REGENERON PHARMACEUTICALS INC

Form 10-Q April 26, 2012

UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, DC 20549

Form 10-Q

(X)	(Mark One) QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EX	CHANGE ACT OF 1934
	For the quarterly period ended March 31, 2012		
		OR	
()	TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 ((d) OF THE SECURITIES EX	CHANGE ACT OF 1934
	For the transition period fromtoto Commission File Nu	mber <u>0-19034</u>	
	<u>REGENERON PHARM</u> (Exact name of registrant :		
	New York (State or other jurisdiction of incorporation or organization)	13-3444607 (I.R.S. Employer Identification	on No.)
	777 Old Saw Mill River Road <u>Tarrytown, New York</u> (Address of principal executive offices)	10591-6707 (Zip Code)	
	(Registrant s telephone nu	<u>7-7000</u> Imber, including area code)	
of 193	ate by check mark whether the registrant: (1) has filed all reports real 34 during the preceding 12 months (or for such shorter period that the filing requirements for the past 90 days.		
	Yes X	No	
File re	rate by check mark whether the registrant has submitted electronical required to be submitted and posted pursuant to Rule 405 of Regula such shorter period that the registrant was required to submit and post	tion S-T (§232.405 of this cha	
	Yes X	No	
compa Large	eate by check mark whether the registrant is a large accelerated file any. See the definitions of large accelerated filer, accelerated filer accelerated filer X accelerated filer (Do not check if a smaller reporting compa	ler and smaller reporting co	ompany in Rule 12b-2 of the Exchange Ac Accelerated filer
INOII-8	accelerated filer (Do not check if a smaller reporting compa	any)	Smaller reporting company
Indica	ate by check mark whether the registrant is a shell company (as defi Yes	ned in Rule 12b-2 of the Exch	ange Act).

Number of shares outstanding of each of the registrant s classes of common stock as of April 11, 2012:

Class of Common Stock Class A Stock, \$0.001 par value Common Stock, \$0.001 par value

Number of Shares 2,089,512 93,032,889

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[&]quot;ARCALYST®", "EYLEA®", "ZALTRAP®, VelocImmun®, VelociGene, VelociMouse, VelociMab, and VelociSunde are trademarks of Regeneron Pharmaceuticals, Inc. All other trademarks in this Form 10-Q are the property of their respective owners.

PART I. FINANCIAL INFORMATION ITEM 1. FINANCIAL STATEMENTS

REGENERON PHARMACEUTICALS, INC. CONDENSED BALANCE SHEETS (Unaudited)

(In thousands, except share data)

		arch 31,	December 31,		
SSETS		12	201	1	
Current assets:					
Cash and cash equivalents	\$	394,585	\$	483,610	
Marketable securities		37,713		43,332	
Accounts receivable - trade, net		159,462		28,254	
Accounts receivable from Sanofi		78,885		74,781	
Prepaid expenses and other current assets		26,270		22,898	
Total current assets		696,915		652,875	
		0,0,,,10		002,070	
Restricted cash and marketable securities		8,154		7,721	
Marketable securities		254,738		275,887	
Property, plant, and equipment, at cost, net of accumulated		,,,,,,,		,	
depreciation and amortization		369,959		367,955	
Other assets		20,393		19,145	
Total assets	\$	1,350,159	\$	1,323,583	
LIABILITIES and STOCKHOLDERS' EQUITY					
Current liabilities:					
Accounts payable and accrued expenses	\$	106,723	\$	95,625	
Deferred revenue from Sanofi, current portion		20,141		20,011	
Deferred revenue - other, current portion		32,429		31,629	
Facility lease obligations, current portion		1,093		1,006	
Total current liabilities		160,386		148,271	
Deferred revenue from Sanofi		83,625		86,017	
Deferred revenue - other		154,929		162,593	
Facility lease obligations		159,534		159,508	
Convertible senior notes		280,206		275,019	
Other long term liabilities		7,455		6,443	
Total liabilities		846,135		837,851	
Commitments and contingencies					
and the second of the second o					
Stockholders' equity:					
Preferred stock, \$.01 par value; 30,000,000 shares authorized; issued and outstanding - none					
Class A Stock, convertible, \$.001 par value; 40,000,000 shares authorized;					
shares issued and outstanding - 2,089,512 at March 31, 2012 and 2,109,512 at					
December 31, 2011		2		2	
Common Stock, \$.001 par value; 160,000,000 shares authorized;					
shares issued and outstanding - 92,969,427 at March 31, 2012 and 90,692,071 at		0.0		0.4	
December 31, 2011		93		91	
Additional paid-in capital		1,760,938		1,754,824	
Accumulated deficit		(1,255,672)		(1,267,323)	
Accumulated other comprehensive loss		(1,337)		(1,862)	
Total stockholders' equity Total liabilities and stockholders' equity	\$	504,024 1,350,159	¢	485,732 1,323,583	
Total natifices and stockholders equity	Э	1,330,139	\$	1,323,383	

