b>		
<b>Current liabilities</b>		
Accounts payable and accrued expenses	\$ 58,256	\$ 49,031
Deferred revenue from sanofi-aventis, current portion	19,126	17,523
Deferred revenue - other, current portion	41,741	27,021
Facility lease obligations, current portion	448	
<b>Total current liabilities</b>	<b>119,571</b>	<b>93,575</b>
Deferred revenue from sanofi-aventis	96,168	90,933
Deferred revenue - other	42,009	46,951
Facility lease obligations	157,359	109,022
Other long term liabilities	4,318	3,959
<b>Total liabilities</b>	<b>419,425</b>	<b>344,440</b>
<b>Commitments and contingencies</b>		
<b>Stockholders' equity</b>		
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 2010 and 2,244,698 in 2009	2	2
Common Stock, \$.001 par value; 160,000,000 shares authorized; shares issued and outstanding - 79,923,216 in 2010 and 78,860,862 in 2009	80	79
Additional paid-in capital	1,368,531	1,336,732
Accumulated deficit	(997,091)	(941,095)
Accumulated other comprehensive (loss) income	(306)	1,044
<b>Total stockholders' equity</b>	<b>371,216</b>	<b>396,762</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 790,641</b>	<b>\$ 741,202</b>

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



Edgar Filing: REGENERON PHARMACEUTICALS INC - Form 10-Q

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

	Three months ended June 30,		Six months ended June 30,	
	2010	2009	2010	2009
<b>Revenues</b>				
Sanofi-aventis collaboration revenue	\$ 84,941	\$ 60,732	\$ 153,612	\$ 110,392
Other collaboration revenue	13,635	12,846	26,722	22,794
Technology licensing	10,037	10,000	20,075	20,000
Net product sales	5,197	4,500	15,049	8,391
Contract research and other	2,076	1,954	3,962	3,436
	115,886	90,032	219,420	165,013
<b>Expenses</b>				
Research and development	124,526	94,231	241,997	174,538
Selling, general, and administrative	14,679	11,632	28,902	23,052
Cost of goods sold	405	435	1,122	827
	139,610	106,298	272,021	198,417
Loss from operations	(23,724)	(16,266)	(52,601)	(33,404)
<b>Other income (expense)</b>				
Investment income	592	1,328	1,031	3,078
Interest expense	(2,342)		(4,426)	
	(1,750)	1,328	(3,395)	3,078
Net loss	\$ (25,474)	\$ (14,938)	\$ (55,996)	\$ (30,326)
Net loss per share, basic and diluted	\$ (0.31)	\$ (0.19)	\$ (0.69)	\$ (0.38)
Weighted average shares outstanding, basic and diluted	81,492	79,626	81,330	79,562

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

Edgar Filing: REGENERON PHARMACEUTICALS INC - Form 10-Q

REGENERON PHARMACEUTICALS, INC.  
 CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY (Unaudited)  
 For the six months ended June 30, 2010 and 2009  
 (In thousands)

	Class A Stock		Common Stock		Additional	Accumulated	Accumulated	Total
	Shares	Amount	Shares	Amount	Paid-in Capital	Deficit	Other Comprehensive Income (Loss)	Stockholders' Equity
Balance, December 31, 2009	2,245	\$ 2	78,861	\$ 79	\$ 1,336,732	\$ (941,095)	\$ 1,044	\$ 39
Issuance of Common Stock in connection with exercise of stock options, net of shares tendered			878	1	11,391			1
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			111		2,867			
Issuance of restricted Common Stock under Long-Term Incentive Plan			10					
Conversion of Class A Stock to Common Stock	(63)		63					
Stock-based compensation expense					17,541			1
Net loss						(55,996)		(5)
Change in net unrealized gain (loss) on marketable securities							(1,350)	
Balance, June 30, 2010	2,182	\$ 2	79,923	\$ 80	\$ 1,368,531	\$ (997,091)	\$ (306)	\$ 39
Balance, December 31, 2008	2,249	\$ 2	77,642	\$ 78	\$ 1,294,813	\$ (873,265)	\$ (114)	\$ 42
Issuance of Common Stock in connection with exercise of stock options, net of shares tendered			196		1,705			
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			81		1,391			
Conversion of Class A Stock to Common Stock	(2)		2					
Stock-based compensation expense					15,094			
Net loss						(30,326)		(3)
Change in net unrealized gain (loss) on marketable securities							1,128	
Balance, June 30, 2009	2,247	\$ 2	77,921	\$ 78	\$ 1,313,003	\$ (903,591)	\$ 1,014	\$ 41

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

Edgar Filing: REGENERON PHARMACEUTICALS INC - Form 10-Q

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

	Six months ended June 30,	
	2010	2009
<b>Cash flows from operating activities</b>		
Net loss	\$ (55,996)	\$ (30,326)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	8,707	5,722
Non-cash compensation expense	17,541	15,094
Other non-cash charges and expenses	225	
Net realized loss on marketable securities	200	
Changes in assets and liabilities		
Increase in accounts receivable	(29,628)	(24,834)
Decrease (increase) in prepaid expenses and other assets	1,604	(578)
Increase in deferred revenue	16,616	5,873
Increase in accounts payable, accrued expenses, and other liabilities	18,105	13,045
Total adjustments	33,370	14,322
Net cash used in operating activities	(22,626)	(16,004)
<b>Cash flows from investing activities</b>		
Purchases of marketable securities	(222,168)	(105,315)
Sales or maturities of marketable securities	137,909	190,723
Capital expenditures	(45,324)	(52,671)
(Increase) decrease in restricted cash	(1,800)	50
Net cash (used in) provided by investing activities	(131,383)	32,787
<b>Cash flows from financing activities</b>		
Proceeds in connection with facility lease obligations	47,544	5,182
Payments in connection with facility lease obligations	(674)	
Net proceeds from the issuance of Common Stock	12,064	1,705
Net cash provided by financing activities	58,934	6,887
Net (decrease) increase in cash and cash equivalents	(95,075)	23,670
Cash and cash equivalents at beginning of period	207,075	247,796
Cash and cash equivalents at end of period	\$ 112,000	\$ 271,466

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



## Edgar Filing: REGENERON PHARMACEUTICALS INC - Form 10-Q

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, 2009 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, 2009.

Effective in the first quarter of 2010, the estimated useful lives of certain capitalized laboratory and other equipment, which is a component of property, plant, and equipment, was extended. The effect of this change in estimate was to lower depreciation expense by \$1.0 million and \$2.0 million and to lower the Company’s net loss per share by \$0.01 and \$0.02 for the three and six months ended June 30, 2010, respectively.

### 2. ARCALYST® (riloncept) 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.

ARCALYST® net product sales totaled \$5.2 million and \$4.5 million for the three months ended June 30, 2010 and 2009, respectively, and \$15.0 million and \$8.4 million for the six months ended June 30, 2010 and 2009, respectively. ARCALYST® net product sales during the first six months of 2010 included \$10.2 million of net product sales made during this period and \$4.8 million of previously deferred net product sales, as described above. There was no deferred ARCALYST® net product sales revenue at June 30, 2010. At June 30, 2009, deferred ARCALYST® net product sales revenue was \$4.9 million. 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 six months ended June 30, 2010.

Cost of goods sold related to ARCALYST® sales, which consisted primarily of royalties, totaled \$0.4 million for both the three months ended June 30, 2010 and 2009, and \$1.1 million and \$0.8 million for the six months ended June 30, 2010 and 2009, respectively. To date, ARCALYST® shipments to the Company’s customers have consisted of supplies of inventory manufactured and expensed prior to FDA approval of ARCALYST®; therefore, the costs of these supplies were not included in costs of goods sold. At both June 30, 2010 and December 31, 2009, the Company had \$0.4 million of inventoried work-in-process costs related to ARCALYST®, which is included in prepaid expenses and other current assets.

Edgar Filing: REGENERON PHARMACEUTICALS INC - Form 10-Q

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

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

3. Per Share Data

The Company's basic and diluted net loss per share amounts have been computed by dividing net loss by the weighted average number of shares of Common Stock and Class A Stock outstanding. Net loss per share is presented on a combined basis, inclusive of Common Stock and Class A Stock outstanding, as each class of stock has equivalent economic rights. For the three and six months ended June 30, 2010 and 2009, the Company reported net losses; therefore, no common stock equivalents were included in the computation of diluted net loss per share for these periods, since such inclusion would have been antidilutive. The calculations of basic and diluted net loss per share are as follows:

	Three Months Ended June 30,	
	2010	2009
Net loss (Numerator)	\$ (25,474)	\$ (14,938)
Weighted-average shares, in thousands (Denominator)	81,492	79,626
Basic and diluted net loss per share	\$ (0.31)	\$ (0.19)

	Six Months Ended June 30,	
	2010	2009
Net loss (Numerator)	\$ (55,996)	\$ (30,326)
Weighted-average shares, in thousands (Denominator)	81,330	79,562
Basic and diluted net loss per share	\$ (0.69)	\$ (0.38)

Shares issuable upon the exercise of stock options and vesting of restricted stock awards, which have been excluded from the June 30, 2010 and 2009 diluted per share amounts because their effect would have been antidilutive, include the following:

	Three months ended June 30,	
	2010	2009
<b>Stock Options:</b>		
Weighted average number, in thousands	21,288	20,106
Weighted average exercise price	\$ 18.67	\$ 17.56

<b>Restricted Stock:</b>		
Weighted average number, in thousands	510	500

	Six months ended June 30,	
	2010	2009
<b>Stock Options:</b>		
Weighted average number, in thousands	21,344	20,161
Weighted average exercise price	\$ 18.63	\$ 17.56

<b>Restricted Stock:</b>		
Weighted average number, in thousands	506	500

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

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

4. Statement of Cash Flows

Supplemental disclosure of noncash investing and financing activities:

Included in accounts payable and accrued expenses at June 30, 2010 and December 31, 2009 were \$4.1 million and \$9.8 million, respectively, of accrued capital expenditures. Included in accounts payable and accrued expenses at June 30, 2009 and December 31, 2008 were \$12.1 million and \$7.0 million, respectively, of accrued capital expenditures.

Included in accounts payable and accrued expenses at December 31, 2009 and 2008 were \$2.6 million and \$1.5 million, respectively, of accrued Company 401(k) Savings Plan contribution expense. In the first quarter of 2010 and 2009, the Company contributed 111,419 and 81,086 shares, respectively, of Common Stock to the 401(k) Savings Plan in satisfaction of these obligations.

Pursuant to the application of authoritative guidance issued by the Financial Accounting Standards Board ("FASB") to the Company's lease of office and laboratory facilities in Tarrytown, New York, the Company recognized a facility lease obligation of \$1.3 million for the six months ended June 30, 2009, in connection with capitalizing, on the Company's books, the landlord's costs of constructing new facilities that the Company has leased.

Included in facility lease obligations and property, plant, and equipment at June 30, 2010 was \$1.7 million of capitalized and deferred interest for the six months ended June 30, 2010, as the related facilities being leased by the Company are currently under construction and lease payments on these facilities do not commence until January 2011.

Included in other assets at December 31, 2009 was \$0.7 million due to the Company in connection with employee exercises of stock options.

Included in marketable securities at June 30, 2010 and December 31, 2009 were \$1.3 million and \$0.6 million, respectively, of accrued interest income. Included in marketable securities at June 30, 2009 and December 31, 2008 were \$1.3 million and \$1.7 million, respectively, of accrued interest income.

5. Marketable Securities

Marketable securities at June 30, 2010 and December 31, 2009 consisted of debt securities, as detailed below, and an equity security, the aggregate fair value of which was \$3.8 million and \$5.5 million at June 30, 2010 and December 31, 2009, respectively, and the aggregate cost basis of which was \$4.0 million at both June 30, 2010 and December 31, 2009. The following tables summarize the amortized cost basis of debt securities included in marketable securities, the aggregate fair value of those securities, and gross unrealized gains and losses on those securities at June 30, 2010 and December 31, 2009. 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.

