

LILLY ELI & CO
Form 10-Q
April 30, 2015

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 MARCH 31, 2015

COMMISSION FILE NUMBER 001-6351

ELI LILLY AND COMPANY

(Exact name of Registrant as specified in its charter)

INDIANA

(State or other jurisdiction of
incorporation or organization)

35-0470950

(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

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 Non-accelerated filer Smaller reporting Company

(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 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

The number of shares of common stock outstanding as of April 20, 2015:

Class	Number of Shares Outstanding
Common	1,109,741,140

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” 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, particularly under the captions “Forward-Looking Statements” and “Risk Factors.”

All forward-looking statements 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	
	March 31,	
	2015	2014
Revenue	\$4,644.7	\$4,683.1
Cost of sales	1,192.7	1,222.7
Research and development	1,039.3	1,109.3
Marketing, selling, and administrative	1,523.5	1,484.9
Acquired in-process research and development (Note 3)	256.0	—
Asset impairment, restructuring, and other special charges (Note 5)	108.0	31.4
Other—net, (income) expense (Note 14)	(92.7) (56.0
	4,026.8	3,792.3
Income before income taxes	617.9	890.8
Income taxes (Note 10)	88.4	162.9
Net income	\$529.5	\$727.9
Basic earnings per share:		
Weighted-average number of common shares outstanding, including incremental shares	1,064.2	1,072.7
Basic earnings per share	\$0.50	\$0.68
Diluted earnings per share:		
Weighted-average number of common shares outstanding, including incremental shares and stock options	1,067.0	1,075.8
Diluted earnings per share	\$0.50	\$0.68
Dividends paid per share	\$0.50	\$0.49

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 March 31,	
	2015	2014
Net income	\$529.5	\$727.9
Other comprehensive income (loss), net of tax (Note 13)	(665.7) 45.4
Comprehensive income (loss)	\$(136.2) \$773.3

See Notes to Consolidated Condensed Financial Statements.

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

	March 31, 2015 (Unaudited)	December 31, 2014
Assets		
Current Assets		
Cash and cash equivalents (Note 6)	\$3,064.8	\$3,871.6
Short-term investments (Note 6)	1,075.0	955.4
Accounts receivable, net of allowances of \$49.9 (2015) and \$55.0 (2014)	3,142.5	3,234.6
Other receivables	683.2	566.7
Inventories	2,980.2	2,740.0
Prepaid expenses and other	797.0	811.5
Total current assets	11,742.7	12,179.8
Other Assets		
Restricted cash (Note 3)	—	5,405.6
Investments (Note 6)	4,576.5	4,568.9
Goodwill (Note 7)	3,946.9	1,758.1
Other intangibles, net (Note 7)	4,947.7	2,884.2
Sundry	2,489.4	2,417.7
Total other assets	15,960.5	17,034.5
Property and Equipment		
Land, buildings, equipment, and construction in progress	16,213.3	16,029.3
Accumulated depreciation	(8,262.6)	(8,065.4)
Property and equipment, net	7,950.7	7,963.9
Total assets	\$35,653.9	\$37,178.2
Liabilities and Equity		
Current Liabilities		
Short-term borrowings and current maturities of long-term debt	\$805.4	\$2,688.7
Accounts payable	1,179.6	1,128.1
Employee compensation	518.7	759.0
Sales rebates and discounts	2,025.7	2,068.8
Dividends payable	—	530.3
Deferred income taxes	1,296.7	1,466.5
Other current liabilities	2,516.8	2,566.1
Total current liabilities	8,342.9	11,207.5
Other Liabilities		
Long-term debt	7,415.3	5,367.7
Accrued retirement benefits (Note 11)	2,520.8	2,562.9
Long-term income taxes payable	954.0	998.5
Other noncurrent liabilities	1,474.4	1,653.5
Total other liabilities	12,364.5	10,582.6
Commitments and Contingencies (Note 12)		
Eli Lilly and Company Shareholders' Equity (Notes 8 and 9)		
Common stock	694.1	694.6
Additional paid-in capital	5,279.6	5,292.3
Retained earnings	16,706.8	16,482.7
Employee benefit trust	(3,013.2)	(3,013.2)
Accumulated other comprehensive loss (Note 13)	(4,657.5)	(3,991.8)

Edgar Filing: LILLY ELI & CO - Form 10-Q

Cost of common stock in treasury	(90.0) (91.4)
Total Eli Lilly and Company shareholders' equity	14,919.8	15,373.2	
Noncontrolling interests	26.7	14.9	
Total equity	14,946.5	15,388.1	
Total liabilities and equity	\$35,653.9	\$37,178.2	

See Notes to Consolidated Condensed Financial Statements.

5

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

	Three Months Ended	
	March 31,	
	2015	2014
Cash Flows from Operating Activities		
Net income	\$529.5	\$727.9
Adjustments to Reconcile Net Income to Cash Flows from Operating Activities:		
Depreciation and amortization	357.5	348.8
Change in deferred income taxes	(107.1)) 70.0
Stock-based compensation expense	48.9	38.3
Payments for terminations of interest rate swaps	(206.3)) (6.9)
Acquired in-process research and development	256.0	—
Other changes in operating assets and liabilities, net of acquisitions and divestitures	(913.7)) (917.8)
Other non-cash operating activities, net	(49.6)) 12.0
Net Cash Provided by (Used for) Operating Activities	(84.8)) 272.3
Cash Flows from Investing Activities		
Net purchases of property and equipment	(188.6)) (202.0)
Proceeds from sales and maturities of short-term investments	507.2	1,166.9
Purchases of short-term investments	(165.8)) (402.8)
Proceeds from sales of noncurrent investments	596.2	2,633.4
Purchases of noncurrent investments	(924.4)) (2,770.2)
Restricted cash released for acquisition	5,405.6	—
Cash paid for acquisitions, net of cash acquired	(5,276.7)) —
Proceeds from sale of product rights	410.0	—
Purchase of in-process research and development	(200.0)) —
Other investing activities, net	(2.7)) (36.9)
Net Cash Provided by Investing Activities	160.8	388.4
Cash Flows from Financing Activities		
Dividends paid	(527.9)) (524.1)
Net change in short term borrowings	(2,088.6)) —
Proceeds from issuance of long-term debt	2,182.0	992.9
Repayment of long-term debt	(1.5)) (1,002.0)
Purchases of common stock	(310.6)) (55.0)
Other financing activities, net	45.4	(6.9)
Net Cash Used for Financing Activities	(701.2)) (595.1)
Effect of exchange rate changes on cash and cash equivalents	(181.6)) (7.8)
Net increase (decrease) in cash and cash equivalents	(806.8)) 57.8
Cash and cash equivalents at January 1	3,871.6	3,830.2
Cash and Cash Equivalents at March 31	\$3,064.8	\$3,888.0
See Notes to Consolidated Condensed Financial Statements		

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 dilutive stock options and other incremental shares.

Note 2: Implementation of New Financial Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued a final standard on revenue recognition. Under the new standard, an entity should recognize revenue 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. In order to do so, an entity would follow the five-step process for in-scope transactions: 1) identify the contract with a customer, 2) identify the separate performance obligations in the contract, 3) determine the transaction price, 4) allocate the transaction price to the separate performance obligations in the contract, and 5) recognize revenue when (or as) the entity satisfies a performance obligation. For public entities, the provisions of the new standard are effective for annual reporting periods beginning after December 15, 2016 and early adoption is not permitted. In April 2015, the FASB proposed to defer the effective date of the new revenue recognition standard by one year, but to permit entities to adopt the new standard on the original effective date if they choose. This proposed delay is not a final decision and will be subject to the FASB's due process requirements, which include a period for public comment. 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. 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 condensed 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.