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

	Three months ended March 31, 2012 2011					
Condensed Statements of Operations	2012		2011			
Revenues:						
Net product sales	\$	127,931	\$	4,427		
Sanofi collaboration revenue		85,005		85,329		
Bayer HealthCare collaboration revenue		12,483		12,481		
Technology licensing		5,893		7,845		
Contract research and other		477		2,122		
		231,789		112,204		
Expenses:						
Research and development		138,862		129,392		
Selling, general, and administrative		58,428		23,411		
Cost of goods sold		12,298		382		
		209,588		153,185		
Income (loss) from operations		22,201		(40,981)		
Other income (expense):						
Investment income		610		1,037		
Interest expense		(11,160)		(3,719)		
		(10,550)		(2,682)		
Net income (loss) before income tax benefit		11,651		(43,663)		
Income tax benefit				216		
Net income (loss)	\$	11,651	\$	(43,447)		
Net income (loss) per share - basic	\$	0.12	\$	(0.49)		
Net income (loss) per share - diluted	\$	0.11	\$	(0.49)		
Weighted average shares outstanding - basic		93,446		89,162		
Weighted average shares outstanding - diluted		107,734		89,162		
Condensed Statements of Comprehensive Income (Loss)						
Net income (loss)	\$	11,651	\$	(43,447)		
Other comprehensive income (loss):						
Unrealized gain on marketable securities, net of tax		525		316		
Comprehensive income (loss)	\$	12,176	\$	(43,131)		

REGENERON PHARMACEUTICALS, INC.

CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY (Unaudited)

For the three months ended March 31,2012 and 2011

(In thousands)

	Class A St		Common St		Additional Paid-in	Acc Def	cumulated	Accur Other Comp
Balance, December 31, 2011	Shares 2.109	\$ 2	90.692	\$ 91	### sntCapital ### \$ 1,754,824	\$	(1,267,323)	Incon \$
Issuance of Common Stock in connection with exercise of stock options	2,109	Φ 2	2,662	2	31,744	Φ	(1,207,323)	φ
Common Stock tendered upon exercise of stock options in connection with employee tax obligations			(469)		(49,078)			
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			(409)		(45,076)			
Conversion of Class A Stock to Common Stock	(20)		20					
Stock-based compensation charges	, ,				23,448			
Net income							11,651	
Other comprehensive income, net of tax								
Balance, March 31, 2012	2,089	\$ 2	92,969	\$ 93	\$ 1,760,938	\$	(1,255,672)	\$
Balance, December 31, 2010	2,182	\$ 2	87,238	\$ 87	\$ 1,575,780	\$	(1,045,563)	\$
Issuance of Common Stock in connection with exercise of stock options, net of shares tendered Issuance of Common Stock in connection with Company	·		1,218	2	15,102		· · · · ·	
401(k) Savings Plan contribution			92		3,405			
Stock-based compensation charges Net loss Other comprehensive income, net of tax					14,898		(43,447)	
Balance, March 31, 2011	2,182	\$ 2	88,548	\$ 89	\$ 1,609,185	\$	(1,089,010)	\$

