

LILLY ELI & CO  
Form 10-Q  
July 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 JUNE 30, 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 July 20, 2015:

Class	Number of Shares Outstanding
Common	1,108,540,541

Eli Lilly and Company  
 Form 10-Q  
 For the Quarter Ended June 30, 2015  
 Table of Contents

	Page
<u>PART I. Financial Information</u>	<u>4</u>
<u>Item 1.</u>	
<u>Financial Statements</u>	<u>4</u>
<u>Consolidated Condensed Statements of Operations</u>	<u>4</u>
<u>Consolidated Condensed Statements of Comprehensive Income (Loss)</u>	<u>5</u>
<u>Consolidated Condensed Balance Sheets</u>	<u>6</u>
<u>Consolidated Condensed Statements of Cash Flows</u>	<u>7</u>
<u>Notes to Consolidated Condensed Financial Statements</u>	<u>8</u>
<u>Item 2.</u>	
<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>32</u>
<u>Executive Overview</u>	<u>32</u>
<u>Revenue</u>	<u>38</u>
<u>Gross Margin, Costs, and Expenses</u>	<u>41</u>
<u>Financial Condition</u>	<u>42</u>
<u>Financial Expectations</u>	<u>43</u>
<u>Available Information on our Website</u>	<u>43</u>
<u>Item 4.</u>	
<u>Controls and Procedures</u>	<u>43</u>
<u>PART II. Other Information</u>	<u>44</u>
<u>Item 1.</u>	
<u>Legal Proceedings</u>	<u>44</u>
<u>Item 1A.</u>	
<u>Risk Factors</u>	<u>45</u>
<u>Item 2.</u>	
<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	<u>45</u>
<u>Item 6.</u>	
<u>Exhibits</u>	<u>46</u>
<u>Signatures</u>	<u>47</u>
<u>Index to Exhibits</u>	<u>48</u>

### 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 and our Quarterly Report on Form 10-Q for the period ended March 31, 2015, 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		Six Months Ended	
	June 30, 2015	2014	June 30, 2015	2014
Revenue	\$4,978.7	\$4,935.6	\$9,623.4	\$9,618.7
Cost of sales	1,218.4	1,189.7	2,411.1	2,412.4
Research and development	1,169.5	1,195.4	2,208.8	2,304.7
Marketing, selling, and administrative	1,635.4	1,663.9	3,158.9	3,148.8
Acquired in-process research and development (Note 3)	80.0	—	336.0	—
Asset impairment, restructuring, and other special charges (Note 5)	72.4	—	180.4	31.4
Other—net, (income) expense (Note 13)	123.3	(53.8	) 30.6	(109.8
	4,299.0	3,995.2	8,325.8	7,787.5
Income before income taxes	679.7	940.4	1,297.6	1,831.2
Income taxes (Note 9)	78.9	206.9	167.3	369.8
Net income	\$600.8	\$733.5	\$1,130.3	\$1,461.4
Basic earnings per share:				
Weighted-average number of common shares outstanding, including incremental shares	1,061.7	1,071.7	1,063.0	1,072.3
Basic earnings per share	\$0.57	\$0.68	\$1.06	\$1.36
Diluted earnings per share:				
Weighted-average number of common shares outstanding, including incremental shares and stock options	1,065.6	1,076.4	1,066.3	1,076.4
Diluted earnings per share	\$0.56	\$0.68	\$1.06	\$1.36
Dividends paid per share	\$0.50	\$0.49	\$1.00	\$0.98

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		Six Months Ended	
	June 30,		June 30,	
	2015	2014	2015	2014
Net income	\$600.8	\$733.5	\$1,130.3	\$1,461.4
Other comprehensive income (loss), net of tax (Note 12)	254.3	22.0	(411.4 )	67.4
Comprehensive income	\$855.1	\$755.5	\$718.9	\$1,528.8

See Notes to Consolidated Condensed Financial Statements.

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

	June 30, 2015 (Unaudited)	December 31, 2014
Assets		
Current Assets		
Cash and cash equivalents (Note 6)	\$3,315.5	\$3,871.6
Short-term investments (Note 6)	915.4	955.4
Accounts receivable, net of allowances of \$48.9 (2015) and \$55.0 (2014)	3,348.8	3,234.6
Other receivables	747.8	566.7
Inventories	3,288.4	2,740.0
Prepaid expenses and other	730.1	811.5
Total current assets	12,346.0	12,179.8
Other Assets		
Restricted cash (Note 3)	—	5,405.6
Investments (Note 6)	4,099.1	4,568.9
Goodwill (Note 7)	4,024.7	1,758.1
Other intangibles, net (Note 7)	4,842.9	2,884.2
Sundry	2,701.3	2,382.8
Total other assets	15,668.0	16,999.6
Property and Equipment		
Land, buildings, equipment, and construction in progress	16,404.2	16,029.3
Accumulated depreciation	(8,381.6)	(8,065.4)
Property and equipment, net	8,022.6	7,963.9
Total assets	\$36,036.6	\$37,143.3
Liabilities and Equity		
Current Liabilities		
Short-term borrowings and current maturities of long-term debt	\$10.8	\$2,688.7
Accounts payable	1,153.0	1,128.1
Employee compensation	672.6	759.0
Sales rebates and discounts	2,328.1	2,068.8
Dividends payable	529.2	530.3
Deferred income taxes	912.8	1,466.5
Other current liabilities	2,625.5	2,566.1
Total current liabilities	8,232.0	11,207.5
Other Liabilities		
Long-term debt	7,988.6	5,332.8
Accrued retirement benefits (Note 10)	2,629.7	2,562.9
Long-term income taxes payable	1,026.8	998.5
Other noncurrent liabilities	1,454.1	1,653.5
Total other liabilities	13,099.2	10,547.7
Commitments and Contingencies (Note 11)		
Eli Lilly and Company Shareholders' Equity (Note 8)		
Common stock	693.3	694.6
Additional paid-in capital	5,368.5	5,292.3
Retained earnings	16,114.9	16,482.7
Employee benefit trust	(3,013.2)	(3,013.2)
Accumulated other comprehensive loss (Note 12)	(4,403.2)	(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	14,670.3	15,373.2	
Noncontrolling interests	35.1	14.9	
Total equity	14,705.4	15,388.1	
Total liabilities and equity	\$36,036.6	\$37,143.3	

See Notes to Consolidated Condensed Financial Statements.