Edgar Filing: REGENERON PHARMACEUTICALS INC - Form 10-Q

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

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

At June 30, 2010	Amortized	Fair	Unrealized		Net
	Cost Basis	Value	Gains	(Losses)	
<b>Maturities within one year</b>					
U.S. government obligations	\$ 156,142	\$ 156,208	\$ 70	\$ (4)	\$ 66
U.S. government guaranteed corporate bonds	31,216	31,362	146		146
Corporate bonds	3,053	3,067	14		14
Mortgage-backed securities	773	707		(66)	(66)
U.S. government guaranteed collateralized mortgage obligations	2,803	2,993	190		190
	193,987	194,337	420	(70)	350
<b>Maturities between one and four years</b>					
U.S. government obligations	30,476	30,536	60		60
U.S. government guaranteed corporate bonds	32,240	32,648	408		408
Mortgage-backed securities	1,450	1,313		(137)	(137)
Municipal bonds	2,196	2,192	3	(7)	(4)
	66,362	66,689	471	(144)	327
	\$ 260,349	\$ 261,026	\$ 891	\$ (214)	\$ 677
<b>At December 31, 2009</b>					
<b>Maturities within one year</b>					
U.S. government obligations	\$ 100,491	\$ 100,573	\$ 82		\$ 82
U.S. government guaranteed corporate bonds	17,176	17,340	164		164
Corporate bonds	10,142	10,342	200		200
Mortgage-backed securities	2,471	2,338		(133)	(133)
U.S. government guaranteed collateralized mortgage obligations	3,612	3,662	50		50
	133,892	134,255	496	(133)	363
<b>Maturities between one and two years</b>					
U.S. government obligations	9,413	9,367		(46)	(46)
U.S. government guaranteed corporate bonds	31,064	31,344	280		280
Mortgage-backed securities	1,168	900		(268)	(268)
	41,645	41,611	280	(314)	(34)
	\$ 175,537	\$ 175,866	\$ 776	\$ (447)	\$ 329

At June 30, 2010 and December 31, 2009, marketable securities included an additional unrealized loss of \$0.3 million and an additional unrealized gain of \$1.4 million, respectively, related to the equity security in the Company's marketable securities portfolio.

The following table shows the fair value of the Company's marketable securities that have unrealized losses and that are deemed to be only temporarily impaired, aggregated by investment category and length of time that the individual securities have been in a continuous unrealized loss position, at June 30, 2010 and December 31, 2009. The debt securities listed at June 30, 2010 mature at various dates through July 2013.

At June 30, 2010	Less than 12 Months Unrealized		12 Months or Greater Unrealized		Total Unrealized	
	Fair Value	Loss	Fair Value	Loss	Fair Value	Loss
U.S. government obligations	\$ 23,417	\$ (4)			\$ 23,417	\$ (4)
Mortgage-backed securities			\$ 2,020	\$ (203)	2,020	(203)
Municipal bonds	1,188	(7)			1,188	(7)

Edgar Filing: REGENERON PHARMACEUTICALS INC - Form 10-Q

Equity security	3,776	(268)			3,776	(268)
	\$ 28,381	\$ (279)	\$ 2,020	\$ (203)	\$ 30,401	\$ (482)
At December 31, 2009						
U.S. government obligations	\$ 9,367	\$ (46)			\$ 9,367	\$ (46)
Mortgage-backed securities			\$ 3,238	\$ (401)	3,238	(401)
	\$ 9,367	\$ (46)	\$ 3,238	\$ (401)	\$ 12,605	\$ (447)

Edgar Filing: REGENERON PHARMACEUTICALS INC - Form 10-Q

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

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

Realized gains and losses are included as a component of investment income. For the three and six months ended June 30, 2010 and 2009, 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 June 30, 2010 and December 31, 2009, were as follows:

	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)
<b>At June 30, 2010</b>				
Available-for-sale marketable securities				
U.S. government obligations	\$ 186,744		\$ 186,744	
U.S. government guaranteed corporate bonds	64,010		64,010	
Corporate bonds	3,067		3,067	
Mortgage-backed securities	2,020		2,020	
U.S. government guaranteed collateralized mortgage obligations	2,993		2,993	
Municipal bonds	2,192		2,192	
Equity security	3,776	\$ 3,776		
	\$ 264,802	\$ 3,776	\$ 261,026	
<b>At December 31, 2009</b>				
Available-for-sale marketable securities				
U.S. government obligations	\$ 109,940		\$ 109,940	
U.S. government guaranteed corporate bonds	48,684		48,684	
Corporate bonds	10,342		10,342	
Mortgage-backed securities	3,238		3,238	
U.S. government guaranteed collateralized mortgage obligations	3,662		3,662	
Equity security	5,469	\$ 5,469		
	\$ 181,335	\$ 5,469	\$ 175,866	

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 six months ended June 30, 2010, deterioration in the credit quality of a marketable security from one issuer subjected the Company to the risk of not being able to recover the carrying value of the security. As a result, the Company recognized a \$0.1 million impairment charge related to this Level 2 marketable security, which the Company considered to be other-than-temporarily impaired. During the three months ended June 30, 2010, and the three and six months ended June 30, 2009, the Company did not record any charges for other-than-temporary impairment of its Level 2 marketable securities.

At June 30, 2009 and December 31, 2008, the Company held one Level 3 marketable security whose fair value was \$0.1 million. This Level 3 security was valued using information provided by the Company's investment advisors, including quoted bid prices which took into consideration the securities' lack of liquidity. During the three and six months ended June 30, 2009, the Company did not record any settlements,

## Edgar Filing: REGENERON PHARMACEUTICALS INC - Form 10-Q

realized gains or losses, or charges for other-than-temporary impairment related to this Level 3 marketable security. In addition, there were no purchases, sales, or maturities of Level 3 marketable securities and no unrealized gains or losses related to Level 3 marketable securities for the three and six months ended June 30, 2010 and 2009. The Company held no Level 3 marketable securities at June 30, 2010 and December 31, 2009. There were no transfers of marketable securities between Levels 1, 2, or 3 classifications during the three and six months ended June 30, 2010 and 2009.

## Edgar Filing: REGENERON PHARMACEUTICALS INC - Form 10-Q

### REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

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

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.

The current economic environment, the deterioration in the credit quality of issuers of securities that the Company holds, and the continuing volatility of securities markets increase the risk of potential declines in the current market value of marketable securities in the Company's investment portfolio. Such declines could result in charges against income in future periods for other-than-temporary impairments and the amounts could be material.

#### 6. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses as of June 30, 2010 and December 31, 2009 consist of the following:

	June 30, 2010	December 31, 2009
Accounts payable	\$ 15,525	\$ 18,638
Accrued payroll and related costs	19,469	9,444
Accrued clinical trial expense	16,141	11,673
Accrued property, plant, and equipment expenditures	2,041	1,883
Accrued expenses, other	5,080	6,207
Payable to Bayer HealthCare		1,186
	<b>\$ 58,256</b>	<b>\$ 49,031</b>

#### 7. Comprehensive Loss

Comprehensive loss of the Company includes net loss adjusted for the change in net unrealized gain (loss) on marketable securities, net of any tax effect. For the three and six months ended June 30, 2010 and 2009, the components of comprehensive loss are:

	Three months ended June 30,	
	2010	2009
Net loss	\$ (25,474)	\$ (14,938)
Change in net unrealized gain (loss) on marketable securities	(1,023)	2,262
Total comprehensive loss	<b>\$ (26,497)</b>	<b>\$ (12,676)</b>

  

	Six months ended June 30,	
	2010	2009
Net loss	\$ (55,996)	\$ (30,326)
Change in net unrealized gain (loss) on marketable securities	(1,350)	1,128
Total comprehensive loss	<b>\$ (57,346)</b>	<b>\$ (29,198)</b>



REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

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

#### 8. Legal Matters

From time to time, the Company is a party to legal proceedings in the course of its business. The Company does not expect any such current legal proceedings to have a material adverse effect on the Company's business or financial condition.

#### 9. Future Impact of Recently Issued Accounting Standards

In March 2010, the FASB amended its authoritative guidance on the milestone method of revenue recognition. The milestone method of revenue recognition has now been codified as an acceptable revenue recognition model when a milestone is deemed to be substantive. This guidance may be applied retrospectively to all arrangements or prospectively for milestones achieved after the adoption of the guidance. The Company will be required to adopt this amended guidance for the fiscal year beginning January 1, 2011, although earlier adoption is permitted. Management does not anticipate that the adoption of this guidance will have a material impact on the Company's financial statements.

#### 10. Subsequent Event- Extension of Technology Licensing Agreement with Astellas

In March 2007, the Company entered into a six-year non-exclusive license agreement with Astellas Pharma Inc. that allows Astellas to utilize the Company's 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 the Company in each of 2010, 2009, 2008, and 2007. In July 2010, the license agreement with Astellas was amended and extended through June 2023. Under the terms of the amended agreement, Astellas will make a \$165.0 million up-front payment to the Company. In addition, Astellas will make a \$130.0 million payment to the Company in June 2018 unless the license agreement has been terminated prior to that date. Astellas has the right to terminate this license agreement at any time by providing 90 days' advance written notice. Under certain limited circumstances, such as a material breach of the agreement by the Company, Astellas may terminate the agreement and receive a refund of a portion of its payment to the Company under the July 2010 amendment to the agreement. The Company is entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by Astellas using the Company's VelocImmune® technology.

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. These statements concern, among other things, the possible success and therapeutic applications of our product candidates and research programs, anticipated sales of our marketed product, the timing and nature of the clinical and research programs now underway or planned, and the future sources and uses of capital and our financial needs. 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 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 eight product candidates in clinical development, including three product candidates that are in late-stage (Phase 3) clinical development. Our late stage programs are ARCALYST®, which is being developed for the prevention of gout flares in patients initiating uric acid-lowering treatment; VEGF Trap-Eye, which is being developed using intraocular delivery for the treatment of eye diseases in collaboration with Bayer HealthCare LLC; and aflibercept (VEGF Trap), which is being developed in oncology in collaboration with the sanofi-aventis Group. Our earlier stage clinical programs are REGN727, an antibody to 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; REGN421, an antibody to Delta-like ligand-4 (Dl14), which is being developed in oncology; REGN668, an antibody to the interleukin-4 receptor (IL-4R), which is being developed in atopic dermatitis; and REGN475, an antibody to Nerve Growth Factor (NGF), which is being developed for the treatment of pain. All five of our earlier stage clinical programs are fully human antibodies that are being developed in collaboration with sanofi-aventis.

Our core business strategy is to maintain a strong foundation in basic scientific research and discovery-enabling technologies and combine that foundation with our clinical development and manufacturing capabilities. Our long-term objective is to build a successful, integrated biopharmaceutical company that provides patients and medical professionals with new and better options for preventing and treating human diseases. However, developing and commercializing new medicines entails significant risk and expense.

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 design and produce new product candidates directed against the disease target. Our five 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 over the next eight years. We continue to invest in the development of enabling technologies to assist in our efforts to identify, develop, manufacture, and commercialize new product candidates.

We and Astellas Pharma Inc. announced in July 2010 that Astellas has extended through 2023 the non-exclusive license agreement that allows Astellas to utilize our VelocImmune® technology in its internal research programs to discover fully human monoclonal antibody product candidates. Astellas will pay \$165.0 million up-front and another \$130.0 million in June 2018 unless it terminates the agreement prior to that date. Upon commercialization of any antibody products discovered utilizing VelocImmune®, Astellas will pay us a mid-single-digit royalty on product sales.

Commercial Product:

ARCALYST®— Cryopyrin-Associated Periodic Syndromes (CAPS)

Net product sales of ARCALYST® Injection for Subcutaneous Use in the second quarter of 2010 were \$5.2 million, compared to \$4.5 million during the same period of 2009. We recognized \$15.0 million of net product sales during the first six months of 2010, which included \$10.2 million of ARCALYST® net product sales made during the first half of 2010 and \$4.8 million of previously deferred net product sales, as described below under “Results of Operations.” In the first six months of 2009, we recognized \$8.4 million of ARCALYST® net product sales. ARCALYST® 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.

ARCALYST® is a protein-based product designed to bind the interleukin-1 (called IL-1) cytokine and prevent its interaction with cell surface receptors. CAPS is 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. ARCALYST®— Inflammatory Diseases

ARCALYST® is being developed for the prevention of gout flares in patients initiating uric acid-lowering therapy. Gout, a disease in which, as in CAPS, 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 with allopurinol, is prescribed to eliminate the urate crystals and prevent reformation. 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.

During the first quarter of 2009, we initiated a Phase 3 clinical development program with ARCALYST® for the treatment of gout. The program included four clinical trials called PRE-SURGE 1 (PREvention Study against URate-lowering drug-induced Gout Exacerbations), PRE-SURGE 2, SURGE (Study Utilizing Rilonacept in Gout Exacerbations), and RE-SURGE (REview of Safety Utilizing Rilonacept in Gout Exacerbations), each of which are described below.