In addition to the acquisitions of businesses, we also acquired assets in development in 2015 which are further discussed 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 March 31, 2015, we recorded acquired IPR&D charges of \$256.0 million related to the collaboration with Innovent Biologics, Inc. (Innovent) and the upfront fee of \$200.0 million related to tanezumab. See Note 4 for additional information related to the tanezumab arrangement. There were no acquired IPR&D charges for the three months ended March 31, 2014.

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 \$5.29 billion, subject to working capital and other adjustments. 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 United States (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	\$386.7	
Acquired in-process research and development	294.0	
Marketed products ¹	1,940.0	
Property and equipment	218.9	
Assets held for sale (primarily the U.S. Sentinel rights)	426.7	
Deferred income taxes	(84.9)
Other assets and liabilities - net	(86.2)
Total identifiable net assets	3,095.2	
Goodwill ²	2,196.8	
Total consideration transferred - net of cash acquired	\$5,292.0	

¹ These intangible assets will be amortized on a straight-line basis over their estimated useful lives, which 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 Animal Health operations, future unidentified projects and products, and the assembled workforce of Novartis AH. Approximately \$900 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 months ended March 31, 2015 includes Novartis AH revenue of \$236.4 million. 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 March 31,	
	2015	2014
Revenue	\$4,644.7	\$4,934.9
Net Income	574.9	627.1
Diluted earnings per share	0.54	0.58

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

• Additional amortization expense of approximately \$26 million in 2014 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 \$63 million related to the fair value adjustments to acquisition date inventory that has been sold in the three months ended March 31, 2015.

• A decrease to pro forma net income of approximately \$20 million in 2014 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. Amounts recorded in connection with this acquisition include \$275.4 million of marketed product assets, \$23.9 million of other intangible assets, \$89.8 million of property and equipment, \$243.7 million of goodwill, and \$92.7 million of deferred tax liabilities, with \$51.1 million of other net assets. Goodwill associated with this acquisition is not deductible for tax purposes.

Product and Other Acquisitions

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.

In March 2015, we entered into a collaboration agreement with Innovent to develop and commercialize a portfolio of cancer treatments. Currently, the compounds included in the collaboration are Innovent's monoclonal antibody targeting protein CD-20, which has received investigational new drug approval in China to begin Phase I development, a pre-clinical immuno-oncology molecule, and our cMet monoclonal antibody, which is in pre-clinical development for China. 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 molecule outside of China. We will also receive rights to develop and commercialize up to three pre-clinical bispecific immuno-oncology molecules outside of China. Separate from the collaboration, we will continue the development of our cMet monoclonal antibody gene outside of China. Under the terms of the agreement, we paid an upfront fee of \$56.0 million, which was expensed as acquired IPR&D in the first quarter of 2015.

In March 2015, we entered into a collaboration agreement with Hanmi Pharmaceutical Co., Ltd. (Hanmi) to develop and commercialize Hanmi's oral Bruton's tyrosine kinase inhibitor known as HM71224, a compound being investigated for the treatment of autoimmune and other diseases. HM71224 has completed Phase I testing, and we and Hanmi will progress HM71224 into Phase II testing for patients with rheumatoid arthritis, lupus, lupus nephritis, Sjögren's syndrome, and other related conditions. In April 2015, we received Hart-Scott-Rodino Antitrust Improvements Act clearance associated with this transaction, which was a condition to closing. 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. We expect to pay an upfront fee of \$50.0 million in cash and a related charge will be recorded for acquired IPR&D in the second quarter of 2015.

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. We recognized collaboration and other revenue of \$196.1 million and \$181.2 million for the three months ended March 31, 2015 and 2014, respectively. 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® in the U.S.).

Trajenta was approved in 2011 and launched in the U.S., Japan, certain countries in Europe, and other countries. Jentaducto®, the single pill combination of linagliptin and metformin hydrochloride, is being commercialized with Trajenta and included in the Trajenta family results. Jardiance was approved in Europe, the U.S., and Japan in May, August, and December 2014, respectively. The product was launched in certain European countries and the U.S. in the third quarter of 2014. Glyxambi®, the single pill combination of linagliptin and empagliflozin, launched in the U.S. in March 2015, and is included in the Jardiance family results. Our new insulin glargine product was approved by the European Commission in Europe in September 2014 and regulatory authorities in Japan in December 2014. 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 is subject to a delay of up to 30 months as a result of patent infringement litigation filed by Sanofi, which markets Lantus® (insulin glargine). Under the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act), the initiation of the lawsuit automatically invoked a stay of final FDA approval for a period of 30 months (until July 2016), which may be shortened in the event of an earlier court decision in our favor.

In connection with the approval of Trajenta in the U.S., Europe, and Japan, we paid \$478.7 million in success-based regulatory milestones, all of which were capitalized as intangible assets and are being amortized to cost of sales. In connection with the approval of Jardiance in the U.S., Europe, and Japan, we paid success-based regulatory milestones of \$300.5 million, which were capitalized as intangible assets and will be amortized to cost of sales. We incurred milestone-related expenses of \$97.2 million in connection with regulatory submissions for Jardiance in the U.S., Europe, and Japan during 2013. These regulatory submission milestones were recorded as research and development expenses.

Upon the approval of our new insulin glargine product in Europe and Japan during 2014, we recorded, as deferred revenue, a \$62.5 million milestone which will be amortized to collaboration and other revenue upon product launch in Europe and Japan through the term of the collaboration (2029). During 2013, we earned \$50.0 million in milestones for the regulatory submissions of our new insulin glargine product in the U.S., Europe, and Japan. These submission milestones were recorded as income in other-net, (income) expense. In the future, we will be eligible to receive up to \$187.5 million in success-based regulatory milestones on our new insulin glargine product.

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 will continue their co-promotion work in 17 countries, representing over 90 percent of the collaboration's anticipated market opportunity. In the other countries, the companies will 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 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 our new insulin glargine product 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 and, if successful, 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, and 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. Our revenue related to Trajenta was \$82.3 million and \$76.9 million for the three months ended March 31, 2015 and 2014, respectively. Our revenue related to Jardiance was not material for the three months ended March 31, 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 the U.S. and Canada (Merck KGaA). Certain rights to Erbitux outside the U.S. and Canada (collectively 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 March 31,	
	2015	2014
Net product revenues	\$13.8	\$13.2
Collaboration and other revenue	74.4	77.7
Revenue	\$88.2	\$90.9

Bristol-Myers Squibb Company

Pursuant to commercial agreements with Bristol-Myers Squibb Company and E.R. Squibb (collectively, BMS), we have been co-developing Erbitux in North America with BMS exclusively, and in Japan with BMS and Merck through 2032. In April 2015, we and BMS agreed to modify the existing arrangement to provide for the transfer to us of BMS's commercialization rights with respect to Erbitux in North America with the transition expected to be completed in the fourth quarter of 2015. 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 sales of Erbitux in North America estimated to average 38 percent from the completion of the transition through September 2018. The transfer of the commercialization rights will be accounted for as an acquisition of a business at the time control of the business is transferred to us. 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 beginning on the completion of the transition of the Erbitux commercialization rights to us through the co-development period in North America, as set forth in the original agreement, which was scheduled to expire in September 2018.