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

	Three 2012	months ended	March 31, 2011		
Cash flows from operating activities:					
Net income (loss)	\$	11,651	\$	(43,447)	
Adjustments to reconcile net income (loss) to net cash					
used in operating activities:					
Depreciation and amortization		8,416		6,978	
Non-cash compensation expense		23,244		14,801	
Other non-cash charges and expenses, net		5,863		582	
Changes in assets and liabilities:					
Increase in Sanofi and trade accounts receivable		(135,312)		(4,317)	
(Increase) decrease in prepaid expenses and other assets		(4,487)		11,559	
Decrease in deferred revenue		(9,126)		(10,310)	
Increase in accounts payable, accrued expenses, and other liabilities		12,710		13,574	
Total adjustments		(98,692)		32,867	
Net cash used in operating activities		(87,041)		(10,580)	
Cash flows from investing activities: Purchases of marketable securities Sales or maturities of marketable securities (Increase) decrease in restricted cash and marketable securities Capital expenditures Net cash provided by investing activities		(48,569) 75,853 (463) (11,055) 15,766		(15,638) 58,119 32 (22,166) 20,347	
Cash flows from financing activities:					
Payments in connection with facility and capital lease obligations		(500)		(306)	
Net proceeds from issuances of Common Stock		31,828		14,406	
Payments in connection with Common Stock tendered for employee tax obligations Net cash (used in) provided by financing activities		(49,078) (17,750)		(1,063) 13,037	
Net (decrease) increase in cash and cash equivalents		(89,025)		22,804	
Cash and cash equivalents at beginning of period		483,610		112,572	
Cash and cash equivalents at end of period	\$	394,585	\$	135,376	

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

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

1. Interim Financial Statements

The interim Condensed Financial Statements of Regeneron Pharmaceuticals, Inc. (Regeneron or the Company) have been prepared in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all information and disclosures necessary for a presentation of the Company s financial position, results of operations, and cash flows in conformity with accounting principles generally accepted in the United States of America. In the opinion of management, these financial statements reflect all normal recurring adjustments and accruals necessary for a fair statement of the Company s financial position, results of operations, and cash flows for such periods. The results of operations for any interim periods are not necessarily indicative of the results for the full year. The December 31, 2011 Condensed Balance Sheet data were derived from audited financial statements, but do not include all disclosures required by accounting principles generally accepted in the United States of America. These financial statements should be read in conjunction with the financial statements and notes thereto contained in the Company s Annual Report on Form 10-K for the year ended December 31, 2011.

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

2. Product Revenue

In November 2011, the Company received marketing approval from the U.S. Food and Drug Administration (FDA) for EYLEA (aflibercept) Injection for the treatment of neovascular wet age-related macular degeneration (wet AMD). EYLEA net product sales totaled \$123.5 million for the three months ended March 31, 2012.

In February 2008, the Company received marketing approval from the FDA for ARCALYST® Injection for Subcutaneous Use for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS). ARCALYST net product sales totaled \$4.4 million for both the three months ended March 31, 2012 and March 31, 2011.

The Company sells EYLEA in the United States to three distributors and several specialty pharmacies. The Company sells ARCALYST in the United States to two specialty pharmacies. Under these distribution models, the distributors and specialty pharmacies (collectively, the Company s customers) generally take physical delivery of product. For EYLEA, the distributors and specialty pharmacies generally sell the product directly to healthcare providers; whereas for ARCALYST, the specialty pharmacies sell the product directly to patients. The Company records revenue from product sales upon delivery to its customers. For the three months ended March 31, 2012, the Company recorded 81% of its gross product revenue from sales to Besse Medical, a subsidiary of AmerisourceBergen Corporation.

Revenue from product sales are recorded net of applicable provisions for prompt pay discounts, rebates and chargebacks under governmental programs (including Medicaid), product returns, distribution-related fees, and other sales-related deductions. The following table summarizes the provisions, and credits/payments, for government rebates and chargebacks, distribution-related fees, and other sales-related deductions for the three months ended March 31, 2012; such amounts were not material for the three months ended March 31, 2011.