In June 2010, we announced that our PRE-SURGE 1 study in gout patients initiating allopurinol therapy to lower their uric acid levels 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 who received ARCALYST® at a weekly, self-administered, subcutaneous dose of 160 milligrams (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% (3.7% with ARCALYST® 160 mg, 5.0% with ARCALYST® 80 mg, and 31.6% with placebo,  $p < 0.0001$ ). 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, a North America-based double-blind, placebo-controlled study. 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 addition, in June 2010, we reported results from a placebo-controlled, Phase 3 study (called SURGE), evaluating pain in patients presenting with an acute gout flare. The results of this study showed that there was no significant benefit from combining ARCALYST® with indomethacin (a non-steroidal anti-inflammatory drug considered the standard of care), as measured by the primary study endpoint of the average intensity of gout pain from 24 to 72 hours after initiation of treatment. Patients treated with indomethacin alone experienced an average reduction in patient-reported pain scores (0 to 4 Likert scale where 0 represents no pain and 4 represents extreme pain) of 1.40 points from baseline compared to an average reduction of 1.55 points from baseline in patients treated with both indomethacin and ARCALYST® (p=0.33). Patients who received ARCALYST® alone experienced an average pain reduction of 0.69 points. Treatment with ARCALYST® was generally well tolerated with no reported drug-related serious adverse events. The most commonly reported adverse event with ARCALYST® was headache.

There are two ongoing studies in the Phase 3 program with ARCALYST® in the prevention of gout flares in patients initiating uric acid-lowering therapy. The global PRE-SURGE 2 study, which has a similar trial design as PRE-SURGE 1, is evaluating the number of gout flares per patient over the first 16 weeks of initiation of allopurinol therapy. In addition, the global RE-SURGE study is evaluating the safety of ARCALYST® versus placebo over 16 weeks in patients who are at risk for gout flares because they are taking uric acid-lowering drug treatment. PRE-SURGE 2 is fully enrolled and RE-SURGE is over 90% enrolled. Data from both studies are expected in early 2011. We own worldwide rights to ARCALYST®.

#### Royalty Agreement with Novartis Pharma AG

Under a June 2009 agreement with Novartis Pharma AG (that replaced a previous collaboration and license agreement), we receive tiered royalties on worldwide sales of Novartis' canakinumab, a fully human anti-interleukin-IL1 $\beta$  antibody. The multi-tiered royalty rates in the agreement start at 4% and reach 15% when annual sales exceed \$1.5 billion. Canakinumab is approved to treat Cryopyrin-Associated Periodic Syndrome (CAPS) and is in development for gout, type 2 diabetes, and other inflammatory diseases.

#### 2. VEGF Trap-Eye – Ophthalmologic Diseases

VEGF Trap-Eye is a specially purified and formulated form of VEGF Trap, which is being developed for use in intraocular applications. We and Bayer HealthCare are testing VEGF Trap-Eye in Phase 3 programs in patients with the neovascular form of age-related macular degeneration (wet AMD) and central retinal vein occlusion (CRVO). We and Bayer HealthCare are also conducting a Phase 2 study of VEGF Trap-Eye in patients with diabetic macular edema (DME). Wet AMD and diabetic retinopathy (which includes DME) are two of the leading causes of adult blindness in the developed world. In both 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), are comparing VEGF Trap-Eye and Lucentis® (ranibizumab injection), owned by Genentech, Inc., an anti-angiogenic agent approved for use in wet AMD. VIEW 1 is being conducted in North America and VIEW 2 is being conducted in Europe, Asia Pacific, Japan, and Latin America. The VIEW 1 and VIEW 2 trials are both evaluating 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 (after three monthly doses) compared with Lucentis (Genentech) 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 will be evaluated in the second year of the studies, although patients will be dosed no less frequently than every 12 weeks. VIEW 1 and VIEW 2 were fully enrolled in 2009, and initial data are expected in the fourth quarter of 2010.

VEGF Trap-Eye is also in Phase 3 development for the treatment of central retinal vein occlusion (CRVO), another cause of visual impairment. The COPERNICUS (COntrolled Phase 3 Evaluation of Repeated iNtravitreal administration of VEGF Trap-Eye In Central retinal vein occlusion: Utility and Safety) study is being led by Regeneron and the GALILEO (General Assessment Limiting Infiltration of Exudates in central retinal vein Occlusion with VEGF Trap-Eye) study is being led by Bayer HealthCare. Patients in both studies will receive six monthly intravitreal injections of either VEGF Trap-Eye at a dose of 2 mg or sham control injections. The primary endpoint of both studies is improvement in visual acuity versus baseline after six months of treatment. At the end of the initial six months, patients will be dosed on a PRN basis for another six months. All patients will be eligible for rescue laser treatment. COPERNICUS is fully enrolled and GALILEO is over 90% enrolled. Initial data from both studies are anticipated in early 2011.

The Phase 2 DME study, known as DA VINCI (DME And VEGF Trap-Eye: INvestigation of Clinical Impact), is a double-masked, randomized, controlled trial that is evaluating four different dosing regimens of VEGF Trap-Eye versus laser treatment. In February 2010, we and Bayer HealthCare announced that treatment with VEGF Trap-Eye demonstrated a statistically significant improvement in visual acuity compared to focal laser therapy, the primary endpoint of the study. Visual acuity was measured by the mean number of letters gained over the initial 24 weeks of the study. Patients in each of the four dosing groups receiving VEGF Trap-Eye achieved statistically significantly greater mean improvements in visual acuity (8.5 to 11.4 letters of vision gained) compared to patients receiving focal laser therapy (2.5 letters gained) at week 24 ( $p < 0.01$  for each VEGF Trap-Eye group versus focal laser). VEGF Trap-Eye was generally well-tolerated, and no ocular or non-ocular drug-related serious adverse events were reported. The adverse events reported were those typically associated with intravitreal injections or the underlying disease. Following the initial 24 weeks of treatment, patients continue to be treated for another 24 weeks on the same dosing regimens. Initial one-year results will be available later in 2010.

#### Collaboration with Bayer HealthCare

In October 2006, we entered into a collaboration agreement with Bayer HealthCare for the global development and commercialization outside the United States of VEGF Trap-Eye. Under the agreement, we and Bayer HealthCare will collaborate on, and share the costs of, the development of VEGF Trap-Eye through an integrated global plan that encompasses wet AMD, DME, and CRVO. Bayer HealthCare will market VEGF Trap-Eye outside the United States, where the companies will share equally in profits from any future sales of VEGF Trap-Eye. If VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States, we will be obligated to reimburse Bayer HealthCare for 50% of the development costs that it has incurred under the agreement from our share of the collaboration profits. Within the United States, we retain exclusive commercialization rights to VEGF Trap-Eye and are entitled to all profits from any such sales. We can earn up to \$70 million in future development and regulatory milestone payments related to the development of VEGF Trap-Eye and marketing approvals in major market countries outside the United States. We can also earn up to \$135 million in sales milestone payments if total annual sales of VEGF Trap-Eye outside the United States achieve certain specified levels starting at \$200 million.

#### 3. Aflibercept (VEGF Trap) – Oncology

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.

Aflibercept is being developed globally in cancer indications in collaboration with sanofi-aventis. We and sanofi-aventis are conducting three randomized, double-blind Phase 3 trials, all of which are fully enrolled, that are evaluating combinations of standard chemotherapy regimens with either aflibercept or placebo for the treatment of cancer. One trial (called VELOUR) is evaluating aflibercept as a 2nd-line treatment for metastatic colorectal cancer in combination with FOLFIRI (folinic acid [leucovorin], 5-fluorouracil, and irinotecan). A second trial (VITAL) is evaluating aflibercept as a 2nd-line treatment for locally advanced or metastatic non-small cell lung cancer in combination with docetaxel. A third trial (VENICE) is evaluating aflibercept as a 1st-line treatment for metastatic castration-resistant prostate cancer in combination with docetaxel/prednisone. In addition, a Phase 2 study (called AFFIRM) of aflibercept in 1st-line metastatic colorectal cancer in combination with FOLFOX (folinic acid [leucovorin], 5-fluorouracil, and oxaliplatin) is also fully enrolled.

Each of the Phase 3 studies is 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 studies 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 each trial. Based on projected event rates, (i) an interim analysis of VELOUR at 65% of the prespecified number of events required for the final analysis of overall survival is expected to be conducted by an independent statistician and reviewed by an IDMC in the second half of 2010, (ii) final results are anticipated in the first half of 2011 from the VITAL study and in the second half of 2011 from the VELOUR study, and (iii) an interim analysis of VENICE is expected to be reviewed by an IDMC in mid-2011, with final results anticipated in 2012. Initial data from the AFFIRM study are anticipated in the second half of 2011.

#### Aflibercept Collaboration with the sanofi-aventis Group

We and sanofi-aventis U.S. (successor to Aventis Pharmaceuticals, Inc.) globally collaborate on the development and commercialization of aflibercept. 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 aflibercept 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 aflibercept, 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 aflibercept oncology and other indications in the United States or the European Union and up to \$40 million related to the receipt of marketing approvals for up to five oncology indications in Japan.

Under the aflibercept 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 for 50% of aflibercept development expenses in accordance with a formula based on the amount of development expenses and our share of the collaboration profits and Japan royalties, or at a faster rate at our option.

#### 4. REGN727 (Anti-PCSK9 Antibody) for LDL cholesterol reduction

Elevated low density lipoprotein (LDL) cholesterol levels is a validated risk factor leading to cardiovascular disease. Statins are a class of drugs that lower LDL by upregulating the expression of the LDL receptor (LDLR), which removes LDL from circulation. PCSK9 (proprotein convertase subtilisin/kexin type 9) is a protein that binds to LDLR and prevents LDLR from binding to and removing LDL from circulation. People who have a mutation that reduces the activity of PCSK9 have lower levels of LDL, as well as a reduced risk of adverse cardiovascular events. 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 through a novel mechanism of action. REGN727 is targeted at inhibiting PCSK9, which results in prevention of the degradation of LDLRs in the liver, thereby facilitating LDL clearance from the systemic circulation leading to lower LDL levels in the blood.

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 (bad) cholesterol. Each dosing cohort consisted of six treated and two placebo patients. In July 2010, we presented additional data from the 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. Dose escalation is ongoing in both studies.

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 to-date, in eleven patients, a single dose of REGN727 achieved an approximately 40% maximum mean reduction of LDL cholesterol from baseline. No serious adverse events and no dose limiting toxicities have been reported. Dose escalation in this study is ongoing. REGN727 is being developed in collaboration with sanofi-aventis.

5. REGN88 (Anti-IL-6R Antibody) for inflammatory diseases

Interleukin-6 (IL-6) is a key cytokine involved in the pathogenesis of rheumatoid arthritis, causing inflammation and joint destruction. A therapeutic antibody to the IL-6 receptor (IL-6R), tocilizumab, developed by Roche, 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 meeting of the European League Against Rheumatism (EULAR) in June 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. REGN88 is being developed in collaboration with sanofi-aventis.

6. REGN421 (Anti-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 Delta-like ligand 4 (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.

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

Interleukin-4 receptor (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 VelocImmune® antibody that is designed to bind to IL-4R. REGN668, which is being developed in collaboration with sanofi-aventis, has completed a Phase 1 trial in healthy volunteers, and will be initiating a Phase 2 trial in atopic dermatitis in the second half of 2010.

8. REGN475 (Anti-NGF Antibody) for pain

Nerve growth factor (NGF) is a member of the neurotrophin family of secreted proteins. NGF antagonists have been shown to prevent increased sensitivity to pain and abnormal pain response in animal models of neuropathic and chronic inflammatory pain. Mutations in the genes that code for the NGF receptors were identified in people suffering from a loss of deep pain perception. For these and other reasons, we believe blocking NGF could be a promising therapeutic approach to a variety of pain indications.

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. REGN475 is being developed in collaboration with sanofi-aventis.

In May 2010, we announced 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. The primary endpoint of this study is safety, and REGN475 was generally well tolerated. Serious treatment emergent adverse events were rare and balanced between placebo and drug arms with three events (5.5%) in the placebo group and four events (2.5%) in the combined REGN475 groups. The most frequent adverse events reported among patients receiving REGN475 included sensory abnormalities, arthralgias, hyper/hypo-reflexia, peripheral edema, and injection site reactions. The types and frequencies of adverse events reported were similar to those previously reported from other investigational studies involving an anti-NGF antibody.

In the first interim efficacy analysis, REGN475 demonstrated significant improvements at the two highest doses tested as compared to placebo in average walking pain scores over 8 weeks following a single intravenous infusion ( $p < 0.01$ ). In July 2010, we reported that REGN475 demonstrated significant improvements at the two highest doses tested as compared to placebo in average walking pain scores over 16 weeks following a second intravenous infusion at week 8 ( $p < 0.01$ ). Pain was measured by the Numeric Rating Scale (NRS), as well as the Western Ontario and McMaster Osteoarthritis Index (WOMAC) pain and function subscales

Analysis of efficacy data from a Phase 2 trial in the acute setting of nerve root compression induced pain (acute sciatica) suggests that REGN475 therapy will not be effective in this setting.