6

---

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

	Six Months Ended	
	June 30,	
	2015	2014
Cash Flows from Operating Activities		
Net income	\$1,130.3	\$1,461.4
Adjustments to Reconcile Net Income to Cash Flows from Operating Activities:		
Depreciation and amortization	726.0	697.2
Change in deferred income taxes	(666.5)	) 121.2
Debt extinguishment loss	166.7	—
Stock-based compensation expense	104.7	76.9
Net payments for terminations of interest rate swaps	(186.1)	) (6.9)
Acquired in-process research and development	336.0	—
Other changes in operating assets and liabilities, net of acquisitions and divestitures	(686.3)	) (1,021.3)
Other non-cash operating activities, net	(61.0)	) (2.3)
Net Cash Provided by Operating Activities	863.8	1,326.2
Cash Flows from Investing Activities		
Net purchases of property and equipment	(412.5)	) (456.9)
Proceeds from sales and maturities of short-term investments	1,285.3	1,889.7
Purchases of short-term investments	(588.5)	) (804.5)
Proceeds from sales of noncurrent investments	1,750.5	5,540.1
Purchases of noncurrent investments	(1,832.8)	) (5,594.7)
Restricted cash released for acquisition	5,405.6	—
Cash paid for acquisitions, net of cash acquired	(5,276.7)	) (551.4)
Proceeds from sale of product rights	410.0	—
Purchase of in-process research and development	(336.0)	) —
Other investing activities, net	(61.7)	) (102.8)
Net Cash Provided by (Used for) Investing Activities	343.2	(80.5)
Cash Flows from Financing Activities		
Dividends paid	(1,067.7)	) (1,051.0)
Net change in short term borrowings	(2,679.3)	) 2.3
Proceeds from issuance of long-term debt	4,454.6	992.9
Repayment of long-term debt	(1,949.2)	) (1,033.8)
Purchases of common stock	(435.5)	) (200.0)
Other financing activities, net	32.7	(8.0)
Net Cash Used for Financing Activities	(1,644.4)	) (1,297.6)
Effect of exchange rate changes on cash and cash equivalents	(118.7)	) (12.6)
Net decrease in cash and cash equivalents	(556.1)	) (64.5)
Cash and cash equivalents at January 1	3,871.6	3,830.2
Cash and Cash Equivalents at June 30	\$3,315.5	\$3,765.7
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

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

Standard	Description	Effective Date	Effect on the financial statements or other significant matters
Accounting Standards Update 2014-09, Revenue from Contracts with Customers	This standard will replace existing revenue recognition standards and will require entities to recognize revenues to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. An entity can apply the new revenue standard retrospectively to each prior reporting period presented or with the cumulative effect of initially applying the standard recognized at the date of initial application in retained earnings.	January 1, 2017 <sup>(1)</sup>	There are areas within the standard that are currently under review and reconsideration by the Financial Accounting Standards Board (FASB), which could lead to updates to the standard. As the outcomes of this review and reconsideration could lead to significant changes to the standard, we are still in the process of determining our approach to the adoption of the standard, as well as the anticipated impact to our consolidated financial statements.

<sup>(1)</sup> In July 2015, the FASB announced the decision to defer the effective date of the new revenue recognition standard by one year (to January 1, 2018 for us), but to permit entities to adopt the new standard on the original effective date if they choose. We are evaluating our anticipated date of adoption.

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 and six months ended June 30, 2015, we recorded acquired IPR&D charges of \$80.0 million and \$336.0 million, respectively, related to the collaborations with Innovent Biologics, Inc. (Innovent), Hanmi Pharmaceutical Co., Ltd. (Hanmi), BioNTech AG (BioNTech), 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 and six months ended June 30, 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<sup>®</sup> 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	\$381.5	
Acquired in-process research and development	295.0	
Marketed products <sup>(1)</sup>	1,940.0	
Property and equipment	218.9	
Assets held for sale (primarily the U.S. Sentinel rights)	426.7	
Accrued retirement benefits	(169.5	)
Deferred income taxes	(32.5	)
Other assets and liabilities - net	(34.0	)
Total identifiable net assets	3,026.1	
Goodwill <sup>(2)</sup>	2,259.5	
Total consideration transferred - net of cash acquired	\$5,285.6	

<sup>(1)</sup> 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.

<sup>(2)</sup> 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.

9

---

### Actual and Supplemental Pro Forma Information

Our consolidated condensed statement of operations for the three and six months ended June 30, 2015 includes Novartis AH revenue of \$268.1 million and \$504.5 million, respectively. Novartis AH has been partially integrated into our animal health segment and as a result of these integration efforts, certain parts of the animal health business are operating on a combined basis, and we cannot distinguish the operations between Novartis AH and our legacy animal health business.

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

	Unaudited Pro Forma Consolidated Results			
	Three Months Ended		Six Months Ended	
	June 30, 2015	2014	June 30, 2015	2014
Revenue	\$4,978.7	\$5,211.2	\$9,623.4	\$10,146.1
Net income	649.7	643.8	1,224.6	1,270.9
Diluted earnings per share	0.61	0.60	1.15	1.18

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

Additional amortization expense of approximately \$26 million and \$52 million for the three and six months ended June 30, 2014, respectively, related to the fair value of identifiable intangible assets acquired.

Additional cost of sales in 2014, and a corresponding reduction in cost of sales in 2015, of approximately \$68 million and \$132 million related to the fair value adjustments to acquisition date inventory that has been sold in the three and six months ended June 30, 2015, respectively.

A decrease to pro forma net income of approximately \$31 million and \$51 million in the three and six months ended June 30, 2014, respectively, associated with an increase to interest expense related to the incremental debt that we issued to partially finance the acquisition and a reduction of interest income associated with investments which would have been used to partially fund the acquisition.

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

#### Lohmann AH Acquisition

On April 30, 2014, we acquired Lohmann AH, a privately-held company headquartered in Cuxhaven, Germany, through a stock purchase for a total purchase price of \$591.2 million, comprised of \$551.4 million of net cash plus \$39.8 million of assumed debt. Lohmann AH is a global leader in poultry vaccines. As part of this transaction, we acquired the rights to a range of vaccines, commercial capabilities, and manufacturing sites in Germany and the United States. The acquisition is not material to our consolidated financial statements. Amounts recorded in connection with this acquisition include \$275.4 million of marketed product assets, \$23.9 million of other intangible assets, \$81.9 million of property and equipment, \$251.6 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. The compounds included in the collaboration were Innovent's monoclonal antibody targeting protein CD-20, which had received investigational new drug approval in China to begin Phase I development, a pre-clinical immuno-oncology molecule, and our cMet monoclonal antibody, which was 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 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 had 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. Under the terms of the agreement, we paid an upfront fee of \$50.0 million, which was expensed as acquired IPR&D in the second quarter of 2015.

In May 2015, we entered into a research collaboration with BioNTech to discover novel cancer immunotherapies. Upon entering the agreement, we paid an upfront fee of \$30.0 million, which was expensed as 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.

The following table summarizes our collaboration and other revenue recognized:

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2015	2014	2015	2014
Collaboration and other revenue	\$233.4	\$208.7	\$429.5	\$389.9

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

#### Diabetes Collaboration

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

Trajenta was approved in 2011 and launched in the U.S., Europe, Japan, and other countries. Jentadueto<sup>®</sup>, the single pill combination of linagliptin and metformin hydrochloride, is being commercialized with Trajenta and is included in the Trajenta family results. Jardiance was approved in the U.S., Europe, and Japan in 2014. It was



launched in the U.S. and Europe in 2014 and in Japan in the first quarter of 2015. Glyxambi®, the single pill combination of linagliptin and empagliflozin, launched in the U.S. in the first quarter of 2015, and is included in the Jardiance family results. Synjardy®, the single pill combination of empagliflozin and metformin hydrochloride, was approved in Europe in May 2015, and will be included in the Jardiance family results once launched. Our new insulin glargine product was approved in Europe and Japan in September and December 2014, respectively. The first launch in Europe and Japan occurred in the second and third quarter of 2015, respectively. 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 Aventis U.S. LLC, 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 June 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 all of which were capitalized as intangible assets and are being 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 in Japan during 2014, we recorded, as deferred revenue, a \$62.5 million milestone which will be amortized through the term of the collaboration (2029) to collaboration and other revenue upon product launch in European countries and Japan where we co-promote our new insulin glargine product with Boehringer Ingelheim. 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, 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.