	Rebat	Rebates &		ribution- ted	Other Relat	Sales- ed		
	Charg	gebacks	Fees		Deductions		To	tal
Balance as of December 31, 2011	\$	585	\$	1,451	\$	182	\$	2,218
Provision related to current period sales		2,386		6,965		761		10,112
Credits/payments		(161)		(2,907)		(495)		(3,563)
Balance as of March 31, 2012	\$	2,810	\$	5,509	\$	448	\$	8,767

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

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

3. Per Share Data

The Company s basic net income (loss) per share amounts have been computed by dividing net income (loss) by the weighted average number of shares of Common Stock and Class A Stock outstanding. Net income (loss) per share is presented on a combined basis, inclusive of Common Stock and Class A Stock outstanding, as each class of stock has equivalent economic rights. Diluted net income per share is based on the weighted-average number of shares of Common Stock and Class A Stock outstanding plus additional weighted-average common stock equivalent shares outstanding during the period when the effect is dilutive. For the three months ended March 31, 2011, the Company reported a net loss; therefore, no common stock equivalents were included in the computation of diluted net loss per share for this period, since such inclusion would have been antidilutive. The calculations of basic and diluted net income (loss) per share are as follows:

	Three Months Ended March 31,									
	2012		2011							
Numerator										
Net income (loss) - basic and diluted	\$	11,651	\$	(43,447)						
Denominator										
Weighted-average shares - basic		93,446		89,162						
Effect of dilutive securities:										
Stock options		13,630								
Restricted stock		658								
Dilutive potential shares		14,288								
Weighted-average shares - diluted		107,734		89,162						
Net income (loss) per share - basic	\$	0.12	\$	(0.49)						
Net income (loss) per share - diluted	\$	0.11	\$	(0.49)						

Shares issuable upon the exercise of stock options and warrants, vesting of restricted stock awards, and conversion of convertible senior notes, which have been excluded from the March 31, 2012 and 2011 diluted per share amounts because their effect would have been antidilutive, include the following:

	Three M 2012	Ionths Ended	March 31, 2011	
Stock options:				
Weighted average number, in thousands		89		22,378
Weighted average exercise price	\$	94.13	\$	20.26
Restricted stock:				
Weighted average number, in thousands				845
Convertible senior notes:				
Weighted average number, in thousands		4,761		
Warrants:				
Weighted average number, in thousands		4,761		

4. Statement of Cash Flows

Supplemental disclosure of noncash investing and financing activities:

Included in accounts payable and accrued expenses at March 31, 2012 and December 31, 2011 were \$5.8 million and \$6.2 million, respectively, of accrued capital expenditures. Included in accounts payable and accrued expenses at March 31, 2011 and December 31, 2010 were \$5.7 million and \$10.7 million, respectively, of accrued capital expenditures.

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REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

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

Included in marketable securities at March 31, 2012 and December 31, 2011 were \$1.0 million and \$0.7 million, respectively, of accrued interest income. Included in marketable securities at March 31, 2011 and December 31, 2010 were \$2.0 million and \$1.4 million, respectively, of accrued interest income.

5. Marketable Securities

Marketable securities at March 31, 2012 and December 31, 2011 consisted of debt securities, as detailed below, and equity securities. The aggregate fair value of the equity securities was \$3.6 million and \$3.0 million at March 31, 2012 and December 31, 2011, respectively, and the aggregate cost basis was \$4.0 million at both March 31, 2012 and December 31, 2011. The Company also held restricted marketable securities at both March 31, 2012 and December 31, 2011, which consisted of debt securities, as detailed below, that collateralize letters of credit and lease obligations.