Until the effective date of the transfer of the business, the existing arrangements between us and BMS, which are set forth in this paragraph, will remain in effect. Erbitux research and development and other costs continue to be shared by both companies according to a predetermined ratio. Responsibilities associated with clinical and other ongoing studies are apportioned between the parties under the current 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 are recorded as a reduction to the respective expense line items on the consolidated statement of operations. We receive a distribution fee in the form of a royalty from BMS, based on a percentage of net sales in North America, which is recorded in collaboration and other revenue. Royalties due to third parties are recorded as a reduction of collaboration and other revenue, net of any royalty reimbursements due from third parties. We are 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 will purchase all of its requirements of API for commercial use from us, subject to certain stipulations per the agreement. Sales of Erbitux to BMS for commercial use are 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. A third party manufactures bulk product, and we produce the finished product for our exclusive and co-promotion territories. 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. All royalties due to Daiichi Sankyo and the third-party manufacturer are recorded in cost of sales. Effient revenues were \$121.8 million and \$119.3 million for the three months ended March 31, 2015 and 2014, respectively.

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 their 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 March 31, 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. In March 2015, the FDA lifted a partial clinical hold after reviewing the nonclinical data which was submitted in February 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. Tanezumab is currently in Phase III development. 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. Amylin also agreed to make future revenue-sharing payments to us in an amount equal to 15.0 percent of its global net sales of exenatide products until Amylin made aggregate payments to us of \$1.20 billion plus interest, which would accrue at 9.5 percent. Upon completion of the acquisition of Amylin by Bristol-Myers Squibb Company in August 2012, Amylin's obligation of \$1.26 billion, including accrued interest, was paid in full, with \$1.21 billion representing a prepayment of the obligation. 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. We were responsible for certain development costs related to certain clinical trials outside the U.S. that we were conducting as of the date of the termination agreement as well as commercialization costs outside the U.S. until the commercial rights were transferred to Amylin.

Payments received from Amylin were allocated 65 percent to the U.S., which was treated as a contract termination, and 35 percent to the business outside the U.S., which was treated as the disposition of a business. The allocation was based upon relative fair values. The revenue-sharing income allocated to the U.S. was recognized as collaboration and other revenue, consistent with our policy for royalty revenue, while the income related to the prepayment of Amylin's obligation allocated to the U.S. was recognized in other-net, (income) expense. 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. and our sales of Byetta pen delivery devices to Amylin. 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 will not record any additional revenues from exenatide in 2015 or in future periods.

Summary of Commission and Profit-Share Payments

The aggregate amount of marketing, selling, and administrative expense associated with our commission and profit-sharing obligations for the collaborations and other arrangements described above was \$49.3 million and \$48.0 million for the three months ended March 31, 2015 and 2014, respectively.

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

We recognized asset impairment, restructuring, and other special charges of \$108.0 million and \$31.4 million during the three months ended March 31, 2015 and 2014, respectively. Substantially all of the 2015 charges were attributable to our animal health business segment and related primarily to integration costs, intangible asset impairments due to product rationalization, and severance costs resulting from our acquisition of Novartis AH. Substantially all of the 2014 charges were attributable to our human pharmaceuticals business segment and related primarily to severance costs for actions taken to reduce our cost structure.

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 March 31, 2015, we had outstanding foreign currency forward commitments to purchase 559.2 million U.S. dollars and sell 521.8 million euro, commitments to purchase 1.23 billion euro and sell 1.31 billion U.S. dollars, commitments to purchase 308.1 million U.S. dollars and sell 37.22 billion Japanese yen, commitments to purchase 142.8 million British pounds and sell 200.3 million euro, and commitments to purchase 285.2 million U.S. dollars and sell 192.7 million British pounds, which will all settle within 30 days.

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 March 31, 2015, substantially all of our total long-term debt is at a fixed rate. We have converted approximately 50 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.

Investments in debt securities are subject to different interest rate risks based on their maturities. We may manage the average maturity of our investments in debt securities to achieve economic returns using interest rate contracts, none of which are designated as hedging instruments. As of March 31, 2015, there were no interest rate contracts on investments in debt 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.

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 discussed above, we terminated forward-starting interest rate contracts in designated cash flow hedging instruments with a total 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.

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 March 31,	
	2015	2014
Fair value hedges:		
Effect from hedged fixed-rate debt	\$58.9	\$51.8
Effect from interest rate contracts	(58.9) (51.8
Cash flow hedges:		
Effective portion of losses on equity contracts reclassified from accumulated other comprehensive loss ⁽¹⁾	—	39.5
Effective portion of losses on interest rate contracts reclassified from accumulated other comprehensive loss	2.7	2.2
Net (gains) losses on foreign currency exchange contracts not designated as hedging instruments	23.3	(0.3

⁽¹⁾ Realized gains on the sale of the underlying equity securities recognized in other-net, (income) expense for the three months ended March 31, 2014 were \$69.0 million.

The effective portion of net gains on equity contracts in designated cash flow hedging relationships recorded in other comprehensive income (loss) was \$85.9 million for the three months ended March 31, 2014. There were no equity contracts in designated cash flow hedging relationships during the three months ended March 31, 2015.

During the next 12 months, we expect to reclassify from accumulated other comprehensive loss to earnings \$14.6 million of pretax net losses on cash flow hedges of the variability in expected future interest payments on our floating rate debt.

During the three months ended March 31, 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.

Edgar Filing: LILLY ELI & CO - Form 10-Q

Fair Value of Financial Instruments

The following tables summarize certain fair value information at March 31, 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			Fair Value
			Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
March 31, 2015						
Cash equivalents	\$1,056.8	\$1,056.8	\$1,005.0	\$51.8	\$—	\$1,056.8
Short-term investments:						
U.S. government and agencies	\$282.2	\$282.2	\$278.2	\$4.0	\$—	\$282.2
Corporate debt securities	790.2	789.3	—	790.2	—	790.2
Other securities	2.6	2.6	—	2.6	—	2.6
Short-term investments	\$1,075.0	\$1,074.1				
Noncurrent investments:						
U.S. government and agencies	\$698.0	\$696.8	\$676.0	\$22.0	\$—	\$698.0
Corporate debt securities	2,369.5	2,362.6	—	2,369.5	—	2,369.5
Mortgage-backed securities	223.0	222.1	—	223.0	—	223.0
Asset-backed securities	486.0	486.1	—	486.0	—	486.0
Other securities	4.9	4.9	—	4.9	—	4.9
Marketable equity securities	284.5	54.8	284.5	—	—	284.5
Equity method and other investments ⁽¹⁾	510.6	510.6				
Noncurrent investments	\$4,576.5	\$4,337.9				
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
	446.7	446.7				

Equity method and other
investments⁽¹⁾

Noncurrent investments	\$4,568.9	\$4,415.9
------------------------	-----------	-----------

⁽¹⁾ Fair value not applicable

17

Edgar Filing: LILLY ELI & CO - Form 10-Q

Description	Carrying Amount	Fair Value Measurements Using			Fair Value
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
Short-term borrowings ⁽¹⁾					
March 31, 2015	\$(590.0)	\$—	\$(590.0)	\$—	\$(590.0)
December 31, 2014	(2,680.6)	—	(2,680.6)	—	(2,680.6)
Long-term debt, including current portion					
March 31, 2015	\$(7,630.7)	\$—	\$(8,053.4)	\$—	\$(8,053.4)
December 31, 2014	(5,375.8)	—	(5,722.1)	—	(5,722.1)

⁽¹⁾ Represents short-term commercial paper borrowings

Description	Carrying Amount	Fair Value Measurements Using			Fair Value
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
March 31, 2015					
Risk-management instruments					
Interest rate contracts designated as hedging instruments:					
Other receivables	\$2.2	\$—	\$2.2	\$—	\$2.2
Sundry	158.5	—	158.5	—	158.5
Foreign exchange contracts not designated as hedging instruments:					
Other receivables	31.9	—	31.9	—	31.9
Other current liabilities	(21.3)	—	(21.3)	—	(21.3)
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.