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

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2015	2014	2015	2014
Collaboration and other revenue	\$80.0	\$90.3	\$162.4	\$167.1

Our revenues related to the Jardiance family of products and our new insulin glargine product were not material for the three and six months ended June 30, 2015.

Erbitux®

We have several collaborations with respect to Erbitux. The most significant collaborations are in the U.S., Canada, and Japan (Bristol-Myers Squibb Company); and worldwide except the U.S. and Canada (Merck KGaA). Certain

12

---

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		Six Months Ended	
	June 30,		June 30,	
	2015	2014	2015	2014
Net product revenues	\$ 11.0	\$ 12.4	\$ 24.8	\$ 25.6
Collaboration and other revenue	123.6	81.1	198.0	158.7
Revenue	\$ 134.6	\$ 93.5	\$ 222.8	\$ 184.3

#### 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. A separate agreement grants co-exclusive rights among Merck, BMS, and us in Japan and expires in 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 net 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.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Revenue	\$128.8	\$133.6	\$250.6	\$252.9
Solanezumab				

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

#### Baricitinib

We have a worldwide license and collaboration agreement with Incyte Corporation (Incyte) which provides us the development and commercialization rights to its Janus tyrosine kinase inhibitor compound, now known as baricitinib, and certain follow-on compounds, for the treatment of inflammatory and autoimmune diseases. Incyte has the right to receive tiered, double-digit royalty payments on future global sales with rates ranging up to 20 percent if the product is successfully commercialized. The agreement provides Incyte with options to co-develop these compounds on an indication-by-indication basis by funding 30 percent of the associated development costs from the initiation of a Phase IIb trial through regulatory approval in exchange for increased tiered royalties ranging up to percentages in the high twenties. In 2010, Incyte exercised its option to co-develop baricitinib in rheumatoid arthritis. The agreement also provides Incyte with an option to co-promote in the U.S. and calls for payments associated with certain development, success-based regulatory, and sales-based milestones. As of June 30, 2015, Incyte is eligible to receive up to \$415.0 million of additional payments from us contingent upon certain development and success-based regulatory milestones as well as an additional \$150.0 million of potential sales-based milestones.

#### Tanezumab

In October 2013, we entered into a collaboration agreement with Pfizer Inc. (Pfizer) to jointly develop and globally commercialize tanezumab for the treatment of osteoarthritis pain, chronic low back pain and cancer pain. Under the agreement, the companies share equally the ongoing development costs and, if successful, in gross margins and certain commercialization expenses. 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 following table summarizes our aggregate amount of marketing, selling, and administrative expense associated with our commission and profit-sharing obligations for the collaborations and other arrangements described above:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Marketing, selling, and administrative	\$53.5	\$53.9	\$102.8	\$101.9

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Severance	\$22.1	\$—	\$53.2	\$19.4
Asset impairment and other special charges	50.3	—	127.2	12.0
Asset impairment, restructuring, and other special charges	\$72.4	\$—	\$180.4	\$31.4

Severance costs recognized during the three and six months ended June 30, 2015 were primarily attributable to our animal health business segment resulting from our acquisition of Novartis AH, as well as severance costs for actions taken to reduce our cost structure. Substantially all of the severance costs recognized during the six months ended June 30, 2014 were attributable to our human pharmaceuticals business segment and related to actions taken to reduce our cost structure.

Asset impairment and other special charges recognized during the three and six months ended June 30, 2015 were primarily attributable to our animal health business segment and related primarily to integration costs and intangible asset impairments due to product rationalization resulting from our acquisition of Novartis AH. Substantially all of the asset impairment and other special charges recognized during the six months ended June 30, 2014 were attributable to our human pharmaceuticals business segment and related to the closure of a manufacturing plant.





#### Note 6: Financial Instruments

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

#### Accounting Policy for Risk-Management Instruments

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

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

We may enter into foreign currency forward or option contracts to reduce the effect of fluctuating currency exchange rates (principally the euro, the British pound, and the Japanese yen). Foreign currency derivatives used for hedging are put in place using the same or like currencies and duration as the underlying exposures. Forward and option contracts are principally used to manage exposures arising from subsidiary trade and loan payables and receivables denominated in foreign currencies. These contracts are recorded at fair value with the gain or loss recognized in other-net, (income) expense. We may enter into foreign currency forward and option contracts and currency swaps as fair value hedges of firm commitments. Forward contracts generally have maturities not exceeding 12 months. At June 30, 2015, we had outstanding foreign currency forward commitments to purchase 986.1 million U.S. dollars and sell 882.6 million euro, commitments to purchase 1.15 billion euro and sell 1.29 billion U.S. dollars, commitments to purchase 482.4 million U.S. dollars and sell 59.36 billion Japanese yen, commitments to purchase 142.4 million British pounds and sell 196.7 million euro, and commitments to purchase 299.4 million U.S. dollars and sell 192.9 million British pounds, which will all settle within 30 days.

Foreign currency exchange risk is also managed through the use of foreign currency debt. Our euro-denominated notes issued in June 2015, which have a carrying amount of \$2.30 billion as of June 30, 2015, have been designated as, and are effective as, economic hedges of net investments in certain of our euro-denominated foreign operations. Accordingly, foreign currency translation gains or losses due to spot rate fluctuations on the euro-denominated notes are included as a component of other comprehensive income (loss). During the three and six months ended June 30, 2015, we recorded a pretax foreign currency translation loss of \$33.8 million from the euro-denominated notes.

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 June 30, 2015, substantially all of our total long-term debt is at a fixed rate. We have converted approximately 40 percent of our long-term fixed-rate notes to floating rates through the use of interest rate swaps. We may enter into forward contracts and designate them as cash flow hedges to limit the potential volatility of earnings and cash flow associated with forecasted sales of available-for-sale securities.

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 June 30, 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.

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

We may enter into forward-starting interest rate swaps, which we designate as cash flow hedges, as part of any anticipated future debt issuances in order to reduce the risk of cash flow volatility from future changes in interest rates. Upon completion of a debt issuance and termination of the swap, the change in fair value of these instruments is recorded as part of other comprehensive income (loss) and is amortized to interest expense over the life of the underlying debt. Upon issuance of the underlying fixed-rate notes in March 2015, we terminated forward-starting interest rate contracts in designated cash flow hedging instruments with an aggregate notional amount of \$1.35 billion and paid \$206.3 million in cash to the counterparties for settlement. The settlement amount represented the fair value of the forward-starting interest rate contracts at the time of termination and was recorded in other comprehensive loss. In connection with the note purchase and redemption discussed above, we terminated certain interest rate swaps designated as fair value hedges with an aggregate notional amount of \$876.0 million. As a result of the termination, we received cash of \$20.2 million, which represented the fair value of the interest rate swaps at the time of termination. The related fair value adjustment was recorded as an increase to the carrying value of the underlying notes and was included as a component of the debt extinguishment loss.

