SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

Quarterly Report Under Section 13 or 15(d) of the Securities Exchange Act of 1934

FOR THE QUARTER ENDED SEPTEMBER 30, 2015

COMMISSION FILE NUMBER 001-6351

ELI LILLY AND COMPANY

(Exact name of Registrant as specified in its charter)

INDIANA	35-0470950
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

LILLY CORPORATE CENTER, INDIANAPOLIS, INDIANA 46285
(Address of principal executive offices)

Registrant's telephone number, including area code (317) 276-2000

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 and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No o

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 a "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☒	Accelerated filer o	Non-accelerated filer o	Smaller reporting Company o

(Do not check if a smaller reporting company)

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

Yes o 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 o

The number of shares of common stock outstanding as of October 19, 2015:

Class	Number of Shares Outstanding
Common	1,108,076,549

Eli Lilly and Company

Form 10-Q
For the Quarter Ended September 30, 2015

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Forward-Looking Statements

This Quarterly Report on Form 10-Q includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 (Exchange Act). Forward-looking statements include all statements that do not relate solely to historical or current facts, and can generally be identified by the use of words such as “may,” “believe,” “will,” “expect,” “project,” “estimate,” “intend,” “anticipate,” “plan,” “continue” or similar expressions.

In particular, information appearing under “Management's Discussion and Analysis of Financial Condition and Results of Operations” includes forward-looking statements. Forward-looking statements inherently involve many risks and uncertainties that could cause actual results to differ materially from those projected in these statements. Where, in any forward-looking statement, we ("Lilly" or the "company") express an expectation or belief as to future results or events, it is based on management's current plans and expectations, expressed in good faith and believed to have a reasonable basis. However, we can give no assurance that any such expectation or belief will result or will be achieved or accomplished.

More information on factors that could cause actual results or events to differ materially from those anticipated is included from time to time in our reports filed with the Securities and Exchange Commission (SEC), including our Annual Report on Form 10-K for the year ended December 31, 2014 and our Quarterly Reports on Form 10-Q for the periods ended March 31, 2015 and June 30, 2015, particularly under the captions “Forward-Looking Statements” and, where applicable, “Risk Factors.”

All forward-looking statements herein speak only as of the date of this report and are expressly qualified in their entirety by the cautionary statements included in or incorporated by reference into this report. Except as is required by law, we expressly disclaim any obligation to publicly release any revisions to forward-looking statements to reflect events after the date of this report.

PART I. Financial Information

Item 1. Financial Statements

Consolidated Condensed Statements of Operations
(Unaudited)
ELI LILLY AND COMPANY AND SUBSIDIARIES
(Dollars and shares in millions, except per-share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	**2014**	**2015**	**2014**
Revenue	**$ 4,959.7**	$ 4,875.6	**$ 14,583.1**	$ 14,494.3
Costs, expenses, and other:				
Cost of sales	**1,236.9**	1,267.0	**3,648.0**	3,679.4
Research and development	**1,143.4**	1,243.2	**3,352.2**	3,547.9
Marketing, selling, and administrative	**1,575.7**	1,672.1	**4,734.6**	4,820.9
Acquired in-process research and development (Note 3)	**—**	95.0	**336.0**	95.0
Asset impairment, restructuring, and other special charges (Note 5)	**42.4**	36.3	**222.8**	67.7
Other–net, (income) expense (Note 13)	**(86.5)**	(93.5)	**(55.9)**	(203.3)
	3,911.9	4,220.1	**12,237.7**	12,007.6
Income before income taxes	**1,047.8**	655.5	**2,345.4**	2,486.7
Income taxes (Note 9)	**248.1**	154.9	**415.4**	524.7
Net income	**$ 799.7**	$ 500.6	**$ 1,930.0**	$ 1,962.0
Earnings per share:				
Basic	**$ 0.75**	$ 0.47	**$ 1.82**	$ 1.83
Diluted	**$ 0.75**	$ 0.47	**$ 1.81**	$ 1.82
Shares used in calculation of earnings per share:				
Basic	**1,061.4**	1,069.6	**1,062.4**	1,071.4
Diluted	**1,065.2**	1,074.4	**1,066.0**	1,075.7
Dividends paid per share	**$ 0.50**	$ 0.49	**$ 1.50**	$ 1.47

See Notes to Consolidated Condensed Financial Statements.

Consolidated Condensed Statements of Comprehensive Income (Loss)
(Unaudited)
ELI LILLY AND COMPANY AND SUBSIDIARIES
(Dollars in millions)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	**2014**	**2015**	**2014**
Net income	**$ 799.7**	$ 500.6	**$ 1,930.0**	$ 1,962.0
Other comprehensive loss, net of tax (Note 12)	**(263.8)**	(616.3)	**(675.2)**	(548.9)
Comprehensive income (loss)	**$ 535.9**	$ (115.7)	**$ 1,254.8**	$ 1,413.1

See Notes to Consolidated Condensed Financial Statements.

Consolidated Condensed Balance Sheets
ELI LILLY AND COMPANY AND SUBSIDIARIES
(Dollars in millions)

	September 30, 2015	December 31, 2014
Assets	(Unaudited)	
Current Assets		
Cash and cash equivalents (Note 6)	**$ 3,238.8**	$ 3,871.6
Short-term investments (Note 6)	**1,080.4**	955.4
Accounts receivable, net of allowances of **$47.8 (2015)** and $55.0 (2014)	**3,401.9**	3,234.6
Other receivables	**665.8**	566.7
Inventories	**3,417.7**	2,740.0
Prepaid expenses and other	**762.4**	811.5
Total current assets	**12,567.0**	12,179.8
Other Assets		
Restricted cash (Note 3)	**—**	5,405.6
Investments (Note 6)	**4,102.0**	4,568.9
Goodwill (Note 7)	**4,054.9**	1,758.1
Other intangibles, net (Note 7)	**4,615.9**	2,884.2
Sundry	**2,889.6**	2,382.8
Total other assets	**15,662.4**	16,999.6
Property and Equipment		
Land, buildings, equipment, and construction in progress	**16,611.5**	16,029.3
Accumulated depreciation	**(8,536.2)**	(8,065.4)
Property and equipment, net	**8,075.3**	7,963.9
Total assets	**$ 36,304.7**	$ 37,143.3
Liabilities and Equity		
Current Liabilities		
Short-term borrowings and current maturities of long-term debt	**$ 9.3**	$ 2,688.7
Accounts payable	**1,179.3**	1,128.1
Employee compensation	**829.6**	759.0
Sales rebates and discounts	**2,541.8**	2,068.8
Dividends payable	**—**	530.3
Income taxes payable	**700.0**	93.5
Deferred income taxes	**943.6**	1,466.5
Other current liabilities	**2,099.7**	2,472.6
Total current liabilities	**8,303.3**	11,207.5
Other Liabilities		
Long-term debt	**8,069.6**	5,332.8
Accrued retirement benefits (Note 10)	**2,358.2**	2,562.9
Long-term income taxes payable	**910.6**	998.5
Other noncurrent liabilities	**1,422.1**	1,653.5
Total other liabilities	**12,760.5**	10,547.7
Commitments and Contingencies (Note 11)		
Eli Lilly and Company Shareholders' Equity (Note 8)		
Common stock	**693.0**	694.6
Additional paid-in capital	**5,441.9**	5,292.3
Retained earnings	**16,856.7**	16,482.7
Employee benefit trust	**(3,013.2)**	(3,013.2)
Accumulated other comprehensive loss (Note 12)	**(4,667.0)**	(3,991.8)
Cost of common stock in treasury	**(90.0)**	(91.4)
Total Eli Lilly and Company shareholders' equity	**15,221.4**	15,373.2
Noncontrolling interests	**19.5**	14.9
Total equity	**15,240.9**	15,388.1
Total liabilities and equity	**$ 36,304.7**	$ 37,143.3

See Notes to Consolidated Condensed Financial Statements.

Consolidated Condensed Statements of Cash Flows
(Unaudited)
ELI LILLY AND COMPANY AND SUBSIDIARIES
(Dollars in millions)

	Nine Months Ended September 30,	
	2015	**2014**
Cash Flows from Operating Activities		
Net income	**$ 1,930.0**	$ 1,962.0
Adjustments to Reconcile Net Income to Cash Flows from Operating Activities:		
Depreciation and amortization	**1,084.3**	1,039.6
Change in deferred income taxes	**(671.0)**	151.9
Debt extinguishment loss	**166.7**	—
Stock-based compensation expense	**159.4**	115.4
Net proceeds (payments) for terminations of interest rate swaps	**(186.1)**	252.5
Acquired in-process research and development	**336.0**	95.0
Other changes in operating assets and liabilities, net of acquisitions and divestitures	**(660.1)**	(548.3)
Other non-cash operating activities, net	**(190.7)**	(50.6)
Net Cash Provided by Operating Activities	**1,968.5**	3,017.5
Cash Flows from Investing Activities		
Net purchases of property and equipment	**(686.0)**	(753.8)
Proceeds from sales and maturities of short-term investments	**1,585.8**	2,661.6
Purchases of short-term investments	**(764.2)**	(1,401.8)
Proceeds from sales of noncurrent investments	**2,271.8**	7,355.5
Purchases of noncurrent investments	**(2,673.4)**	(8,636.7)
Restricted cash released for acquisition	**5,405.6**	—
Cash paid for acquisitions, net of cash acquired	**(5,287.8)**	(551.4)
Proceeds from sale of product rights	**410.0**	—
Purchase of in-process research and development	**(386.0)**	(45.0)
Other investing activities, net	**(102.7)**	(358.6)
Net Cash Used for Investing Activities	**(226.9)**	(1,730.2)
Cash Flows from Financing Activities		
Dividends paid	**(1,594.0)**	(1,576.0)
Net change in short term borrowings	**(2,680.7)**	304.9
Proceeds from issuance of long-term debt	**4,454.6**	992.9
Repayment of long-term debt	**(1,950.6)**	(1,034.3)
Purchases of common stock	**(496.6)**	(500.0)
Other financing activities, net	**27.7**	109.0
Net Cash Used for Financing Activities	**(2,239.6)**	(1,703.5)
Effect of exchange rate changes on cash and cash equivalents	**(134.8)**	(248.2)
Net decrease in cash and cash equivalents	**(632.8)**	(664.4)
Cash and cash equivalents at January 1	**3,871.6**	3,830.2
Cash and Cash Equivalents at September 30	**$ 3,238.8**	$ 3,165.8

See Notes to Consolidated Condensed Financial Statements

(Tables present dollars in millions, except per-share data)

Note 1: Basis of Presentation

We have prepared the accompanying unaudited consolidated condensed financial statements in accordance with the requirements of Form 10-Q and, therefore, they do not include all information and footnotes necessary for a fair presentation of financial position, results of operations, and cash flows in conformity with accounting principles generally accepted in the United States (GAAP). In our opinion, the financial statements reflect all adjustments (including those that are normal and recurring) that are necessary for a fair presentation of the results of operations for the periods shown. In preparing financial statements in conformity with GAAP, we must make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses, and related disclosures at the date of the financial statements and during the reporting period. Actual results could differ from those estimates.

The information included in this Quarterly Report on Form 10-Q should be read in conjunction with our consolidated financial statements and accompanying notes included in our Annual Report on Form 10-K for the year ended December 31, 2014. We issued our financial statements by filing with the Securities and Exchange Commission and have evaluated subsequent events up to the time of the filing.

Certain reclassifications have been made to prior periods in the consolidated condensed financial statements and accompanying notes to conform with the current presentation.

All per-share amounts, unless otherwise noted in the footnotes, are presented on a diluted basis, that is, based on the weighted-average number of outstanding common shares plus the effect of incremental shares from our stock-based compensation programs.

Note 2: Implementation of New Financial Accounting Pronouncements

The following table provides a brief description of an accounting standard that has not yet been adopted that could have a material effect on our financial statements:

Standard	Description	Effective Date	Effect on the financial statements or other significant matters
Accounting Standards Update 2014-09, *Revenue from Contracts with Customers*	This standard will replace existing revenue recognition standards and will require entities to recognize revenues to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. An entity can apply the new revenue standard retrospectively to each prior reporting period presented or with the cumulative effect of initially applying the standard recognized at the date of initial application in retained earnings.	In August 2015, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update 2015-14, *Revenue from Contracts with Customers*, which deferred the effective date of the new revenue recognition standard by one year (to January 1, 2018 for us), but permits entities to adopt the new standard on the original effective date if they choose. We are evaluating our anticipated date of adoption.	There are areas within the standard that are currently under review and reconsideration by the FASB, which could lead to updates to the standard. As the outcomes of this review and reconsideration could lead to significant changes to the standard, we are still in the process of determining our approach to the adoption of the standard, as well as the anticipated impact to our consolidated financial statements.

Note 3: Acquisitions

During 2015 and 2014, we completed the acquisitions of Novartis Animal Health (Novartis AH) and Lohmann SE (Lohmann AH), respectively. These acquisitions were accounted for as business combinations under the acquisition method of accounting. The assets acquired and liabilities assumed were recorded at their respective fair values as of the acquisition date in our consolidated financial statements. The determination of estimated fair value required management to make significant estimates and assumptions. The excess of the purchase price over the fair value of the acquired net assets, where applicable, has been recorded as goodwill. The results of operations of these acquisitions are included in our consolidated condensed financial statements from the date of acquisition.

Additionally, on October 1, 2015, Bristol-Myers Squibb Company and E.R. Squibb (collectively, BMS) transferred to us their commercialization rights with respect to Erbitux® in the United States (U.S.) and Canada (collectively, North America) through a modification of our existing arrangement. This will be accounted for as a business combination under the acquisition method of accounting discussed above. See Note 4 for additional information related to the Erbitux arrangement.

In addition to the acquisitions of businesses, we also acquired assets in development in 2015 and 2014, which are further discussed in this note below in Product and Other Acquisitions. Upon acquisition, the acquired in-process research and development (IPR&D) related to these products was immediately written off as an expense because the products had no alternative future use. For the three months ended September 30, 2015, we recorded no acquired IPR&D charges. For the nine months ended September 30, 2015, we recorded acquired IPR&D charges of $336.0 million, associated with these transactions and the upfront fee of $200.0 million related to tanezumab. See Note 4 for additional information related to the tanezumab arrangement. There were acquired IPR&D charges of $95.0 million for the three and nine months ended September 30, 2014 associated with these transactions.

In October 2015, we acquired the worldwide rights to Locemia Solutions' intranasal glucagon, a glucagon nasal powder being investigated for the treatment for severe hypoglycemia. Upon entry into the agreement, we paid approximately $150 million, which will be accounted for in the fourth quarter of 2015.

Acquisition of Businesses

Novartis AH Acquisition

Overview of Transaction

On January 1, 2015, we acquired from Novartis AG all of the shares of certain Novartis subsidiaries and the assets and liabilities of other Novartis subsidiaries that are exclusively related to the Novartis AH business in an all-cash transaction for a total purchase price of $5.28 billion, subject to certain contractual adjustments which should be completed by December 31, 2015. As of December 31, 2014, there was $5.41 billion of cash held in escrow for the pending acquisition of Novartis AH. This cash was classified as restricted cash, a noncurrent asset, on our consolidated condensed balance sheet.

As a condition to the clearance of the transaction under the Hart-Scott-Rodino Antitrust Improvements Act, following the closing of the acquisition of Novartis AH, we divested certain animal health assets in the U.S. related to the Sentinel® canine parasiticide franchise to Virbac Corporation (Virbac) for approximately $410 million.

The acquired Novartis AH business consists of the research and development, manufacture, marketing, sale and distribution of veterinary products to prevent and treat diseases in pets, farm animals, and farmed fish. Under the terms of the agreement, we acquired manufacturing sites, research and development facilities, a global commercial infrastructure and portfolio of products, a pipeline of projects in development, and employees.

Assets Acquired and Liabilities Assumed

Our access to Novartis AH information was limited prior to the acquisition. As a consequence, we are in the process of determining the fair values and tax bases of a significant portion of the assets acquired and liabilities assumed, including the identification and valuation of intangible assets, inventory, property and equipment, accrued expenses, and tax exposures. The final determination of these amounts will be completed as soon as possible but no later than one year from the acquisition date. The final determination may result in asset and liability fair values and tax bases that differ from the preliminary estimates and require changes to the preliminary amounts recognized.

The following table summarizes the preliminary amounts recognized for assets acquired and liabilities assumed as of the acquisition date:

Estimated Fair Value at January 1, 2015		
Inventories	$	380.2
Acquired in-process research and development		295.0
Marketed products [1]		1,940.0
Property and equipment		218.9
Assets held for sale (primarily the U.S. Sentinel rights)		422.7
Accrued retirement benefits		(167.6)
Deferred income taxes		(57.4)
Other assets and liabilities - net		(38.9)
Total identifiable net assets		2,992.9
Goodwill [2]		2,290.2
Total consideration transferred - net of cash acquired	$	5,283.1

[1] These intangible assets, which will be amortized to cost of sales on a straight-line basis over their estimated useful lives, are expected to have a weighted average useful life of 19 years.

[2] The goodwill recognized from this acquisition is attributable primarily to expected synergies that we believe will result from combining the operations of Novartis AH with our legacy Animal Health operations, future unidentified projects and products, and the assembled workforce of Novartis AH. Approximately $950 million of the goodwill associated with this acquisition is estimated to be deductible for tax purposes.