18

The table below summarizes the contractual maturities of our investments in debt securities measured at fair value as of March 31, 2015:

	Maturities by Period				
	Total	Less Than 1 Year	2-5 Years	6-10 Years	More Than 10 Years
Fair value of debt securities	\$4,856.4	\$1,075.0	\$3,224.8	\$317.2	\$239.4

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:

	March 31, 2015	December 31, 2014
Unrealized gross gains	\$250.7	\$171.9
Unrealized gross losses	11.2	18.3
Fair value of securities in an unrealized gain position	2,885.6	1,778.8
Fair value of securities in an unrealized loss position	2,048.3	3,129.2

Other-than-temporary impairment losses on investment securities of \$3.6 million was recognized in the consolidated condensed statement of operations for the three months ended March 31, 2015. There were no other-than-temporary impairment losses recognized in the consolidated condensed statement of operations for the three months ended March 31, 2014. For fixed-income securities, the amount of credit losses represents the difference between the present value of cash flows expected to be collected on these securities and the amortized cost. Factors considered in assessing the credit loss were the position in the capital structure, vintage and amount of collateral, delinquency rates, current credit support, and geographic concentration.

The securities in an unrealized loss position include 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 90 percent of the securities in a loss position are investment-grade debt securities. At this time, there is no indication of default on interest or principal payments for debt securities other than those for which an other-than-temporary impairment charge has been recorded. 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 we have concluded that no additional other-than-temporary loss is required to be charged to earnings as of March 31, 2015.

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

	Three Months Ended March 31,	
	2015	2014
Proceeds from sales	\$969.8	\$3,742.2
Realized gross gains on sales	54.5	79.8
Realized gross losses on sales	0.7	4.0

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 and other indefinite-lived intangible assets were as follows:

	March 31, 2015	December 31, 2014
Goodwill (by segment):		
Human pharmaceutical products	\$ 1,359.1	\$ 1,359.4
Animal health	2,587.8	398.7
Total goodwill	3,946.9	1,758.1
In-process research and development	295.7	11.4
Total indefinite-lived intangible assets	\$ 4,242.6	\$ 1,769.5

The increases in goodwill for the animal health segment and acquired IPR&D in 2015 are due to the acquisition of Novartis AH (Note 3).

The components of finite-lived intangible assets were as follows:

Description	March 31, 2015			December 31, 2014		
	Carrying Amount— Gross	Accumulated Amortization	Carrying Amount— Net	Carrying Amount— Gross	Accumulated Amortization	Carrying Amount— Net
	Marketed products	\$7,614.3	\$(3,062.0)	\$4,552.3	\$5,684.3	\$(2,915.6)
Other	147.4	(47.7)	99.7	149.3	(45.2)	104.1
Total finite-lived intangible assets	\$7,761.7	\$(3,109.7)	\$4,652.0	\$5,833.6	\$(2,960.8)	\$2,872.8

The increase in marketed products in 2015 is due to the acquisition of Novartis AH (Note 3).

Amortization expense related to these finite-lived intangibles was \$154.2 million and \$131.9 million for the three months ended March 31, 2015 and 2014, respectively.

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

Note 8: Stock-Based Compensation

Our stock-based compensation expense consists of performance awards (PAs), shareholder value awards (SVAs), and restricted stock units (RSUs). We recognized pretax stock-based compensation expense of \$48.9 million and \$38.3 million for the three months ended March 31, 2015 and 2014, respectively.

PAs are granted to officers and management and are payable in shares of our common stock. The number of PA shares actually issued, if any, varies depending on the achievement of certain pre-established earnings-per-share targets over a two-year period. PA shares are accounted for at fair value based upon the closing stock price on the date of grant and fully vest at the end of the measurement periods. As of March 31, 2015, the total remaining unrecognized compensation cost related to nonvested PAs was \$115.5 million, which will be amortized over the weighted-average remaining requisite service period of 19 months.

SVAs are granted to officers and management and are payable in shares of common stock at the end of a three-year period. The number of shares actually issued, if any, varies depending on our stock price at the end of the three-year vesting period compared to pre-established target stock prices. We measure the fair value of the SVA unit on the grant date using a Monte Carlo simulation model. The model utilizes multiple input variables that determine the probability of satisfying the market condition stipulated in the award grant and calculates the fair value of the award. As of March 31, 2015, the total remaining unrecognized compensation cost related to nonvested SVAs was \$103.3 million, which will be amortized over the weighted-average remaining requisite service period of 26 months.

RSUs are granted to certain employees and are payable in shares of our common stock. RSU shares are accounted for at fair value based upon the closing stock price on the date of grant. The corresponding expense is amortized over the vesting period, typically three years. As of March 31, 2015, the total remaining unrecognized compensation cost related to nonvested RSUs was \$145.0 million, which will be amortized over the weighted-average remaining requisite service period of 29 months.

Note 9: Shareholders' Equity

During the three months ended March 31, 2015 and 2014, we purchased \$310.6 million and \$55.0 million of shares, respectively, associated with our \$5.00 billion share repurchase program announced in October 2013.

Note 10: Income Taxes

The U.S. examination of tax years 2010-2012 commenced during the fourth quarter of 2013. While it is reasonably possible that the examination of 2010-2012 could conclude within the next 12 months, resolution of certain matters is dependent upon a number of factors, including the potential for formal administrative and legal proceedings. As a result, it is not possible to estimate the range of the reasonably possible changes in unrecognized tax benefits that could occur within the next 12 months related to these years, nor is it possible to reliably estimate the total future cash flows related to these unrecognized tax benefits.

Note 11: Retirement Benefits

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

	Defined Benefit Pension Plans		Retiree Health Benefit Plans	
	Three Months Ended March 31,		Three Months Ended March 31,	
	2015	2014	2015	2014
Components of net periodic benefit cost:				
Service cost	\$77.0	\$62.7	\$9.8	\$11.3
Interest cost	117.1	119.2	15.4	21.2
Expected return on plan assets	(191.8)	(189.3)	(37.1)	(36.0)
Amortization of prior service cost	2.5	0.9	(21.6)	(7.3)
Recognized actuarial loss	92.4	69.1	9.4	5.1
Net periodic benefit cost	\$97.2	\$62.6	\$(24.1)	\$(5.7)

On a global basis, we have contributed approximately \$20 million required to satisfy minimum funding requirements to our defined benefit pension plans in 2015. Additional discretionary funding in the aggregate was not material during the three months ended March 31, 2015. During the remainder of 2015, we expect to make contributions to our defined benefit pension plans of approximately \$30 million to satisfy minimum funding requirements along with approximately \$270 million of additional discretionary contributions.

Note 12: 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 Hatch-Waxman Act. Nine 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 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. The defendants filed their notice of appeal in April 2014.

In June 2014, the U.S. Supreme Court vacated the *Akamai* decision. In July 2014, the court of appeals in the Teva/APP litigation entered an order remanding the case back to the district court to consider the issue of infringement. A hearing has been scheduled for May 2015.