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Fair value hedges:				
Effect from hedged fixed-rate debt	\$(99.2 )	\$41.9	\$(40.3 )	\$93.7
Effect from interest rate contracts	99.2	(41.9 )	40.3	(93.7 )
Cash flow hedges:				
Effective portion of losses on equity contracts reclassified from accumulated other comprehensive loss <sup>(1)</sup>	—	27.9	—	67.4
Effective portion of losses on interest rate contracts reclassified from accumulated other comprehensive loss	3.6	2.2	6.3	4.4
Net (gains) losses on foreign currency exchange contracts not designated as hedging instruments	(1.2 )	20.9	22.1	20.6

(1) Realized gains on the sale of the underlying equity securities recognized in other-net, (income) expense for the three and six months ended June 30, 2014 were \$57.3 million and \$126.3 million, respectively.

17

---

The effective portion of net gains on equity contracts in designated cash flow hedging relationships recorded in other comprehensive income (loss) was \$34.6 million and \$120.5 million for the three and six months ended June 30, 2014, respectively. There were no equity contracts in designated cash flow hedging relationships during the three and six months ended June 30, 2015.

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

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

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

Fair Value of Financial Instruments

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

Description	Carrying Amount	Amortized Cost	Fair Value Measurements Using			Fair Value
			Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
June 30, 2015						
Cash equivalents	\$1,739.7	\$1,739.7	\$1,721.7	\$18.0	\$—	\$1,739.7
Short-term investments:						
U.S. government and agencies	\$195.7	\$195.6	\$195.7	\$—	\$—	\$195.7
Corporate debt securities	716.6	716.5	—	716.6	—	716.6
Asset-backed securities	0.2	0.2	—	0.2	—	0.2
Other securities	2.9	2.9	—	2.9	—	2.9
Short-term investments	\$915.4	\$915.2				
Noncurrent investments:						
U.S. government and agencies	\$437.9	\$438.8	\$416.9	\$21.0	\$—	\$437.9
Corporate debt securities	2,193.2	2,197.7	—	2,193.2	—	2,193.2
Mortgage-backed securities	170.4	171.6	—	170.4	—	170.4
Asset-backed securities	478.9	478.9	—	478.9	—	478.9
Other securities	4.6	4.6	—	4.6	—	4.6
Marketable equity securities	236.8	44.1	236.8	—	—	236.8
Equity method and other investments (1)	577.3	577.3				
Noncurrent investments	\$4,099.1	\$3,913.0				
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

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

Equity method and other investments	446.7	446.7
(1)		
Noncurrent investments	\$4,568.9	\$4,415.9
(1) Fair value not applicable		

19

---

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 <sup>(1)</sup>					
June 30, 2015	\$—	\$—	\$—	\$—	\$—
December 31, 2014	(2,680.6 )	—	(2,680.6 )	—	(2,680.6 )
Long-term debt, including current portion					
June 30, 2015	\$(7,999.4 )	\$—	\$(8,125.0 )	\$—	\$(8,125.0 )
December 31, 2014	(5,340.9 )	—	(5,722.1 )	—	(5,722.1 )

<sup>(1)</sup> 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)	
June 30, 2015					
Risk-management instruments					
Interest rate contracts designated as hedging instruments:					
Sundry	\$43.1	\$—	\$43.1	\$—	\$43.1
Other noncurrent liabilities	(1.8 )	—	(1.8 )	—	(1.8 )
Foreign exchange contracts not designated as hedging instruments:					
Other receivables	10.8	—	10.8	—	10.8
Other current liabilities	(14.8 )	—	(14.8 )	—	(14.8 )
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.

20

---

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

	Maturities by Period				
	Total	Less Than 1 Year	2-5 Years	6-10 Years	More Than 10 Years
Fair value of debt securities	\$4,200.4	\$915.4	\$2,971.8	\$123.5	\$189.7

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:

	June 30, 2015	December 31, 2014
Unrealized gross gains	\$204.5	\$171.9
Unrealized gross losses	18.2	18.3
Fair value of securities in an unrealized gain position	1,986.0	1,778.8
Fair value of securities in an unrealized loss position	2,287.1	3,129.2

We periodically assess our investment securities for other-than-temporary impairment losses. Other-than-temporary impairment losses recorded during the three and six months ended June 30, 2015 were \$6.2 million and \$9.8 million, respectively. Other-than-temporary impairment losses recorded during the three and six months ended June 30, 2014 were \$7.4 million.

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

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

As of June 30, 2015, the securities in an unrealized loss position include primarily fixed-rate debt securities of varying maturities. The value of fixed-income securities is sensitive to changes in the yield curve and other market conditions. Approximately 85 percent of the securities in a loss position are investment-grade debt securities. As of June 30, 2015, we do not intend to sell, and it is not more likely than not that we will be required to sell the securities in a loss position before the market values recover or the underlying cash flows have been received, and there is no indication of default on interest or principal payments for any of our debt securities.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Proceeds from sales	\$1,900.1	\$3,447.0	\$2,869.9	\$7,189.2
Realized gross gains on sales	47.8	84.8	102.3	164.6
Realized gross losses on sales	1.7	11.1	2.4	15.1

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

## Note 7: Goodwill and Other Intangibles

Goodwill by segment was as follows:

	June 30, 2015	December 31, 2014
Human pharmaceutical products	\$1,359.1	\$1,359.4
Animal health	2,665.6	398.7
Total goodwill	\$4,024.7	\$1,758.1

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

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

Description	June 30, 2015			December 31, 2014		
	Carrying Amount— Gross	Accumulated Amortization	Carrying Amount— Net	Carrying Amount— Gross	Accumulated Amortization	Carrying Amount— Net
Finite-lived intangible assets:						
Marketed products	\$7,760.8	\$(3,211.6 )	\$4,549.2	\$5,684.3	\$(2,915.6 )	\$2,768.7
Other	148.5	(53.4 )	95.1	149.3	(45.2 )	104.1
Total finite-lived intangible assets	7,909.3	(3,265.0 )	4,644.3	5,833.6	(2,960.8 )	2,872.8
Indefinite-lived intangible assets:						
In-process research and development	198.6	—	198.6	11.4	—	11.4
Other intangibles	\$8,107.9	\$(3,265.0 )	\$4,842.9	\$5,845.0	\$(2,960.8 )	\$2,884.2

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

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

	Three Months Ended		Six Months Ended	
	June 30, 2015	2014	June 30, 2015	2014
Amortization expense	\$153.4	\$134.1	\$307.7	\$265.9

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

## Note 8: Shareholders' Equity

During the six months ended June 30, 2015 and 2014, we purchased \$435.5 million and \$200.0 million of shares, respectively, associated with our \$5.00 billion share repurchase program announced in October 2013. As of June 30, 2015, there were \$3.26 billion of shares remaining in that program.