At the request of the U.S. Food and Drug Administration (FDA), another pharmaceutical company has suspended its anti-NGF antibody clinical program in osteoarthritis and certain other chronic pain indications. We have responded to FDA requests for information about patients in our REGN475 clinical trials. REGN475 is currently not on clinical hold, and our Phase 2 trials in patients with vertebral fracture pain and chronic pancreatitis pain are ongoing. Our Phase 2 trial in osteoarthritis of the knee has been completed. We will update our plans for REGN475 following feedback from the FDA.

#### 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 aflibercept 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. VelociSuite™ is our second technology platform and it is used for discovering, developing, and producing fully human monoclonal antibodies that can address both secreted and cell-surface targets.

#### VelociSuite™

VelociSuite™ consists of VelocImmune®, VelociGene®, VelociMouse®, and VelociMab®. The VelocImmune® mouse platform is utilized to produce fully human monoclonal antibodies. VelocImmune® was generated by exploiting our VelociGene® technology (see below), in a process in which six megabases of mouse immune gene loci were replaced, or “humanized,” with corresponding human immune gene loci. VelocImmune® mice can be used to generate efficiently fully human monoclonal antibodies to targets of therapeutic interest. VelocImmune® and our entire VelociSuite™ offer the potential to increase the speed and efficiency through which human monoclonal antibody therapeutics may be discovered and validated, thereby improving the overall efficiency of our early stage drug development activities. We are utilizing the VelocImmune® technology to produce our next generation of drug candidates for preclinical and clinical development.



Our VelociGene® platform allows custom and precise manipulation of very large sequences of DNA to produce highly customized alterations of a specified target gene, or genes, and accelerates the production of knock-out and transgenic expression models without using either positive/negative selection or isogenic DNA. In producing knock-out models, a color or fluorescent marker may be substituted in place of the actual gene sequence, allowing for high-resolution visualization of precisely where the gene is active in the body during normal body functioning as well as in disease processes. For the optimization of pre-clinical 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, the VelociMice 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. We received a non-refundable, up-front payment of \$85.0 million from sanofi-aventis under the discovery agreement. In addition, sanofi-aventis is funding research at Regeneron to identify and validate potential drug discovery targets and develop fully human monoclonal antibodies against these targets. Sanofi-aventis funded approximately \$175 million of research from the collaboration's inception through December 31, 2009.

In November 2009, we and sanofi-aventis amended these agreements to expand and extend our antibody collaboration. Sanofi-aventis will now 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 are not satisfied. In addition, sanofi-aventis will 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 scale up our capacity to conduct antibody discovery activities, we will incur and seek reimbursement of only \$130-\$140 million of antibody discovery costs, with the balance between that amount and \$160 million added to the funding otherwise available to us in 2011-2012. As under the original 2007 agreement, sanofi-aventis also has an option to extend the discovery program for up to an additional three years for further antibody development and preclinical activities. We will lead the design and conduct of research activities, including target identification and validation, antibody development, research and preclinical activities through filing of an Investigational New Drug Application, toxicology studies, and manufacture of preclinical and clinical supplies. 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 over the next eight years.

For each drug candidate identified 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 will be shared between the companies, with sanofi-aventis generally funding drug candidate development 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 will be 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 United States. The parties will share profits outside the United States 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 United States 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 United States exceed \$1.0 billion on a rolling 12-month basis.

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. Sanofi-aventis will 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.

AstraZeneca UK Limited. In February 2007, we entered into a non-exclusive license agreement with AstraZeneca UK Limited that allows AstraZeneca to utilize our VelocImmune® technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, AstraZeneca made \$20.0 million annual, non-refundable payments to us in the first quarter of 2007, 2008, 2009, and 2010. AstraZeneca is required to make up to two additional annual payments of \$20.0 million, subject to its ability to terminate the agreement. We are entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by AstraZeneca using our VelocImmune® technology.

Astellas Pharma Inc. In March 2007, we entered into a non-exclusive license agreement with Astellas Pharma Inc. that allows Astellas to utilize our VelocImmune® technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, Astellas made \$20.0 million annual, non-refundable payments to us in the second quarter 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 will make a \$165.0 million up-front payment to us. In addition, Astellas will make a \$130.0 million payment to us in June 2018 unless the license agreement has been terminated prior to that date. Astellas has the right to terminate this license 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 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.

#### 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 \$18.1 million through June 30, 2010 and are entitled to receive an additional \$7.2 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.

Regeneron plans to file an Investigational New Drug Application for REGN910, an antibody to Angiopoietin-2, a novel anti-angiogenesis target, by the end of 2010.

#### 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 June 30, 2010, we had a cumulative loss of \$997.1 million. In the absence of significant revenues from the commercialization of ARCALYST® or our other product candidates or other sources, the amount, timing, nature, and source of which cannot be predicted, our losses will continue as we conduct our research and development activities. We expect to incur substantial losses over the next several years as we continue the clinical development of VEGF Trap-Eye and ARCALYST®; advance new product candidates into clinical development from our existing research programs utilizing our technology for discovering fully human monoclonal antibodies; continue our research and development programs; and commercialize additional product candidates that receive regulatory approval, if any. Also, our activities may expand over time and require additional resources, and we expect our operating losses to be substantial over at least the next several years. Our losses may fluctuate from quarter to quarter and will depend on, among other factors, the progress of our research and development efforts, the timing of certain expenses, and the amount and timing of payments that we receive from collaborators.

## Edgar Filing: REGENERON PHARMACEUTICALS INC - Form 10-Q

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 to date in 2010 and plans over the next 12 months are as follows:

Clinical Program	2010 Events to Date	2010-11 Plans (next 12 months)
<p>ARCALYST® (rilonacept)</p>	<ul style="list-style-type: none"> <li>● Reported positive results from PRE-SURGE 1 and completed patient enrollment of PRE-SURGE 2. Both Phase 3 studies are evaluating ARCALYST® in the prevention of gout flares associated with the initiation of uric acid-lowering drug therapy</li> <li>● Reported results showing no significant improvement in pain relief from a Phase 3 study (SURGE) evaluating ARCALYST® in the treatment of acute gout flares</li> </ul>	<ul style="list-style-type: none"> <li>● Complete patient enrollment of an additional Phase 3 study (RE-SURGE) and report data from PRE-SURGE 2 and RE-SURGE in early 2011</li> <li>● If PRE-SURGE 2 and RE-SURGE are successful, file for regulatory approval of ARCALYST® in the prevention of gout flares associated with the initiation of uric acid-lowering drug therapy by mid-2011</li> </ul>
<p>VEGF Trap – Eye</p>	<ul style="list-style-type: none"> <li>● Completed patient enrollment in the first of two Phase 3 CRVO trials (COPERNICUS)</li> <li>● Reported positive 24-week primary endpoint results from the Phase 2 DME trial</li> </ul>	<ul style="list-style-type: none"> <li>● Report data from VIEW 1 and VIEW 2 trials in the fourth quarter of 2010</li> <li>● Complete patient enrollment in the second Phase 3 CRVO trial (GALILEO) and report initial data from both trials</li> <li>● Report one-year results from the Phase 2 DME trial</li> </ul>
<p>Aflibercept (VEGF Trap – Oncology)</p>	<ul style="list-style-type: none"> <li>● Completed patient enrollment in the Phase 3 studies in non-small cell lung cancer, prostate cancer, and colorectal cancer</li> <li>● Completed patient enrollment in a Phase 2 1st-line study in metastatic colorectal cancer in combination with chemotherapy</li> </ul>	<ul style="list-style-type: none"> <li>● During the second half of 2010, an Independent Data Monitoring Committee is expected to conduct an interim analysis of the Phase 3 study (VELOUR) in colorectal cancer</li> <li>● Report data from the Phase 3 study (VITAL) in non-small cell lung cancer.</li> <li>● In mid-2011, an Independent Data Monitoring Committee is expected to conduct an interim analysis of the Phase 3 study (VENICE) in prostate cancer</li> </ul>
<p>Monoclonal Antibodies</p>	<ul style="list-style-type: none"> <li>● REGN727: Reported interim proof-of-concept data from a Phase 1 study for LDL cholesterol reduction</li> <li>● REGN88: Initiated a Phase 2/3 dose-ranging study in rheumatoid arthritis and a Phase 2 dose-ranging study in ankylosing spondylitis</li> <li>● REGN88: Reported data from the Phase 1 program in rheumatoid arthritis</li> <li>● REGN475: Reported interim data from the Phase 2 studies in osteoarthritis of the knee and acute sciatica</li> </ul>	<ul style="list-style-type: none"> <li>● REGN727: Report additional data from the Phase 1 program and initiate a Phase 2 program for LDL cholesterol reduction</li> <li>● REGN668: Initiate a Phase 2 program in the treatment of atopic dermatitis</li> <li>● REGN475: Report additional data from the Phase 2 study in osteoarthritis of the knee</li> <li>● REGN475: Update clinical plans following feedback from the FDA</li> <li>● Advance additional antibody candidates into clinical development, including REGN910</li> </ul>

Results of Operations

Three Months Ended June 30, 2010 and 2009

Net Loss

Regeneron reported a net loss of \$25.5 million, or \$0.31 per share (basic and diluted), for the second quarter of 2010, compared to a net loss of \$14.9 million, or \$0.19 per share (basic and diluted) for the second quarter of 2009. The increase in our net loss was principally due to higher research and development expenses, as detailed below, partly offset by higher collaboration revenue primarily in connection with our antibody collaboration with sanofi-aventis.

## Edgar Filing: REGENERON PHARMACEUTICALS INC - Form 10-Q

### Revenues

Revenues for the three months ended June 30, 2010 and 2009 consist of the following:

(In millions)	2010	2009
<b>Collaboration revenue</b>		
Sanofi-aventis	\$ 84.9	\$ 60.7
Bayer HealthCare	13.7	12.8
Total collaboration revenue	98.6	73.5
<b>Technology licensing revenue</b>	10.0	10.0
<b>Net product sales</b>	5.2	4.5
<b>Contract research and other revenue</b>	2.1	2.0
<b>Total revenue</b>	<b>\$ 115.9</b>	<b>\$ 90.0</b>

### Sanofi-aventis Collaboration Revenue

The collaboration revenue we earn from sanofi-aventis, as detailed below, consists 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 aflibercept collaboration and \$85.0 million related to the antibody collaboration.

### Sanofi-aventis Collaboration Revenue

(In millions)

Three months ended  
June 30,  
2010                  2009

<b>Aflibercept:</b>		
Regeneron expense reimbursement	\$ 3.8	\$ 9.2
Recognition of deferred revenue related to up-front payments	2.5	2.5
Total aflibercept	6.3	11.7
<b>Antibody:</b>		
Regeneron expense reimbursement	76.4	45.7
Recognition of deferred revenue related to up-front and other payments	1.8	2.6
Recognition of revenue related to VelociGene® agreement	0.4	0.7
Total antibody	78.6	49.0
<b>Total sanofi-aventis collaboration revenue</b>	<b>\$ 84.9</b>	<b>\$ 60.7</b>

Sanofi-aventis' reimbursement of our aflibercept expenses decreased in the second quarter of 2010 compared to same period in 2009, primarily due to lower costs related to manufacturing aflibercept clinical supplies as well as a decrease in internal research activities. As of June 30, 2010, \$37.5 million of the original \$105.0 million of up-front payments related to our aflibercept collaboration with sanofi-aventis was deferred and will be recognized as revenue in future periods.

In the second quarter of 2010, sanofi-aventis' reimbursement of our antibody expenses consisted of \$36.6 million under the discovery agreement and \$39.8 million of development costs under the license agreement, compared to \$28.3 million and \$17.4 million, respectively, in the second quarter of 2009. The higher reimbursement amounts in the second quarter of 2010 compared to the same period in 2009 were due to an increase in our research activities conducted under the discovery agreement and increases in our development activities for antibody candidates under the license agreement.

Recognition of deferred revenue, related primarily to sanofi-aventis' \$85.0 million up-front payment, decreased during the second quarter of 2010 compared to the same period in 2009 due to the November 2009 amendments to expand and extend the companies' antibody collaboration. 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, of which \$14.3 million was received or receivable from sanofi-aventis as of June 30, 2010. Payments for such funding from sanofi-aventis are deferred and recognized as collaboration revenue prospectively over the related performance period in conjunction with the original \$85.0 million up-front payment. As of June 30, 2010, \$74.6 million of the original up-front payment and subsequent payments to fund expansion of our Rensselaer facilities was deferred and will be recognized as revenue in future periods.