Throughout the course of 2012 through 2014, 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 decision to grant us a vitamin regimen patent. The Opposition Division of the European Patent Office upheld the patent and the generic manufacturers lodged an appeal. In addition, in the United Kingdom (U.K.), Actavis Group ehf and other Actavis companies 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. This trial occurred in April 2014. In May 2014, the court ruled that the vitamin regimen patents for Alimta would not be infringed by the defendants' commercialization of alternative salt forms of pemetrexed, after expiration of the compound patents in December 2015. We appealed, and a hearing on the appeal was held in March 2015. We are awaiting a decision.

We commenced separate infringement proceedings against certain Actavis companies in Germany. The German case was heard by the trial court in March 2014. 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. A hearing was held on one of the demands in February 2015. We are awaiting a decision.

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 March 2015, a group of the defendant companies filed petitions with the U.S. Patent and Trademark Office, requesting inter partes review of the method patents.

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 5,700 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 issued an order substantially reducing 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 intend to vigorously challenge this outcome through all available legal means. We and Takeda have appealed this judgment and plaintiffs have filed a cross-appeal objecting to the reduction in punitive damages.

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 product liability lawsuits involving Actos, including Allen, and the other cases involving us. The settlement will become effective if at least 95 percent of current litigants opt into the settlement, and will release us and Takeda of all remaining liability for these cases.

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. 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 450 Byetta product liability lawsuits involving approximately 980 plaintiffs. Approximately 100 of these lawsuits, covering about 580 plaintiffs, are filed in California state court and coordinated in a Los Angeles Superior Court. Approximately 340 lawsuits, covering about 380 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 10 lawsuits, representing about 25 plaintiffs, are in various state courts. Approximately 390 of the lawsuits, involving approximately 610 plaintiffs, contain allegations that Byetta caused or contributed to the plaintiffs' cancer (primarily pancreatic cancer or thyroid cancer). We are aware of approximately 225 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 560 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 \$310 million as of March 31, 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 13: Other Comprehensive Income (Loss)

The following tables summarize the activity related to each component of other comprehensive income (loss) during the three months ended March 31, 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 December 31, 2014	\$ (498.4)	\$ 99.7	\$ (3,402.0)	\$ (191.1)	\$ (3,991.8)
Other comprehensive income (loss) before reclassifications	(796.0)	67.8	55.2	(36.9)	(709.9)
Net amount reclassified from accumulated other comprehensive loss	—	(11.9)	53.7	2.4	44.2
Net other comprehensive income (loss)	(796.0)	55.9	108.9	(34.5)	(665.7)
Balance at March 31, 2015	\$ (1,294.4)	\$ 155.6	\$ (3,293.1)	\$ (225.6)	\$ (4,657.5)
(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 December 31, 2013	\$ 463.0	\$ 205.2	\$ (2,489.1)	\$ (181.8)	\$ (2,002.7)
Other comprehensive income (loss) before reclassifications	(3.3)	10.3	1.5	15.1	23.6
Net amount reclassified from accumulated other comprehensive loss	—	(49.3)	44.1	27.0	21.8
Net other comprehensive income (loss)	(3.3)	(39.0)	45.6	42.1	45.4

Edgar Filing: LILLY ELI & CO - Form 10-Q

Balance at March 31, 2014 \$ 459.7 \$ 166.2 \$ (2,443.5) \$ (139.7) \$ (1,957.3)

The tax effect on the unrealized net gains (losses) on securities was an expense of \$30.0 million and a benefit of \$21.2 million for the three months ended March 31, 2015 and 2014, respectively.

The tax effect related to our defined benefit pension and retiree health benefit plans was an expense of \$42.5 million and \$23.5 million for the three months ended March 31, 2015 and 2014, respectively.

The tax effect on the effective portion of cash flow hedges was a benefit of \$18.5 million and an expense of \$22.4 million for the three months ended March 31, 2015 and 2014, respectively. Income taxes are not provided for foreign currency translation.

Details about Accumulated Other Comprehensive Loss Components	Reclassifications Out of Accumulated Other Comprehensive Loss Three Months Ended		Affected line Item in the Consolidated Condensed Statements of Operations
	March 31, 2015	2014	
Amortization of retirement benefit items:			
Prior service benefits, net	\$(19.1)	\$(6.4)	(1)
Actuarial losses	101.8	74.2	(1)
Total before tax	82.7	67.8	
Tax benefit	(29.0)	(23.7)	Income Taxes
Net of tax	53.7	44.1	
Unrealized gains/losses on available-for-sale securities:			
Realized gains, net before tax	(18.3)	(75.8)	Other-net, (income) expense
Total before tax	(18.3)	(75.8)	
Tax expense	6.4	26.5	Income Taxes
Net of tax	(11.9)	(49.3)	
Other, net of tax	2.4	27.0	Other-net, (income) expense
Total reclassifications for the period (net of tax)	\$44.2	\$21.8	

¹ These accumulated other comprehensive loss components are included in the computation of net periodic benefit (see Note 11).

Note 14: Other-Net, (Income) Expense

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

	Three Months Ended	
	March 31,	
	2015	2014
Interest expense	\$40.9	\$37.8
Interest income	(21.4)	(34.4)
Other income	(112.2)	(59.4)
Other-net, (income) expense	\$(92.7)	\$(56.0)

Other-net, income for the three months ended March 31, 2015 reflects a favorable legal judgment and net gains on investments.

Note 15: Segment Information

We operate in two business segments—human pharmaceutical products and animal health. 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 months ended March 31, 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 March 31,	
	2015	2014
Segment revenue—to unaffiliated customers:		
Human pharmaceutical products:		
Endocrinology:		
Humalog®	\$684.0	\$650.0
Humulin®	315.7	316.2
Forteo®	293.0	300.4
Evista®	66.8	150.1
Trajenta	82.3	76.9
Other Endocrinology	184.5	145.6
Total Endocrinology	1,626.3	1,639.2
Neuroscience:		
Cymbalta®	287.0	478.2
Zyprexa®	219.5	283.1
Strattera®	173.7	154.4
Other Neuroscience	45.1	48.7
Total Neuroscience	725.3	964.4
Oncology:		
Alimta	573.0	632.0
Erbitux	88.2	90.9
Cyramza®	67.5	—
Other Oncology	30.3	41.4
Total Oncology	759.0	764.3
Cardiovascular:		
Cialis®	538.3	532.4
Effient	121.8	119.3
Other Cardiovascular	55.1	61.1
Total Cardiovascular	715.2	712.8
Other pharmaceuticals	69.1	75.0
Total human pharmaceutical products	3,894.9	4,155.7
Animal health	749.8	527.4
Revenue	\$4,644.7	\$4,683.1

	Three Months Ended March 31,	
	2015	2014
Segment profits ⁽¹⁾ :		
Human pharmaceutical products	\$1,083.1	\$787.8
Animal health	115.0	134.4
Total segment profits	\$1,198.1	\$922.2
Reconciliation of total segment profits to consolidated income before taxes:		
Segment profits	\$1,198.1	\$922.2
Other profits (losses):		
Acquired in-process research and development (Note 3)	(256.0) —
Asset impairment, restructuring, and other special charges (Note 5)	(108.0) (31.4
Amortization of intangible assets ⁽²⁾	(152.7) —
Inventory fair value adjustment related to Novartis AH (Note 3)	(63.5) —
Consolidated income before taxes	\$617.9	\$890.8

Human pharmaceutical products segment profit includes total depreciation expense of \$188.1 million and \$206.4 million for the three months ended March 31, 2015 and 2014, respectively. Animal health segment profit includes total depreciation expense of \$16.7 million and \$13.6 million for the three months ended March 31, 2015 and 2014, respectively.