## Note 9: Income Taxes

The U.S. examination of tax years 2010-2012 commenced during the fourth quarter of 2013. 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 10: Retirement Benefits

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

	Defined Benefit Pension Plans			
	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Components of net periodic benefit cost:				
Service cost	\$85.5	\$67.6	\$162.5	\$130.3
Interest cost	117.2	118.0	234.3	237.2
Expected return on plan assets	(192.2 )	(189.1 )	(384.0 )	(378.4 )
Amortization of prior service cost	2.6	0.9	5.1	1.8
Recognized actuarial loss	90.9	69.4	183.3	138.5
Net periodic benefit cost	\$104.0	\$66.8	\$201.2	\$129.4
	Retiree Health Benefit Plans			
	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Components of net periodic benefit income:				
Service cost	\$11.2	\$11.7	\$21.0	\$23.0
Interest cost	15.3	22.6	30.7	43.8
Expected return on plan assets	(37.1 )	(35.9 )	(74.2 )	(71.9 )
Amortization of prior service cost	(21.6 )	(7.3 )	(43.2 )	(14.6 )
Recognized actuarial loss	9.5	5.0	18.9	10.1
Net periodic benefit income	\$(22.7 )	\$(3.9 )	\$(46.8 )	\$(9.6 )

On a global basis, we have contributed approximately \$35 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 six months ended June 30, 2015. During the remainder of 2015, we expect to make contributions to our defined benefit pension plans of approximately \$15 million to satisfy minimum funding requirements along with approximately \$250 million of additional discretionary contributions.

## Note 11: Contingencies

We are a party to various legal actions and government investigations. The most significant of these are described below. It is not possible to determine the outcome of these matters and we cannot reasonably estimate the maximum potential exposure or the range of possible loss in excess of amounts accrued for any of these matters; however, we believe that, except as noted below with respect to the Alimta<sup>®</sup> 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. Ten Abbreviated New Drug Applications (ANDAs) seeking approval to market generic versions of Alimta prior to the expiration of our vitamin regimen patent (expiring in 2021 plus pediatric exclusivity expiring in 2022) have been filed by a number of companies, including Teva Parenteral Medicines, Inc. (Teva) and APP Pharmaceuticals, LLC (APP). These companies have also alleged the patent is invalid.

In October 2010, we filed a lawsuit in the U.S. District Court for the Southern District of Indiana against Teva, APP and two other defendants seeking rulings that the U.S. vitamin regimen patent is valid and infringed (the Teva/APP litigation). Teva and APP stipulated to infringement of our vitamin regimen patent, with the contingency that Teva and APP would be permitted to litigate the issue of infringement if the U.S. Supreme Court vacated an en banc decision of the 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 on the issue of infringement took place in May 2015, and we are awaiting a decision from the district court.

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

#### European Patent Litigation and Administrative Proceedings

Generic manufacturers filed an opposition to the European Patent Office's (EPO) decision to grant us a vitamin regimen patent. The Opposition Division of the EPO upheld the patent and the generic manufacturers lodged an appeal. The EPO appeal hearing has been scheduled for November 2015.

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. In May 2014, the trial court ruled that the vitamin regimen patents for Alimta would not be infringed by commercialization of alternative salt forms of pemetrexed, after expiration of the compound patents in December 2015. We appealed, and in June 2015, the U.K. Court of Appeal reversed the trial court, ruling that the Alimta vitamin regimen patent in the U.K. would be indirectly infringed by commercialization of Actavis' products as proposed prior to the patent's expiration in June 2021. The Court of Appeal also held there was no difference between the law in the U.K. and that in France, Italy, and Spain as it relates to indirect infringement, and so reversed the trial court's decision granting declarations of noninfringement over the Alimta vitamin regimen patents in those countries.

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

#### Japanese Administrative Proceedings

Three companies have filed demands for invalidation of our vitamin regimen patents with the Japanese Patent Office. 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 2015, several generic pharmaceutical 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<sup>®</sup> Product Liability Litigation

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

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

Our agreement with Takeda calls for Takeda to defend and indemnify us against our losses and expenses with respect to the U.S. litigation arising out of the manufacture, use, or sale of Actos and other related expenses in accordance with the terms of the agreement. After the jury reached its verdict in Allen, Takeda notified us that it was reserving its right to challenge its obligations to defend and indemnify us with respect to the Allen case. We believe we are entitled to full indemnification of our losses and expenses in Allen and all other U.S. cases; however, there can be no guarantee we will ultimately be successful in obtaining full indemnification.

In April 2015, Takeda announced they will pay approximately \$2.4 billion to resolve the vast majority of the 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

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

We are named as a defendant in approximately 480 Byetta product liability lawsuits involving approximately 1,015 plaintiffs. Approximately 105 of these lawsuits, covering about 590 plaintiffs, are filed in California state court and coordinated in a Los Angeles Superior Court. Approximately 365 lawsuits, covering about 405 plaintiffs, are filed in

25

---



federal court, the majority of which are coordinated in a multi-district litigation in the Southern District of California. The remaining approximately five lawsuits, representing about 20 plaintiffs, are in various state courts. Approximately 415 of the lawsuits, involving approximately 645 plaintiffs, contain allegations that Byetta caused or contributed to the plaintiffs' cancer (primarily pancreatic cancer or thyroid cancer). We are aware of approximately 220 additional claimants who have not yet filed suit. The majority of these additional claims allege damages for pancreatitis. We believe these lawsuits and claims are without merit and are prepared to defend against them vigorously.

#### Prozac® Product Liability Litigation

We are named as a defendant in approximately 10 U.S. lawsuits primarily related to allegations that the antidepressant Prozac caused or contributed to birth defects in the children of women who ingested the drug during pregnancy. We are aware of approximately 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 \$320 million as of June 30, 2015) plus interest. We strongly disagree with the decision and filed an appeal in May 2014. We are also named in approximately 30 lawsuits filed in the same court by individual former employees making similar claims. We believe these lawsuits are without merit and are prepared to defend against them vigorously.

#### Product Liability Insurance

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

## Note 12: Other Comprehensive Income (Loss)

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

(Amounts presented net of taxes)	Foreign Currency Translation Gains (Losses)	Unrealized Net Gains (Losses) on Securities	Defined Benefit Pension and Retiree Health Benefit Plans	Effective Portion of Cash Flow Hedges	Accumulated Other Comprehensive Loss
Balance at April 1, 2015	\$ (1,294.4 )	\$ 155.6	\$ (3,293.1 )	\$ (225.6 )	\$ (4,657.5 )
Other comprehensive income (loss) before reclassifications	256.8	(8.7 )	(24.6 )	—	223.5
Net amount reclassified from accumulated other comprehensive loss	—	(25.9 )	54.4	2.3	30.8
Net other comprehensive income (loss)	256.8	(34.6 )	29.8	2.3	254.3
Balance at June 30, 2015	\$ (1,037.6 )	\$ 121.0	\$ (3,263.3 )	\$ (223.3 )	\$ (4,403.2 )
(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 April 1, 2014	\$ 459.7	\$ 166.2	\$ (2,443.5 )	\$ (139.7 )	\$ (1,957.3 )
Other comprehensive income (loss) before reclassifications	8.2	6.4	(8.0 )	(4.4 )	2.2
Net amount reclassified from accumulated other comprehensive loss	—	(47.9 )	48.2	19.5	19.8
Net other comprehensive income (loss)	8.2	(41.5 )	40.2	15.1	22.0
Balance at June 30, 2014	\$ 467.9	\$ 124.7	\$ (2,403.3 )	\$ (124.6 )	\$ (1,935.3 )