## Edgar Filing: REGENERON PHARMACEUTICALS INC - Form 10-Q

In August 2008, we entered into a separate VelociGene® agreement with sanofi-aventis. For the three months ended June 30, 2010 and 2009, we recognized \$0.4 million and \$0.7 million, respectively, in revenue related to this agreement.

### Bayer HealthCare Collaboration Revenue

The collaboration revenue we earn from Bayer HealthCare, as detailed below, consists 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 June 30,	
	2010	2009
Cost-sharing of Regeneron VEGF Trap-Eye development expenses	\$ 11.2	\$ 10.4
Recognition of deferred revenue related to up-front and milestone payments	2.5	2.4
Total Bayer HealthCare collaboration revenue	\$ 13.7	\$ 12.8

In periods when we recognize VEGF Trap-Eye development expenses that we incur under our collaboration with Bayer HealthCare, we also recognize, as collaboration revenue, the portion of those VEGF Trap-Eye development expenses that is reimbursable by Bayer HealthCare. Cost-sharing of our VEGF Trap-Eye development expenses with Bayer HealthCare increased in the second quarter of 2010, compared to the same period in 2009, due to higher clinical development costs in connection with our Phase 3 trial in CRVO and Phase 2 trial in DME and higher costs related to VEGF Trap-Eye clinical drug supplies. In 2010 and 2009, development expenses incurred by Regeneron and Bayer HealthCare under the VEGF Trap-Eye global development plan were shared equally. As of June 30, 2010, \$51.9 million of the \$75.0 million up-front licensing and \$20.0 million milestone payments was deferred and will be recognized as revenue in future periods.

### Technology Licensing Revenue

In connection with our VelocImmune® license agreements with AstraZeneca and Astellas, each of the \$20.0 million annual, non-refundable payments are deferred upon receipt and recognized as revenue ratably over approximately the ensuing year of each agreement. In the second quarter of both 2010 and 2009, we recognized \$10.0 million of technology licensing revenue related to these agreements.

### Net Product Sales

For the three months ended June 30, 2010, ARCALYST® net product sales were \$5.2 million, compared to \$4.5 million during the same period in 2009. There was no deferred ARCALYST® net product sales revenue at June 30, 2010. At June 30, 2009, deferred ARCALYST® net product sales revenue was \$4.9 million.

### Contract Research and Other Revenue

Contract research and other revenue for the three months ended June 30, 2010 and 2009 included \$1.2 million and \$1.5 million, respectively, recognized in connection with our five-year grant from the NIH, which we were awarded in September 2006 as part of the NIH's Knockout Mouse Project.

### Expenses

Total operating expenses increased to \$139.6 million in the second quarter of 2010 from \$106.3 million in the second quarter of 2009. Our average headcount increased to 1,214 in the second quarter of 2010 from 966 in the same period of 2009 principally as a result of our expanding research and development activities, which are primarily attributable to our antibody collaboration with sanofi-aventis.



## Edgar Filing: REGENERON PHARMACEUTICALS INC - Form 10-Q

Operating expenses in the second quarter of 2010 and 2009 include a total of \$8.7 million and \$7.4 million, respectively, of non-cash compensation expense related to employee stock option and restricted stock awards (Non-cash Compensation Expense), as detailed below:

Expenses (In millions)	For the three months ended June 30, 2010		
	Expenses before inclusion of Non-cash Compensation Expense	Non-cash Compensation Expense	Expenses Reported
Research and development	\$ 119.5	\$ 5.0	\$ 124.5
Selling, general, and administrative	11.0	3.7	14.7
Cost of goods sold	0.4		0.4
Total operating expenses	\$ 130.9	\$ 8.7	\$ 139.6

Expenses (In millions)	For the three months ended June 30, 2009		
	Expenses before inclusion of Non-cash Compensation Expense	Non-cash Compensation Expense	Expenses Reported
Research and development	\$ 89.5	\$ 4.7	\$ 94.2
Selling, general, and administrative	9.0	2.7	11.7
Cost of goods sold	0.4		0.4
Total operating expenses	\$ 98.9	\$ 7.4	\$ 106.3

### Research and Development Expenses

Research and development expenses increased to \$124.5 million in the second quarter of 2010 from \$94.2 million in the same period of 2009. The following table summarizes the major categories of our research and development expenses for the three months ended June 30, 2010 and 2009:

Research and Development Expenses (In millions)	For the three months ended June 30,		Increase (Decrease)
	2010	2009	
Payroll and benefits (1)	\$ 31.9	\$ 23.6	\$ 8.3
Clinical trial expenses	28.5	30.2	(1.7)
Clinical manufacturing costs (2)	27.6	13.8	13.8
Research and other development costs	13.8	9.9	3.9
Occupancy and other operating costs	12.7	8.9	3.8
Cost-sharing of Bayer HealthCare VEGF Trap-Eye development expenses (3)	10.0	7.8	2.2
Total research and development	\$ 124.5	\$ 94.2	\$ 30.3

- (1) Includes \$4.2 million and \$4.0 million of Non-cash Compensation Expense for the three months ended June 30, 2010 and 2009, 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 \$0.8 million and \$0.7 million of Non-cash Compensation Expense for the three months ended June 30, 2010 and 2009, 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.

## Edgar Filing: REGENERON PHARMACEUTICALS INC - Form 10-Q

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 ARCALYST® clinical development program in gout. Clinical manufacturing costs increased primarily due to higher costs related to manufacturing clinical supplies of monoclonal antibodies. Research and other development costs increased primarily due to higher costs associated with our antibody programs. 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 the VIEW 2 trial in wet AMD and the GALILEO trial in CRVO, both of which are being conducted by Bayer HealthCare.

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		Increase (Decrease)
	June 30, 2010	2009	
ARCALYST®	\$ 11.6	\$ 15.7	\$ (4.1)
VEGF Trap-Eye	31.2	27.0	4.2
Aflibercept	3.0	7.4	(4.4)
REGN88	9.8	8.5	1.3
Other antibody candidates in clinical development	26.2	5.1	21.1
Other research programs & unallocated costs	42.7	30.5	12.2
<b>Total research and development expenses</b>	<b>\$ 124.5</b>	<b>\$ 94.2</b>	<b>\$ 30.3</b>

Drug development and approval in the United States is a multi-step process regulated by the FDA. The process begins with discovery and preclinical evaluation, leading up to the submission of an IND to the FDA which, if successful, allows the opportunity for study in humans, or clinical study, of the potential new drug. Clinical development typically involves three phases of study: Phases 1, 2, and 3. The most significant costs in clinical development are in Phase 3 clinical trials, as they tend to be the longest and largest studies in the drug development process. Following successful completion of Phase 3 clinical trials for a biological product, a biologics license application (or 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®, aflibercept, and VEGF Trap-Eye in different disease indications.

## Edgar Filing: REGENERON PHARMACEUTICALS INC - Form 10-Q

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 Item 1A, "Risk Factors" under "Risks Related to ARCALYST® (rilonacept) and the Development of Our Product Candidates," "Regulatory and Litigation Risks," and "Risks Related to Commercialization of Products." 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 product and the uncertainties related to future indications to be studied, the estimated cost and scope of the projects, and our ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the total cost to bring our product candidates to market are not available. Similarly, we are currently unable to reasonably estimate if our product candidates in clinical development will generate material product revenues and net cash inflows. 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 \$14.7 million in the second quarter of 2010 from \$11.7 million in the same period of 2009. In the second quarter of 2010, we incurred higher compensation expense due primarily to increases in headcount, higher Non-cash Compensation Expense, and higher recruitment costs.

### Cost of Goods Sold

Cost of goods sold related to ARCALYST® sales, which consisted primarily of royalties and other period costs, totaled \$0.4 million for both of the quarters ended June 30, 2010 and 2009. To date, ARCALYST® shipments to our customers have consisted of supplies of inventory manufactured and expensed prior to FDA approval of ARCALYST® in February 2008; therefore, the costs of these supplies were not included in costs of goods sold.

### Other Income and Expense

Investment income decreased to \$0.6 million in the second quarter of 2010 from \$1.3 million in the comparable quarter of 2009, primarily due to lower balances of, and lower yields on, cash and marketable securities and a \$0.1 million other-than-temporary impairment charge. Interest expense of \$2.3 million in the second quarter of 2010 was attributable to the imputed interest portion of payments to our landlord to lease newly constructed laboratory and office facilities in Tarrytown, New York. These payments commenced in the third quarter of 2009.

### Six Months Ended June 30, 2010 and 2009

#### Net Loss

Regeneron reported a net loss of \$56.0 million, or \$0.69 per share (basic and diluted), for the first half of 2010, compared to a net loss of \$30.3 million, or \$0.38 per share (basic and diluted) for the first half of 2009. The increase in our net loss was principally due to higher research and development expenses, as detailed below, partly offset by higher collaboration revenue primarily in connection with our antibody collaboration with sanofi-aventis.

#### Revenues

Revenues for the six months ended June 30, 2010 and 2009 consist of the following:

(In millions)	2010	2009
Collaboration revenue		
Sanofi-aventis	\$ 153.6	\$ 110.4
Bayer HealthCare	26.7	22.8
Total collaboration revenue	180.3	133.2
Technology licensing revenue	20.1	20.0
Net product sales	15.0	8.4

Edgar Filing: REGENERON PHARMACEUTICALS INC - Form 10-Q

Contract research and other revenue	4.0	3.4
Total revenue	\$ 219.4	\$ 165.0

## Edgar Filing: REGENERON PHARMACEUTICALS INC - Form 10-Q

### Sanofi-aventis Collaboration Revenue

The collaboration revenue we earn from sanofi-aventis, as detailed below, consists 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 aflibercept collaboration and \$85.0 million related to the antibody collaboration.

Sanofi-aventis Collaboration Revenue (In millions)	Six months ended June 30,	
	2010	2009
<b>Aflibercept:</b>		
Regeneron expense reimbursement	\$ 8.7	\$ 14.6
Recognition of deferred revenue related to up-front payments	5.0	5.0
<b>Total aflibercept</b>	<b>13.7</b>	<b>19.6</b>
<b>Antibody:</b>		
Regeneron expense reimbursement	135.8	84.1
Recognition of deferred revenue related to up-front and other payments	3.3	5.3
Recognition of revenue related to VelociGene® agreement	0.8	1.4
<b>Total antibody</b>	<b>139.9</b>	<b>90.8</b>
<b>Total sanofi-aventis collaboration revenue</b>	<b>\$ 153.6</b>	<b>\$ 110.4</b>

Sanofi-aventis' reimbursement of our aflibercept expenses decreased in the first half of 2010 compared to the same period in 2009, primarily due to lower costs related to manufacturing aflibercept clinical supplies as well as a decrease in internal research activities.

In the first half of 2010, sanofi-aventis' reimbursement of our antibody expenses consisted of \$63.4 million under the discovery agreement and \$72.4 million of development costs under the license agreement, compared to \$51.0 million and \$33.1 million, respectively, in the first half of 2009. The higher reimbursement amounts in the first half of 2010 compared to the same period in 2009 were due to an increase in our research activities conducted under the discovery agreement and increases in our development activities for antibody candidates under the license agreement.

Recognition of deferred revenue, related primarily to sanofi-aventis' \$85.0 million up-front payment, decreased during the first half of 2010 compared to the same period in 2009 due to the November 2009 amendments to expand and extend the companies' antibody collaboration.

In August 2008, we entered into a separate VelociGene® agreement with sanofi-aventis. For the six months ended June 30, 2010 and 2009, we recognized \$0.8 million and \$1.4 million, respectively, in revenue related to this agreement.

### Bayer HealthCare Collaboration Revenue

The collaboration revenue we earn from Bayer HealthCare, as detailed below, consists 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)	Six months ended June 30,	
	2010	2009
Cost-sharing of Regeneron VEGF Trap-Eye development expenses	\$ 21.8	\$ 17.9
Recognition of deferred revenue related to up-front and milestone payments	4.9	4.9
<b>Total Bayer HealthCare collaboration revenue</b>	<b>\$ 26.7</b>	<b>\$ 22.8</b>

## Edgar Filing: REGENERON PHARMACEUTICALS INC - Form 10-Q

Cost-sharing of our VEGF Trap-Eye development expenses with Bayer HealthCare increased in the first half of 2010, compared to the same period in 2009, due to higher clinical development costs in connection with our Phase 3 trial in CRVO and Phase 2 trial in DME and higher costs related to VEGF Trap-Eye clinical drug supplies.

### Technology Licensing Revenue

In connection with our VelocImmune® license agreements with AstraZeneca and Astellas, each of the \$20.0 million annual, non-refundable payments are deferred upon receipt and recognized as revenue ratably over approximately the ensuing year of each agreement. In the first half of both 2010 and 2009, we recognized \$20.0 million of technology licensing revenue related to these agreements.