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 March 31, 2014 to conform with the 2015 presentation and exclude amortization of intangible assets, the human pharmaceutical products and animal health segment profits would be increased by \$116.9 million and \$11.9 million, respectively.

For internal management reporting presented to the chief operating decision maker, certain costs are fully allocated to our human pharmaceutical products 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

Worldwide revenue decreased 1 percent to \$4.64 billion in the first quarter of 2015. The decline was due to the unfavorable impact of foreign exchange rates and the continuing impact of Cymbalta[®] and Evista[®] patent expirations, largely offset by the inclusion of revenue from Novartis Animal Health (Novartis AH), higher United States (U.S.) prices, U.S. wholesale buying patterns, and increased volumes for several other products. Net income for the first quarter of 2015 decreased 27 percent to \$529.5 million and EPS for the first quarter of 2015 decreased 26 percent to \$0.50 per share. The decreases were driven by increased acquired in-process research and development (IPR&D) charges and asset impairment, restructuring, and other special charges, partially offset by a lower effective tax rate in 2015 and increased other income.

The following highlighted items affect comparisons of our financial results for the three months ended March 31, 2015 and 2014:

2015

Acquisitions (Note 3)

We recognized expense of \$63.5 million (pretax), or \$0.04 per share, related to the fair value adjustments to Novartis AH acquisition date inventory that has been sold.

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

We recognized acquired IPR&D charges of \$256.0 million (pretax), or \$0.15 per share, related to acquired IPR&D from 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 \$108.0 million (pretax), or \$0.07 per share, primarily attributable to our animal health business segment and related primarily to integration costs, intangible asset impairments due to product rationalization, and severance costs resulting from our acquisition of Novartis AH.

2014

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

We recognized charges of \$31.4 million (pretax), or \$0.02 per share, primarily attributable to our human pharmaceuticals business segment and related primarily to severance costs for actions taken to reduce our cost structure.

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 60 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 for potential use in the disease 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. 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.

Evacetrapib (Q4 2012)—a cholesteryl ester transfer protein inhibitor for the treatment of high-risk vascular disease.

Solanezumab* (Q2 2009)—an anti-amyloid beta monoclonal antibody for the treatment of 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). Tanezumab was previously subject to a partial clinical hold by the U.S. Food and Drug Administration (FDA) which was lifted in the first quarter of 2015 (Note 4).

*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	Phase III	Phase III	Phase III	Studies are ongoing.
Endocrinology					
	Type 1 diabetes	Phase III	Phase III	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. Jardiance approved and launched in U.S. and Europe in 2014. In Japan, approved in 2014 and launched in the first quarter of 2015.
Basal insulin peglispro	Type 2 diabetes	Phase III	Phase III	Phase III	
Jardiance®	Type 2 diabetes	Launched	Launched	Launched	Glyxambi®, combination tablet of empagliflozin and linagliptin, approved in the U.S. in January 2015 and launched in March 2015. Intend to submit to European regulatory authorities in late 2015.
New insulin glargine product	Type 1 diabetes	Tentatively approved	Approved	Approved	See Note 4.
	Type 2 diabetes	Tentatively approved	Approved	Approved	
Trulicity™	Type 2 diabetes	Launched	Launched	Submitted	Launched in certain European countries in first quarter of 2015.

Edgar Filing: LILLY ELI & CO - Form 10-Q

Compound	Indication	U.S.	Europe	Japan	Developments
Immunology					
Baricitinib	Rheumatoid arthritis	Phase III	Phase III	Phase III	Announced in February 2015 top-line results of RA-BUILD trial which met primary endpoint. Submitted to regulatory authorities in the U.S. in first quarter of 2015.
	Psoriasis	Submitted	Phase III	Phase III	
Ixekizumab	Psoriatic arthritis	Phase III	Phase III	Phase III	Announced in April 2015 top-line results of SPIRIT-P1 trial which met primary endpoint.
Neuroscience					
Solanezumab	Mild Alzheimer's disease	Phase III	Phase III	Phase III	Enrollment in EXPEDITION 3 study completed.
	Osteoarthritis pain	Phase III	Phase III	Phase III	
Tanezumab	Chronic low back pain	Phase III	Phase III	Phase III	FDA clinical hold lifted in March 2015. Phase III studies expected to resume in 2015.
	Cancer pain	Phase III	Phase III	Phase III	
Oncology					
Abemaciclib	Metastatic breast cancer	Phase III	Phase III	Phase III	Studies are ongoing.
	NSCLC	Phase III	Phase III	Phase III	Study is ongoing.
	Gastric cancer (first-line)	Phase III	Phase III	Phase III	Initiated Phase III study of Cyramza in first-line gastric cancer in January 2015.
	Gastric cancer (second-line)	Launched	Launched	Approved	Launched in certain European countries in first quarter of 2015. In Japan, approved for patients with unresectable, advanced, or recurrent gastric cancer in March 2015.
Cyramza®	NSCLC (second-line)	Launched	Submitted	Phase III	Launched in the U.S. in first quarter of 2015. Submitted to European regulatory authorities in first quarter of 2015. Intend to submit to Japanese regulatory authorities in 2015.
	Liver cancer (second-line)	Phase III	Phase III	Phase III	Announced plans to conduct new Phase III study in 2015.
	Metastatic colorectal cancer (second-line)	Approved	Submitted	Phase III	Approved in the U.S. in April 2015. Submitted in Europe in first quarter of 2015.
Necitumumab	Squamous NSCLC	Submitted	Submitted	Phase Ib/II	Anticipate FDA action in late 2015.

There are many difficulties and uncertainties inherent in pharmaceutical research and development (R&D) and the introduction of new products. A high rate of failure is inherent in new drug discovery and development. The process to bring a drug from the discovery phase to regulatory approval can take 12 to 15 years or longer and cost more than \$1 billion. Failure can occur at any point in the process, including late in the process after substantial investment. As a result, most research programs will not generate financial returns. New product candidates that appear promising in development may fail to reach the market or may have only limited commercial success. Delays and uncertainties in the regulatory approval processes in the U.S. and in other countries can result in delays in product launches and lost market opportunities. Consequently, it is very difficult to predict which products will ultimately be approved.

We manage R&D spending across our portfolio of molecules, and a delay in, or termination of, any one project will not necessarily cause a significant change in our total R&D spending. Due to the risks and uncertainties involved in the R&D process, we cannot reliably estimate the nature, timing, completion dates, and costs of the efforts necessary to complete the development of our R&D projects, nor can we reliably estimate the future potential revenue that will be generated from a successful R&D project. Each project represents only a portion of the overall pipeline, and none is individually material to our consolidated R&D expense. While we do accumulate certain R&D costs on a project level for internal reporting purposes, we must make significant cost estimations and allocations, some of which rely on data that are neither reproducible nor validated through accepted control mechanisms. Therefore, we do not have sufficiently reliable data to report on total R&D costs by project, by preclinical versus clinical spend, or by therapeutic category.

