

REGENERON PHARMACEUTICALS INC  
Form 10-Q  
August 04, 2016

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, DC 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, 2016

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) 847-7000

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(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

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

Yes  No

Number of shares outstanding of each of the registrant's classes of common stock as of July 14, 2016:

Class of Common Stock	Number of Shares
Class A Stock, \$.001 par value	1,911,456
Common Stock, \$.001 par value	103,383,050

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 QUARTERLY REPORT ON FORM 10-Q  
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"ARCALYST®", "EYLEA®", "ZALTRAP®", "VelocImmune®", "VelociGene®", "VelociMouse®", "VelociMab®", and "VelociSuite®" are trademarks of Regeneron Pharmaceuticals, Inc. Trademarks and trade names of other companies appearing in this report are, to the knowledge of Regeneron Pharmaceuticals, Inc., the property of their respective owners.

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ITEM 1. FINANCIAL STATEMENTSREGENERON PHARMACEUTICALS, INC.  
CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)  
(In thousands, except share data)

	June 30, 2016	December 31, 2015
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$646,508	\$809,102
Marketable securities	398,656	236,121
Accounts receivable - trade, net	1,431,966	1,152,489
Accounts receivable from Sanofi	138,067	153,152
Accounts receivable from Bayer	181,938	162,152
Inventories	316,073	238,578
Prepaid expenses and other current assets	96,017	163,501
Total current assets	3,209,225	2,915,095
Marketable securities	589,852	632,162
Property, plant, and equipment, net	1,772,923	1,594,120
Deferred tax assets	626,191	461,945
Other assets	6,715	5,810
Total assets	\$6,204,906	\$5,609,132
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$759,643	\$644,112
Deferred revenue from Sanofi, current portion	104,141	101,573
Deferred revenue - other, current portion	84,084	51,914
Other current liabilities	3,695	13,563
Total current liabilities	951,563	811,162
Deferred revenue from Sanofi	549,342	582,664
Deferred revenue - other	146,449	82,015
Facility lease obligations	361,523	362,919
Other long-term liabilities	119,523	115,535
Total liabilities	2,128,400	1,954,295
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 - 1,911,456 in 2016 and 1,913,776 in 2015	2	2
Common Stock, \$.001 par value; 320,000,000 shares authorized; shares issued - 107,132,543 in 2016 and 106,378,001 in 2015	107	106
Additional paid-in capital	3,156,942	3,099,526
Retained earnings	1,230,303	852,700

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Accumulated other comprehensive income	5,204	8,572
Treasury stock, at cost; 3,761,628 shares in 2016 and 3,642,820 in 2015	(316,052 )	(306,069 )
Total stockholders' equity	4,076,506	3,654,837
Total liabilities and stockholders' equity	\$6,204,906	\$5,609,132

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

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## REGENERON PHARMACEUTICALS, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME

(Unaudited)

(In thousands, except per share data)

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2016	2015	2016	2015
Statements of Operations				
Revenues:				
Net product sales	\$834,219	\$657,819	\$1,618,401	\$1,202,392
Sanofi collaboration revenue	163,414	195,110	383,108	368,466
Bayer collaboration revenue	191,896	134,237	371,488	258,083
Other revenue	23,100	11,451	40,481	39,288
	1,212,629	998,617	2,413,478	1,868,229
Expenses:				
Research and development	559,930	390,330	1,030,042	733,443
Selling, general, and administrative	292,038	174,588	581,715	333,579
Cost of goods sold	41,247	60,855	120,189	103,425
Cost of collaboration and contract manufacturing	27,786	27,985	60,596	69,370
	921,001	653,758	1,792,542	1,239,817
Income from operations	291,628	344,859	620,936	628,412
Other income (expense):				
Investment income	2,801	1,653	5,050	1,833
Interest and other expense, net	(2,173 )	(18,516 )	(3,579 )	(25,726 )
	628	(16,863 )	1,471	(23,893 )
Income before income taxes	292,256	327,996	622,407	604,519
Income tax expense	(96,038 )	(133,353 )	(244,804 )	(333,855 )
Net income	\$196,218	\$194,643	\$377,603	\$270,664
Net income per share - basic	\$1.88	\$1.89	\$3.61	\$2.64
Net income per share - diluted	\$1.69	\$1.69	\$3.24	\$2.35
Weighted average shares outstanding - basic	104,633	102,886	104,462	102,558
Weighted average shares outstanding - diluted	116,231	115,259	116,617	114,962
Statements of Comprehensive Income				
Net income	\$196,218	\$194,643	\$377,603	\$270,664
Other comprehensive income (loss):				
Unrealized gain (loss) on marketable securities, net of tax	840	(28,751 )	(3,368 )	(33,098 )
Comprehensive income	\$197,058	\$165,892	\$374,235	\$237,566