Actual and Supplemental Pro Forma Information

Our consolidated condensed statement of operations for the three and nine months ended September 30, 2015 includes Novartis AH revenue of $255.5 million and $760.0 million, respectively. Novartis AH has been partially integrated into our animal health segment and as a result of these integration efforts, certain parts of the animal health business are operating on a combined basis, and we cannot distinguish the operations between Novartis AH and our legacy animal health business.

The following unaudited pro forma financial information presents the combined consolidated results of our operations with Novartis AH as if the portion of Novartis AH that we retained after the sale to Virbac had been acquired as of January 1, 2014. We have adjusted the historical consolidated financial information to give effect to pro forma events that are directly attributable to the acquisition. The unaudited pro forma financial information is not necessarily indicative of what our consolidated results of operations would have been had we completed the acquisition at the beginning of 2014. In addition, the unaudited pro forma financial information does not attempt to project the future results of operations of our combined company.

	Unaudited Pro Forma Consolidated Results			
	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Revenue	**$ 4,959.7**	$ 5,151.0	**$ 14,583.1**	$ 15,297.1
Net income	**815.0**	452.8	**2,039.6**	1,723.7
Diluted earnings per share	**0.77**	0.42	**1.91**	1.60

The unaudited pro forma financial information above reflects primarily the following pro forma pre-tax adjustments:

- Additional amortization expense of approximately $26 million and $78 million for the three and nine months ended September 30, 2014, respectively, related to the fair value of identifiable intangible assets acquired.
- Additional cost of sales in 2014, and a corresponding reduction in cost of sales in 2015, of approximately $21 million and $153 million related to the fair value adjustments to acquisition date inventory that has been sold in the three and nine months ended September 30, 2015, respectively.
- A decrease to pro forma net income of approximately $31 million and $82 million in the three and nine months ended September 30, 2014, respectively, associated with an increase to interest expense related to the incremental debt that we issued to partially finance the acquisition and a reduction of interest income associated with investments which would have been used to partially fund the acquisition.

In addition, all of the above adjustments were adjusted for the applicable tax impact. The taxes associated with the adjustments above reflect the statutory tax rates in the various jurisdictions where the fair value adjustments occurred.

Lohmann AH Acquisition

On April 30, 2014, we acquired Lohmann AH, a privately-held company headquartered in Cuxhaven, Germany, through a stock purchase for a total purchase price of $591.2 million, comprised of $551.4 million of net cash plus $39.8 million of assumed debt. Lohmann AH is a global leader in poultry vaccines. As part of this transaction, we acquired the rights to a range of vaccines, commercial capabilities, and manufacturing sites in Germany and the United States. The acquisition is not material to our consolidated financial statements.

The following table summarizes the amounts recognized for assets acquired and liabilities assumed as of the acquisition date:

Estimated Fair Value at April 30, 2014		
Marketed products	$	275.4
Other intangible assets		23.9
Property and equipment		81.9
Deferred income taxes		(92.7)
Other assets and liabilities - net		51.1
Total identifiable net assets		339.6
Goodwill[(1)]		251.6
Total consideration transferred - net of cash acquired	$	591.2

[(1)] Goodwill associated with this acquisition is not deductible for tax purposes.

Product and Other Acquisitions

The following table summarizes our product and other acquisitions which are discussed in detail below:

Counterparty	**Compound(s) or Therapy**	**Acquisition Month**	**Phase of Development[(1)]**	**Acquired IPR&D Expense**
Innovent Biologics, Inc. (Innovent)	Monoclonal antibody targeting protein CD-20 Immuno-oncology molecules cMet monoclonal antibody	March 2015	Pre-clinical[(2)]	$ 56.0
Hanmi Pharmaceutical Co., Ltd. (Hanmi)	BTK Inhibitor - HM71224	April 2015	Phase I	50.0
BioNTech AG (BioNTech)	Cancer immunotherapies	May 2015	Pre-clinical	30.0
Immunocore Limited (Immunocore)	T cell-based cancer therapies	July 2014	Pre-clinical	45.0
AstraZeneca UK Limited (AstraZeneca)	Oral beta-secretase cleaving enzyme inhibitor - AZD3293	September 2014	Phase I	50.0

[(1)] The phase of development presented is as of the date of the arrangement.

[(2)] Prior to acquisition, Innovent's monoclonal antibody targeting protein CD-20 had received investigational new drug approval in China to begin Phase I development.

In connection with the arrangements described below, our partners may be entitled to future royalties based on sales should these products be approved for commercialization and/or milestones based on the successful progress of the drug candidate through the development process.

Our collaboration agreement with Innovent is to develop and commercialize a portfolio of cancer treatments. In China, we will be responsible for the commercialization efforts, while Innovent will lead the development and manufacturing efforts. Innovent also has co-promotion rights in China. We will be responsible for development, manufacturing, and commercialization efforts of Innovent's pre-clinical immuno-oncology molecules outside of China. Separate from the collaboration, we will continue the development of our cMet monoclonal antibody gene outside of China.

Our collaboration agreement with Hanmi is to develop and commercialize Hanmi's compound being investigated for the treatment of autoimmune and other diseases. We received rights to the molecule for all indications on a worldwide basis excluding China, Hong Kong, Taiwan, and Korea. We will be responsible for leading development, regulatory, manufacturing, and commercial efforts in our territories.

Our research collaboration with BioNTech is to discover novel cancer immunotherapies.

Our co-discovery and co-development collaboration with Immunocore is to research and potentially develop pre-clinical novel T cell-based cancer therapies.

Our collaboration agreement with AstraZeneca is for the worldwide co-development and co-commercialization of AstraZeneca’s compound being investigated for the potential treatment of Alzheimer’s disease. We will be responsible for leading development efforts, while AstraZeneca will be responsible for manufacturing efforts. If successful, both parties will take joint responsibility for commercialization of AZD3293. Under the agreement, both parties will share equally in the ongoing development costs, gross margins and certain other costs associated with the commercialization of the compound.

Note 4: Collaborations and Other Arrangements

We often enter into collaborative and other similar arrangements to develop and commercialize drug candidates. Collaborative activities may include research and development, marketing and selling (including promotional activities and physician detailing), manufacturing, and distribution. These arrangements often require milestone and royalty or profit-share payments, contingent upon the occurrence of certain future events linked to the success of the asset in development, as well as expense reimbursements or payments to the collaboration partner. Elements within a collaboration are separated into individual units of accounting if they have standalone value from other elements within the arrangement. In these situations, the arrangement consideration is allocated to the elements on a relative selling price basis. Revenues related to products we sell pursuant to these arrangements are included in net product revenues, while other sources of revenue (e.g., royalties and profit-sharing due from our partner) are included in collaboration and other revenue.

The following table summarizes our collaboration and other revenue recognized:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Collaboration and other revenue	**$ 215.2**	$ 204.0	**$ 644.7**	$ 593.9

Operating expenses for costs incurred pursuant to these arrangements are reported in their respective expense line item, net of any payments due to or reimbursements due from our collaboration partners, with such reimbursements being recognized at the time the party becomes obligated to pay. Each collaboration is unique in nature, and our more significant arrangements are discussed below.

Diabetes Collaboration

We and Boehringer Ingelheim have a global agreement to jointly develop and commercialize a portfolio of diabetes compounds. Currently, the compounds included in the collaboration are Boehringer Ingelheim's two oral diabetes agents, linagliptin (trade name Trajenta®) and empagliflozin (trade name Jardiance®), and our new insulin glargine product (trade name Basaglar®).

The table below summarizes significant regulatory and commercialization events and milestones (received) paid for the compounds included in this collaboration:

	Product Status			Milestones (Earned) Expensed[1]		Milestones (Deferred) Capitalized[2]	
Product Family	U.S.	Europe	Japan	Year	Amount	Year	Amount
Trajenta[3]	Launched 2011	Launched 2011	Launched 2011	2015	$ —	2015	$ —
				2014	—	2014	—
				2013	—	2013	—
						Cumulative[6]	446.4
Jardiance[4]	Launched 2014	Launched 2014	Launched 2015	2015	—	2015	—
				2014	—	2014	299.5
				2013	97.2	2013	—
						Cumulative[6]	299.5
Basaglar	Tentatively Approved [5]	Launched 2015	Launched 2015	2015	—	2015	—
				2014	—	2014	(62.5)
				2013	(50.0)	2013	—
						Cumulative[6]	(62.5)

[1] Milestones earned for Basaglar as a result of regulatory submissions were recorded as income in other-net, (income) expense. Milestones expensed for Jardiance as a result of regulatory submissions were recorded as research and development expenses.

[2] In connection with the regulatory approvals of Basaglar in Europe and Japan, milestone payments received were recorded as deferred revenue and are being amortized through the term of the collaboration (2029) to collaboration and other revenue. In the future, we will be eligible to receive up to $187.5 million in success-based regulatory milestones on Basaglar. In connection with the regulatory approvals of Trajenta and Jardiance, milestone payments made were capitalized as intangible assets and are being amortized to cost of sales.

[3] Jentadueto® is included in the Trajenta family of product results.

[4] Glyxambi® and Synjardy® are included in the Jardiance family of product results.

[5] Basaglar received tentative approval in the U.S. in August 2014. The U.S. Food and Drug Administration (FDA) has determined that Basaglar meets all regulatory requirements for approval, but final approval was subject to a delay of up to 30 months as a result of patent infringement litigation filed by Sanofi-Aventis U.S. LLC (Sanofi), which markets Lantus® (insulin glargine). In September 2015, we entered into a settlement agreement to resolve the patent litigation with Sanofi. As part of the agreement and pending FDA approval, Basaglar can be launched in the U.S. beginning on December 15, 2016.

[6] The cumulative amount represents the total amounts as of the end of the reporting period that have been (deferred) or capitalized since the start of this collaboration.

In October 2014, we and Boehringer Ingelheim agreed upon certain changes to the operational and financial structure of our diabetes collaboration. Under the revised agreement the companies have continued their co-promotion work in 17 countries, representing over 90 percent of the collaboration's anticipated market opportunity. In the other countries, the companies exclusively commercialize the respective molecules they brought to the collaboration. The modifications became effective at the end of 2014 and changed the financial terms related to the modified countries; however, the financial impact resulting from the revised terms of the agreement in these countries has not been and is not anticipated to be material. As a result of these changes, we recorded a gain of $92.0 million in 2014 related to the transfer to Boehringer Ingelheim of our license rights to co-promote linagliptin and empagliflozin in these countries, which was recorded as income in other–net, (income) expense. We also incurred a charge of $55.2 million related to the transfer to us of Boehringer Ingelheim's rights to co-promote Basaglar in countries where it is not yet approved, which was recorded as acquired IPR&D expense.

With the exception of the countries affected by the amendment to the collaboration agreement, the companies share equally the ongoing development costs, commercialization costs and gross margin for any product resulting from the collaboration. We record our portion of the gross margin associated with Boehringer Ingelheim's compounds as collaboration and other revenue. We record our sales of Basaglar to third parties as net product revenues with the payments made to Boehringer Ingelheim for their portion of the gross margin recorded as cost of sales. For all compounds under this collaboration, we record our portion of the commercialization costs as marketing, selling, and administrative expense. Each company will also be entitled to potential performance payments on sales of the molecules they contribute to the collaboration.

The following table summarizes our revenue recognized with respect to the Trajenta family of products:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Collaboration and other revenue	**$ 92.7**	$ 78.9	**$ 255.0**	$ 246.1

Our revenues related to the Jardiance family of products and Basaglar were not significant for the three and nine months ended September 30, 2015.

Erbitux

We have several collaborations with respect to Erbitux. The most significant collaborations are in the U.S., Canada, and Japan (Bristol-Myers Squibb Company); and worldwide except North America (Merck KGaA). Certain rights to Erbitux outside North America will remain with Merck KGaA (Merck) upon expiration of that agreement.

The following table summarizes our revenue recognized with respect to Erbitux:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Net product revenues	**$ (2.3)**	$ 8.8	**$ 22.6**	$ 34.5
Collaboration and other revenue	**88.2**	84.1	**286.2**	242.8
Revenue	**$ 85.9**	$ 92.9	**$ 308.8**	$ 277.3

Bristol-Myers Squibb Company

Pursuant to commercial agreements with BMS, we have been co-developing Erbitux in North America with BMS exclusively. A separate agreement grants co-exclusive rights among Merck, BMS, and us in Japan and expires in 2032. On October 1, 2015, BMS transferred their commercialization rights to us with respect to Erbitux in North America pursuant to a modification of our existing arrangement. This modification did not affect our rights with respect to Erbitux in other jurisdictions. In connection with the modification of terms, we will provide consideration to BMS based upon a tiered percentage of net sales of Erbitux in North America estimated to average 38 percent through September 2018. The transfer of the commercialization rights will be accounted for as an acquisition of a business. As a result, we will record the fair value of the commercialization rights as a marketed product asset and the fair value of the contingent consideration as a liability. The marketed product asset will be amortized to cost of sales using the straight-line method through the co-development period in North America, as set forth in the original agreement, which was scheduled to expire in September 2018.

We are in the process of determining the fair values of the assets acquired and liabilities assumed. Our preliminary estimates are as follows: marketed product assets, approximately $550 million; inventory, approximately $50 million; goodwill, approximately $50 million; and contingent consideration liability, approximately $650 million. The final determination of these amounts may result in asset and liability fair values that differ from the preliminary estimates. Including the Erbitux business as if we had acquired it on January 1, 2015, our combined consolidated revenue would have been approximately $14.8 billion for the nine months ended September 30, 2015. There would have been no material change to our consolidated net income.

Until the effective date of the transfer of the business, the arrangements between us and BMS, were as set forth in this paragraph. Erbitux research and development and other costs were shared by both companies according to a predetermined ratio. Responsibilities associated with clinical and other ongoing studies were apportioned between the parties under the agreements. Collaborative reimbursements due to us for supply of clinical trial materials; for research and development; and for a portion of marketing, selling, and administrative expenses were recorded as a reduction to the respective expense line items on the consolidated statement of operations. We received a

distribution fee in the form of a royalty from BMS, based on a percentage of net sales in North America, which was recorded in collaboration and other revenue. Royalties due to third parties were recorded as a reduction of collaboration and other revenue, net of any royalty reimbursements due from third parties. We were responsible for the manufacture and supply of all requirements of Erbitux in bulk-form active pharmaceutical ingredient (API) for clinical and commercial use in North America, and BMS purchased all of its requirements of API from us, subject to certain stipulations per the agreement. Sales of Erbitux API to BMS were reported in net product revenues.

Merck KGaA

A development and license agreement grants Merck exclusive rights to market Erbitux outside of North America until December 2018. A separate agreement grants co-exclusive rights among Merck, BMS, and us in Japan and expires in 2032. This agreement was amended in 2015 to grant Merck exclusive commercialization rights in Japan but did not result in any changes to our rights.

Merck manufactures Erbitux for supply in its territory as well as for Japan. We receive a royalty on the sales of Erbitux outside of North America, which is included in collaboration and other revenue as earned. Royalties due to third parties are recorded as a reduction of collaboration and other revenue, net of any royalty reimbursements due from third parties.

Effient®

We are in a collaborative arrangement with Daiichi Sankyo Co., Ltd. (Daiichi Sankyo) to develop, market, and promote Effient. We and Daiichi Sankyo co-promote Effient in certain territories (including the U.S. and five major European markets), while we have exclusive marketing rights in certain other territories. Daiichi Sankyo has exclusive marketing rights in Japan and certain other territories. The parties share approximately 50/50 in the profits, as well as in the costs of development and marketing in the co-promotion territories. Beginning January 1, 2016, we will cease co-promotion efforts for Effient in the major European markets, and Daiichi Sankyo will exclusively promote Effient in the major European markets; however, the economic results for these countries will continue to be shared in the same proportion as they are currently. A third party manufactures bulk product, and we produce the finished product for our exclusive and co-promotion territories. We will also continue to produce the finished product for the major European markets subsequent to January 1, 2016. We record net product revenues in our exclusive and co-promotion territories. In our exclusive territories, we pay Daiichi Sankyo a royalty specific to these territories. Profit-share payments due to Daiichi Sankyo are recorded as marketing, selling, and administrative expenses. Subsequent to January 1, 2016, any profit-share payments due to us from Daiichi Sankyo for the major European markets will be recorded as collaboration and other revenue. All royalties due to Daiichi Sankyo and the third-party manufacturer are recorded in cost of sales.

The following table summarizes our revenue recognized with respect to Effient:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Revenue	**$ 132.1**	$ 131.5	**$ 382.7**	$ 384.4

Solanezumab

We have an agreement with an affiliate of TPG-Axon Capital (TPG) whereby TPG funded a portion of the Phase III development of solanezumab. Under the agreement, TPG's obligation to fund solanezumab costs ended in 2011. In exchange for its funding, TPG may receive success-based sales milestones totaling approximately $70 million and mid-single digit royalties contingent upon the successful development of solanezumab. The royalties would be paid for approximately 10 years after launch of a product.