Other Matters

Novartis Animal Health Acquisition

On January 1, 2015, we completed our acquisition of Novartis AH in an all-cash transaction for \$5.29 billion. 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 is expected to increase our animal health product portfolio, expand our global commercial presence, and augment our animal health manufacturing and research and development. In particular, it is expected to provide Elanco with a greater commercial presence in the companion animal and swine markets, expand Elanco's presence in equine and vaccines areas, and create 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. In April 2015, the Japan Patent Office issued an administrative ruling that our method of use patent for Evista, which expires in 2018, is invalid. We plan to appeal this ruling. Revenues of Evista in Japan are not material to our results of operations or cash flows.

We lost our data package protection for Cymbalta in major European countries in 2014, and we began to see the entry of generic competition in a few countries in the first quarter of 2015. We anticipate generic launches in additional European countries throughout 2015. We expect that the entry of generic competition for Cymbalta into the markets where it has lost 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. We will also lose patent exclusivity in December 2015 for Zyprexa® in Japan.

Additionally, as described in Note 12 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 where it has lost 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 May 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.

31

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, Chinese yuan, the British pound, and the Japanese yen, 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 measures may be enacted. As a result, pharmaceutical companies may see either a reduction in revenue or increase in expenses. President Obama's fiscal year 2016 budget includes a number of key health legislative proposals affecting biopharmaceuticals, including a reduction in biologic data exclusivity, modifications to Medicare Parts B and D, and 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. 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, the growth of Managed Care Organizations (MCOs) is also a major factor in the competitive marketplace for human pharmaceuticals. It is estimated that approximately two-thirds of the U.S. now participates in some form of managed care. MCOs have been consolidating into fewer, larger entities, thus enhancing their purchasing strength and importance. MCOs typically maintain formularies specifying which drugs are covered under their plans. Exclusion of a drug from a formulary can lead to its sharply reduced usage in the MCO patient population. Consequently, pharmaceutical companies compete aggressively to have their branded products included. Price is becoming an increasingly important factor in MCO formulary decisions, particularly in treatment areas in which the MCO has taken the position that multiple branded products are therapeutically comparable. These downward pricing pressures could negatively impact future consolidated results of operations.

In 2014, the main coverage expansion provisions of the Affordable Care Act (ACA) took 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 changes resulting from the ACA, 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 launched and continues to advance an initiative to analyze and 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 effect on our consolidated operating results and cash flows.

Legal Matters

Information regarding contingencies relating to certain legal proceedings can be found in Note 12 and is incorporated here by reference.

Revenue

Worldwide revenue decreased 1 percent to \$4.64 billion for the first quarter of 2015 compared with the same period of 2014. For the first quarter, the 1 percent worldwide revenue decline was comprised of 6 percent due to the unfavorable impact of foreign exchange rates, largely offset by increases of 3 percent due to higher prices and 3 percent due to increased volume. The 3 percent increase in worldwide volume was primarily due to the inclusion of revenue from Novartis AH, U.S. wholesaler buying patterns, and increased volumes for several other products including Cyramza and Humalog. These worldwide volume increases were partially offset by lower demand for Cymbalta and Evista, largely due to U.S. patent expirations in December 2013 and March 2014, respectively. Revenue in the U.S. increased 6 percent to \$2.21 billion, driven primarily by higher prices, wholesaler buying patterns, increased volumes for Cyramza, and the inclusion of revenue from Novartis AH, partially offset by lower demand for Cymbalta and Evista following their patent expirations. Revenue outside the U.S. decreased 6 percent to \$2.43 billion, driven by the unfavorable impact of foreign exchange rates, partially offset by the inclusion of revenue from Novartis AH.

The following table summarizes our revenue activity:

Product	Three Months Ended March 31, 2015			Three Months Ended March 31, 2014	Percent Change from 2014	
	U.S. ⁽¹⁾	Outside U.S.	Total	Total		
	(Dollars in millions)					
Humalog	\$420.6	\$263.4	\$684.0	\$650.0	5	%
Alimta	252.7	320.3	573.0	632.0	(9))%
Cialis®	247.1	291.2	538.3	532.4	1	%
Humulin®	179.5	136.2	315.7	316.2	—	%
Forteo®	122.0	171.0	293.0	300.4	(2))%
Cymbalta	54.4	232.6	287.0	478.2	(40))%
Zyprexa	26.6	192.9	219.5	283.1	(22))%
Strattera®	108.5	65.2	173.7	154.4	13	%
Effient®	94.6	27.2	121.8	119.3	2	%
Evista	24.2	42.6	66.8	150.1	(55))%
Other human pharmaceutical products	207.8	218.2	426.0	358.4	19	%
Animal health products	356.8	393.0	749.8	527.4	42	%
Total net product revenues	2,094.8	2,353.8	4,448.6	4,501.9	(1))%
Collaboration and other revenue ⁽²⁾	116.5	79.6	196.1	181.2	8	%
Revenue	\$2,211.3	\$2,433.4	\$4,644.7	\$4,683.1	(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®. Revenues of Humalog, our injectable human insulin analog for the treatment of diabetes, increased 12 percent in the U.S. during the first quarter of 2015, driven by wholesaler buying patterns and higher prices. Revenues outside the U.S. decreased 4 percent during the first quarter of 2015, driven by the unfavorable impact of foreign exchange rates, partially offset by increased volume.

Revenues of Alimta, a treatment for various cancers, increased 3 percent in the U.S. during the first quarter of 2015, driven by higher net effective selling prices. Revenues outside the U.S. decreased 17 percent during the first quarter of 2015, driven by the unfavorable impact of foreign exchange rates and lower prices.

Revenues of Cialis, a treatment for erectile dysfunction and benign prostatic hyperplasia, increased 20 percent in the U.S. during the first quarter of 2015, driven by higher prices and, to a lesser extent, wholesale buying patterns. Revenues outside the U.S. decreased 11 percent during the first quarter of 2015, driven by the unfavorable impact of foreign exchange rates.

Revenues of Humulin, an injectable human insulin for the treatment of diabetes, increased 16 percent in the U.S. in the first quarter of 2015, driven primarily by higher prices and wholesaler buying patterns, partially offset by lower demand. Revenues outside the U.S. decreased 16 percent in the first quarter of 2015, driven by the unfavorable impact of foreign exchange rates and decreased volume.

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 21 percent in the U.S. in the first quarter of 2015, driven by higher prices and wholesaler buying patterns, partially offset by lower demand. Revenues outside the U.S. decreased 14 percent in the first quarter of 2015 driven by 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 in the U.S. for the treatment of chronic musculoskeletal pain and the management of fibromyalgia, decreased 69 percent in the U.S. for the first quarter of 2015 due to the loss of U.S. patent exclusivity in December 2013. Revenues outside the U.S. decreased 23 percent in the first quarter of 2015 driven by the unfavorable impact of foreign exchange rates, as well as decreased volume and lower prices due to the entrance of generic competitors in select European markets following the loss of data package protection in 2014.

Revenues of Zyprexa, a treatment for schizophrenia, acute mixed or manic episodes associated with bipolar I disorder, and bipolar maintenance, decreased 2 percent in the U.S. in the first quarter of 2015. Revenues outside the U.S. decreased 25 percent in the first quarter of 2015, due to lower volume in Japan, the unfavorable impact of foreign exchange rates, and, to a lesser extent, lower prices. We will lose patent exclusivity for Zyprexa in Japan in December 2015. Zyprexa revenues in Japan were approximately \$94 million for the first quarter of 2015, compared with approximately \$143 million for the first quarter of 2014.