The following tables summarize the amortized cost basis of debt securities included in marketable securities, the aggregate fair value of those securities, and gross unrealized gains and losses on those securities at March 31, 2012 and December 31, 2011. The Company classifies its debt securities, other than mortgage-backed securities, based on their contractual maturity dates. Maturities of mortgage-backed securities have been estimated based primarily on repayment characteristics and experience of the senior tranches that the Company holds. The debt securities listed at March 31, 2012, excluding mortgage-backed securities, mature at various dates through March 2015. The mortgage-backed securities listed at March 31, 2012 mature at various dates through March 2020.

		Amortized		ir	Un	realize	d			
At March 31, 2012	Cost	Basis	Va	lue	Ga	ins	(Lo	osses)	Ne	et
Unrestricted										
Maturities within one year:										
U.S. government obligations	\$ 1	10,017	\$	10,049	\$	32			\$	32
U.S. government guaranteed corporate										
bonds		15,285		15,324		39				39
U.S. government guaranteed										
collateralized mortgage obligations		188		188						
Municipal bonds	1	12,147		12,152		6	\$	(1)		5
•	3	37,637		37,713		77		(1)		76
Maturities after one year through five years:		.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		07,710				(-)		, 0
U.S. government obligations	25	50,719		251,004		387		(102)		285
	2.	103		30		307				
Mortgage-backed securities						20-		(73)		(73)
	25	50,822		251,034		387		(175)		212
Maturities after five years through ten years:										
Mortgage-backed securities		162		93				(69)		(69)
	28	38,621		288,840		464		(245)		219
Restricted										
Maturities within one year:										
U.S. government obligations		3,330		3,335		5				5
		,		,						
Maturities after one year through five years:										
U.S. government obligations		4,724		4,728		8		(4)		4
		8,054		8,063		13		(4)		9
	\$ 29	96,675	\$	296,903	\$	477	\$	(249)	\$	228
				,				, ,		

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

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

	Amortized	Fair	Unrealized	i	
At December 31, 2011	Cost Basis	Value	Gains	(Losses)	Net
Unrestricted					
Maturities within one year:					
U.S. government obligations	\$ 12,025	\$ 12,067	\$ 42		\$ 42
U.S. government guaranteed corporate bonds	15,263	15,316	53		53
U.S. government guaranteed collateralized	623	622		¢ (1)	(1)
mortgage obligations				\$ (1)	(1)
Municipal bonds	15,314	15,326	13	(1)	12
	43,225	43,331	108	(2)	106
Maturities after one year through five years:					
U.S. government obligations	272,433	272,752	400	(81)	319
Mortgage-backed securities	104	28	400	(76)	(76)
mongage busined securities	272,537	272,780	400	(157)	243
Maturities after five years through ten years:					
Mortgage-backed securities	164	87		(77)	(77)
	315,926	316,198	508	(236)	272
Restricted					
Maturities within one year:					
U.S. government obligations	3,347	3,357	10		10
Maturities after one year through five years:					
U.S. government obligations	2,572	2,583	11		11
_	5,919	5,940	21		21
	\$ 321,845	\$ 322,138	\$ 529	\$ (236)	\$ 293
	Ψ 321,043	Ψ 322,130	Ψ 32)	φ (230)	Ψ 273

At March 31, 2012 and December 31, 2011, marketable securities included an additional unrealized loss of \$0.4 million and \$1.0 million, respectively, related to one equity security in the Company s marketable securities portfolio.