Baricitinib

We have a worldwide license and collaboration agreement with Incyte Corporation (Incyte) which provides us the development and commercialization rights to its Janus tyrosine kinase inhibitor compound, now known as baricitinib, and certain follow-on compounds, for the treatment of inflammatory and autoimmune diseases. Incyte has the right to receive tiered, double-digit royalty payments on future global sales with rates ranging up to 20 percent if the product is successfully commercialized. The agreement provides Incyte with options to co-develop these compounds on an indication-by-indication basis by funding 30 percent of the associated development costs from the initiation of a Phase IIb trial through regulatory approval in exchange for increased tiered royalties ranging up to percentages in the high twenties. In 2010, Incyte exercised its option to co-develop baricitinib in rheumatoid

arthritis. The agreement also provides Incyte with an option to co-promote in the U.S. and calls for payments associated with certain development, success-based regulatory, and sales-based milestones. As of September 30, 2015, Incyte is eligible to receive up to $415.0 million of additional payments from us contingent upon certain development and success-based regulatory milestones as well as an additional $150.0 million of potential sales-based milestones.

Tanezumab

In October 2013, we entered into a collaboration agreement with Pfizer Inc. (Pfizer) to jointly develop and globally commercialize tanezumab for the treatment of osteoarthritis pain, chronic low back pain and cancer pain. Under the agreement, the companies share equally the ongoing development costs and, if successful, in gross margins and certain commercialization expenses. Following the FDA's decision in March 2015 to lift the partial clinical hold on tanezumab, Phase III trials resumed beginning in July 2015. Upon the FDA's lifting of the partial clinical hold and the decision to continue the collaboration with Pfizer, we paid an upfront fee of $200.0 million, which was expensed as acquired IPR&D in the first quarter of 2015. In addition to this fee, we may pay up to $350.0 million in success-based regulatory milestones and up to $1.23 billion in a series of sales-based milestones, contingent upon the commercial success of tanezumab. Both parties have the right to terminate the agreement under certain circumstances.

Exenatide

In November 2011, we agreed with Amylin Pharmaceuticals, Inc. (Amylin) to terminate our collaborative arrangement for the joint development, marketing, and selling of Byetta® (exenatide injection) and other forms of exenatide such as Bydureon® (exenatide extended-release for injectable suspension). Under the terms of the termination agreement, Amylin made a one-time, upfront payment to us of $250.0 million and agreed to make other payments. Upon completion of the acquisition of Amylin by Bristol-Myers Squibb Company in August 2012, Amylin's obligation of $1.26 billion was paid in full. We would also receive a $150.0 million milestone payment contingent upon FDA approval of a once-monthly suspension version of exenatide.

Commercial operations were transferred to Amylin in the U.S. in late 2011. Outside the U.S., we transferred to Amylin exenatide commercial rights and control in all markets during the first quarter of 2013. All income allocated to the business outside the U.S. that was transferred during the first quarter of 2013 was recognized as a gain on the disposition of a business in other–net, (income) expense, net of the goodwill allocated to the business transferred.

Under the terms of our prior arrangement, we reported as net product revenues 100 percent of sales outside the U.S. We paid Amylin a percentage of the gross margin of exenatide sales outside of the U.S., and these costs were recorded in cost of sales. This arrangement for the commercial operations outside the U.S. continued until those rights were transferred to Amylin during the first quarter of 2013.

Our net product revenues from exenatide were not significant in 2014. We have not recorded any additional revenues from exenatide in 2015 and will not do so in future periods.

Summary of Commission and Profit-Share Payments

The following table summarizes our aggregate amount of marketing, selling, and administrative expense associated with our commission and profit-sharing obligations for the collaborations and other arrangements described above:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Marketing, selling, and administrative	**$ 53.6**	$ 53.5	**$ 156.5**	$ 155.4

Note 5: Asset Impairment, Restructuring, and Other Special Charges

The following table summarizes the components of the recognized charges included in asset impairment, restructuring, and other special charges by segment:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Severance:				
Human pharmaceutical	**$ 9.6**	$ 17.1	**$ 26.5**	$ 36.5
Animal health	**2.5**	—	**38.8**	—
Total severance	**12.1**	17.1	**65.3**	36.5
Asset impairment and other special charges:				
Human pharmaceutical	**0.9**	2.7	**18.0**	14.7
Animal health	**29.4**	16.5	**139.5**	16.5
Asset impairment and other special charges	**30.3**	19.2	**157.5**	31.2
Asset impairment, restructuring, and other special charges	**$ 42.4**	$ 36.3	**$ 222.8**	$ 67.7

Severance costs recognized during the three and nine months ended September 30, 2015 related primarily to the integration of Novartis AH as well as actions taken to reduce our cost structure. Substantially all of the severance costs recognized during the three and nine months ended September 30, 2014 were related to actions taken to reduce our cost structure.

Asset impairment and other special charges recognized during the three and nine months ended September 30, 2015 related primarily to integration costs. The asset impairment and other special charges recognized during the nine months ended September 30, 2015 also related to intangible asset impairments due to product rationalization resulting from our acquisition of Novartis AH. Asset impairment and other special charges recognized during the three months ended September 30, 2014 consisted primarily of integration costs from our acquisition of Novartis AH. Asset impairment and other special charges recognized during the nine months ended September 30, 2014 included both integration costs resulting from our then pending acquisition of Novartis AH, as well as costs associated with the closure of a manufacturing plant.

Note 6: Financial Instruments

Financial instruments that potentially subject us to credit risk consist principally of trade receivables and interest-bearing investments. Wholesale distributors of life-sciences products account for a substantial portion of trade receivables; collateral is generally not required. The risk associated with this concentration is mitigated by our ongoing credit-review procedures and insurance. A large portion of our cash is held by a few major financial institutions. We monitor our exposures with these institutions and do not expect any of these institutions to fail to meet their obligations. Major financial institutions represent the largest component of our investments in corporate debt securities. In accordance with documented corporate policies, we monitor the amount of credit exposure to any one financial institution or corporate issuer. We are exposed to credit-related losses in the event of nonperformance by counterparties to risk-management instruments but do not expect any counterparties to fail to meet their obligations given their high credit ratings.

Accounting Policy for Risk-Management Instruments

Our derivative activities are initiated within the guidelines of documented corporate risk-management policies and offset losses and gains on the assets, liabilities, and transactions being hedged. Management reviews the correlation and effectiveness of our derivatives on a quarterly basis.

For derivative contracts that are designated and qualify as fair value hedges, the derivative instrument is marked to market with gains and losses recognized currently in income to offset the respective losses and gains recognized on the underlying exposure. For derivative contracts that are designated and qualify as cash flow hedges, the effective portion of gains and losses on these contracts is reported as a component of accumulated other comprehensive loss and reclassified into earnings in the same period the hedged transaction affects earnings. Hedge ineffectiveness is immediately recognized in earnings. Derivative contracts that are not designated as hedging instruments are recorded at fair value with the gain or loss recognized in current earnings during the period of change.

We may enter into foreign currency forward or option contracts to reduce the effect of fluctuating currency exchange rates (principally the euro, the British pound, and the Japanese yen). Foreign currency derivatives used for hedging are put in place using the same or like currencies and duration as the underlying exposures. Forward and option contracts are principally used to manage exposures arising from subsidiary trade and loan payables and receivables denominated in foreign currencies. These contracts are recorded at fair value with the gain or loss recognized in other–net, (income) expense. We may enter into foreign currency forward and option contracts and currency swaps as fair value hedges of firm commitments. Forward contracts generally have maturities not exceeding 12 months. At September 30, 2015, we had outstanding foreign currency forward commitments to purchase 1.08 billion U.S. dollars and sell 956.5 million euro, commitments to purchase 1.06 billion euro and sell 1.19 billion U.S. dollars, commitments to purchase 501.3 million U.S. dollars and sell 60.15 billion Japanese yen, commitments to purchase 79.2 million British pounds and sell 107.9 million euro, and commitments to purchase 289.2 million U.S. dollars and sell 187.7 million British pounds, which will all settle within 30 days.

Foreign currency exchange risk is also managed through the use of foreign currency debt. Our euro-denominated notes issued in June 2015, which have a carrying amount of $2.32 billion as of September 30, 2015, have been designated as, and are effective as, economic hedges of net investments in certain of our euro-denominated foreign operations. Accordingly, foreign currency translation gains or losses due to spot rate fluctuations on the euro-denominated notes are included as a component of other comprehensive income (loss). During the three and nine months ended September 30, 2015, we recorded pretax foreign currency translation losses from the euro-denominated notes of $16.8 million and $50.6 million, respectively.

In the normal course of business, our operations are exposed to fluctuations in interest rates which can vary the costs of financing, investing, and operating. We address a portion of these risks through a controlled program of risk management that includes the use of derivative financial instruments. The objective of controlling these risks is to limit the impact of fluctuations in interest rates on earnings. Our primary interest-rate risk exposure results from changes in short-term U.S. dollar interest rates. In an effort to manage interest-rate exposures, we strive to achieve an acceptable balance between fixed- and floating-rate debt and investment positions and may enter into interest rate swaps or collars to help maintain that balance.

Interest rate swaps or collars that convert our fixed-rate debt to a floating rate are designated as fair value hedges of the underlying instruments. Interest rate swaps or collars that convert floating-rate debt to a fixed rate are designated as cash flow hedges. Interest expense on the debt is adjusted to include the payments made or received under the swap agreements. Cash proceeds from or payments to counterparties resulting from the termination of interest rate swaps are classified as operating activities in our consolidated condensed statement of cash flows. At September 30, 2015, substantially all of our total long-term debt is at a fixed rate. We have converted approximately 40 percent of our long-term fixed-rate notes to floating rates through the use of interest rate swaps.

We may enter into forward contracts and designate them as cash flow hedges to limit the potential volatility of earnings and cash flow associated with forecasted sales of available-for-sale securities.

In March 2015, we issued $600.0 million of 1.25 percent fixed-rate notes due March 1, 2018, $800.0 million of 2.75 percent fixed-rate notes due June 1, 2025, and $800.0 million of 3.70 percent fixed-rate notes due March 1, 2045 with interest to be paid semi-annually. The proceeds from the issuance of the notes were used primarily to repay outstanding commercial paper issued in connection with our January 2015 acquisition of Novartis AH.

In June 2015, we issued euro-denominated notes consisting of €600.0 million of 1.00 percent fixed-rate notes due June 2, 2022, €750.0 million of 1.63 percent fixed-rate notes due June 2, 2026, and €750.0 million of 2.13 percent fixed-rate notes due June 3, 2030 with interest to be paid annually. The net cash proceeds of the offering of $2.27 billion were used primarily to purchase and redeem certain higher interest rate U.S. dollar-denominated notes and to repay outstanding commercial paper. We paid $1.95 billion to purchase and redeem notes with an aggregate principal amount of $1.65 billion and a net carrying value of $1.78 billion in June 2015, resulting in a pretax debt extinguishment loss of $166.7 million, which was included in other–net, (income) expense in our consolidated condensed statement of operations during the nine months ended September 30, 2015.

We may enter into forward-starting interest rate swaps, which we designate as cash flow hedges, as part of any anticipated future debt issuances in order to reduce the risk of cash flow volatility from future changes in interest rates. Upon completion of a debt issuance and termination of the swap, the change in fair value of these instruments is recorded as part of other comprehensive income (loss) and is amortized to interest expense over the life of the underlying debt. Upon issuance of the underlying fixed-rate notes in March 2015, we terminated forward-starting interest rate contracts in designated cash flow hedging instruments with an aggregate notional amount of $1.35 billion and paid $206.3 million in cash to the counterparties for settlement. The settlement amount

represented the fair value of the forward-starting interest rate contracts at the time of termination and was recorded in other comprehensive loss.

In connection with the note purchase and redemption discussed above, we terminated certain interest rate swaps designated as fair value hedges with an aggregate notional amount of $876.0 million. As a result of the termination, we received cash of $20.2 million, which represented the fair value of the interest rate swaps at the time of termination. The related fair value adjustment was recorded as an increase to the carrying value of the underlying notes and was included as a component of the debt extinguishment loss.

The Effect of Risk-Management Instruments on the Consolidated Condensed Statement of Operations

The following effects of risk-management instruments were recognized in other–net, (income) expense:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	**2014**	**2015**	**2014**
Fair value hedges:				
Effect from hedged fixed-rate debt	**$ 66.1**	$ (7.7)	**$ 25.8**	$ 86.0
Effect from interest rate contracts	**(66.1)**	7.7	**(25.8)**	(86.0)
Cash flow hedges:				
Effective portion of losses on equity contracts reclassified from accumulated other comprehensive loss [(1)]	**—**	20.2	**—**	87.6
Effective portion of losses on interest rate contracts reclassified from accumulated other comprehensive loss	**3.7**	2.3	**10.0**	6.7
Net (gains) losses on foreign currency exchange contracts not designated as hedging instruments	**(14.9)**	(8.3)	**7.2**	12.7

[(1)] Realized gains on the sale of the underlying equity securities recognized in other–net, (income) expense for the three and nine months ended September 30, 2014 were $56.8 million and $183.1 million, respectively.

The effective portion of net (losses) gains on equity contracts in designated cash flow hedging relationships recorded in other comprehensive loss was $(11.8) million and $108.7 million for the three and nine months ended September 30, 2014, respectively. There were no equity contracts in designated cash flow hedging relationships during the three and nine months ended September 30, 2015.

During the next 12 months, we expect to reclassify from accumulated other comprehensive loss to earnings $14.7 million of pretax net losses on cash flow hedges of the variability in expected future interest payments on our floating rate debt.

During the nine months ended September 30, 2015 and 2014, net losses related to ineffectiveness, as well as net losses related to the portion of our risk-management hedging instruments, fair value hedges, and cash flow hedges that were excluded from the assessment of effectiveness, were not material.

Fair Value of Financial Instruments

The following tables summarize certain fair value information at September 30, 2015 and December 31, 2014 for assets and liabilities measured at fair value on a recurring basis, as well as the carrying amount and amortized cost of certain other investments:

Description	Carrying Amount	Amortized Cost	Fair Value Measurements Using: Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Fair Value
September 30, 2015						
Cash equivalents	**$ 1,537.8**	**$ 1,537.8**	**$ 1,381.9**	**$ 155.9**	**$ —**	**$ 1,537.8**
Short-term investments:						
U.S. government and agencies	**$ 301.5**	**$ 301.4**	**$ 301.5**	**$ —**	**$ —**	**$ 301.5**
Corporate debt securities	**770.9**	**770.8**	**—**	**770.9**	**—**	**770.9**
Asset-backed securities	**3.5**	**3.5**	**—**	**3.5**	**—**	**3.5**
Other securities	**4.5**	**4.5**	**—**	**4.5**	**—**	**4.5**
Short-term investments	**$ 1,080.4**	**$ 1,080.2**				
Noncurrent investments:						
U.S. government and agencies	**$ 412.2**	**$ 411.6**	**$ 411.2**	**$ 1.0**	**$ —**	**$ 412.2**
Corporate debt securities	**2,306.9**	**2,331.5**	**—**	**2,306.9**	**—**	**2,306.9**
Mortgage-backed securities	**161.7**	**161.6**	**—**	**161.7**	**—**	**161.7**
Asset-backed securities	**494.7**	**494.6**	**—**	**494.7**	**—**	**494.7**
Other securities	**4.6**	**4.6**	**—**	**4.6**	**—**	**4.6**
Marketable equity securities	**85.0**	**45.3**	**85.0**	**—**	**—**	**85.0**
Other investments [1]	**636.9**	**636.9**				
Noncurrent investments	**$ 4,102.0**	**$ 4,086.1**				
December 31, 2014						
Cash equivalents	$ 2,443.5	$ 2,443.5	$ 2,415.5	$ 28.0	$ —	$ 2,443.5
Short-term investments:						
U.S. government and agencies	$ 185.5	$ 185.6	$ 156.5	$ 29.0	$ —	$ 185.5
Corporate debt securities	767.4	766.7	—	767.4	—	767.4
Other securities	2.5	2.5	—	2.5	—	2.5
Short-term investments	$ 955.4	$ 954.8				
Noncurrent investments:						
U.S. government and agencies	$ 756.7	$ 757.5	$ 747.5	$ 9.2	$ —	$ 756.7
Corporate debt securities	2,462.7	2,468.9	—	2,462.7	—	2,462.7
Mortgage-backed securities	217.0	217.6	—	217.0	—	217.0
Asset-backed securities	477.8	478.0	—	477.8	—	477.8
Other securities	3.2	3.2	—	3.2	—	3.2
Marketable equity securities	204.8	44.0	204.8	—	—	204.8
Other investments [1]	446.7	446.7				
Noncurrent investments	$ 4,568.9	$ 4,415.9				

[1] Primarily includes investments accounted for under the cost method and equity method for which fair value disclosures are not applicable.