Revenues of Strattera, a treatment for attention-deficit hyperactivity disorder, increased 31 percent in the U.S. in the first quarter of 2015, driven primarily by higher prices. Revenues outside the U.S. decreased 9 percent during the first quarter of 2015 driven by the unfavorable impact of foreign exchange rates, partially 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 8 percent in the U.S. in the first quarter of 2015, driven by higher prices, partially offset by lower demand. Revenue outside the U.S. decreased 14 percent in the first quarter of 2015, 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, decreased 75 percent in the U.S. in the first quarter of 2015 due to the loss of U.S. patent exclusivity in March 2014. Revenues outside the U.S. decreased 18 percent in the first quarter of 2015, driven by the unfavorable impact of foreign exchange rates and, to a lesser extent, decreased volume.

Revenues of animal health products increased 16 and 79 percent in the U.S. and outside the U.S., respectively, in the first quarter of 2015. The increases were primarily driven by the inclusion of revenue from Novartis AH and, to a lesser extent, the inclusion of revenue from Lohmann SE (Lohmann AH) (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 decreased 3 percent, primarily driven by decreased volume due to increased competition for companion animal products. Revenues outside the U.S. would have decreased 4 percent, driven by the unfavorable impact of foreign exchange rates, partially offset by the inclusion of revenue from Lohmann AH and higher prices for food animal products.

Gross Margin, Costs, and Expenses

Gross margin as a percent of revenue increased 0.4 percentage points to 74.3 percent for the first quarter of 2015. The increase in gross margin percent was primarily due to the favorable impact of foreign exchange rates, partially offset by the inclusion of Novartis AH and inventory step-up costs.

Research and development expenses decreased 6 percent to \$1.04 billion for the first quarter of 2015, primarily driven by lower late-stage clinical development costs and, to a lesser extent, the favorable impact of foreign exchange rates, partially offset by expenses of Novartis AH.

Marketing, selling, and administrative expenses increased 3 percent to \$1.52 billion for the first quarter of 2015, primarily due to expenses of Novartis AH and marketing and selling expenses related to the launches of Trulicity and Jardiance, partially offset by the favorable impact of foreign exchange rates and ongoing cost-containment measures.

Acquired in-process research and development charges of \$256.0 million were recognized in the first quarter of 2015 compared to no charges for the same period in 2014. These charges included 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. See Notes 3 and 4 for additional information.

In the first quarter of 2015, we recognized \$108.0 million of asset impairment, restructuring, and other special charges, compared to \$31.4 million charges for the first quarter of 2014. The 2015 charges primarily relate to integration, severance costs, and intangible asset impairments due to product rationalization resulting from the acquisition of Novartis AH. The 2014 charges were primarily related to severance costs for actions taken to reduce our cost structure. See Note 5 for additional information.

Other-net, (income) expense was income of \$92.7 million for the first quarter of 2015 compared with income of \$56.0 million for the first quarter of 2014. Other income in 2015 reflects a favorable legal judgment and net gains on investments. See Note 14 for additional information.

The effective tax rate was 14.3 percent for the first quarter of 2015, compared with 18.3 percent for the same respective period in 2014. The decrease in the effective tax rate for the first quarter of 2015 is primarily due to the tax impact of acquired IPR&D charges and asset impairment, restructuring, and other special charges. The effective tax rate for the first quarter of 2014 includes a discrete tax benefit of approximately \$30 million. Neither period includes the benefit of certain expired U.S. tax provisions, including the R&D tax credit.

Financial Condition

Cash and cash equivalents decreased to \$3.06 billion as of March 31, 2015, compared with \$3.87 billion as of December 31, 2014. A significant source of cash included proceeds from the sale of product rights of \$410.0 million. Significant uses of cash included dividends paid of \$527.9 million, share repurchases of \$310.6 million, the purchase of in-process research and development of \$200.0 million, and net purchases of property and equipment of \$188.6 million. In addition, in the first quarter of 2015, \$5.41 billion of restricted cash was released to fund the acquisition of Novartis AH for \$5.28 billion, net of cash acquired.

In addition to our cash and cash equivalents, we held total investments of \$5.65 billion and \$5.52 billion as of March 31, 2015 and December 31, 2014, respectively. See Note 6 for additional details.

Total debt increased to \$8.22 billion as of March 31, 2015, compared with \$8.06 billion as of December 31, 2014 primarily due to the issuance of \$2.20 billion of fixed-rate notes, largely offset by \$2.09 billion of net repayments of commercial paper borrowings, and, to a lesser extent, due to the increase in fair value of our hedged debt. The fixed-rate notes were comprised of \$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 primarily used to repay outstanding commercial paper issued in connection with our January 2015 acquisition of Novartis AH. At March 31, 2015, we had approximately \$3.2 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 three months ended March 31, 2015, we purchased \$310.6 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), Evista (U.S.), 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 \$2.21 to \$2.31. We still anticipate that total revenue will be between \$19.5 billion and \$20.0 billion.

We now anticipate that gross margin as a percent of revenue will be approximately 74.5 percent in 2015 due to the impact of the transfer of Erbitux rights (Note 4). Research and development expenses are still expected to be in the range of \$4.7 billion to \$4.9 billion. Marketing, selling, and administrative expenses are now expected to be in the range of \$6.4 billion to \$6.7 billion due to revised acquisition accounting adjustments associated with the inclusion of Novartis AH. Other—net, (income) expense is still expected to be in a range between \$75 million and \$125 million of income.

The 2015 tax rate is now expected to be approximately 16.5 percent due to the tax impact of acquired IPR&D charges and asset impairment, restructuring, and other special charges. 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 still expected to be approximately \$1.3 billion.

Our 2015 financial guidance is subject to final acquisition accounting adjustments for the acquisitions of Novartis AH and Erbitux rights.

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

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 March 31, 2015, and concluded that they are effective.

Changes in Internal Controls. During the first 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 12, 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 Acto[®], 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 9th Circuit Court of Appeals requesting permission to file an interlocutory appeal of the denial of class certification, which was denied. The first case is scheduled for trial on May 5, 2015.

Additionally, we have been named in approximately 60 individual lawsuits filed in various federal and state courts by claimants alleging injuries arising from discontinuation of treatment with Cymbalta. Counsel for plaintiffs have 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 Central District of California. In December 2014, the Judicial Panel on Multidistrict Litigation denied the plaintiffs' petition for creation of an MDL.

We believe all these Cymbalta lawsuits and claims are without merit and are prepared to defend against them vigorously.

We have been named as a defendant in approximately 135 U.S. product liability lawsuits involving Axiron[®]. In some 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 injuries. We believe these claims are without merit and are prepared to defend against them vigorously.

Other Matters

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 March 31, 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)
January 2015	2,042.5	\$69.82	2,042.5	\$3,557.4
February 2015	394.9	69.84	394.9	3,529.8
March 2015	2,000.4	70.15	2,000.4	3,389.4
Total	4,437.8	69.97	4,437.8	

In October 2013, we announced a \$5.00 billion share repurchase program. During the three months ended March 31, 2015, we purchased \$310.6 million of shares under the program.

Item 6. Exhibits

The following documents are filed as exhibits to this Report:

EXHIBIT 4.3	Long-term debt instruments under which the total amount of securities authorized does not exceed 10% of our total consolidated assets are not filed as exhibits to this report. We will furnish a copy of these agreements to the SEC upon request.
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: April 30, 2015

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

Date: April 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 4.3	Long-term debt instruments under which the total amount of securities authorized does not exceed 10% of our total consolidated assets are not filed as exhibits to this report. We will furnish a copy of these agreements to the SEC upon request.
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