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

(Amounts presented net of taxes)	Foreign Currency Translation Gains (Losses)	Unrealized Net Gains (Losses) on Securities	Defined Benefit Pension and Retiree Health Benefit Plans	Effective Portion of Cash Flow Hedges	Accumulated Other Comprehensive Loss
Balance at January 1, 2015	\$ (498.4 )	\$ 99.7	\$ (3,402.0 )	\$ (191.1 )	\$ (3,991.8 )
Other comprehensive income (loss) before reclassifications	(539.2 )	59.1	30.6	(36.9 )	(486.4 )
Net amount reclassified from accumulated other comprehensive loss	—	(37.8 )	108.1	4.7	75.0
Net other comprehensive income (loss)	(539.2 )	21.3	138.7	(32.2 )	(411.4 )
Balance at June 30, 2015	\$ (1,037.6 )	\$ 121.0	\$ (3,263.3 )	\$ (223.3 )	\$ (4,403.2 )
(Amounts presented net of taxes)	Foreign Currency	Unrealized Net Gains	Defined Benefit	Effective Portion of	Accumulated Other

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

	Translation Gains (Losses)	(Losses) on Securities	Pension and Retiree Health Benefit Plans	Cash Flow Hedges	Comprehensive Loss
Balance at January 1, 2014	\$ 463.0	\$205.2	\$ (2,489.1 )	\$ (181.8 )	\$ (2,002.7 )
Other comprehensive income (loss) before reclassifications	4.9	16.7	(6.5 )	10.7	25.8
Net amount reclassified from accumulated other comprehensive loss	—	(97.2 )	92.3	46.5	41.6
Net other comprehensive income (loss)	4.9	(80.5 )	85.8	57.2	67.4
Balance at June 30, 2014	\$ 467.9	\$124.7	\$ (2,403.3 )	\$ (124.6 )	\$ (1,935.3 )

27

---

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

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2015	2014	2015	2014
Tax (benefit) expense				
Foreign currency translation losses	\$(11.8 )	\$—	\$(11.8 )	\$—
Unrealized net gains (losses) on securities	(18.6 )	(22.3 )	11.4	(43.5 )
Defined benefit pension and retiree health benefit plans	20.3	16.5	62.8	40.0
Effective portion of cash flow hedges	1.3	8.2	(17.2 )	30.6
Provision for income taxes allocated to other comprehensive income (loss)	\$(8.8 )	\$2.4	\$45.2	\$27.1

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

Details about Accumulated Other Comprehensive Loss Components	Reclassifications Out of Accumulated Other Comprehensive Loss				Affected line Item in the Consolidated Condensed Statements of Operations
	Three Months Ended		Six Months Ended		
	June 30, 2015	2014	June 30, 2015	2014	
Amortization of retirement benefit items:					
Prior service benefits, net	\$(19.0 )	\$(6.4 )	\$(38.1 )	\$(12.8 )	(1)
Actuarial losses	100.4	74.4	202.2	148.6	(1)
Total before tax	81.4	68.0	164.1	135.8	
Tax benefit	(27.0 )	(19.8 )	(56.0 )	(43.5 )	Income taxes
Net of tax	54.4	48.2	108.1	92.3	
Unrealized gains/losses on available-for-sale securities:					
Realized gains, net before tax	(46.1 )	(73.7 )	(64.4 )	(149.5 )	Other—net, (income) expense
Impairment losses	6.2	—	6.2	—	Other—net, (income) expense
Total before tax	(39.9 )	(73.7 )	(58.2 )	(149.5 )	
Tax expense	14.0	25.8	20.4	52.3	Income taxes
Net of tax	(25.9 )	(47.9 )	(37.8 )	(97.2 )	
Other, net of tax	2.3	19.5	4.7	46.5	Other—net, (income) expense
Total reclassifications for the period (net of tax)	\$30.8	\$19.8	\$75.0	\$41.6	

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

Note 13: Other–Net, (Income) Expense

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Interest expense	\$36.8	\$35.5	\$77.7	\$73.3
Interest income	(20.6 )	(33.6 )	(42.0 )	(68.0 )
Debt extinguishment loss (Note 6)	166.7	—	166.7	—
Other income	(59.6 )	(55.7 )	(171.8 )	(115.1 )
Other–net, (income) expense	\$123.3	\$(53.8 )	\$30.6	\$(109.8 )

Other income consists primarily of net gains on investments.

## Note 14: 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 and six months ended June 30, 2015 include the results of operations from Novartis AH which was acquired on January 1, 2015. See Note 3 for additional information regarding the Novartis AH acquisition.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Segment revenue—to unaffiliated customers:				
Human pharmaceutical products:				
Endocrinology:				
Humalog®	\$654.3	\$700.1	\$1,338.2	\$1,350.1
Humulin®	316.4	352.4	632.1	668.6
Forteo®	328.4	308.6	621.4	608.9
Trajenta	80.0	90.3	162.4	167.1
Evista®	59.7	108.3	126.5	258.3
Other Endocrinology	199.1	179.9	383.6	325.8
Total Endocrinology	1,637.9	1,739.6	3,264.2	3,378.8
Neuroscience:				
Cymbalta®	274.1	401.3	561.1	879.5
Zyprexa®	253.7	243.8	473.2	526.9
Strattera®	191.8	197.4	365.5	351.8
Other Neuroscience	44.3	51.2	89.4	99.9
Total Neuroscience	763.9	893.7	1,489.2	1,858.1
Oncology:				
Alimta	664.3	711.6	1,237.4	1,343.6
Erbix	134.6	93.5	222.8	184.3
Cyramza®	87.7	13.7	155.2	13.7
Other Oncology	36.0	39.6	66.2	81.1
Total Oncology	922.6	858.4	1,681.6	1,622.7
Cardiovascular:				
Cialis®	567.9	567.8	1,106.2	1,100.2
Effient	128.8	133.6	250.6	252.9
Other Cardiovascular	66.5	63.9	121.6	125.0
Total Cardiovascular	763.2	765.3	1,478.4	1,478.1
Other pharmaceuticals	50.3	77.4	119.5	152.4
Total human pharmaceutical products	4,137.9	4,334.4	8,032.9	8,490.1
Animal health	840.8	601.2	1,590.5	1,128.6
Revenue	\$4,978.7	\$4,935.6	\$9,623.4	\$9,618.7

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Segment profits:				
Human pharmaceutical products	\$1,016.8	\$803.1	\$2,099.9	\$1,590.8
Animal health	188.3	137.3	303.3	271.8
Total segment profits	\$1,205.1	\$940.4	\$2,403.2	\$1,862.6
Reconciliation of total segment profits to consolidated income before taxes:				
Segment profits	\$1,205.1	\$940.4	\$2,403.2	\$1,862.6
Other profits (losses):				
Acquired in-process research and development (Note 3)	(80.0 )	—	(336.0 )	—
Amortization of intangible assets <sup>(1)</sup>	(151.9 )	—	(304.6 )	—
Asset impairment, restructuring, and other special charges (Note 5)	(72.4 )	—	(180.4 )	(31.4 )
Debt repurchase charges, net <sup>(2)</sup> (Note 6)	(152.7 )	—	(152.7 )	—
Inventory fair value adjustment related to Novartis AH (Note 3)	(68.4 )	—	(131.9 )	—
Consolidated income before taxes	\$679.7	\$940.4	\$1,297.6	\$1,831.2

<sup>(1)</sup> 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 June 30, 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 \$116.6 million and \$15.5 million, respectively, and \$233.5 million and \$27.4 million for the six months ended June 30, 2014, respectively.