Description	Carrying Amount	Fair Value Measurements Using: Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Fair Value
Short-term borrowings [1]					
September 30, 2015	**$ —**	**$ —**	**$ —**	**$ —**	**$ —**
December 31, 2014	(2,680.6)	—	(2,680.6)	—	(2,680.6)
Long-term debt, including current portion					
September 30, 2015	**$ (8,078.9)**	**$ —**	**$ (8,191.5)**	**$ —**	**$ (8,191.5)**
December 31, 2014	(5,340.9)	—	(5,722.1)	—	(5,722.1)

[1] Represents short-term commercial paper borrowings

Description	Carrying Amount	Fair Value Measurements Using: Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Fair Value
September 30, 2015					
Risk-management instruments					
Interest rate contracts designated as hedging instruments:					
Sundry	**$ 107.4**	**$ —**	**$ 107.4**	**$ —**	**$ 107.4**
Foreign exchange contracts not designated as hedging instruments:					
Other receivables	**16.2**	**—**	**16.2**	**—**	**16.2**
Other current liabilities	**(11.3)**	**—**	**(11.3)**	**—**	**(11.3)**
December 31, 2014					
Risk-management instruments					
Interest rate contracts designated as hedging instruments:					
Sundry	$ 102.5	$ —	$ 102.5	$ —	$ 102.5
Other current liabilities	(149.5)	—	(149.5)	—	(149.5)
Other noncurrent liabilities	(0.7)	—	(0.7)	—	(0.7)
Foreign exchange contracts not designated as hedging instruments:					
Other receivables	9.1	—	9.1	—	9.1
Other current liabilities	(14.0)	—	(14.0)	—	(14.0)

Risk-management instruments above are disclosed on a gross basis. There are various rights of setoff associated with certain of the risk-management instruments above that are subject to an enforceable master netting arrangement or similar agreements. Although various rights of setoff and master netting arrangements or similar agreements may exist with the individual counterparties to the risk-management instruments above, individually, these financial rights are not material.

We determine fair values based on a market approach using quoted market values, significant other observable inputs for identical or comparable assets or liabilities, or discounted cash flow analyses. The fair value of equity method investments and other investments is not readily available.

The table below summarizes the contractual maturities of our investments in debt securities measured at fair value as of September 30, 2015:

		Maturities by Period			
	Total	Less Than 1 Year	2-5 Years	6-10 Years	More Than 10 Years
Fair value of debt securities	$ 4,460.5	$ 1,080.4	$ 3,034.4	$ 165.3	$ 180.4

A summary of the fair value of available-for-sale securities in an unrealized gain or loss position and the amount of unrealized gains and losses (pretax) in accumulated other comprehensive loss follows:

	September 30, 2015	December 31, 2014
Unrealized gross gains	**$ 54.8**	$ 171.9
Unrealized gross losses	**38.7**	18.3
Fair value of securities in an unrealized gain position	**2,012.6**	1,778.8
Fair value of securities in an unrealized loss position	**2,365.8**	3,129.2

We periodically assess our investment securities for other-than-temporary impairment losses. Other-than-temporary impairment losses recorded during the three and nine months ended September 30, 2015 were $31.5 million and $41.3 million, respectively, and related primarily to our equity method and other investments. Other-than-temporary impairment losses recorded during the three and nine months ended September 30, 2014 were $3.6 million and $11.0 million, respectively.

For fixed-income securities, the amount of credit losses are determined by comparing the difference between the present value of future cash flows expected to be collected on these securities and the amortized cost. Factors considered in assessing credit losses include the position in the capital structure, vintage and amount of collateral, delinquency rates, current credit support, and geographic concentration.

For equity securities, factors considered in assessing other-than-temporary impairment losses include the length of time and the extent to which the fair value has been less than cost, the financial condition and near term prospects of the issuer, our intent and ability to retain the securities for a period of time sufficient to allow for recovery in fair value, and general market conditions and industry specific factors.

As of September 30, 2015, the securities in an unrealized loss position include primarily fixed-rate debt securities of varying maturities. The value of fixed-income securities is sensitive to changes in the yield curve and other market conditions. Approximately 80 percent of the securities in a loss position are investment-grade debt securities. As of September 30, 2015, we do not intend to sell, and it is not more likely than not that we will be required to sell the securities in a loss position before the market values recover or the underlying cash flows have been received, and there is no indication of default on interest or principal payments for any of our debt securities.

Activity related to our investment portfolio, substantially all of which related to available-for-sale securities and other investments, was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Proceeds from sales	**$ 621.9**	$ 2,491.2	**$ 3,491.8**	$ 9,680.4
Realized gross gains on sales	**151.0**	92.7	**253.3**	257.3
Realized gross losses on sales	**1.5**	1.1	**3.9**	16.2

Realized gains and losses on sales of investments are computed based upon specific identification of the initial cost adjusted for any other-than-temporary declines in fair value that were recorded in earnings.

Note 7: Goodwill and Other Intangibles

Goodwill by segment was as follows:

	September 30, 2015	December 31, 2014
Human pharmaceutical	**$ 1,359.2**	$ 1,359.4
Animal health	**2,695.7**	398.7
Total goodwill	**$ 4,054.9**	$ 1,758.1

The increase in goodwill for the animal health segment is due to the acquisition of Novartis AH (Note 3).

The components of intangible assets other than goodwill were as follows:

	September 30, 2015			December 31, 2014		
Description	Carrying Amount—Gross	Accumulated Amortization	Carrying Amount—Net	Carrying Amount—Gross	Accumulated Amortization	Carrying Amount—Net
Finite-lived intangible assets:						
Marketed products	**$ 7,708.6**	**$ (3,357.6)**	**$ 4,351.0**	$ 5,684.3	$ (2,915.6)	$ 2,768.7
Other	**147.6**	**(57.4)**	**90.2**	149.3	(45.2)	104.1
Total finite-lived intangible assets	**7,856.2**	**(3,415.0)**	**4,441.2**	5,833.6	(2,960.8)	2,872.8
Indefinite-lived intangible assets:						
In-process research and development	**174.7**	**—**	**174.7**	11.4	—	11.4
Other intangibles	**$ 8,030.9**	**$ (3,415.0)**	**$ 4,615.9**	$ 5,845.0	$ (2,960.8)	$ 2,884.2

The increases in marketed products and acquired IPR&D assets in 2015 are primarily due to the acquisition of Novartis AH (Note 3).

Amortization expense related to finite-lived intangible assets was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Amortization expense	**$ 154.1**	$ 134.0	**$ 461.7**	$ 399.9

See Note 3 for further discussion of intangible assets acquired in recent business combinations.

Note 8: Shareholders' Equity

During the nine months ended September 30, 2015 and 2014, we purchased $496.6 million and $500.0 million of shares, respectively, associated with our $5.00 billion share repurchase program announced in October 2013. As of September 30, 2015, there were $3.20 billion of shares remaining in that program.

Note 9: Income Taxes

The U.S. examination of tax years 2010-2012 commenced during the fourth quarter of 2013 and is expected to be completed by the end of 2015. We currently estimate that it is reasonably possible there will be a reduction in gross uncertain tax positions of approximately $400 million by the end of 2015. It is also possible that up to $250 million of cash payments will be due upon resolution of the 2010-2012 tax years. We do not expect that resolution of the U.S. examination will result in a material change to our consolidated financial position. We anticipate that the U.S. examination of tax years 2013-2014, and possibly 2015, will begin in 2016.

Note 10: Retirement Benefits

Net pension and retiree health benefit expense included the following components:

	Defined Benefit Pension Plans			
	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Components of net periodic benefit cost:				
Service cost	**$ 82.8**	$ 65.4	**$ 245.3**	$ 195.7
Interest cost	**117.1**	118.3	**351.4**	355.5
Expected return on plan assets	**(195.7)**	(188.9)	**(579.7)**	(567.3)
Amortization of prior service cost	**2.5**	0.9	**7.6**	2.7
Recognized actuarial loss	**91.5**	68.8	**274.8**	207.3
Net periodic benefit cost	**$ 98.2**	$ 64.5	**$ 299.4**	$ 193.9

	Retiree Health Benefit Plans			
	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Components of net periodic benefit income:				
Service cost	**$ 10.5**	$ 10.3	**$ 31.5**	$ 33.2
Interest cost	**15.3**	20.9	**46.0**	64.7
Expected return on plan assets	**(37.1)**	(36.0)	**(111.3)**	(107.9)
Amortization of prior service cost	**(21.6)**	(7.4)	**(64.8)**	(22.0)
Recognized actuarial loss	**9.4**	5.0	**28.3**	15.1
Net periodic benefit income	**$ (23.5)**	$ (7.2)	**$ (70.3)**	$ (16.9)

On a global basis, we have contributed approximately $40 million required to satisfy minimum funding requirements to our defined benefit pension and retiree health benefit plans in 2015. Additional discretionary funding in the aggregate was approximately $260 million during the nine months ended September 30, 2015. During the remainder of 2015, we expect to make contributions to our defined benefit pension and retiree health benefit plans of approximately $10 million to satisfy minimum funding requirements. Additional discretionary funding for the remainder of the year is not expected to be material.

Note 11: Contingencies

We are a party to various legal actions and government investigations. The most significant of these are described below. It is not possible to determine the outcome of these matters and we cannot reasonably estimate the maximum potential exposure or the range of possible loss in excess of amounts accrued for any of these matters; however, we believe that, except as noted below with respect to the Alimta® patent litigation and administrative proceedings, the resolution of all such matters will not have a material adverse effect on our consolidated financial position or liquidity, but could possibly be material to our consolidated results of operations in any one accounting period.

Alimta Patent Litigation and Administrative Proceedings

A number of generic manufacturers are seeking approvals in various countries to market generic forms of Alimta prior to the expiration of our vitamin regimen patents, alleging that those patents are invalid, not infringed, or both. We believe our Alimta vitamin regimen patents are valid and enforceable against these generic manufacturers. However, it is not possible to determine the ultimate outcome of the proceedings, and accordingly, we can provide no assurance that we will prevail. An unfavorable outcome could have a material adverse impact on our future consolidated results of operations, liquidity, and financial position. We expect that a loss of exclusivity for Alimta would result in a rapid and severe decline in future revenues in the relevant market.

U.S. Patent Litigation

We are engaged in various U.S. patent litigation matters involving Alimta brought pursuant to procedures set out in the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act). More than ten Abbreviated New Drug Applications (ANDAs) seeking approval to market generic versions of Alimta prior to the expiration of our vitamin regimen patent (expiring in 2021 plus pediatric exclusivity expiring in 2022) have been filed by a number of companies, including Teva Parenteral Medicines, Inc. (Teva) and APP Pharmaceuticals, LLC (APP). These companies have also alleged the patent is invalid.

In October 2010, we filed a lawsuit in the U.S. District Court for the Southern District of Indiana against Teva, APP and two other defendants seeking rulings that the U.S. vitamin regimen patent is valid and infringed (the Teva/APP litigation). Teva and APP stipulated to infringement of our vitamin regimen patent, with the contingency that Teva and APP would be permitted to litigate the issue of infringement if the U.S. Supreme Court vacated an en banc decision of the U.S. Court of Appeals for the Federal Circuit that dealt with the issues of liability related to infringement (*Akamai v. Limelight Networks*). Thus, the sole issue before the district court was to determine the issue of patent validity.

Trial occurred in August 2013. In March 2014, the court ruled that the asserted claims of the vitamin regimen patent are valid. In June 2014, the U.S. Supreme Court vacated the *Akamai* decision, and the U.S. District Court for the Southern District of Indiana held a hearing on the issue of infringement in May 2015. In September 2015, the U.S. District Court for the Southern District of Indiana ruled that the vitamin regimen patent would be infringed by the generic challengers' proposed products. Teva and APP filed a notice of appeal with respect to all of the district court’s substantive decisions. A decision from the U.S. Court of Appeals for the Federal Circuit is expected next year.

Throughout the course of 2012 through 2015, we filed similar lawsuits against other ANDA defendants seeking a ruling that our patents are valid and infringed. The majority of these cases have been stayed pending the outcome of the Teva/APP litigation, and these parties have agreed to be bound by the outcome of the Teva/APP litigation.

European Patent Litigation and Administrative Proceedings

Generic manufacturers filed an opposition to the European Patent Office's (EPO) decision to grant us a vitamin regimen patent. The Opposition Division of the EPO upheld the patent and the generic manufacturers lodged an appeal. The EPO appeal hearing was scheduled for November 2015. In October 2015 the generic manufacturers withdrew the appeal, and the hearing was canceled. As a result, the original EPO decision upholding the patent will now be final.

In addition, in the United Kingdom (U.K.), Actavis Group ehf and other Actavis companies (collectively, Actavis) filed litigation asking for a declaratory judgment that commercialization of certain salt forms of pemetrexed (the active ingredient in Alimta) would not infringe the vitamin regimen patents in the U.K., Italy, France, and Spain. In May 2014, the trial court ruled that the vitamin regimen patents for Alimta would not be infringed by commercialization of alternative salt forms of pemetrexed, after expiration of the compound patents in December 2015. We appealed, and in June 2015, the U.K. Court of Appeal reversed the trial court, ruling that the Alimta vitamin regimen patent in the U.K. would be indirectly infringed by commercialization of Actavis' products as proposed prior to the patent's expiration in June 2021. The Court of Appeal also held there was no difference between the law in the U.K. and that in France, Italy, and Spain as it relates to indirect infringement, and so reversed the trial court's decision granting declarations of noninfringement over the Alimta vitamin regimen patents in those countries. We and Actavis have asked for permission to appeal different aspects of the Court of Appeals’ judgment to the U.K. Supreme Court. The U.K. Supreme Court has not yet decided if it will consider the case. Actavis has asked the trial court for a declaratory judgment that commercialization of a different proposed product would not infringe the patent in the U.K., Italy, France, and Spain. Trial on this matter was originally scheduled for November 2015, but has been postponed and is expected to be rescheduled for early 2016.

We commenced separate infringement proceedings against certain Actavis companies in Germany. Following a trial, in April 2014, the German trial court ruled in our favor. The defendants appealed, and after a hearing in March 2015, the appellate court overturned the trial court and ruled that our vitamin regimen patent in Germany would not be infringed by a dipotassium salt form of pemetrexed. We have asked for permission to appeal this ruling to the German Supreme Court.

Japanese Administrative Proceedings

Three companies have filed demands for invalidation of our vitamin regimen patents with the Japanese Patent Office (JPO). A hearing was held on one of the demands in February 2015. In October 2015, the JPO issued a notice of closure in the invalidation trial relating to the parent case, one of two currently pending decisions relating to the February 2015 hearing. We expect to receive a written decision upholding our patent in the parent case within a few weeks. We also expect a ruling in the other pending decision soon. This is the first of several decisions relating to the vitamin regimen patents before the JPO.

Effient Patent Litigation and Administrative Proceedings

We, along with Daiichi Sankyo, Daiichi Sankyo, Inc., and Ube Industries (Ube) are engaged in various U.S. patent litigation matters involving Effient brought pursuant to procedures set out in the Hatch-Waxman Act. More than ten different companies have submitted ANDAs seeking approval to market generic versions of Effient prior to the expiration of Daiichi Sankyo's and Ube's patents (expiring in 2022) covering methods of using Effient with aspirin, and alleging the patents are invalid. One of these ANDAs also alleges that the compound patent for Effient (expiring in 2017) is invalid.

Beginning in March 2014, we filed lawsuits in the U.S. District Court for the Southern District of Indiana against these companies, seeking a ruling that the patents are valid and infringed. The majority of these cases have been consolidated. The remainder have been stayed, and the parties have agreed to be bound by the outcome of the consolidated litigation.

In 2015, several generic pharmaceutical companies filed petitions with the U.S. Patent and Trademark Office, requesting *inter partes* review of the method patents. In September 2015, the U.S. Patent and Trademark Office granted the generic pharmaceutical companies' request and scheduled review in mid-2016.

We believe the Effient patents are valid and enforceable against these generic manufacturers. However, it is not possible to determine the outcome of the proceedings, and accordingly, we can provide no assurance that we will prevail. We expect a loss of exclusivity for Effient would result in a rapid and severe decline in future revenues for the product in the relevant market.

Actos® Product Liability Litigation

We are named along with Takeda Chemical Industries, Ltd., and Takeda affiliates (collectively, Takeda) as a defendant in approximately 6,500 product liability cases in the U.S. related to the diabetes medication Actos, which we co-promoted with Takeda in the U.S. from 1999 until 2006. In general, plaintiffs in these actions allege that Actos caused or contributed to their bladder cancer. Almost all of the active cases have been consolidated in federal multi-district litigation in the Western District of Louisiana or are pending in a coordinated state court proceeding in California or a coordinated state court proceeding in Illinois. We believe these lawsuits are without merit, and we and Takeda are prepared to defend against them vigorously.

In April 2014, a jury in the Western District of Louisiana found in favor of the plaintiffs in the case of *Allen, et al. v. Takeda Pharmaceuticals, et al.,* no. 6:12-md-00064. In September 2014, judgment was entered awarding $1.3 million in compensatory damages to plaintiffs (allocated 75 percent to Takeda and 25 percent to us) and punitive damages of $6.00 billion against Takeda and $3.00 billion against us. In October 2014, the judge reduced the amount of punitive damages awarded to approximately $28 million against Takeda and approximately $9 million against us. We continue to believe the evidence did not support plaintiffs' claims and strongly disagree with the verdict. We and Takeda appealed this judgment and plaintiffs filed a cross-appeal objecting to the reduction in punitive damages; however, in light of the proposed resolution described below, both appeals have been dismissed without prejudice, subject to reinstatement by any party within six months of the dismissal.