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

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

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

		ess tha air	n 1	2 Month Unreal			12 N	Montl	hs or G		er ealized		otal air	Unre	ealized
At March 31, 2012	\mathbf{V}	alue		Loss			Fair Value		ue	Loss		V	alue	Loss	1
Unrestricted															
U.S. government obligations	\$	261,0		\$,	02)						\$	- ,	\$	(102)
Municipal bonds		12,1:				(1)							12,152		(1)
Equity security		3,6	11		(43	34)	_			_			3,611		(434)
Mortgage-backed securities							\$		123	\$	(142)		123		(142)
		276,8	16		(53	37)			123		(142)		276,939		(679)
Restricted		2.4	1.7			(4)							0.417		(4)
U.S. government obligations		2,4				(4)							2,417		(4)
		2,4	1 /			(4)							2,417		(4)
	\$	279,2	33	\$	(54	41)	\$		123	\$	(142)	\$	279,356	\$	(683)
		Less than 12		2 Months 12 Month		Ionths	hs or Greater Unrealized			Total	Un	realized			
			Fa										Fair		
At December 31, 2011			Va	lue	Los	SS		Fair	Value	· I	Loss		Value	Los	SS
Unrestricted															
U.S. government obligations			\$	103,529	\$	(8	31)						\$ 103,529	\$	(81)
U.S. government guaranteed															
collateralized mortgage obligations				623		((1)						623		(1)
Municipal bonds				4,603		((1)						4,603		(1)
Equity security				3,019		(1,02	25)						3,019		(1,025)
Mortgage-backed securities			Ф	111 77 4	Ф	(1.10	10)	\$		16 \$		52)	116	Φ	(152)
			\$	111,774	\$	(1,10	18)	\$	1.	16 \$	(1:	52)	\$ 111,890	\$	(1,260)

Realized gains and losses are included as a component of investment income. For the three months ended March 31, 2012 and 2011, total realized gains and losses on sales of marketable securities were not material.

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

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

The Company s assets that are measured at fair value on a recurring basis, at March 31, 2012 and December 31, 2011, were as follows:

AAM1-21-2012		W. N. I.	Fair Value Me Using Quoted Prices in Active Markets for Identical Assets (Level 1)		Significant Other Observable Inputs		Significant Unobservable Inputs
At March 31, 2012 Unrestricted	rai	r Value	(Le	vei 1)	(Le	vel 2)	(Level 3)
Available-for-sale marketable securities:							
U.S. government obligations	\$	261,053			\$	261,053	
U.S. government guaranteed							
corporate bonds		15,324				15,324	
U.S. government guaranteed							
collateralized mortgage obligations		188				188	
Municipal bonds		12,152				12,152	
Mortgage-backed securities		123	Φ.	2 (11		123	
Equity security		3,611	\$	3,611		200.040	
		292,451		3,611		288,840	
Restricted Available-for-sale marketable securities: U.S. government obligations		8,063				8,063	
	\$	300,514	\$	3,611	\$	296,903	
At December 31, 2011	Fair Value		Fair Value Mo Using Quoted Prices in Active Markets for Identical Assets (Level 1)		Significant Other Observable Inputs (Level 2)		Significant Unobservable Inputs (Level 3)
Unrestricted							
Available-for-sale marketable securities:	\$	204 010			\$	284,819	
U.S. government obligations U.S. government guaranteed	ф	284,819			Þ	204,819	
corporate bonds		15,316				15,316	
U.S. government guaranteed		22,010				,010	
collateralized mortgage obligations		622				622	
Municipal bonds		15,326				15,326	
Mortgage-backed securities		115				115	
Equity security		3,019	\$	3,019			
		319,217		3,019		316,198	

Restricted				
Available-for-sale marketable securities:				
U.S. government obligations	5,940		5,940	
	\$ 325,157	\$ 3,019	\$ 322,138	

Marketable securities included in Level 2 were valued using a market approach utilizing prices and other relevant information, such as interest rates, yield curves, prepayment speeds, loss severities, credit risks and default rates, generated by market transactions involving identical or comparable assets. The Company considers market liquidity in determining the fair value for these securities. The Company did not record any charges for other-than-temporary impairment of its Level 2 marketable securities during the three months ended March 31, 2012 or 2011.

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

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

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

6. Inventory

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

	March 31, 2012	Dece: 31, 2011	mber
Raw materials	\$ 641	\$	1,608
Work in process	16,616		10,806
Finished goods	3,360		1,142
	\$ 20,617	\$	13,556

At March 31, 2012, \$6.2 million of inventories were included in prepaid expenses and other current assets and \$14.4 million of inventories were included in other assets. At December 31, 2011, \$3.5 million of inventories were included in prepaid expenses and other current assets and \$10.1 million of inventories were included in other assets.