### Net Product Sales

In February 2008, we received marketing approval from the FDA for ARCALYST® for the treatment of CAPS. We had limited historical return experience for ARCALYST® beginning with initial sales in 2008 through the end of 2009; therefore, ARCALYST® net product sales were deferred until the right of return no longer existed and rebates could be reasonably estimated. Effective in the first quarter of 2010, we determined that we had accumulated sufficient historical data to reasonably estimate both product returns and rebates of ARCALYST®. As a result, for the six months ended June 30, 2010, we recognized as revenue \$15.0 million of ARCALYST® net product sales, which included \$10.2 million of ARCALYST® net product sales made during the period and \$4.8 million of previously deferred net product sales. For the six months ended June 30, 2009, we recognized as revenue \$8.4 million of ARCALYST® net product sales.

### Contract Research and Other Revenue

Contract research and other revenue for the first half of 2010 and 2009 included \$2.3 million and \$3.0 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 \$272.0 million in the first half of 2010 from \$198.4 million in the same period of 2009. Our average headcount increased to 1,151 in the first half of 2010 from 952 in the same period of 2009 principally as a result of our expanding research and development activities, which are primarily attributable to our antibody collaboration with sanofi-aventis.

Operating expenses in the first half of 2010 and 2009 include a total of \$17.5 million and \$15.1 million, respectively, of Non-cash Compensation Expense, as detailed below:

Expenses (In millions)	For the six months ended June 30, 2010		
	Expenses before inclusion of		Expenses Reported
	Non-cash Compensation Expense	Non-cash Compensation Expense	
Research and development	\$ 232.0	\$ 10.0	\$ 242.0
Selling, general, and administrative	21.4	7.5	28.9
Cost of goods sold	1.1		1.1
Total operating expenses	\$ 254.5	\$ 17.5	\$ 272.0

Edgar Filing: REGENERON PHARMACEUTICALS INC - Form 10-Q

Expenses (In millions)	For the six months ended June 30, 2009		
	Expenses before inclusion of		Expenses Reported
	Non-cash	Non-cash	
	Compensation Expense	Compensation Expense	as
Research and development	\$ 165.1	\$ 9.4	\$ 174.5
Selling, general, and administrative	17.4	5.7	23.1
Cost of goods sold	0.8		0.8
Total operating expenses	\$ 183.3	\$ 15.1	\$ 198.4

Research and Development Expenses

Research and development expenses increased to \$242.0 million in the first half of 2010 from \$174.5 million in the same period of 2009. The following table summarizes the major categories of our research and development expenses for the six months ended June 30, 2010 and 2009:

Research and Development Expenses (In millions)	For the six months ended		
	June 30, 2010	2009	Increase
Payroll and benefits (1)	\$ 59.6	\$ 46.5	\$ 13.1
Clinical trial expenses	60.8	49.5	11.3
Clinical manufacturing costs (2)	47.5	27.9	19.6
Research and other development costs	26.6	18.4	8.2
Occupancy and other operating costs	24.7	17.4	7.3
Cost-sharing of Bayer HealthCare VEGF Trap-Eye development expenses (3)	22.8	14.8	8.0
Total research and development	\$ 242.0	\$ 174.5	\$ 67.5

- (1) Includes \$8.5 million and \$8.0 million of Non-cash Compensation Expense for the six months ended June 30, 2010 and 2009, respectively.
- (2) Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Non-cash Compensation Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes \$1.5 million and \$1.4 million of Non-cash Compensation Expense for the six months ended June 30, 2010 and 2009, 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 increased due primarily to higher costs related to our clinical development programs for (i) VEGF Trap-Eye, principally in connection with our COPERNICUS trial in CRVO, (ii) ARCALYST®, related to our Phase 3 clinical development program in gout, and (iii) monoclonal antibody candidates, which are in earlier stage clinical development. Clinical manufacturing costs increased primarily due to higher costs related to manufacturing clinical supplies of monoclonal antibodies. Research and other development costs increased primarily due to higher costs associated with our antibody programs. 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 the VIEW 2 trial in wet AMD and the GALILEO trial in CRVO, both of which are being conducted by Bayer HealthCare.





## Edgar Filing: REGENERON PHARMACEUTICALS INC - Form 10-Q

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 six months ended June 30,		Increase (Decrease)
	2010	2009	
ARCALYST®	\$ 31.7	\$ 33.6	\$ (1.9)
VEGF Trap-Eye	64.8	47.8	17.0
Aflibercept	6.9	11.7	(4.8)
REGN88	14.7	17.5	(2.8)
Other antibody candidates in clinical development	50.3	10.0	40.3
Other research programs & unallocated costs	73.6	53.9	19.7
Total research and development expenses	\$ 242.0	\$ 174.5	\$ 67.5

For the reasons described above under "Research and Development Expenses" for the three months ended June 30, 2010 and 2009, and due to the variability in the costs necessary to develop a product and the uncertainties related to future indications to be studied, the estimated cost and scope of the projects, and our ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the total cost to bring our product candidates to market are not available. Similarly, we are currently unable to reasonably estimate if our product candidates in clinical development will generate material product revenues and net cash inflows. 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 \$28.9 million in the first half of 2010 from \$23.1 million in the same period of 2009. In the first half of 2010, we incurred higher compensation expense due primarily to increases in headcount, higher Non-cash Compensation Expense, and higher recruitment costs.

### Cost of Goods Sold

Cost of goods sold related to ARCALYST® sales, which consisted primarily of royalties and other period costs, totaled \$1.1 million and \$0.8 million for the six months ended June 30, 2010 and 2009, respectively. To date, ARCALYST® shipments to our customers have consisted of supplies of inventory manufactured and expensed prior to FDA approval of ARCALYST® in February 2008; therefore, the costs of these supplies were not included in costs of goods sold.

### Other Income and Expense

Investment income decreased to \$1.0 million in the first half of 2010 from \$3.1 million in the comparable quarter of 2009, primarily due to lower balances of, and lower yields on, cash and marketable securities and a \$0.1 million other-than-temporary impairment charge. Interest expense of \$4.4 million in the first half of 2010 was attributable to the imputed interest portion of payments to our landlord to lease newly constructed laboratory and office facilities in Tarrytown, New York. These payments commenced in the third quarter of 2009.

## 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.

Six months ended June 30, 2010 and 2009

At June 30, 2010, we had \$380.2 million in cash, cash equivalents, restricted cash, and marketable securities compared with \$390.0 million at December 31, 2009. In February 2010, we received \$47.5 million from our landlord in connection with tenant improvement costs for the new laboratory and office facilities that we lease in Tarrytown, New York. In addition, in February and June 2010, we received \$20.0 million annual technology licensing payments from AstraZeneca and Astellas, respectively.

### Cash Used in Operations:

Net cash used in operations was \$22.6 million in the first six months of 2010 and \$16.0 million in the first six months of 2009. Our net losses of \$56.0 million in the first half of 2010 and \$30.3 million in the first half of 2009 included \$17.5 million and \$15.1 million, respectively, of Non-cash Compensation Expense, and \$8.7 million and \$5.7 million, respectively, of depreciation and amortization.

At June 30, 2010, accounts receivable increased by \$29.6 million, compared to end-of-year 2009, primarily due to a higher receivable balance related to our antibody collaboration with sanofi-aventis. Also, our deferred revenue balances at June 30, 2010 increased by \$16.6 million, compared to end-of-year 2009, primarily due to (i) the receipt of the \$20.0 million payments from AstraZeneca and Astellas, as described above, which were deferred and are being recognized ratably over the ensuing year and (ii) sanofi-aventis' funding of \$13.8 million of agreed-upon costs incurred by us during the first half of 2010 to expand our manufacturing capacity at our Rensselaer facilities, which was deferred and is being recognized as collaboration revenue prospectively over the related performance period in conjunction with the original \$85.0 million up-front payment received from sanofi-aventis. These increases were partially offset by amortization of previously received deferred payments under our sanofi-aventis and Bayer HealthCare collaborations. At June 30, 2010, accounts payable, accrued expenses, and other liabilities increased by \$18.1 million, compared to end-of-year 2009, primarily in connection with our expanded levels of activities and expenditures, including higher liabilities for payroll and related costs and clinical trial expenses.

At June 30, 2009, accounts receivable increased by \$24.8 million, compared to end-of-year 2008, primarily due to a higher receivable balance related to our antibody collaboration with sanofi-aventis. Also, our deferred revenue balances at June 30, 2009 increased by \$5.9 million, compared to end-of-year 2008, primarily due to the receipt of \$20.0 million annual payments from AstraZeneca and Astellas in February and June 2009, respectively, which were deferred and recognized ratably over the ensuing year. This increase was partially offset by amortization of previously received deferred payments under our sanofi-aventis and Bayer HealthCare collaborations. At June 30, 2009, accounts payable, accrued expenses, and other liabilities increased by \$13.0 million compared to end-of-year 2008. The increase was due primarily to higher liabilities for clinical trial and payroll-related costs, partially offset by a \$9.8 million cost-sharing payment which was due to Bayer HealthCare at December 31, 2008 in connection with the companies' VEGF Trap-Eye collaboration; no cost-sharing payment was due to Bayer HealthCare at June 30, 2009.

### Cash (Used in) Provided by Investing Activities:

Net cash used in investing activities was \$131.4 million in the first six months of 2010 and net cash provided by investing activities was \$32.8 million in the first six months of 2009. In the first half of 2010, purchases of marketable securities exceeded sales or maturities by \$84.3 million, whereas in the first half of 2009, sales or maturities of marketable securities exceeded purchases by \$85.4 million. Capital expenditures in the first half of 2010 and 2009 included costs in connection with expanding our manufacturing capacity at our Rensselaer, New York facilities and tenant improvements and related costs in connection with our leased office and laboratory facilities in Tarrytown, New York.

## Edgar Filing: REGENERON PHARMACEUTICALS INC - Form 10-Q

### Cash Provided by Financing Activities:

Net cash provided by financing activities was \$58.9 million in the first six months of 2010 and \$6.9 million in the first six months of 2009. In the first half of 2010 and 2009, we received \$47.5 million and \$5.2 million, respectively, 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 \$12.1 million in the first six months of 2010 and \$1.7 million in the first six months of 2009.

### Fair Value of Marketable Securities:

At June 30, 2010 and December 31, 2009, we held marketable securities whose aggregate fair value totaled \$264.8 million and \$181.3 million, respectively. The composition of our portfolio of marketable securities on these dates was as follows:

Investment type	June 30, 2010		December 31, 2009	
	Fair Value	Percent	Fair Value	Percent
U.S. Treasury securities	\$ 25.0	10%	\$ 80.4	44%
U.S. government agency securities	161.7	61%	29.6	16%
U.S. government-guaranteed corporate bonds	64.0	24%	48.7	27%
U.S. government guaranteed collateralized mortgage obligations	3.0	1%	3.7	2%
Corporate bonds	3.1	1%	10.3	6%
Mortgage-backed securities	2.0	1%	3.2	2%
Equity security	3.8	1%	5.4	3%
Other	2.2	1%		
<b>Total marketable securities</b>	<b>\$ 264.8</b>	<b>100%</b>	<b>\$ 181.3</b>	<b>100%</b>

In addition, at June 30, 2010 and December 31, 2009, we had \$115.4 million and \$208.7 million, respectively, of cash, cash equivalents, and restricted cash, primarily held in money market funds that invest in U.S. government securities.

During 2009 and 2010 to date, as marketable securities in our portfolio matured or paid down, we purchased higher quality securities such as U.S. Treasury securities, U.S. government agency obligations, and U.S. government-guaranteed debt. This shift in our investment portfolio, which we initiated in 2008, has reduced the risk profile, as well as the overall yield, of our portfolio.

### Funding of Antibody Discovery Activities under Collaboration with sanofi-aventis

As described above under “Antibody Collaboration and License Agreements,” in November 2009, we and sanofi-aventis amended our collaboration agreements to expand and extend our antibody collaboration. Sanofi-aventis will now 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 are not satisfied. In 2010, as we scale up our capacity to conduct antibody discovery activities, we will incur and seek reimbursement of only \$130-\$140 million of antibody discovery costs, with the balance between that amount and \$160 million added to the funding otherwise available to us in 2011-2012. The discovery agreement under the antibody collaboration will expire at the end of 2017; however, sanofi-aventis has an option to extend the agreement for up to an additional three years for further antibody development and preclinical activities.

### Extension of License Agreement with Astellas

As described above under “Antibody Collaboration and License Agreements,” in July 2010, the non-exclusive license agreement with Astellas was amended and extended through June 2023. Under the terms of the amended agreement, Astellas will make a \$165.0 million up-front payment to us, and will make a \$130.0 million payment to us in June 2018 unless the license agreement has been terminated prior to that date.