Our agreement with Takeda calls for Takeda to defend and indemnify us against our losses and expenses with respect to the U.S. litigation arising out of the manufacture, use, or sale of Actos and other related expenses in accordance with the terms of the agreement. After the jury reached its verdict in *Allen*, Takeda notified us that it was reserving its right to challenge its obligations to defend and indemnify us with respect to the *Allen* case. We believe

we are entitled to full indemnification of our losses and expenses in *Allen* and all other U.S. cases*;* however, there can be no guarantee we will ultimately be successful in obtaining full indemnification.

In April 2015, Takeda announced they will pay approximately $2.4 billion to resolve the vast majority of the U.S. product liability lawsuits involving Actos, including *Allen*, and the other cases involving us. This resolution will become effective if at least 95 percent of current litigants opt into the Actos product liability resolution program, and will release us and Takeda of all remaining liability for these cases. In September 2015, Takeda announced that more than 96 percent of eligible claimants have opted into the resolution program that was announced in April 2015. Takeda is now evaluating the submissions to determine whether they satisfy various criteria specified under terms of the resolution program. Takeda expects the resolution program to become effective upon completion of that review.

We are also named along with Takeda as a defendant in three purported product liability class actions in Canada related to Actos, including one in Ontario (*Casseres et al. v. Takeda Pharmaceutical North America, Inc., et al*.), one in Quebec (*Whyte et al. v. Eli Lilly et al.*), and one in Alberta (*Epp v. Takeda Canada et al.*). We promoted Actos in Canada until 2009. These claims are not part of the U.S. resolution program. We believe these claims are without merit and are prepared to defend against them vigorously.

Byetta Product Liability Litigation

We are named as a defendant in approximately 500 Byetta product liability lawsuits involving approximately 1,050 plaintiffs. Approximately 110 of these lawsuits, covering about 640 plaintiffs, are filed in California state court and coordinated in a Los Angeles Superior Court. Approximately 380 lawsuits, covering about 385 plaintiffs, are filed in federal court, the majority of which are coordinated in a multi-district litigation in the Southern District of California. The remaining approximately five lawsuits, representing about 20 plaintiffs, are in various state courts. Approximately 435 of the lawsuits, involving approximately 675 plaintiffs, contain allegations that Byetta caused or contributed to the plaintiffs' cancer (primarily pancreatic cancer or thyroid cancer). We are aware of approximately 220 additional claimants who have not yet filed suit. The majority of these additional claims allege damages for pancreatitis. We believe these lawsuits and claims are without merit and are prepared to defend against them vigorously.

Prozac® Product Liability Litigation

We are named as a defendant in approximately 10 U.S. lawsuits primarily related to allegations that the antidepressant Prozac caused or contributed to birth defects in the children of women who ingested the drug during pregnancy. We are aware of approximately 535 additional claims related to birth defects, which have not yet been filed. We believe these lawsuits and claims are without merit and are prepared to defend against them vigorously.

Brazil–Employee Litigation

Our subsidiary in Brazil, Eli Lilly do Brasil (Lilly Brasil), is named in a lawsuit brought by the Labor Attorney for 15th Region in the Labor Court of Paulinia, State of Sao Paulo, Brazil, alleging possible harm to employees and former employees caused by exposure to heavy metals at a former Lilly manufacturing facility in Cosmopolis, Brazil, operated by the company between 1977 and 2003. The plaintiffs allege that some employees at the facility were exposed to benzene and heavy metals; however, Lilly Brasil maintains that these alleged contaminants were never used in the facility. In May 2014, the labor court judge ruled against Lilly Brasil. The judge's ruling orders Lilly Brasil to undertake several actions of unspecified financial impact, including paying lifetime medical insurance for the employees and contractors who worked at the Cosmopolis facility more than six months during the affected years and their children born during and after this period. While we cannot currently estimate the range of reasonably possible financial losses that could arise in the event we do not ultimately prevail in the litigation, the judge has estimated the total financial impact of the ruling to be approximately 1.0 billion Brazilian real (approximately $250 million as of September 30, 2015) plus interest. We strongly disagree with the decision and filed an appeal in May 2014.

We are also named in approximately 30 lawsuits filed in the same court by individual former employees making similar claims. We believe these lawsuits are without merit and are prepared to defend against them vigorously.

Product Liability Insurance

Because of the nature of pharmaceutical products, it is possible that we could become subject to large numbers of product liability and related claims in the future. Due to a very restrictive market for product liability insurance, we are self-insured for product liability losses for all our currently marketed products.

Note 12: Other Comprehensive Income (Loss)

The following tables summarize the activity related to each component of other comprehensive income (loss) during the three months ended September 30, 2015 and 2014:

(Amounts presented net of taxes)	Foreign Currency Translation Gains (Losses)	Unrealized Net Gains (Losses) on Securities	Defined Benefit Pension and Retiree Health Benefit Plans	Effective Portion of Cash Flow Hedges	Accumulated Other Comprehensive Loss
Balance at July 1, 2015	**$ (1,037.6)**	**$ 121.0**	**$ (3,263.3)**	**$ (223.3)**	**$ (4,403.2)**
Other comprehensive income (loss) before reclassifications	**(226.7)**	**(16.2)**	**16.2**	**—**	**(226.7)**
Net amount reclassified from accumulated other comprehensive loss	**—**	**(94.3)**	**54.8**	**2.4**	**(37.1)**
Net other comprehensive income (loss)	**(226.7)**	**(110.5)**	**71.0**	**2.4**	**(263.8)**
Balance at September 30, 2015	**$ (1,264.3)**	**$ 10.5**	**$ (3,192.3)**	**$ (220.9)**	**$ (4,667.0)**

(Amounts presented net of taxes)	Foreign Currency Translation Gains (Losses)	Unrealized Net Gains (Losses) on Securities	Defined Benefit Pension and Retiree Health Benefit Plans	Effective Portion of Cash Flow Hedges	Accumulated Other Comprehensive Loss
Balance at July 1, 2014	$ 467.9	$ 124.7	$ (2,403.3)	$ (124.6)	$ (1,935.3)
Other comprehensive income (loss) before reclassifications	(635.4)	17.3	36.5	(34.5)	(616.1)
Net amount reclassified from accumulated other comprehensive loss	—	(59.5)	44.7	14.6	(0.2)
Net other comprehensive income (loss)	(635.4)	(42.2)	81.2	(19.9)	(616.3)
Balance at September 30, 2014	$ (167.5)	$ 82.5	$ (2,322.1)	$ (144.5)	$ (2,551.6)

The following tables summarize the activity related to each component of other comprehensive income (loss) during the nine months ended September 30, 2015 and 2014:

(Amounts presented net of taxes)	Foreign Currency Translation Gains (Losses)	Unrealized Net Gains (Losses) on Securities	Defined Benefit Pension and Retiree Health Benefit Plans	Effective Portion of Cash Flow Hedges	Accumulated Other Comprehensive Loss
Balance at January 1, 2015	**$ (498.4)**	**$ 99.7**	**$ (3,402.0)**	**$ (191.1)**	**$ (3,991.8)**
Other comprehensive income (loss) before reclassifications	**(765.9)**	**42.9**	**46.8**	**(36.9)**	**(713.1)**
Net amount reclassified from accumulated other comprehensive loss	**—**	**(132.1)**	**162.9**	**7.1**	**37.9**
Net other comprehensive income (loss)	**(765.9)**	**(89.2)**	**209.7**	**(29.8)**	**(675.2)**
Balance at September 30, 2015	**$ (1,264.3)**	**$ 10.5**	**$ (3,192.3)**	**$ (220.9)**	**$ (4,667.0)**

(Amounts presented net of taxes)	Foreign Currency Translation Gains (Losses)	Unrealized Net Gains (Losses) on Securities	Defined Benefit Pension and Retiree Health Benefit Plans	Effective Portion of Cash Flow Hedges	Accumulated Other Comprehensive Loss
Balance at January 1, 2014	$ 463.0	$ 205.2	$ (2,489.1)	$ (181.8)	$ (2,002.7)
Other comprehensive income (loss) before reclassifications	(630.5)	34.0	30.0	(23.8)	(590.3)
Net amount reclassified from accumulated other comprehensive loss	—	(156.7)	137.0	61.1	41.4
Net other comprehensive income (loss)	(630.5)	(122.7)	167.0	37.3	(548.9)
Balance at September 30, 2014	$ (167.5)	$ 82.5	$ (2,322.1)	$ (144.5)	$ (2,551.6)

The tax effects allocated to each component of other comprehensive income (loss) for the three and nine months ended September 30, were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
Tax (benefit) expense	**2015**	**2014**	**2015**	**2014**
Foreign currency translation losses	**$ (5.9)**	$ —	**$ (17.7)**	$ —
Unrealized net losses on securities	**(59.6)**	(22.8)	**(48.2)**	(66.3)
Defined benefit pension and retiree health benefit plans	**31.1**	30.8	**93.9**	70.8
Effective portion of cash flow hedges	**1.3**	(10.7)	**(15.9)**	19.9
Provision for income taxes allocated to other comprehensive income (loss)	**$ (33.1)**	$ (2.7)	**$ 12.1**	$ 24.4

Except for the tax effects of foreign currency translation gains (losses) related to our euro-denominated notes (see Note 6), income taxes were not provided for foreign currency translation. Generally, the assets and liabilities of foreign operations are translated into U.S. dollars using the current exchange rate. For those operations, changes in exchange rates generally do not affect cash flows; therefore, resulting translation adjustments are made in shareholders' equity rather than in income.

	Reclassifications Out of Accumulated Other Comprehensive Loss				
	Three Months Ended September 30,		Nine Months Ended September 30,		
Details about Accumulated Other Comprehensive Loss Components	**2015**	**2014**	**2015**	**2014**	**Affected Line Item in the Consolidated Condensed Statements of Operations**
Amortization of retirement benefit items:					
Prior service benefits, net	**$ (19.1)**	$ (6.5)	**$ (57.2)**	$ (19.3)	[1]
Actuarial losses	**100.9**	73.8	**303.1**	222.4	[1]
Total before tax	**81.8**	67.3	**245.9**	203.1	
Tax benefit	**(27.0)**	(22.6)	**(83.0)**	(66.1)	Income taxes
Net of tax	**54.8**	44.7	**162.9**	137.0	
Unrealized gains/losses on available-for-sale securities:					
Realized gains, net before tax	**(149.5)**	(91.6)	**(213.9)**	(241.1)	Other–net, (income) expense
Impairment losses	**4.5**	—	**10.7**	—	Other–net, (income) expense
Total before tax	**(145.0)**	(91.6)	**(203.2)**	(241.1)	
Tax expense	**50.7**	32.1	**71.1**	84.4	Income taxes
Net of tax	**(94.3)**	(59.5)	**(132.1)**	(156.7)	
Other, net of tax	**2.4**	14.6	**7.1**	61.1	Other–net, (income) expense
Total reclassifications for the period (net of tax)	**$ (37.1)**	$ (0.2)	**$ 37.9**	$ 41.4	

[1] These accumulated other comprehensive loss components are included in the computation of net periodic benefit (see Note 10).

Note 13: Other–Net, (Income) Expense

Other–net, (income) expense consisted of the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Interest expense	**$ 39.3**	$ 38.1	**$ 117.0**	$ 111.4
Interest income	**(21.2)**	(28.8)	**(63.2)**	(96.8)
Debt extinguishment loss (Note 6)	**—**	—	**166.7**	—
Other income	**(104.6)**	(102.8)	**(276.4)**	(217.9)
Other–net, (income) expense	**$ (86.5)**	$ (93.5)	**$ (55.9)**	$ (203.3)

Other income consists primarily of net gains on investments.

Note 14: Segment Information

We operate in two business segments—human pharmaceutical and animal health products. Our business segments are distinguished by the ultimate end user of the product—humans or animals. Performance is evaluated based on profit or loss from operations before income taxes. The animal health segment amounts for the three and nine months ended September 30, 2015 include the results of operations from Novartis AH which was acquired on January 1, 2015. See Note 3 for additional information regarding the Novartis AH acquisition.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	**2014**	**2015**	**2014**
Segment revenue—to unaffiliated customers:				
Human pharmaceutical:				
Endocrinology:				
Humalog®	**$ 705.0**	$ 706.1	**$ 2,043.3**	$ 2,056.1
Forteo®	**348.9**	332.2	**970.4**	941.2
Humulin®	**316.7**	335.9	**948.8**	1,004.5
Trajenta	**92.7**	78.9	**255.0**	246.1
Evista®	**58.0**	89.5	**184.5**	347.8
Trulicity®	**73.7**	—	**136.2**	—
Other Endocrinology	**191.4**	165.7	**512.4**	491.3
Total Endocrinology	**1,786.4**	1,708.3	**5,050.6**	5,087.0
Neuroscience:				
Cymbalta®	**242.9**	368.0	**804.0**	1,247.5
Zyprexa®	**237.9**	257.4	**711.2**	784.2
Strattera®	**196.9**	191.9	**562.4**	543.7
Other Neuroscience	**46.8**	52.6	**136.0**	152.5
Total Neuroscience	**724.5**	869.9	**2,213.6**	2,727.9
Oncology:				
Alimta	**628.5**	723.4	**1,865.8**	2,067.0
Erbitux	**85.9**	92.9	**308.8**	277.3
Cyramza®	**111.2**	28.4	**266.4**	42.0
Other Oncology	**35.7**	37.7	**101.8**	118.8
Total Oncology	**861.3**	882.4	**2,542.8**	2,505.1
Cardiovascular:				
Cialis®	**566.1**	568.4	**1,672.3**	1,668.6
Effient	**132.1**	131.5	**382.7**	384.4
Other Cardiovascular	**61.7**	57.3	**183.3**	182.3
Total Cardiovascular	**759.9**	757.2	**2,238.3**	2,235.3
Other pharmaceuticals	**48.8**	73.1	**168.5**	225.7
Total human pharmaceutical	**4,180.9**	4,290.9	**12,213.8**	12,781.0
Animal health	**778.8**	584.7	**2,369.3**	1,713.3
Revenue	**$ 4,959.7**	$ 4,875.6	**$ 14,583.1**	$ 14,494.3

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Segment profits:				
Human pharmaceutical	**$ 1,124.1**	$ 760.0	**$ 3,224.0**	$ 2,350.8
Animal health	**139.8**	145.8	**443.1**	417.6
Total segment profits	**$ 1,263.9**	$ 905.8	**$ 3,667.1**	$ 2,768.4
Reconciliation of total segment profits to consolidated income before taxes:				
Segment profits	**$ 1,263.9**	$ 905.8	**$ 3,667.1**	$ 2,768.4
Other profits (losses):				
Acquired in-process research and development (Note 3)	**—**	(95.0)	**(336.0)**	(95.0)
Amortization of intangible assets [1]	**(152.5)**	—	**(457.2)**	—
Asset impairment, restructuring, and other special charges (Note 5)	**(42.4)**	(36.3)	**(222.8)**	(67.7)
Debt repurchase charges, net [2] (Note 6)	**—**	—	**(152.7)**	—
Inventory fair value adjustment related to Novartis AH (Note 3)	**(21.2)**	—	**(153.0)**	—
Incremental U.S. Branded Prescription Drug Fee due to issuance of final tax regulations	**—**	(119.0)	**—**	(119.0)
Consolidated income before taxes	**$ 1,047.8**	$ 655.5	**$ 2,345.4**	$ 2,486.7

[1] In 2015, the measurement of segment profitability was changed to exclude the amortization of intangible assets. If we were to adjust the three months ended September 30, 2014 to conform with the 2015 presentation and exclude amortization of intangible assets, the human pharmaceutical and animal health segment profits would be increased by $118.9 million and $15.7 million, respectively, and $352.4 million and $43.1 million for the nine months ended September 30, 2014, respectively.

[2] We recognized pretax net charges of $152.7 million for the nine months ended September 30, 2015, attributable to the debt extinguishment loss of $166.7 million from the purchase and redemption of certain fixed-rate notes, partially offset by net gains from non-hedging interest rate swaps and foreign currency transactions associated with the related issuance of euro-denominated notes.

For internal management reporting presented to the chief operating decision maker, certain costs are fully allocated to our human pharmaceutical segment and therefore are not reflected in the animal health segment's profit. Such items include costs associated with treasury-related financing, global administrative services, certain acquisition-related transaction costs, and certain manufacturing costs.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Results of Operations

Executive Overview

This section provides an overview of our financial results, recent product and late-stage pipeline developments, and legal, regulatory, and other matters affecting our company and the pharmaceutical industry. Earnings per share (EPS) data is presented on a diluted basis.

Financial Results

The following table summarizes our key operating results:

	Three Months Ended September 30,		Percent Change from	Nine Months Ended September 30,		Percent Change from
	2015	2014	2014	2015	2014	2014
Revenue	**$ 4,959.7**	$ 4,875.6	2 %	**$ 14,583.1**	$ 14,494.3	1 %
Gross margin	**3,722.8**	3,608.6	3 %	**10,935.1**	10,814.9	1 %
Gross margin percentage	**75.1%**	74.0%		**75.0%**	74.6%	
Operating expense [1]	**$ 2,719.1**	$ 2,915.3	(7)%	**$ 8,086.8**	$ 8,368.8	(3)%
Acquired in-process research and development	**—**	95.0	NM	**336.0**	95.0	NM
Asset impairment, restructuring, and other special charges	**42.4**	36.3	17 %	**222.8**	67.7	NM
Net income	**799.7**	500.6	60 %	**1,930.0**	1,962.0	(2)%
Earnings per share	**0.75**	0.47	60 %	**1.81**	1.82	(1)%

[1] Operating expense consists of research and development and marketing, selling, and administrative expenses.