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





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

	Six Months Ended June 30, 2016		2015	
Cash flows from operating activities:				
Net income	\$ 377,603		\$ 270,664	
Adjustments to reconcile net income to net cash provided by operating activities:				
Depreciation and amortization	48,006		31,325	
Non-cash compensation expense	273,941		198,016	
Other non-cash charges and expenses, net	7,795		33,017	
Deferred taxes	(162,652)	)	(59,069)	)
Changes in assets and liabilities:				
Increase in Sanofi, Bayer, and trade accounts receivable	(284,178)	)	(418,753)	)
Increase in inventories	(72,888)	)	(45,591)	)
Decrease in prepaid expenses and other assets	57,086		33,842	
Increase (decrease) in deferred revenue	65,850		(16,685)	)
Increase in accounts payable, accrued expenses, and other liabilities	133,925		129,338	
Total adjustments	66,885		(114,560)	)
Net cash provided by operating activities	444,488		156,104	
Cash flows from investing activities:				
Purchases of marketable securities	(228,942)	)	(340,844)	)
Sales or maturities of marketable securities	102,177		193,769	
Capital expenditures	(242,930)	)	(354,055)	)

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Net cash used in investing activities	(369,695	)	(501,130	)
Cash flows from financing activities:				
(Payments) proceeds in connection with facility lease obligations	(1,213	)	26,780	
Repayments of convertible senior notes	(12,650	)	(144,001	)
Payments in connection with reduction of outstanding warrants	(242,117	)	(124,531	)
Proceeds from issuance of Common Stock	63,606		115,825	
Payments in connection with Common Stock tendered for employee tax obligations	(45,013	)	(35,930	)
Excess tax benefit from stock-based compensation	—		248,718	
Net cash (used in) provided by financing activities	(237,387	)	86,861	
Net decrease in cash and cash equivalents	(162,594	)	(258,165	)
Cash and cash equivalents at beginning of period	809,102		648,719	
Cash and cash equivalents at end of period	\$ 646,508		\$ 390,554	

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

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## REGENERON PHARMACEUTICALS, INC.

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

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

## 1. Interim Financial Statements

The interim Condensed Consolidated Financial Statements of Regeneron Pharmaceuticals, Inc. and its subsidiaries ("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, 2015 Condensed Consolidated 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, 2015.

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

## 2. Product Sales

EYLEA<sup>®</sup> net product sales in the United States totaled \$830.9 million and \$654.6 million for the three months ended June 30, 2016 and 2015, respectively, and \$1,611.8 million and \$1,195.7 million for the six months ended June 30, 2016 and 2015, respectively. In addition, ARCALYST<sup>®</sup> net product sales totaled \$3.3 million and \$3.2 million for the three months ended June 30, 2016 and 2015, respectively, and \$6.6 million and \$6.7 million for the six months ended June 30, 2016 and 2015, respectively.

The Company recorded 56% and 69% for the three months ended June 30, 2016 and 2015, respectively, and 58% and 69% for the six months ended June 30, 2016 and 2015, respectively, of its total gross product revenue from sales to Besse Medical, a subsidiary of AmerisourceBergen Corporation.

Revenue from product sales is recorded net of applicable provisions for rebates and chargebacks, distribution-related fees, and other sales-related deductions. The following table summarizes the provisions, and credits/payments, for these sales-related deductions during the six months ended June 30, 2016 and 2015.

	Rebates & Chargebacks	Distribution- Related Fees	Other Sales- Related Deductions	Total
Balance as of December 31, 2015	\$ 6,419	\$ 48,313	\$ 517	\$55,249
Provision related to current period sales	41,326	74,289	12,341	127,956
Credits/payments	(36,110 )	(94,467 )	(11,782 )	(142,359)
Balance as of June 30, 2016	\$ 11,635	\$ 28,135	\$ 1,076	\$40,846
Balance as of December 31, 2014	\$ 3,083	\$ 21,166	\$ 532	\$24,781
Provision related to current period sales	25,481	54,747	3,454	83,682
Credits/payments	(23,090 )	(36,433 )	(3,482 )	(63,005 )
Balance as of June 30, 2015	\$ 5,474	\$ 39,480	\$ 504	\$45,458

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## REGENERON PHARMACEUTICALS, INC.

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

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

## 3. Collaboration Agreements

## a. Sanofi

The collaboration revenue the Company earned from Sanofi is detailed below:

	Three Months Ended June 30,	
	2016	2015
Sanofi Collaboration Revenue		
Antibody:		
Reimbursement of Regeneron research and development expenses	\$ 144,232	\$ 211,516
Reimbursement of Regeneron commercialization-related expenses	85,885	27,347
Regeneron's share of losses in connection with commercialization of antibodies	(122,107 )	(46,313 )
Other	3,054	2,560
Total Antibody	111,064	195,110
Immuno-oncology:		
Reimbursement of Regeneron research and development expenses	32,350	—
Other	20,000	—
Total Immuno-oncology	52,350	—
	\$ 163,414	\$ 195,110
	Six Months Ended June 30,	
	2016	2015
Sanofi Collaboration Revenue		
Antibody:		
Reimbursement of Regeneron research and development expenses	\$ 337,834	\$ 380,336
Reimbursement of Regeneron commercialization-related expenses	159,159	35,805
Regeneron's share of losses in connection with commercialization of antibodies	(221,529 )	(68,718 )
Other	6,019	5,121
Total Antibody	281,483	352,544
Immuno-oncology:		
Reimbursement of Regeneron research and development expenses		