Capital Expenditures:

Our cash expenditures for property, plant, and equipment totaled \$45.3 million and \$52.7 million for the first six months of 2010 and 2009, respectively. We expect to incur capital expenditures of approximately \$50 to \$70 million during the remainder of 2010 and approximately \$40 to \$60 million in 2011, primarily in connection with expanding our Rensselaer, New York manufacturing facilities and tenant improvements at our leased Tarrytown facilities. As described above, in February 2010, we received \$47.5 million from our landlord in connection with tenant improvement costs in Tarrytown. In addition, as described above, sanofi-aventis has funded \$13.8 million of agreed-upon capital expenditures incurred by us during the first half of 2010 to expand our manufacturing capacity at our Rensselaer facilities, which was either received or receivable at June 30, 2010. We expect to be reimbursed for a portion of additional capital expenditures in 2010 and 2011 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 primarily for research and development activities (including preclinical and clinical testing). Before taking into account reimbursements from our collaborators, and exclusive of anticipated funding for capital expenditures as described above, we currently anticipate that approximately 65-75% of our expenditures for 2010 will be directed toward the clinical development of product candidates, including ARCALYST®, aflibercept, VEGF Trap-Eye, and clinical stage monoclonal antibodies; approximately 15-25% of our expenditures for 2010 will be applied to our basic research and preclinical activities; and the remainder of our expenditures for 2010 will be used for the continued development of our novel technology platforms and general corporate purposes. While we expect that funding requirements for our research and development activities will continue to increase in 2010, we also expect that a greater proportion of our research and development expenditures will be reimbursed by our collaborators, especially in connection with our amended and expanded antibody collaboration with sanofi-aventis.

The amount we need to fund operations will depend on various factors, including 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, 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. Currently, we are required to remit 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 otherwise share the profits generated on such sales in connection with our collaboration and licensing 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 and our non-exclusive license agreement with Astellas, which was amended in July 2010 as described above, 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, if we choose to commercialize 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 would expect to prioritize available capital to fund selected preclinical and clinical development programs or license selected products.

Other than a \$3.4 million letter of credit issued to our landlord in connection with our lease for facilities in Tarrytown, New York, we have no off-balance sheet arrangements. In addition, we do not guarantee the obligations of any other entity. As of June 30, 2010, we had no established banking arrangements through which we could obtain short-term financing or a line of credit. In the event we need additional financing for the operation of our business, we will consider collaborative arrangements and additional public or private financing, including additional equity financing. Factors influencing the availability of additional financing include our progress in product development, 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.

#### Future Impact of Recently Issued Accounting Standards

In March 2010, the FASB amended its authoritative guidance on the milestone method of revenue recognition. The milestone method of revenue recognition has now been codified as an acceptable revenue recognition model when a milestone is deemed to be substantive. This guidance may be applied retrospectively to all arrangements or prospectively for milestones achieved after the adoption of the guidance. We are required to adopt this amended guidance for the fiscal year beginning January 1, 2011, although earlier adoption is permitted. Management does not anticipate that the adoption of this guidance will have a material impact on our financial statements.

### ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

#### Interest Rate Risk:

Our earnings and cash flows are subject to fluctuations due to changes in interest rates principally in connection with our investment of excess cash 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 and, to a lesser extent, investment grade debt securities issued by corporations, bank deposits, and asset-backed securities. We do not believe we are materially exposed to changes in interest rates. Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes. We estimate that a one percent unfavorable change in interest rates would have resulted in approximately a \$1.2 million and \$0.8 million decrease in the fair value of our investment portfolio at June 30, 2010 and 2009, respectively.

#### 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 have recognized other-than-temporary impairment charges related to certain marketable securities of \$2.5 million, \$0.1 million, and \$0.1 million in 2008, 2009, and the first six months of 2010, respectively.

The current economic environment, the deterioration in the credit quality of issuers of securities that we hold, and the continuing volatility of securities markets increase the risk of potential declines in the current market value of marketable securities in our investment portfolio. Such declines could result in charges against income in future periods for other-than-temporary impairments and the amounts could be material.

### 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.

## Edgar Filing: REGENERON PHARMACEUTICALS INC - Form 10-Q

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended June 30, 2010 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

### PART II. OTHER INFORMATION

#### ITEM 1. LEGAL PROCEEDINGS

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

#### 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 substantially from those discussed in 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 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 June 30, 2010, we had a cumulative loss of \$997.1 million. 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. We believe our existing capital resources, including funding we are entitled to receive under our collaboration agreements and our non-exclusive license agreement with Astellas, will enable us to meet operating needs through at least 2013; however, one or more of our VelocImmune® licenses or collaboration agreements may terminate, our projected revenue may decrease, or our expenses may increase and that would lead to our capital being consumed significantly before such time. Our expenses may increase for many reasons, including for expenses in connection with the commercial launch of our products, for expenses related to new clinical trials testing ARCALYST® or VEGF Trap-Eye, or for 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 such 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. If we are unable to raise sufficient funds to complete the development of our product candidates, we may face delay, reduction or elimination of our research and development programs or preclinical or clinical trials, 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 June 30, 2010, cash, cash equivalents, restricted cash, and marketable securities totaled \$380.2 million and represented 48% 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 and, to a lesser extent, investment grade debt securities issued by corporations, bank deposits, and asset-backed securities. We consider assets classified as marketable securities to be "available-for-sale," as defined by FASB authoritative guidance. Marketable securities totaled \$264.8 million at June 30, 2010, 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 other-than-temporary impairment charges related to certain marketable securities of \$2.5 million, \$0.1 million, and \$0.1 million in 2008, 2009, and the first six months of 2010, respectively. The current economic environment, the deterioration in the credit quality of some of the issuers of securities that we hold, and the recent 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 ARCALYST® (rilonacept) and the Development of Our Product Candidates

Successful development of any of our product candidates is highly uncertain.

Only a small minority of all research and development programs ultimately result in commercially successful drugs. Even if clinical trials demonstrate 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 their acceptance by patients, the medical community, and third-party payers and on our partners' ability to successfully manufacture and commercialize our product candidates. 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. If our products are not successfully commercialized, we will not be able to recover the significant investment we have made in developing such products and our business would be severely harmed.

We are testing aflibercept, VEGF Trap-Eye, and ARCALYST® 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.

Aflibercept is in Phase 3 clinical trials in combination with standard chemotherapy regimens for the treatment of 2nd-line metastatic colorectal cancer, 1st-line androgen independent prostate cancer, and 2nd-line metastatic non-small cell lung cancer. Aflibercept may not demonstrate the required safety or efficacy to support an application for approval in any of these indications. We do not have proof of concept data from early-stage, double-blind, controlled clinical trials that aflibercept will be safe or effective in any of these cancer settings. In March 2010, Genentech announced that a Phase 3 trial of its VEGF antagonist, Avastin® (bevacizumab), 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 aflibercept in prostate cancer.

We are testing VEGF Trap-Eye in Phase 3 trials for the treatment of wet AMD and the treatment of CRVO. Although we reported positive Phase 2 trial results with VEGF Trap-Eye in wet AMD, based on a limited number of patients, the results from the larger Phase 3 trials may not demonstrate that VEGF Trap-Eye is safe and effective or compares favorably to Lucentis (Genentech). A number of other potential new drugs and biologics which showed promising results in initial clinical trials subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals. VEGF Trap-Eye has not been previously studied in CRVO.



ARCALYST® is in Phase 3 clinical trials for the prevention of gout flares in patients initiating uric acid-lowering drug therapy. Although we reported positive Phase 3 data from one trial in patients with gout initiating uric acid-lowering drug therapy, there is a risk that the results of the other ongoing trials of ARCALYST® in patients initiating uric acid-lowering drug therapy will differ from the previously reported Phase 3 trial. A number of potential new drugs and biologics which showed promising results in initial clinical trials subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals.

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.

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, we will have to delay or may be unable to obtain regulatory approval for our product candidates.

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 or protocol. 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.

Many of our clinical trials are conducted under the oversight of Independent Data Monitoring Committees (or 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 aflibercept as a 1st-line treatment for metastatic pancreatic cancer in combination with gemcitabine was discontinued at the recommendation of an IDMC after a planned analysis of interim efficacy data determined that the trial would not meet its efficacy endpoint. The IDMC for the VELOUR trial, which is studying aflibercept as a 2nd-line treatment for metastatic colorectal cancer in combination with chemotherapy, is expected to conduct an interim analysis of the data from this trial in the second half of 2010. 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 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. 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. The failure of clinical trials to demonstrate safety and effectiveness for the desired indication(s) could harm the development of our product candidate(s), and our business, financial condition, and results of operations may be materially harmed.

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.

Aflibercept (VEGF Trap) 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 vascular endothelial growth factor, or VEGF, that may limit our ability to successfully develop aflibercept 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. These and other complications or side effects could harm the development of aflibercept for the treatment of cancer or VEGF Trap-Eye for the treatment of diseases of the eye.

We have tested ARCALYST® in only a small number of patients. As more patients begin to use our product and as we test it 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 Kineret® (anakinra), marketed by Biogen, Enbrel® (etanercept), marketed by Amgen Inc. and Wyeth Pharmaceuticals, Inc., and Remicade® (infliximab) marketed by Centocor Ortho Biotech, Inc., 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 (Biogen), 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® in gout 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. Recently, another pharmaceutical company that is developing an antibody to NGF announced that it has suspended clinical programs for its agent in patients with osteoarthritis and other chronic use indications at the request of the FDA following a small number of reports of patients experiencing a worsening of osteoarthritis or osteonecrosis leading to joint replacement. Although REGN475 has some differences from this third party antibody, the safety risks reported in clinical trials with this other agent could be risks associated with all antibodies to NGF, including our product candidate. This risk or other complications or side effects could result in the discontinuation or limitation of the further development of REGN475 in osteoarthritis and other pain indications, including as a result of being placed on clinical hold by the FDA.

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 aflibercept and VEGF Trap-Eye with more sensitive assays in different patient populations and larger clinical trials, we will find that subjects given aflibercept 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 develop suitable product formulations or manufacturing processes to support large scale clinical testing of our product candidates, including aflibercept, VEGF Trap-Eye, and 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 involves complex legal and factual questions and, therefore, enforceability cannot be predicted with certainty. Our patents may be challenged, invalidated, or circumvented. Patent applications filed outside the United States may be challenged by third parties who file an opposition. Such opposition proceedings are increasingly common in the European Union and are costly to defend. We have pending patent applications in the European Patent Office and it is likely that we will need to defend patent applications from third party challengers from time to time in the future. 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 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.

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. Although we do not believe that aflibercept or VEGF Trap-Eye infringes any valid claim in these patents or patent applications, Genentech could initiate a lawsuit for patent infringement and assert that its patents are valid and cover aflibercept or VEGF Trap-Eye or uses thereof. Genentech may be motivated to initiate such a lawsuit at some point in an effort to impair our ability to develop and sell aflibercept or VEGF Trap-Eye, which represent potential competitive threats to Genentech's VEGF-binding products and product candidates. An adverse determination by a court in any such potential patent litigation would likely materially harm our business by requiring us to seek a license, which may not be available, or resulting in our inability to manufacture, develop, and sell aflibercept or VEGF Trap-Eye or in a damage award.

We are aware of patents and pending applications owned by Roche that claim antibodies to the interleukin-6 receptor and methods of treating rheumatoid arthritis with such antibodies. We are developing REGN88, an antibody to the interleukin-6 receptor, 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®, aflibercept, 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 United States.

Further, we are aware of a number of other third party patent applications that, if granted, with claims as currently drafted, may cover our current or planned activities. 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.

#### Regulatory and Litigation Risks

If we do not obtain regulatory approval for our product candidates, we will not be able to market or sell them.

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, the value of our company and our results of operations will be harmed. In the United States, we must obtain and maintain approval from the United States Food and Drug Administration (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 the FDA approval of ARCALYST® and the Europeans Medicines Agency approval of riloncept for the treatment of CAPS, none of our product candidates has ever received regulatory approval to be marketed and sold in the United States or any other country. We may never receive regulatory approval for any of our product candidates.

The FDA enforces good clinical practices 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 Good Clinical Practice regulations (GCPs), the study protocol or applicable regulations, the clinical data generated in our 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 and 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, 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 United States, we are subject to a variety of foreign regulatory requirements governing human clinical trials, manufacturing, marketing and approval of drugs, and commercial sale and distribution of drugs in foreign countries. The foreign regulatory approval process 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 United States, we must obtain approval by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of ARCALYST® or any of our product candidates in those countries.