NM - not meaningful

Revenue and gross margin increased slightly for the three and nine months ended September 30, 2015. The decrease in operating expense for both periods was due to decreases in both research and development and marketing, selling, and administrative expenses. The increase in net income and EPS for the three months ended September 30, 2015 was driven by an increased gross margin, decreased operating expenses, and decreased acquired in-process research and development (IPR&D) charges. The decrease in net income and EPS for the nine months ended September 30, 2015 was driven by increased acquired IPR&D charges, charges related to the repurchase of debt, and increased asset impairment, restructuring, and other special charges, partially offset by lower operating expenses and a lower effective tax rate in 2015.

The following highlighted items affect comparisons of our financial results for the three and nine months ended September 30, 2015 and 2014:

2015

Acquisitions (Note 3)

- We recognized expense of $21.2 million (pretax), or $0.01 per share, $68.4 million (pretax), or $0.05 per share, and $63.5 million (pretax), or $0.04 per share, in the third, second, and first quarters, respectively, related to the fair value adjustments to Novartis Animal Health (Novartis AH) acquisition date inventory that has been sold.

Acquired In-Process Research & Development (Notes 3 and 4)

- We recognized acquired IPR&D charges in the second quarter of $80.0 million (pretax), or $0.05 per share, related to upfront fees paid in connection with the collaboration agreements with BioNTech AG (BioNTech) and Hanmi Pharmaceutical Co., Ltd. (Hanmi); and charges in the first quarter of $256.0 million (pretax), or $0.15 per share, related to the upfront fees paid in connection with the collaboration agreements with Pfizer, Inc. (Pfizer) and Innovent Biologics, Inc. (Innovent).

Asset Impairment, Restructuring, and Other Special Charges (Note 5)

- We recognized charges of $42.4 million (pretax), or $0.03 per share, $72.4 million (pretax), or $0.05 per share, and $108.0 million (pretax), or $0.07 per share, in the third, second, and first quarters, respectively, related to integration costs, intangible asset impairments, and severance costs primarily resulting from our acquisition of Novartis AH.

Debt Repurchase (Notes 6 and 13)

- We recognized net charges of $152.7 million (pretax), or $0.09 per share, in the second quarter, attributable to the debt extinguishment loss of $166.7 million from the purchase and redemption of certain fixed-rate notes, partially offset by net gains from non-hedging interest rate swaps and foreign currency transactions associated with the related issuance of euro-denominated notes.

2014

Acquired In-Process Research & Development (IPR&D) (Note 3)

- We recognized expense in the third quarter of $95.0 million (pretax), or $0.06 per share, related to IPR&D from the collaboration agreements with Immunocore Limited (Immunocore) and AstraZeneca UK Limited (AstraZeneca).

Asset Impairment, Restructuring, and Other Special Charges (Note 5)

- We recognized charges in the third quarter of $36.3 million (pretax), or $0.02 per share, related primarily to severance associated with our ongoing cost containment efforts and costs related to the pending acquisition of Novartis AH.
- We recognized charges in the first quarter of $31.4 million (pretax), or $0.02 per share, related primarily to severance costs for actions taken to reduce our cost structure.

Other

- We recognized a marketing, selling, and administrative expense in the third quarter of $119.0 million (non-tax deductible), or $0.11 per share, for an extra year of the United States (U.S.) Branded Prescription Drug Fee due to final regulations issued by the Internal Revenue Service.

Late-Stage Pipeline

Our long-term success depends to a great extent on our ability to continue to discover and develop innovative pharmaceutical products and acquire or collaborate on molecules currently in development by other biotechnology or pharmaceutical companies. We currently have approximately 50 potential new drugs in human testing or under regulatory review, and a larger number of projects in preclinical research.

The following new molecular entities (NMEs) have been submitted for regulatory review in at least one of the major geographies for potential use in the diseases described. The quarter in which each NME initially was submitted for any indication is shown in parentheses:

Necitumumab* (Q4 2014)—an anti-epidermal growth factor receptor monoclonal antibody for the treatment of squamous non-small cell lung cancer (NSCLC).

Ixekizumab* (Q1 2015)—a neutralizing monoclonal antibody to interleukin-17A for the treatment of psoriasis and psoriatic arthritis. Ixekizumab is protected by a compound patent (2026 not including possible patent extension).

The following NMEs are currently in Phase III clinical trial testing for potential use in the diseases described. The quarter in which each NME initially entered Phase III for any indication is shown in parentheses:

Abemaciclib (Q3 2014)—a small molecule cell-cycle inhibitor, selective for cyclin-dependent kinases 4 and 6 for the treatment of metastatic breast cancer and NSCLC.

Baricitinib (Q4 2012)—a Janus tyrosine kinase inhibitor for the treatment of rheumatoid arthritis (in collaboration with Incyte Corporation).

Basal insulin peglispro* (Q4 2011)—a novel basal insulin for the treatment of type 1 and type 2 diabetes.

CGRP monoclonal antibody* (Q2 2015)—a once-monthly subcutaneously injected calcitonin gene-related peptide antibody for the treatment of cluster headache.

Intranasal glucagon* (Q3 2013)—a glucagon nasal powder formulation for the treatment of severe hypoglycemia in patients with diabetes treated with insulin.

Olaratumab* (Q3 2015)—a human lgG1 monoclonal antibody for the treatment of advanced soft tissue sarcoma.

Solanezumab* (Q2 2009)—an anti-amyloid beta monoclonal antibody for the treatment of preclinical and mild Alzheimer's disease.

Tanezumab* (Q3 2008)—an anti-nerve growth factor monoclonal antibody for the treatment of osteoarthritis pain, chronic low back pain, and cancer pain (in collaboration with Pfizer).

Tau Imaging Agent (Q3 2015)—a positron emission tomography (PET) tracer intended to image tau (or neurofibrillary) tangles in the brain, which are an indicator of Alzheimer's disease.

* Biologic molecule subject to the U.S. Biologics Price Competition and Innovation Act

The following table reflects the status of each NME within our late-stage pipeline and recently approved products including developments since January 1, 2015:

Compound	Indication	U.S.	Europe	Japan	Developments
Cardiovascular					
Evacetrapib	High-risk vascular disease	Terminated			Announced decision to discontinue further development in October 2015.
Endocrinology					
Basal insulin peglispro	Type 1 diabetes	Phase III			Announced in February 2015 decision to delay regulatory submission to generate additional clinical data to understand and characterize potential effects, if any, of changes in liver fat observed with basal insulin peglispro treatment.
	Type 2 diabetes	Phase III			
Intranasal glucagon	Severe hypoglycemia	Phase III			Acquired worldwide rights to intranasal glucagon in October 2015. See Note 3 for information on the acquisition.
Jardiance®	Type 1 diabetes	Phase III			Initiated Phase III study in July 2015.
	Type 2 diabetes	Launched			Launched in the first quarter of 2015 in Japan. In August 2015, announced Jardiance demonstrated a significant reduction in both cardiovascular risk and cardiovascular death in adults with Type 2 diabetes at high risk for cardiovascular events. Glyxambi®, combination tablet of empagliflozin and linagliptin, approved in the U.S. and launched in first quarter of 2015. Intend to submit to European regulatory authorities in late 2015.
Basaglar® (new insulin glargine product)	Type 1 diabetes	Tentatively approved	Launched		First launch in Europe and Japan in second and third quarter of 2015, respectively. See Note 4 for information on the U.S. tentative approval.
	Type 2 diabetes	Tentatively approved	Launched		
Trulicity®	Type 2 diabetes	Launched			Launched in certain European countries in first quarter of 2015. In Japan, approved and launched in third quarter of 2015.

Compound	Indication	U.S.	Europe	Japan	Developments
Immunology					
Baricitinib	Rheumatoid arthritis	Phase III			Announced in February, September, and October 2015 top-line results of three Phase III trials which all met primary endpoints.
Ixekizumab	Psoriasis	Submitted			Submitted to regulatory authorities in the U.S., Europe, and Japan in first, second, and third quarter of 2015, respectively.
	Psoriatic arthritis	Phase III		Submitted	Announced in April 2015 top-line results of Phase III trial which met primary endpoints. Submitted to regulatory authorities in Japan in third quarter of 2015.
Neuroscience					
CGRP monoclonal antibody	Cluster headache	Phase III			Initiated first Phase III study in June 2015. Granted Fast Track Designation[(1)] from the U.S. Food and Drug Administration (FDA) in June 2015.
Solanezumab	Preclinical Alzheimer's disease	Phase III			Phase III study in asymptomatic Alzheimer's disease is ongoing.
	Mild Alzheimer's disease	Phase III			Enrollment in the ongoing Phase III study completed. In July 2015, announced clinical trial results indicating the treatment effect was preserved in patients with mild Alzheimer's disease who received solanezumab earlier in disease, compared to patients beginning treatment at later point.
Tanezumab	Osteoarthritis pain	Phase III			FDA clinical hold lifted in March 2015. Phase III studies resumed beginning in July 2015.
	Chronic low back pain	Phase III			
	Cancer pain	Phase III			
Tau imaging agent	Alzheimer's disease	Phase III			Initiated Phase III study in September 2015.

Compound	Indication	U.S.	Europe	Japan	Developments
Oncology					
Abemaciclib	Metastatic breast cancer	Phase III			Phase III studies are ongoing. Announced that abemaciclib was granted Breakthrough Therapy Designation[2] by the FDA.
	NSCLC	Phase III			Phase III study is ongoing.
Cyramza®	Gastric cancer (first-line)	Phase III			Initiated Phase III study of Cyramza in first-line gastric cancer in January 2015.
	Gastric cancer (second-line)	Launched			Launched in certain European countries in first quarter of 2015. In Japan, approved in March 2015 and launched in second quarter of 2015.
	NSCLC (first-line)	Phase III			Initiated Phase III study of Cyramza in first-line NSCLC in May 2015.
	NSCLC (second-line)	Launched	Submitted		Launched in the U.S. in first quarter of 2015. Submitted in Europe and Japan in first and third quarter of 2015, respectively.
	Liver cancer (second-line)	Phase III			Initiated Phase III study of Cyramza in second-line liver cancer in July 2015.
	Metastatic colorectal cancer (second-line)	Launched	Submitted		Approved and launched in the U.S. in second quarter of 2015. Submitted in Europe and Japan in first and second quarter of 2015, respectively.
	Urothelial (bladder) cancer (second-line)	Phase III			Initiated Phase III study of Cyramza in second-line bladder cancer in July 2015.
Necitumumab	Squamous NSCLC (first-line)	Submitted		Phase Ib/II	FDA Oncologic Drugs Advisory Committee met in July 2015 to review data supporting necitumumab in combination with gemcitabine and cisplatin. Anticipate FDA action before the end of 2015.
Olaratumab	Soft tissue sarcoma	Phase III			In third quarter of 2015, announced intention to submit U.S. and European regulatory applications based on Phase II clinical trial data. Intend to initiate a rolling submission to FDA near the end of 2015. Submission to European regulatory authorities expected in 2016. Announced that olaratumab was granted Breakthrough Therapy Designation[2] by the FDA. Initiated Phase III study of olaratumab in soft tissue sarcoma in September 2015.

[1] The FDA Fast Track status is a designation that facilitates the development, and expedites the review, of drugs which treat a serious or life-threatening condition and fill an unmet medical need.

[2] The Breakthrough Therapy Designation is designed to expedite the development and review of potential medicines that are intended to treat a serious condition where preliminary clinical evidence indicates that the treatment may demonstrate substantial improvement over available therapy on a clinically significant endpoint.

Other Matters

Novartis Animal Health Acquisition

On January 1, 2015, we completed our acquisition of Novartis AH in an all-cash transaction for $5.28 billion, subject to certain contractual adjustments which should be completed by December 31, 2015. Novartis AH operates in approximately 40 countries. We acquired Novartis AH's nine manufacturing sites, six dedicated research and development facilities, a global commercial infrastructure with a portfolio of approximately 600 products, a pipeline with more than 40 projects in development, and more than 3,000 employees. The combined organization has increased our animal health product portfolio, expanded our global commercial presence, and augmented our animal health manufacturing and research and development. In particular, it has provided Elanco with a greater commercial presence in the companion animal and swine markets, expanded Elanco's presence in equine and vaccines areas, and created an entry into the aquaculture market. As a condition to the clearance of the transaction under the Hart-Scott-Rodino Antitrust Improvement Act, following the closing of the acquisition of Novartis AH, we divested certain companion animal assets in the U.S. related to the Sentinel® canine parasiticide franchise to Virbac Corporation for approximately $410 million. The Novartis AH business we retained generated revenue of approximately $1.1 billion in 2014.

Patent Matters

We depend on patents or other forms of intellectual-property protection for most of our revenues, cash flows, and earnings. The loss of U.S. patent exclusivity for Cymbalta® in December 2013 and Evista® in March 2014, resulted in the immediate entry of generic competitors and a rapid and severe decline in revenue from the affected products, having a material adverse effect on our consolidated results of operations and cash flows.

We lost our data package protection for Cymbalta in major European countries in 2014. We began to see the entry of generic competition in a few countries in the first quarter of 2015, and as of the end of the third quarter of 2015, we have seen entry in all major European markets. The entry of generic competition for Cymbalta into the markets where it has lost patent protection has caused a rapid and severe decline in revenue, which over time will, in the aggregate, have a material adverse effect on our consolidated results of operations and cash flows. We will also lose patent exclusivity in December 2015 for Zyprexa® in Japan.

Additionally, as described in Note 11 to the consolidated condensed financial statements, the Alimta® vitamin regimen patent, which provides us with patent protection for Alimta through June 2021 in Japan and major European countries, and through May 2022 in the U.S., has been challenged in each of these jurisdictions. Our compound patent for Alimta will expire in the U.S. in January 2017, and in major European countries and Japan in December 2015. We expect that the entry of generic competition for Alimta into the markets when it loses effective patent protection will cause a rapid and severe decline in revenue, which will, in the aggregate, have a material adverse effect on our consolidated results of operations and cash flows.

The U.S. compound patent for Humalog® expired in 2013. Thus far, the loss of compound patent protection for Humalog has not resulted in a rapid and severe decline in revenue. Global regulators have different legal pathways to approve similar versions of Humalog and to date none have been approved in the U.S. or Europe. We are aware that other manufacturers have efforts underway to develop a similar version of Humalog, and it is difficult to predict the likelihood, timing, and impact of these products entering the market.

Foreign Currency Exchange Rates

As a global company with substantial operations outside the U.S., we face foreign currency risk exposure from fluctuating currency exchange rates, primarily the U.S. dollar against the euro, Japanese yen, Chinese yuan, and British pound, and the British pound against the euro. While we manage a portion of these exposures through hedging and other risk management techniques, significant fluctuations in currency rates can have a substantial impact, either positive or negative, on our revenue, cost of sales, and operating expenses. Over the past year we have seen significant foreign currency rate fluctuations as the U.S. dollar strengthened compared to several other foreign currencies, including the euro, the British pound, and the Japanese yen. While there is uncertainty in the future movements in foreign exchange rates, these fluctuations could negatively impact our future consolidated results of operations.

Trends Affecting Pharmaceutical Pricing, Reimbursement, and Access

United States

Prices for specialty and brand name pharmaceuticals, congressional investigations into manufacturer's pricing policies, and the federal budget process continue to drive legislative debate. These policy and political issues increase the risk that taxes, fees, rebates or other federal and state measures may be enacted. As a result, pharmaceutical companies may see either a reduction in revenue or increase in expenses. Key health policy proposals affecting biopharmaceuticals, include a reduction in biologic data exclusivity, modifications to Medicare Parts B and D, new language that would allow the Department of Health and Human Services to negotiate prices for biologics and drugs on the specialty tier in Part D, and the expanded use of value-based insurance design and decision making, with a focus on pharmaceuticals. Savings projected under these proposals are targeted as a means to fund health care expenditures and non-health care expenditures. State and federal health care proposals, including price controls, continue to be debated, and if implemented could negatively affect future consolidated results of operations.

In the U.S. private sector, consolidation and integration among U.S. healthcare providers is also a major factor in the competitive marketplace for human pharmaceuticals. Health plans and pharmaceutical benefit managers have been consolidating into fewer, larger entities, thus enhancing their purchasing strength and importance. Payers typically maintain formularies specifying which drugs are covered and the cost to the consumer. Exclusion of a drug from a formulary can lead to its reduced usage in the patient population. Consequently, pharmaceutical companies compete to have their branded products included by providing offsetting rebates. Price is becoming an increasingly important factor in formulary decisions, particularly in treatment areas in which the payer has taken the position that multiple branded products are therapeutically comparable. These downward pricing pressures could negatively impact future consolidated results of operations.