<sup>(2)</sup> We recognized pretax net charges of \$152.7 million for the three and six months ended June 30, 2015, attributable to the debt extinguishment loss of \$166.7 million from the purchase and redemption of certain fixed-rate notes, partially offset by net gains from non-hedging interest rate swaps and foreign currency transactions associated with the related issuance of euro-denominated notes.

Depreciation expense included in our segment profits was as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Human pharmaceutical products	\$199.2	\$197.5	\$387.3	\$403.9
Animal health	17.4	18.8	34.1	32.4
Total depreciation expense included in segment profits	\$216.6	\$216.3	\$421.4	\$436.3

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

The following table summarizes our key operating results:

	Three Months Ended		Percent Change from 2014	Six Months Ended		Percent Change from 2014		
	June 30, 2015	2014		June 30, 2015	2014			
Revenue	\$4,978.7	\$4,935.6	1	%	\$9,623.4	\$9,618.7	—	%
Gross margin	3,760.3	3,745.9	—	%	7,212.3	7,206.3	—	%
Gross margin percentage	75.5	% 75.9	%		74.9	% 74.9	%	
Operating expense <sup>(1)</sup>	\$2,957.3	\$2,859.3	3	%	\$5,884.1	\$5,484.9	7	%
Net income	600.8	733.5	(18	)%	1,130.3	1,461.4	(23	)%
Earnings per share	0.56	0.68	(18	)%	1.06	1.36	(22	)%

<sup>(1)</sup> Operating expense consists of research and development, marketing, selling, and administrative, acquired in-process research and development, and asset impairment, restructuring, and other special charges.

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

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

## 2015

## Acquisitions (Note 3)

We recognized expense of \$68.4 million (pretax), or \$0.05 per share, and \$131.9 million (pretax), or \$0.09 per share, for the three and six months ended June 30, respectively, related to the fair value adjustments to Novartis Animal Health (Novartis AH) acquisition date inventory that has been sold.

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

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

We recognized acquired IPR&D charges in the first quarter of \$256.0 million (pretax), or \$0.15 per share, related to upfront fees paid in connection with the collaboration agreements with Pfizer, Inc. (Pfizer) and Innovent Biologics, Inc. (Innovent).

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

We recognized charges of \$72.4 million (pretax), or \$0.05 per share, and \$180.4 million (pretax), or \$0.12 per share, for the three and six months ended June 30, respectively, related to integration costs, intangible asset impairments, and severance costs resulting from our acquisition of Novartis AH.



Debt Repurchase (Notes 6 and 13)

We recognized net charges of \$152.7 million (pretax), or \$0.09 per share, for the three and six months ended June 30, attributable to the debt extinguishment loss of \$166.7 million from the purchase and redemption of certain fixed-rate notes, partially offset by net gains from non-hedging interest rate swaps and foreign currency transactions associated with the related issuance of euro-denominated notes.

2014

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

We recognized charges in the first quarter of \$31.4 million (pretax), or \$0.02 per share, related primarily to severance costs for actions taken to reduce our cost structure.

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 55 potential new drugs in human testing or under regulatory review, and a larger number of projects in preclinical research.

The following new molecular entities (NMEs) have been submitted for regulatory review in at least one of the major geographies for potential use in the 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 pегlispro\* (Q4 2011)—a novel basal insulin for the treatment of type 1 and type 2 diabetes.

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

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 United States (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			Studies are ongoing.

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

Compound	Indication	U.S.	Europe	Japan	Developments
Endocrinology	Type 1 diabetes	Phase III			Announced in February 2015 decision to delay regulatory submission to generate additional clinical data to understand and characterize potential effects, if any, of changes in liver fat observed with basal insulin peglispro treatment. 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			
Jardiance®	Type 2 diabetes	Launched			Glyxambi®, combination tablet of empagliflozin and linagliptin, approved in the U.S. in January 2015 and launched in first quarter of 2015. Intend to submit to European regulatory authorities in late 2015. First launch in Europe and Japan in second and third quarter of 2015, respectively. See Note 4 for information on the U.S. tentative approval. Launched in certain European countries in first quarter of 2015. Approved in Japan in July 2015.
New insulin glargine product	Type 1 diabetes	Tentatively approved	Launched		
	Type 2 diabetes	Tentatively approved	Launched		
Trulicity™	Type 2 diabetes	Launched		Approved	
Immunology	Rheumatoid arthritis	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., Europe, and Japan in first, second, and third quarter of 2015, respectively.
Baricitinib	Psoriasis	Submitted			
Ixekizumab	Psoriatic arthritis	Phase III		Submitted	Announced in April 2015 top-line results of SPIRIT-P1 trial which met primary endpoints. Submitted to regulatory authorities in Japan in third quarter of 2015.
Neuroscience CGRP monoclonal antibody	Cluster headache	Phase III			Initiated first Phase III study in June 2015. Granted Fast Track Designation from FDA in June 2015. Enrollment in EXPEDITION 3 study completed. In July 2015, announced clinical trial results indicating the treatment effect was preserved in patients with mild Alzheimer's disease who received solanezumab earlier in disease, compared to patients beginning treatment at later point.
Solanezumab	Mild Alzheimer's disease	Phase III			FDA clinical hold lifted in March 2015. Phase III studies expected to resume in 2015.
Tanezumab	Osteoarthritis pain	Phase III Phase III			

Chronic low back  
pain  
Cancer pain      Phase III

Compound	Indication	U.S.	Europe	Japan	Developments
Abemaciclib	Metastatic breast cancer	Phase III			Studies are ongoing.
	NSCLC	Phase III			Study is ongoing.
	Gastric cancer (first-line)	Phase III			Initiated Phase III study of Cyramza in first-line gastric cancer in January 2015. Launched in certain European countries in first quarter of 2015. In Japan, approved in March 2015 and launched in second quarter of 2015.
	Gastric cancer (second-line)	Launched			Initiated Phase III study of Cyramza in first-line NSCLC in May 2015. Launched in the U.S. in first quarter of 2015. Submitted in Europe and Japan in first and third quarter of 2015, respectively.
Cyramza®	NSCLC (first-line)	Phase III			Initiated Phase III study of Cyramza in first-line NSCLC in May 2015. Launched in the U.S. in first quarter of 2015. Submitted in Europe and Japan in first and third quarter of 2015, respectively.
	NSCLC (second-line)	Launched	Submitted		Submitted in Europe and Japan in first and third quarter of 2015, respectively.
	Liver cancer (second-line)	Phase III			Initiated Phase III study of Cyramza in second-line liver cancer in July 2015. Approved and launched in the U.S. in second quarter of 2015. Submitted in Europe and Japan in first and second quarter of 2015, respectively.
	Metastatic colorectal cancer (second-line)	Launched	Submitted		Submitted in Europe and Japan in first and second quarter of 2015, respectively.
	Urothelial (bladder) cancer (second-line)	Phase III			Initiated Phase III study of Cyramza in second-line bladder cancer in July 2015.
Necitumumab	Squamous NSCLC	Submitted		Phase Ib/II	FDA Oncologic Drugs Advisory Committee met in July 2015 to review data supporting necitumumab in combination with gemcitabine and cisplatin. Anticipate FDA action before the end of 2015.