If we fail to meet the stringent requirements of governmental regulation in the manufacture of our marketed product and clinical candidates, we could incur substantial remedial costs, delays in the development of our clinical candidates, 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 to the FDA and acceptance of the change by the FDA prior to release of product. Because we produce multiple product candidates at our facility in Rensselaer, New York, there are increased risks associated with cGMP compliance. Our inability, or the inability of our third party 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 our marketed product. Any delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our 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 and commercialize our products. Any finding of non-compliance could increase our costs, cause us to delay the development of our product candidates, and cause us to lose revenue from our marketed product.

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 sign up for our clinical trials may not protect us from liability or the cost of litigation. We may be subject to claims by CAPS patients who use ARCALYST® that they have been injured by a side effect associated with the drug. 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.

## Edgar Filing: REGENERON PHARMACEUTICALS INC - Form 10-Q

If we market and sell ARCALYST® 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, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any health care item or service reimbursable under Medicare, Medicaid, or other federally or state financed health care programs.

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, or 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 we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which would also harm our financial condition. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge 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 and were included in health care reform legislation recently enacted by the federal government. 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 action and fines and other penalties, and could receive adverse publicity.

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.

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, 2009, 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 material adverse effect 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 current Good Manufacturing Practice, or cGMPs, that make it more difficult for us to manufacture our marketed product and clinical candidates in accordance with cGMPs.

The enactment in the U.S. of the Patient Protection and Affordable Care Act, or PCCA, 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 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 REGN88, REGN421, REGN475, REGN727, and REGN668 we rely on sanofi-aventis to lead much of the clinical development efforts and assist with obtaining regulatory approval, particularly outside the United States. 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 aflibercept (VEGF Trap) is terminated, or sanofi-aventis materially breaches its obligations thereunder, our business operations and financial condition, and our ability to develop, manufacture, and commercialize aflibercept in the time expected, or at all, would be materially harmed.

We rely heavily on sanofi-aventis to lead much of the development of aflibercept. Sanofi-aventis funds all of the development expenses incurred by both companies in connection with the aflibercept program. If the aflibercept program continues, we will rely on sanofi-aventis to assist with funding the aflibercept program, provide commercial manufacturing capacity, enroll and monitor clinical trials, obtain regulatory approval, particularly outside the United States, and lead the commercialization of aflibercept. While we cannot assure you that aflibercept 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 aflibercept 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 aflibercept 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 aflibercept would create substantial new and additional risks to the successful development and commercialization of aflibercept.

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 develop 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. If the VEGF Trap-Eye program continues, we will rely on Bayer HealthCare to assist with funding the VEGF Trap-Eye development program, lead the development of VEGF Trap-Eye outside the United States, obtain regulatory approval outside the United States, and provide all sales, marketing, and commercial support for the product outside the United States. In particular, Bayer HealthCare has responsibility for selling VEGF Trap-Eye outside the United States using its sales force. While we cannot assure you that VEGF Trap-Eye will ever be successfully developed and 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 United States will be significantly adversely affected. Bayer HealthCare has the right to terminate its collaboration agreement with us at any time upon six or twelve months advance notice, depending on the circumstances giving rise to termination. If Bayer HealthCare were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could require us to seek additional funding 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 United States and result in substantial additional costs to us. We have limited commercial capabilities and would have to develop or outsource these capabilities outside the United States. Termination of the Bayer HealthCare collaboration agreement would create substantial new and additional risks to the successful development and commercialization of VEGF Trap-Eye.

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

We depend upon third-party collaborators, including sanofi-aventis, Bayer HealthCare, and service providers such as clinical research organizations, 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 Good Manufacturing Practices (GMPs), Good Laboratory Practices (GLPs), or Good Clinical Practice (GCP) Standards, we could experience additional costs, delays, and difficulties in the manufacture or development 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 efforts to market and sell ARCALYST® for the treatment of CAPS will not be successful.

#### Risks Related to the Manufacture of Our Product Candidates

We have limited manufacturing capacity, which could inhibit our ability to successfully develop or commercialize our drugs.

Our manufacturing facility is likely to be inadequate to produce sufficient quantities of product for commercial sale. We intend to rely on our corporate collaborators, as well as contract manufacturers, to produce the large quantities of drug material needed for commercialization of our products. We rely entirely on third-party manufacturers for filling and finishing services. We will have to depend on these manufacturers to deliver material on a timely basis and to comply with regulatory requirements. If we are unable to supply sufficient material on acceptable terms, or if we should encounter delays or difficulties in our relationships with our corporate collaborators or contract manufacturers, our business, financial condition, and results of operations may be materially harmed.

We must expand our own manufacturing capacity to support the planned growth of our clinical pipeline. Moreover, we may expand our manufacturing capacity to support commercial production of active pharmaceutical ingredients, or API, for our product candidates. 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. We may be unable to develop manufacturing facilities that are sufficient to produce drug material for clinical trials or commercial use. This may delay our clinical development plans and interfere with our efforts to commercialize our products. In addition, we may be unable to secure adequate filling and finishing services to support our products. As a result, our business, financial condition, and results of operations may be materially harmed.

We may 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.

If any of our clinical programs are discontinued, we may face costs related to the unused capacity at our manufacturing facilities.

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, we will have to absorb one hundred percent of related overhead costs and inefficiencies.

Third-party supply 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 for ARCALYST® and our product candidates at our manufacturing facilities in Rensselaer, New York. We would be unable to supply our product requirements if we 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 manufacturing and formulation of ARCALYST® and our product candidates are provided by single-source unaffiliated third-party suppliers. In addition, we rely on certain third parties to perform filling, finishing, distribution, and other services related to the manufacture of our products. 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, which could materially and adversely affect our business and future prospects.

Also, certain of the raw materials required in the manufacturing and the formulation of our clinical 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

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

We are marketing and selling ARCALYST® for the treatment of CAPS ourselves in the United States, primarily through third party service providers. We have no sales or distribution personnel in the United States and have only a small staff with commercial capabilities. We currently have no sales, marketing, commercial, or distribution capabilities outside the United States. 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 are approved. 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. Under the terms of our collaboration agreement with sanofi-aventis, we will rely on sanofi-aventis for sales, marketing, and distribution of aflibercept in cancer indications, should it be approved in the future by regulatory authorities for marketing. 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 United States and ARCALYST® for patients with gout initiating uric acid-lowering drug therapy, and we may be unsuccessful in developing our own sales, marketing, and distribution organization.

There may be too few patients with CAPS to profitably commercialize ARCALYST® in this indication.

Our only approved product is ARCALYST® for the treatment of CAPS, a group of rare, inherited auto-inflammatory diseases. These rare diseases affect a very small group of people. The incidence of CAPS has been reported to be approximately 1 in 1,000,000 people in the United States. Although the incidence rate of CAPS in Europe has not been reported, it is known to be a rare set of diseases. In October 2009, we received European marketing authorization for riloncept for CAPS. In 2009, Novartis received regulatory approval in the U.S. and Europe for its IL-1 antibody product for the treatment of CAPS. Given the very rare nature of the disease and the competition from Novartis' IL-1 antibody product, we may be unable to profitably commercialize ARCALYST® in this indication.

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

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 aflibercept and may offer competitive advantages over our molecule. Each of Pfizer and Onyx Pharmaceuticals, (together with its partner Bayer HealthCare) has received approval from the FDA to market and sell an oral medication that targets 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 aflibercept and to obtain regulatory approval of aflibercept in these cancer settings. This may delay or impair our ability to successfully develop and commercialize aflibercept. In addition, even if aflibercept is ever approved for sale for the treatment of certain cancers, it will be difficult for our drug to compete against Avastin (Genentech) 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 (Genentech), for the treatment of age-related macular degeneration (wet AMD), DME, and other eye indications. Lucentis (Genentech) was approved by the FDA in June 2006 for the treatment of wet AMD. In addition, in June 2010, Lucentis (Genentech) was approved by the FDA for the treatment of macular edema because of a blockage in a retinal vein. Many other companies are working on the development of product candidates for the potential treatment of wet AMD and DME that act by blocking VEGF and VEGF receptors, and through the use of small interfering ribonucleic acids (siRNAs) that modulate gene expression. In addition, ophthalmologists are using off-label, with success for the treatment of wet AMD, a third-party repackaged version of Genentech's approved VEGF antagonist, Avastin. The National Eye Institute and others are conducting long-term, controlled clinical trials comparing Lucentis (Genentech) to Avastin (Genentech) in the treatment of wet AMD. The marketing approval of Lucentis (Genentech) and the potential off-label use of Avastin (Genentech) make it more difficult for us to enroll patients in our clinical trials and successfully develop VEGF Trap-Eye. Even if VEGF Trap-Eye is ever approved for sale for the treatment of eye diseases, it may be difficult for our drug to compete against Lucentis (Genentech), because doctors and patients will have significant experience using this medicine. Moreover, the relatively low cost of therapy with Avastin (Genentech) in patients with wet AMD presents a further competitive challenge in this indication. While we believe that aflibercept would not be well tolerated if administered directly to the eye, if aflibercept is ever approved for the treatment of certain cancers, there is a risk that third parties will attempt to repackage aflibercept 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 the VEGF Trap-Eye if it is ever approved for sale.

The availability of highly effective FDA approved TNF-antagonists such as Enbrel (Amgen and Wyeth), Remicade (Centocor), Humira® (adalimumab), marketed by Abbott, and Simponi™ (golimumab), marketed by Centocor, and the IL-1 receptor antagonist Kineret (Biovitrum), 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 will have 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 interleukin-1 or inhibit the signaling of interleukin-1. For example, Eli Lilly, Xoma Ltd., and Novartis are each developing antibodies to interleukin-1 and Amgen is developing an antibody to the interleukin-1 receptor. Novartis received marketing approval for its IL-1 antibody for the treatment of CAPS from the FDA in June 2009 and from the European Medicines Agency in October 2009. Novartis is also developing this IL-1 antibody in gout and other inflammatory diseases. Novartis' IL-1 antibody and these other drug candidates could offer competitive advantages over ARCALYST®. For example, Novartis' IL-1 antibody 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 impair our ability to successfully commercialize ARCALYST®.

## Edgar Filing: REGENERON PHARMACEUTICALS INC - Form 10-Q

We are developing ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering therapy. In October 2009, Novartis announced positive Phase 2 results showing that canakinumab is more effective than an injectable corticosteroid at reducing pain and preventing recurrent attacks or “flares” in patients with hard-to-treat gout. Novartis’ IL-1 antibody 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 non-steroidal anti-inflammatory drugs are used as the standard of care to treat the symptoms of gout diseases. These established, inexpensive, orally delivered drugs may make it difficult for us to successfully commercialize ARCALYST® in these diseases.

The successful commercialization of ARCALYST® and 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.

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 non-steroidal anti-inflammatory drugs. 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 United States and foreign governmental, private third-party insurers and payers, and other third-party payers, including Medicare and Medicaid, do not agree to defray or reimburse the cost of our products to the patients. If these entities 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. Payers may especially impose these obstacles to coverage on higher-priced drugs, as our product candidates are likely to be.

We market and sell ARCALYST® in the United States for the treatment of a group of rare genetic disorders called CAPS. We have received European Union marketing authorization for riloncept 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 Patient Protection and Affordable Care Act or PPCA and a related reconciliation bill were signed into law. 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 in clinical development 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 adverse effect on our ability to achieve profitability.

## Edgar Filing: REGENERON PHARMACEUTICALS INC - Form 10-Q

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.

### 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. 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. 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 for developing our business.

### 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:

- 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 14, 2010, our six largest shareholders plus Leonard Schleifer, M.D, Ph.D., our Chief Executive Officer, beneficially owned 51.1% 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 14, 2010. As of April 14, 2010, sanofi-aventis beneficially owned 14,799,552 shares of Common Stock, representing approximately 18.6% of the shares of Common Stock then outstanding. Under our investor agreement, as amended, with sanofi-aventis, sanofi-aventis may not sell these shares until December 20, 2017 except under limited circumstances and subject to earlier termination of these restrictions upon the occurrence of certain events. Notwithstanding these restrictions, 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 14, 2010, holders of Class A Stock held 21.5% of the combined voting power of all shares of Common Stock and Class A Stock then outstanding, including any voting power associated with any shares of Common Stock beneficially owned by such Class A Stock holders. 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 14, 2010:

- our current executive officers and directors beneficially owned 13.7% 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 14, 2010, and 28.1% 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 14, 2010; and
- our six largest shareholders plus Leonard S. Schleifer, M.D., Ph.D. our Chief Executive Officer, beneficially owned 51.1% 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 14, 2010. In addition, these seven shareholders held 56.3% 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 14, 2010.

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 aflibercept 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
10.1	- Sixth Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of June 4, 2010.
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: July 28, 2010

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)