The main coverage expansion provisions of the Affordable Care Act (ACA) are now in effect through both the launch of state-based exchanges and the expansion of Medicaid. An emerging trend has been the prevalence of benefit designs containing high out-of-pocket costs for patients, particularly for pharmaceuticals. In addition to the coverage expansions, many employers in the commercial market, driven in part by ACA changes such as the 2018 implementation of the excise tax on employer-sponsored health care coverage for which there is an excess benefit (the so-called "Cadillac tax"), continue to evaluate strategies such as private exchanges and wider use of consumer-driven health plans to reduce their healthcare liabilities over time. At the same time, the broader paradigm shift towards quality-based reimbursement and the launch of several value-based purchasing initiatives have placed demands on the pharmaceutical industry to offer products with proven real-world outcomes data and a favorable economic profile.

International

International operations also are generally subject to extensive price and market regulations. Cost-containment measures exist in a number of countries, including additional price controls and mechanisms to limit reimbursement for our products. Such policies are expected to increase in impact and reach, given the pressures on national and regional health care budgets that come from a growing aging population and ongoing economic challenges. In addition, governments in many emerging markets are becoming increasingly active in expanding health care system offerings. Given the budget challenges of increasing health care coverage for citizens, policies may be proposed that promote generics only and reduce current and future access to human pharmaceutical products.

Tax Matters

We are subject to income taxes in the U.S. and numerous foreign jurisdictions. Changes in the relevant tax laws, regulations, administrative practices, principles, and interpretations could adversely affect our future effective tax rates. The U.S. and a number of other countries are actively considering or enacting changes in this regard. For example, the Obama administration proposed changes to the manner in which the U.S. would tax the international income of U.S.-based companies, including unremitted earnings of foreign subsidiaries, and other tax proposals under discussion or introduced in the U.S. Congress could change the tax rate and manner in which U.S. companies would be taxed. Additionally, the Organisation for Economic Co-operation and Development issued its final recommendations of international tax reform proposals to influence international tax policy in major countries in which we operate. While outcomes of these initiatives continue to develop and remain uncertain, changes to key elements of the U.S. or international tax framework could have a material adverse effect on our consolidated operating results and cash flows.

Legal Matters

Information regarding contingencies relating to certain legal proceedings can be found in Note 11 and is incorporated here by reference.

Revenue

The following tables summarize our revenue activity by jurisdiction:

	Three Months Ended September 30,		Change in	
	2015	2014	Dollars	Percent
U.S. [1]	**$ 2,537.7**	$ 2,217.8	$ 319.9	14 %
Outside U.S.	**2,422.0**	2,657.8	(235.8)	(9)%
Revenue	**$ 4,959.7**	$ 4,875.6	$ 84.1	2 %

	Nine Months Ended September 30,		Change in	
	2015	2014	Dollars	Percent
U.S. [1]	**$ 7,276.7**	$ 6,681.5	$ 595.3	9 %
Outside U.S.	**7,306.4**	7,812.8	(506.5)	(6)%
Revenue	**$ 14,583.1**	$ 14,494.3	$ 88.8	1 %

Numbers may not add due to rounding

[1] U.S. revenue includes revenue in Puerto Rico.

The following are components of the change in revenue compared to the prior year:

	Three Months Ended September 30, 2015 vs. 2014			Nine Months Ended September 30, 2015 vs. 2014		
	U.S.	Outside U.S.	Consolidated	U.S.	Outside U.S.	Consolidated
Volume	18 %	8 %	12 %	6%	9 %	8 %
Price	(3)%	(2)%	(2)%	3%	(2)%	1 %
Foreign exchange rates	— %	(15)%	(8)%	—%	(14)%	(8)%
Percent change	14 %	(9)%	2 %	9%	(6)%	1 %

Numbers may not add due to rounding

In the U.S., for the three months ended September 30, the volume increase was driven by the Evista authorized generic, the inclusion of revenue from Novartis AH, and to a lesser extent, Cyramza and Trulicity. The price decrease was driven by a lower price for the Evista authorized generic, which more than offset higher prices for other products. For the nine months ended September 30, volume increased as the inclusion of revenue from Novartis AH and increased volume for several products, including Cyramza and Trulicity, as well as increased volume from the Evista authorized generic, were partially offset by decreased demand for Cymbalta. For the nine months ended September 30, price increased as higher prices for other products were partially offset by a lower price for the Evista authorized generic.

Outside the U.S., for the three and nine months ended September 30, the volume increase was primarily attributable to the inclusion of revenue from Novartis AH and increased volumes for the majority of pharmaceutical products.

The following table summarizes our revenue activity by product:

Product	Three Months Ended September 30, 2015 U.S. [1]	Outside U.S.	Total	Three Months Ended September 30, 2014 Total	Percent Change from 2014
			(Dollars in millions)		
Humalog	**$ 440.9**	**$ 264.1**	**$ 705.0**	$ 706.1	— %
Alimta	**296.7**	**331.8**	**628.5**	723.4	(13)%
Cialis®	**313.3**	**252.8**	**566.1**	568.4	— %
Forteo®	**160.1**	**188.8**	**348.9**	332.2	5 %
Humulin®	**185.5**	**131.2**	**316.7**	335.9	(6)%
Cymbalta	**24.6**	**218.3**	**242.9**	368.0	(34)%
Zyprexa	**46.9**	**191.0**	**237.9**	257.4	(8)%
Strattera®	**128.8**	**68.1**	**196.9**	191.9	3 %
Effient®	**106.3**	**25.8**	**132.1**	131.5	— %
Cyramza	**75.9**	**35.3**	**111.2**	28.4	N/M
Trajenta®	**38.4**	**54.3**	**92.7**	78.9	17 %
Trulicity	**63.2**	**10.5**	**73.7**	—	N/M
Evista	**15.5**	**42.5**	**58.0**	89.5	(35)%
Other human pharmaceutical products	**120.5**	**134.6**	**255.1**	275.3	(7)%
Animal health products	**392.6**	**386.2**	**778.8**	584.7	33 %
Total net product revenues	**2,409.2**	**2,335.3**	**4,744.5**	4,671.6	2 %
Collaboration and other revenue [2]	**128.5**	**86.7**	**215.2**	204.0	5 %
Revenue	**$ 2,537.7**	**$ 2,422.0**	**$ 4,959.7**	$ 4,875.6	2 %

Product	Nine Months Ended September 30, 2015 U.S. [1]	Outside U.S.	Total	Nine Months Ended September 30, 2014 Total	Percent Change from 2014
			(Dollars in millions)		
Humalog	$ 1,261.3	$ 782.0	$ 2,043.3	$ 2,056.1	(1)%
Alimta	879.4	986.4	1,865.8	2,067.0	(10)%
Cialis	869.8	802.5	1,672.3	1,668.6	— %
Forteo	426.6	543.8	970.4	941.2	3 %
Humulin	553.1	395.7	948.8	1,004.5	(6)%
Cymbalta	119.5	684.5	804.0	1,247.5	(36)%
Zyprexa	131.0	580.2	711.2	784.2	(9)%
Strattera	358.4	204.0	562.4	543.7	3 %
Effient	303.0	79.7	382.7	384.4	— %
Cyramza	208.6	57.8	266.4	42.0	N/M
Trajenta	104.3	150.7	255.0	246.1	4 %
Trulicity	115.3	20.9	136.2	—	N/M
Evista	53.3	131.2	184.5	347.8	(47)%
Other human pharmaceutical products	322.6	443.5	766.1	854.0	(10)%
Animal health products	1,159.3	1,210.0	2,369.3	1,713.3	38 %
Total net product revenues	6,865.5	7,072.9	13,938.4	13,900.4	— %
Collaboration and other revenue [2]	411.2	233.5	644.7	593.9	9 %
Revenue	$ 7,276.7	$ 7,306.4	$ 14,583.1	$ 14,494.3	1 %

[1] U.S. revenue includes revenue in Puerto Rico.

[2] Collaboration and other revenue consists primarily of royalties for Erbitux® and revenue associated with Trajenta.

NM - not meaningful

Revenues of Humalog, our injectable human insulin analog for the treatment of diabetes, increased 6 percent in the U.S. during the third quarter of 2015, driven by higher prices and, to a lesser extent, increased demand. For the first nine months of 2015, U.S. revenue increased 5 percent driven by higher prices and wholesaler buying patterns. Revenues outside the U.S. decreased 9 percent and 8 percent during the third quarter and first nine months of 2015, respectively, driven by the unfavorable impact of foreign exchange rates, partially offset by increased volume.

Revenues of Alimta, a treatment for various cancers, decreased 7 percent and 1 percent in the U.S. during the third quarter and first nine months of 2015, respectively, driven by decreased volume due to increased competitive pressures and customer buying patterns. For the first nine months of 2015, the volume decrease was partially offset by higher prices. Revenues outside the U.S. decreased 18 percent and 16 percent during the third quarter and first nine months of 2015, respectively, driven by the unfavorable impact of foreign exchange rates and, to a lesser extent, lower prices, partially offset by increased volume.

Revenues of Cialis, a treatment for erectile dysfunction and benign prostatic hyperplasia, increased 25 percent in the U.S. during the third quarter, driven by higher prices, and to a lesser extent, increased volume. For the first nine months of 2015, U.S. revenue increased 20 percent, due to higher prices. Revenues outside the U.S. decreased 21 percent and 15 percent during the third quarter and first nine months of 2015, respectively, driven by the unfavorable impact of foreign exchange rates.

Revenues of Forteo, an injectable treatment for osteoporosis in postmenopausal women and men at high risk for fracture and for glucocorticoid-induced osteoporosis in men and postmenopausal women, increased 26 percent and 20 percent in the U.S. in the third quarter and first nine months of 2015, respectively, driven by higher prices. The increase in third quarter revenue was also driven by increased volume. Revenues outside the U.S. decreased 8 percent and 7 percent in the third quarter and the first nine months of 2015, respectively, due to the unfavorable impact of foreign exchange rates, partially offset by increased volume.

Revenues of Humulin, an injectable human insulin for the treatment of diabetes, increased 12 percent in the U.S. in the third quarter of 2015, driven by higher prices. For the first nine months of 2015, U.S. revenue increased 10 percent, driven by higher prices and, to a lesser extent, increased volume. Revenues outside the U.S. decreased 23 percent and 21 percent in the third quarter and first nine months of 2015, respectively, driven by decreased volume, primarily due to the loss of a government contract in Brazil, and the unfavorable impact of foreign exchange rates.

Revenues of Cymbalta, a product for the treatment of major depressive disorder, diabetic peripheral neuropathic pain, generalized anxiety disorder, and for the treatment of chronic musculoskeletal pain and the management of fibromyalgia, decreased 65 percent and 67 percent in the U.S. for the third quarter and first nine months of 2015, respectively, due to the loss of U.S. patent exclusivity in December 2013. Revenues outside the U.S. decreased 27 percent and 23 percent in the third quarter and first nine months of 2015, respectively, driven by the unfavorable impact of foreign exchange rates and the loss of exclusivity in Europe in 2014.

Revenues of Zyprexa, a treatment for schizophrenia, acute mixed or manic episodes associated with bipolar I disorder, and bipolar maintenance, increased 149 percent and 53 percent in the U.S. in the third quarter and first nine months of 2015, respectively, driven by adjustments to the return reserve resulting from the expiration of the period to return expired product for credit. Revenues outside the U.S. decreased 20 percent and 17 percent in the third quarter and first nine months of 2015, respectively, primarily due to the unfavorable impact of foreign exchange rates. We will lose patent exclusivity for Zyprexa in Japan in December 2015. Zyprexa revenues in Japan were $302.0 million for the first nine months of 2015, compared with $345.0 million for the first nine months of 2014. The revenue decrease in Japan was due to the unfavorable impact of foreign exchange rates.

Revenues of Strattera, a treatment for attention-deficit hyperactivity disorder, increased 7 percent in the U.S. in the third quarter of 2015, driven by higher prices. For the first nine months of 2015, U.S. revenue increased 7 percent, primarily driven by higher prices and, to a lesser extent, increased demand. Revenues outside the U.S. decreased 4 percent and 3 percent during the third quarter and for the first nine months of 2015, respectively, driven by the unfavorable impact of foreign exchange rates, largely offset by increased volume.

Revenues of Effient, a product for the reduction of thrombotic cardiovascular events (including stent thrombosis) in patients with acute coronary syndrome who are managed with an artery-opening procedure known as percutaneous coronary intervention, including patients undergoing angioplasty, atherectomy, or stent placement, increased 7 percent and 5 percent in the U.S. in the third quarter and first nine months of 2015, respectively, due to higher prices, partially offset by decreased demand. Revenue outside the U.S. decreased 19 percent and 18 percent in the third quarter and first nine months of 2015, respectively, driven by the unfavorable impact of foreign exchange rates.

Revenues of Evista, a product for the prevention and treatment of osteoporosis in postmenopausal women and for reduction of risk of invasive breast cancer in postmenopausal women with osteoporosis and postmenopausal women at high risk for invasive breast cancer, amounted to $15.5 million in the U.S. in the third quarter as sales of the authorized generic led to increased volume and lower prices. For the first nine months of 2015, U.S. revenue decreased 72 percent, due to the loss of U.S. patent exclusivity in March 2014. Revenues outside the U.S. decreased 22 percent and 18 percent in the third quarter and first nine months of 2015, respectively, driven primarily by the unfavorable impact of foreign exchange rates.

Revenues of animal health products increased 25 percent and 22 percent in the U.S. in the third quarter and first nine months of 2015, respectively. Revenues outside the U.S. increased 42 percent and 59 percent in the third quarter and first nine months of 2015, respectively. The increases for the third quarter and first nine months of 2015 were primarily driven by the inclusion of revenue from Novartis AH. For the first nine months of 2015, the increase also benefited from the inclusion of revenue from Lohmann SE (Note 3).

On a pro forma basis, which reflects the 2014 revenues of Novartis AH as described in Note 3, revenues of animal health products in the U.S. would have increased 1 percent in the third quarter of 2015, driven by increased volume in food animal products, partially offset by decreased volume in companion animal products due to increased competitive pressures. For the first nine months of 2015, revenue in the U.S. would have remained relatively flat, as decreased volume was offset by higher prices, primarily for food animal products. Revenues outside the U.S. would have decreased 18 percent in the third quarter of 2015, driven by the unfavorable impact of foreign exchange rates, and to a lesser extent, decreased volume, primarily in companion animal products due to increased competitive pressures, partially offset by higher prices. Revenues outside the U.S. would have decreased 11 percent in the first nine months of 2015, driven by the unfavorable impact of foreign exchange rates and, to a lesser extent, decreased volume in companion animal products, partially offset by increased volume for food animal products and, to a lesser extent higher prices.

Gross Margin, Costs, and Expenses

Gross margin as a percent of revenue increased 1.1 percentage points to 75.1 percent for the third quarter of 2015 and increased 0.4 percentage points to 75.0 percent for the first nine months of 2015. For the third quarter and first nine months of 2015, the increase was primarily due to the favorable impact of foreign exchange rates on international inventories sold, partially offset by the inclusion of Novartis AH, and for the first nine months of 2015, inventory step-up costs.

Research and development expenses decreased 8 percent to $1.14 billion for the third quarter of 2015 and decreased 6 percent to $3.35 billion for the first nine months of 2015. For the third quarter of 2015 and first nine months of 2015, the decrease was primarily driven by the favorable impact of foreign exchange rates and a 2014 charge associated with the termination of tabalumab development, partially offset by the inclusion of Novartis AH.

Marketing, selling, and administrative expenses decreased 6 percent to $1.58 billion for the third quarter of 2015 and decreased 2 percent to $4.73 billion for the first nine months of 2015. For the third quarter and first nine months of 2015, the decrease was due to the favorable impact of foreign exchange rates and a 2014 charge associated with the Branded Prescription Drug Fee, partially offset by the inclusion of Novartis AH and expenses related to new product launches.

There were no acquired in-process research and development charges recognized in the third quarter of 2015 while $336.0 million were recognized in the first nine months of 2015, compared to charges of $95.0 million for the three and nine months ended September 30, 2014. The first nine months of 2015 included a $50.0 million payment to Hanmi related to an exclusive license and collaboration agreement for Hanmi's oral Bruton's tyrosine kinase inhibitor, a $30.0 million payment to BioNTech related to the research collaboration to discover novel cancer immunotherapies, a $200.0 million payment to Pfizer following an FDA decision allowing the resumption of Phase III clinical trials for tanezumab, and a $56.0 million payment to Innovent associated with a collaboration to develop potential oncology therapies. The charges for the third quarter of 2014 included charges totaling $95.0 million related to collaboration agreements with Immunocore and AstraZeneca. See Notes 3 and 4 for additional information.

In the third quarter of 2015, we recognized $42.4 million of asset impairment, restructuring, and other special charges, compared to $36.3 million charges for the third quarter of 2014. The 2015 charges primarily relate to integration costs for Novartis AH and severance costs. The 2014 charges primarily relate to severance, associated with cost-containment efforts, and costs related to the then pending acquisition of Novartis AH. For the first nine months of 2015 and 2014, we recognized asset impairment, restructuring, and other special charges of $222.8 million and $67.7 million, respectively. The 2015 charges were primarily attributable to integration costs for Novartis AH, severance costs, and intangible asset impairments primarily due to product rationalization resulting from our acquisition of Novartis AH. The 2014 charges primarily relate to severance costs, integration costs resulting from our then pending acquisition of Novartis AH, as well as costs associated with the closure of a manufacturing plant in our human pharmaceuticals business segment. See Note 5 for additional information.