For the three months ended March 31, 2012, cost of goods sold included inventory write-downs and reserves totaling \$1.9 million. For the three months ended March 31, 2011, there were no inventory write-downs or reserves included in cost of goods sold.

7. Accounts Payable and Accrued Expenses

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

	March 31,	December 31,
	2012	2011
Accounts payable	\$ 25,390	
Accrued payroll and related costs	34,336	42,835
Accrued clinical trial expense	11,342	9,850
Accrued sales-related deductions and royalties	17,456	3,947
Other accrued expenses and liabilities	18,199	11,257
	\$ 106,723	\$ 95,625

8. Income Taxes

For the three months ended March 31, 2012, income tax expense relating to the Company s pre-tax income was fully offset by a reversal of a portion of the Company s valuation allowance. The Company continues to recognize a full valuation allowance against its net operating loss carry-forward and other deferred tax assets since the Company has an extended history of losses. For the three months ended March 31, 2011, the Company incurred a net loss for tax purposes and recognized a full valuation allowance against deferred tax assets.

REGENERON PHARMACEUTICALS, INC.

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

For the three months ended March 31, 2011, the Company recognized an income tax benefit of \$0.2 million in connection with the net tax effect of the change in the Company s unrealized gain/(loss) on available-for-sale marketable securities, which is included in other comprehensive income (loss).

9. Legal Matters

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

Genentech Patent Litigation

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

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

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

REGENERON PHARMACEUTICALS, INC.

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

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

10. Recently Issued Accounting Standards

Presentation of comprehensive income

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

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

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

Overview

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

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

Net product sales of our two marketed products totaled \$127.9 million in the first quarter of 2012, which contributed to our overall net income of \$11.7 million. Our operating results over the next several years will be largely dependent upon our ability to successfully commercialize EYLEA and the market penetration it achieves.

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

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

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

- $\bullet \ Sarilumab\ (REGN88), an \ antibody\ to\ the\ interleukin-6\ receptor\ (IL-6R), which\ is\ being\ developed\ in\ rheumatoid\ arthritis;$
- REGN727, an antibody to Proprotein Convertase Subtilisin/Kexin type 9 (PCSK9), which is being developed for low-density lipoprotein (LDL) cholesterol reduction;

- REGN668, an antibody to the interleukin-4 receptor (IL-4R), which is being developed in atopic dermatitis and eosinophilic asthma;
- REGN421, an antibody to Delta-like ligand-4 (Dll4), a novel angiogenesis target, which is being developed in oncology;
- REGN910, an antibody to Angiopoietin-2 (ANG2), another novel angiogenesis target, which is being developed in oncology;
- REGN728, an antibody in clinical development against an undisclosed target; and
- REGN1033, an antibody in clinical development against an undisclosed target.

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

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

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

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

Commercial Products:

EYLEA (aflibercept) Injection wet AMD

In November 2011, we received U.S. marketing approval from the U.S. Food and Drug Administration (FDA) for EYLEA Injection for the treatment of patients with wet AMD. The approval of EYLEA was granted by the FDA under a Priority Review, a designation that is given to drugs that offer significant advances in treatment, or provide a treatment where no adequate therapy exists. Net product sales of EYLEA in the first quarter of 2012 were \$123.5 million.

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

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

ARCALYST CAPS

Net product sales of ARCALYST (rilonacept) for the treatment of CAPS were \$4.4 million in the first quarters of both 2012 and 2011. We do not expect future net product sales of ARCALYST for the treatment of CAPS to be significant.

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

Clinical Programs:

1. EYLEA Ophthalmologic Diseases

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

In November 2011, we received U.S. marketing approval from the FDA for EYLEA Injection for the treatment of patients with wet AMD. In 2011, Bayer HealthCare submitted regulatory applications for marketing approval of EYLEA in wet AMD in the European Union, Japan, and other countries. In February 2012, Bayer HealthCare received marketing approval in Australia for EYLEA for the treatment of patients with wet AMD.

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

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

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

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