Other–net, (income) expense was income of $86.5 million and $55.9 million for the third quarter and first nine months of 2015, respectively, compared with income of $93.5 million and $203.3 million for the same respective periods in 2014. Other income during the third quarter of 2015 was driven by net gains on investments. Other income during the first nine months of 2015 was driven by net gains on investments, partially offset by a net charge of $152.7 million related to the repurchase of $1.65 billion of debt. Other income during the third quarter and first nine months of 2014 was driven primarily by net gains on investments and income from milestones earned. See Notes 4, 6, and 13 for additional information.

The effective tax rates were 23.7 percent and 17.7 percent for the third quarter and first nine months of 2015, respectively, compared with 23.6 percent and 21.1 percent for the same respective periods in 2014. The effective tax rates for the third quarter and first nine months of 2015 reflect the impact of an increased percentage of forecasted earnings in higher taxed jurisdictions. The effective tax rates for the third quarter and first nine months of 2014 reflect the impact of a $119.0 million non-tax deductible charge associated with the U.S. Branded Prescription Drug Fee. The decrease of the effective tax rate for the first nine months of 2015, compared to the same period in 2014, is primarily due to the tax impact of the net charge related to the repurchase of debt, acquired in-process research and development charges, and asset impairment, restructuring, and other special charges. The effective tax rates for the first nine months of 2015 and 2014 include a net discrete tax benefit of approximately $18 million and $30 million, respectively. Neither period includes the benefit of certain expired U.S. tax provisions, including the research and development (R&D) tax credit.

Financial Condition

Cash and cash equivalents decreased to $3.24 billion as of September 30, 2015, compared with $3.87 billion as of December 31, 2014. Refer to the consolidated condensed statements of cash flows for additional details on the significant sources and uses of cash for the nine months ended September 30, 2015 and 2014.

In addition to our cash and cash equivalents, we held total investments of $5.18 billion and $5.52 billion as of September 30, 2015 and December 31, 2014, respectively. See Note 6 for additional details.

Total debt increased to $8.08 billion as of September 30, 2015, compared with $8.02 billion as of December 31, 2014 primarily due to the issuance of $4.45 billion of fixed-rate notes, and to a lesser extent, the increase in fair value of our hedged debt. This increase was largely offset by $2.68 billion of net repayments of commercial paper borrowings and the repayment of $1.78 billion of fixed-rate notes in connection with the purchase and redemption of certain U.S. dollar-denominated notes in June 2015. See Note 6 for additional details. At September 30, 2015, we had approximately $1.2 billion available to us under our credit facilities, which are available to support our commercial paper program. We believe that amounts accessible through existing commercial paper markets should be adequate to fund short-term borrowings.

During the nine months ended September 30, 2015, we purchased $496.6 million of shares associated with our previously announced $5.00 billion share repurchase program.

We believe that cash generated from operations, along with available cash and cash equivalents, will be sufficient to fund our normal operating needs, including dividends, share repurchases, and capital expenditures. Various risks and uncertainties, including those discussed in "Forward-Looking Statements", may affect our operating results and cash generated from operations.

See "Executive Overview—Other Matters" for information regarding recent and upcoming losses of patent protection for Cymbalta (Europe), Alimta (U.S., Europe, and Japan), and Zyprexa (Japan).

Both domestically and abroad, we continue to monitor the potential impacts of the economic environment; the creditworthiness of our wholesalers and other customers, including foreign government-backed agencies and suppliers; the uncertain impact of recent health care legislation; and various international government funding levels.

Financial Expectations for 2015

We have revised certain elements of our 2015 financial guidance. Full-year 2015 EPS are now expected to be in the range of $2.40 to $2.45. We still anticipate that 2015 revenue will be between $19.7 billion and $20.0 billion.

We still expect gross margin as a percent of revenue will be approximately 74.5 percent. Research and development expenses are now expected to be in the range of $4.6 billion to $4.8 billion. Marketing, selling, and administrative expenses are now expected to be in the range of $6.4 billion to $6.6 billion. Other—net, (income) expense is now expected to be in a range between $50 million and $75 million of income, reflecting net gains on investments realized to date, partially offset by the net charge related to the repurchase of debt.

The 2015 tax rate is now expected to be approximately 16.5 percent, reflecting the impact of an increased percentage of forecasted earnings in higher taxed jurisdictions. The 2015 expected tax rate assumes a full-year 2015 benefit of the R&D tax credit and other tax provisions up for extension.

Capital expenditures are now expected to be approximately $1.1 billion.

Our 2015 financial guidance does not include the impact of the fourth quarter acquisition of worldwide rights to an intranasal glucagon from Locemia Solutions.

Available Information on our Website

We make available through our company website, free of charge, our company filings with the Securities and Exchange Commission (SEC) as soon as reasonably practicable after we electronically file them with, or furnish them to, the SEC. The reports we make available include annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements, registration statements, and any amendments to those documents.

The website link to our SEC filings is **http://investor.lilly.com/sec.cfm**.

Item 4. Controls and Procedures

(a) *Evaluation of Disclosure Controls and Procedures*. Under applicable SEC regulations, management of a reporting company, with the participation of the principal executive officer and principal financial officer, must periodically evaluate the company's "disclosure controls and procedures," which are defined generally as controls and other procedures of a reporting company designed to ensure that information required to be disclosed by the reporting company in its periodic reports filed with the SEC (such as this Form 10-Q) is recorded, processed, summarized, and reported on a timely basis.

Our management, with the participation of John C. Lechleiter, Ph.D., chairman, president, and chief executive officer, and Derica W. Rice, executive vice president, global services, and chief financial officer, evaluated our disclosure controls and procedures as of September 30, 2015, and concluded that they are effective.

(b) *Changes in Internal Controls*. During the third quarter of 2015, there were no changes in our internal control over financial reporting that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. We acquired Novartis AH on January 1, 2015. As part of the ongoing integration activities, we will complete an assessment of existing controls and incorporate our controls and procedures into the acquired operations, as appropriate.

PART II. Other Information

Item 1. Legal Proceedings

See "Notes to Consolidated Condensed Financial Statements—Note 11, Contingencies" for information on various legal proceedings, including but not limited to:

- The patent litigation and administrative proceedings involving Alimta and Effient.
- The product liability litigation involving Actos®, Byetta®, and Prozac®.
- The employee litigation in Brazil.

That information is incorporated into this Item by reference.

This Item should be read in conjunction with the Legal Proceedings disclosures in our Annual Report on Form 10-K for the year ended December 31, 2014 (Part I, Item 3).

Other Product Liability Litigation

We are currently a defendant in a variety of other product liability lawsuits in the U.S.

In October 2012, we were named as a defendant in a purported class-action lawsuit in the U.S. District Court for the Central District of California (*Saavedra et al v. Eli Lilly and Company*) involving Cymbalta. The plaintiffs assert claims under the consumer protection statutes of four states and seek declaratory, injunctive, and monetary relief for various alleged economic injuries arising from discontinuing treatment with Cymbalta and purported to represent a class of all persons within the U.S. who purchased and/or paid for Cymbalta. In December 2014, the district court denied the plaintiffs' motion for class certification. Plaintiffs filed a petition with the U.S. Court of Appeals for the Ninth Circuit requesting permission to file an interlocutory appeal of the denial of class certification, which was denied. Plaintiffs filed a second motion for certification under the consumer protection acts of two states. The district court denied that motion for class certification in July 2015.

Additionally, we have been named in approximately 75 individual and multi-plaintiff lawsuits filed in various federal and state courts by claimants alleging injuries arising from discontinuation of treatment with Cymbalta. Counsel for plaintiffs filed a petition seeking to have then-filed cases and an unspecified number of future cases coordinated into a federal multi-district litigation (MDL) in the U.S. District Court for the Central District of California. In December 2014, the Judicial Panel on Multidistrict Litigation (JPML) denied the plaintiffs' petition for creation of an MDL. Plaintiffs' counsel subsequently filed a second petition seeking MDL consolidation, which petition was denied by the JPML in October 2015. A few individual and multi-plaintiff cases have been coordinated in Los Angeles Superior Court. The first individual product liability cases were tried in August 2015, and resulted in defense verdicts against four plaintiffs.

We have been named as a defendant in approximately 280 U.S. product liability lawsuits involving Axiron®. In more than one-third of the cases, other manufacturers of testosterone are named as co-defendants. These lawsuits have been consolidated in a federal MDL in the U.S. District Court for the Northern District of Illinois. The cases generally allege cardiovascular and related injuries. We believe these claims are without merit and are prepared to defend against them vigorously.

Other Patent Litigation

We have filed applications with the FDA and regulators in Europe, Japan, and other countries seeking approval to market our new insulin glargine product following the expiration of the compound patent for insulin glargine (generally May 2015). In January 2014, Sanofi-Aventis U.S. LLC (Sanofi) filed a lawsuit against us in the U.S. District Court for the District of Delaware alleging patent infringement with respect to our product. Legal proceedings were also underway in France, Japan, and Canada related to various patents asserted by Sanofi against our insulin glargine product and the Kwikpen™ insulin delivery device. In September 2015, we entered into a global settlement agreement to resolve these patent disputes with Sanofi. As a part of the agreement, we and our alliance partner, Boehringer Ingelheim, can launch Basaglar in the U.S. on December 15, 2016. Under the terms of the agreement, Sanofi has granted us a royalty-bearing license so we can manufacture and sell Basaglar in the Kwikpen device globally.

Boehringer Ingelheim, our partner in marketing and development of Tradjenta®, is engaged in various U.S. patent litigation matters involving Tradjenta/Jentadueto® in accordance with the procedures set out in the Drug Price Competition and Patent Term Restoration Act of 1984. Eleven groups of companies submitted Abbreviated New

Drug Applications seeking approval to market generic versions of Tradjenta prior to the expiration of Tradjenta/Jentadueto patents, alleging certain patents, including in some allegations the compound patent, are invalid or would not be infringed.

Other Matters

In September 2015, we were advised that the U.S. Attorney's office for the Eastern District of Pennsylvania and the Civil Division of the U.S. Department of Justice are conducting an inquiry concerning our treatment of certain distribution service agreements with wholesalers when calculating and reporting Average Manufacturer Prices in connection with the Medicaid drug rebate program. We are voluntarily responding to this request.

We are also a defendant in other litigation and investigations, including product liability, patent, employment, and premises liability litigation, of a character we regard as normal to our business.

Item 1A. Risk Factors

Our material risk factors are disclosed in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2014. There have been no material changes from the risk factors previously disclosed in our Annual Report.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

The following table summarizes the activity related to repurchases of our equity securities during the three months ended September 30, 2015:

Period	Total Number of Shares Purchased (in thousands)	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs (in thousands)	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs (in millions)
July 2015	517.3	$ 84.65	517.3	$ 3,220.7
August 2015	211.3	81.89	211.3	3,203.4
September 2015	—	—	—	3,203.4
Total	728.6	83.85	728.6	

In October 2013, we announced a $5.00 billion share repurchase program. During the three months ended September 30, 2015, we purchased $61.1 million of shares under the program.

Item 5. Other Information

Disclosure Pursuant to Section 219 of the Iran Threat Reduction and Syria Human Rights Act of 2012

Section 219 of the Iran Threat Reduction and Syria Human Rights Act of 2012 (ITRSHRA), which added Section 13(r) of the Exchange Act, requires disclosure by public companies of, among other things, certain transactions involving the Government of Iran, as well as entities and individuals designated under Executive Order 13382. ITRSHRA requires companies to disclose these types of transactions even if they were permissible under U.S. law or were conducted by a non-U.S. subsidiary in accordance with the local law under which such entity operates.

As a global pharmaceutical company, we conduct business in multiple jurisdictions throughout the world. Our activities have included supplying medicines for patient use in Iran. We ship our products to Iran and conduct related activities in accordance with our corporate policies and licenses issued by the U.S. Department of the Treasury's Office of Foreign Assets Control.

Pursuant to U.S. government authorizations, we, through a non-U.S. subsidiary, shipped our products to authorized customers in Iran. We recently completed a review in which we determined that between the last quarter of 2013 and the first half of 2015, some of these shipments, which were arranged by a third-party logistics company, were sent to Iran on aircraft owned or operated by Iran Air, which is a designated air carrier under Executive Order 13382. Neither we nor our affiliate entered into agreements with nor made any direct payments to Iran Air. We generated no gross revenues or net profits during the relevant periods attributable to the use of this carrier. Our affiliate paid air freight expenses associated with these shipments to the third-party logistics company in the total amount of approximately $51,700 using exchange rates in effect at the time of each shipment. We have voluntarily self-disclosed this matter to the U.S. government. We also have instructed the third-party logistics company that

arranged these shipments from our non-U.S. affiliate not to use Iran Air to ship our products in the future, and we are implementing additional controls to address this issue.

Item 6. Exhibits

The following documents are filed as exhibits to this Report:

EXHIBIT 3.1	Amended Articles of Incorporation
EXHIBIT 3.2	By-laws, as amended
EXHIBIT 12.	Statement re: Computation of Ratio of Earnings to Fixed Charges
EXHIBIT 31.1	Rule 13a-14(a) Certification of John C. Lechleiter, Ph.D., Chairman, President, and Chief Executive Officer
EXHIBIT 31.2	Rule 13a-14(a) Certification of Derica W. Rice, Executive Vice President, Global Services and Chief Financial Officer
EXHIBIT 32.	Section 1350 Certification
EXHIBIT 101.	Interactive Data File

Signatures

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.

ELI LILLY AND COMPANY
(Registrant)

Date: October 30, 2015

/s/James B. Lootens
James B. Lootens
Corporate Secretary

Date: October 30, 2015

/s/Donald A. Zakrowski
Donald A. Zakrowski
Vice President, Finance and Chief Accounting Officer

Index to Exhibits

The following documents are filed as a part of this Report:

Exhibit	
EXHIBIT 3.1	Amended Articles of Incorporation are incorporated by reference to Exhibit 3.1 to the Company's Report on Form 10-K for the year ended December 31, 2013.
EXHIBIT 3.2	By-laws, as amended, are incorporated by reference to Exhibit 99 to the Company's Report on Form 8-K filed February 27, 2012.
EXHIBIT 12.	Statement re: Computation of Ratio of Earnings to Fixed Charges
EXHIBIT 31.1	Rule 13a-14(a) Certification of John C. Lechleiter, Ph.D., Chairman, President, and Chief Executive Officer
EXHIBIT 31.2	Rule 13a-14(a) Certification of Derica W. Rice, Executive Vice President, Global Services and Chief Financial Officer
EXHIBIT 32.	Section 1350 Certification
EXHIBIT 101.	Interactive Data File

EXHIBIT 12. Statement Re: Computation of Ratio of Earnings to Fixed Charges
(Unaudited)

ELI LILLY AND COMPANY AND SUBSIDIARIES

	Nine Months Ended September 30,	Years Ended December 31,				
	2015	2014	2013	2012	2011	2010
	(Dollars in millions)					
Consolidated pretax income	**$ 2,345.4**	$ 3,000.3	$ 5,889.3	$ 5,408.2	$ 5,349.5	$ 6,525.2
Interest [1]	**159.3**	187.1	184.2	198.8	211.7	211.5
Less interest capitalized during the period	**(42.3)**	(38.3)	(24.1)	(21.0)	(25.7)	(26.0)
Earnings	**$ 2,462.4**	$ 3,149.1	$ 6,049.4	$ 5,586.0	$ 5,535.5	$ 6,710.7
Fixed charges	**$ 159.3**	$ 187.1	$ 184.2	$ 198.8	$ 211.7	$ 211.5
Ratio of earnings to fixed charges	**15.5**	16.8	32.8	28.1	26.1	31.7

(1) Interest is based upon interest expense reported as such in the consolidated condensed statements of operations and does not include any interest related to unrecognized tax benefits, which is included in income tax expense.

EXHIBIT 31.1 Rule 13a-14(a) Certification of John C. Lechleiter, Chairman, President, and Chief Executive Officer

CERTIFICATIONS

I, John C. Lechleiter, certify that:

1. I have reviewed this report on Form 10-Q of Eli Lilly and Company;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and

5. The registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s Board of Directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize, and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: October 30, 2015

By: /s/John C. Lechleiter

John C. Lechleiter, Ph.D.

Chairman, President, and Chief Executive Officer

EXHIBIT 31.2 Rule 13a-14(a) Certification of Derica W. Rice, Executive Vice President, Global Services, and Chief Financial Officer

CERTIFICATIONS

I, Derica W. Rice, certify that:

1. I have reviewed this report on Form 10-Q of Eli Lilly and Company;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and

5. The registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s Board of Directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize, and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: October 30, 2015

By: /s/ Derica W. Rice

Derica W. Rice

Executive Vice President, Global Services,
and Chief Financial Officer

EXHIBIT 32. Section 1350 Certification

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of Eli Lilly and Company, an Indiana corporation (the “Company”), does hereby certify that, to the best of their knowledge:

The Quarterly Report on Form 10-Q for the quarter ended September 30, 2015 (the “Form 10-Q”) of the Company fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 and information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: October 30, 2015

/s/John C. Lechleiter

John C. Lechleiter, Ph.D.

Chairman, President, and Chief Executive Officer

Date: October 30, 2015

/s/Derica W. Rice

Derica W. Rice

Executive Vice President, Global Services, and Chief Financial Officer