In addition to the developments discussed above, in the third quarter of 2015, we announced our intention to submit U.S. and European regulatory applications based on currently-available data from Phase II clinical trials for olaratumab, a human IgG1 monoclonal antibody being studied for the treatment of advanced soft tissue sarcoma. In addition, we disclosed that olaratumab was granted breakthrough therapy designation by the FDA. The breakthrough therapy designation is intended to expedite the development and review of drugs for serious or life-threatening conditions where preliminary clinical evidence demonstrates that the drug may have substantial improvement on at least one clinically significant endpoint over available therapy. The U.S. regulatory submission is expected to occur near the end of 2015.

#### 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 has increased our animal health product portfolio, expanded our global commercial presence, and augmented our animal health manufacturing and research and development. In particular, it has provided Elanco with a greater commercial presence in the companion animal and swine markets, expanded Elanco's presence in equine and vaccines areas, and created an entry into the aquaculture market. As a condition to the clearance of the transaction under the Hart-Scott-Rodino Antitrust Improvement Act, following the closing of the acquisition of Novartis AH, we

divested certain companion animal assets in the U.S. related to the Sentinel® canine parasiticide franchise to Virbac Corporation for approximately \$410 million. The Novartis AH business we retained generated revenue of approximately \$1.1 billion in 2014.

#### Patent Matters

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

We lost our data package protection for Cymbalta in major European countries in 2014, 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 11 to the consolidated condensed financial statements, the Alimta® vitamin regimen patent, which provides us with patent protection for Alimta through June 2021 in Japan and major European countries, and through May 2022 in the U.S., has been challenged in each of these jurisdictions. Our compound patent for Alimta will expire in the U.S. in January 2017, and in major European countries and Japan in December 2015. We expect that the entry of generic competition for Alimta into the markets 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.

#### 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 adverse effect on our consolidated operating results and cash flows.

#### Legal Matters

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



## Revenue

The following tables summarize our revenue activity by jurisdiction:

	Three Months Ended		Change in		
	June 30,		Dollars	Percent	
	2015	2014			
U.S. <sup>(1)</sup>	\$2,527.8	\$2,379.5	\$148.3	6	%
Outside U.S.	2,450.9	2,556.1	(105.2)	(4)	)%
Revenue	\$4,978.7	\$4,935.6	\$43.1	1	%
	Six Months Ended		Change in		
	June 30,		Dollars	Percent	
	2015	2014			
U.S. <sup>(1)</sup>	\$4,739.1	\$4,463.7	\$275.4	6	%
Outside U.S.	4,884.3	5,155.0	(270.6)	(5)	)%
Revenue	\$9,623.4	\$9,618.7	\$4.7	—	%

Numbers may not add due to rounding

<sup>(1)</sup> U.S. revenue includes revenue in Puerto Rico.

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

	Three Months Ended			Six Months Ended		
	June 30,			June 30,		
	2015 vs. 2014			2015 vs. 2014		
	U.S.	Outside U.S.	Consolidated	U.S.	Outside U.S.	Consolidated
Volume	2	%13	%8	% —	%10	%5
Price	4	%(2	)%1	%6	%(1	)%2
Foreign exchange rates	—	%(16	)%8	)% —	%(14	)%7
Percent change	6	%(4	)%1	%6	%(5	)% —

Numbers may not add due to rounding

In the U.S., for the three months ended June 30, the volume increase was primarily attributable to the inclusion of revenue from Novartis AH and increased volume for several products, partially offset by lower demand for Cymbalta and Evista due to patent expirations in December 2013 and March 2014, respectively. For the six months ended June 30, volume remained essentially flat as the inclusion of revenue from Novartis AH and increased volume for several products, including Cyramza and Trulicity, was largely offset by lower demand for Cymbalta and Evista.

Outside the U.S., for the three and six months ended June 30, the volume increase was primarily attributable to the inclusion of revenue from Novartis AH and increased volume for the majority of pharmaceutical products. For the second quarter of 2015, the increased volume for the majority of pharmaceutical products was due in part to wholesaler buying patterns in Japan.

The following table summarizes our revenue activity by product:

Product	Three Months Ended June 30, 2015			Three Months Ended June 30, 2014	Percent Change from 2014	
	U.S. <sup>(1)</sup>	Outside U.S.	Total	Total		
	(Dollars in millions)					
Alimta	\$330.0	\$334.3	\$664.3	\$711.6	(7	)%
Humalog	399.7	254.6	654.3	700.1	(7	)%
Cialis <sup>®</sup>	309.5	258.4	567.9	567.8	—	%
Forteo <sup>®</sup>	144.6	183.8	328.4	308.6	6	%
Humulin <sup>®</sup>	188.1	128.3	316.4	352.4	(10	)%
Cymbalta	40.5	233.6	274.1	401.3	(32	)%
Zyprexa	57.6	196.1	253.7	243.8	4	%
Strattera <sup>®</sup>	121.1	70.7	191.8	197.4	(3	)%
Effient <sup>®</sup>	102.0	26.8	128.8	133.6	(4	)%
Evista	13.7	46.0	59.7	108.3	(45	)%
Other human pharmaceutical products	244.8	220.3	465.1	400.8	16	%
Animal health products	410.0	430.8	840.8	601.2	40	%
Total net product revenues	2,361.6	2,383.7	4,745.3	4,726.9	—	%
Collaboration and other revenue <sup>(2)</sup>	166.2	67.2	233.4	208.7	12	%
Revenue	\$2,527.8	\$2,450.9	\$4,978.7	\$4,935.6	1	%
Product	Six Months Ended June 30, 2015			Six Months Ended June 30, 2014	Percent Change from 2014	
	U.S. <sup>(1)</sup>	Outside U.S.	Total	Total		
	(Dollars in millions)					
Humalog	\$820.3	\$517.9	\$1,338.2	\$1,350.1	(1	)%
Alimta	582.7	654.7	1,237.4	1,343.6	(8	)%
Cialis	556.5	549.7	1,106.2	1,100.2	1	%
Humulin	367.7	264.4	632.1	668.6	(5	)%
Forteo	266.5	354.9	621.4	608.9	2	%
Cymbalta	94.9	466.2	561.1	879.5	(36	)%
Zyprexa	84.1	389.1	473.2	526.9	(10	)%
Strattera	229.6	135.9	365.5	351.8	4	%
Effient	196.6	54.0	250.6	252.9	(1	)%
Evista	37.8	88.7	126.5	258.3	(51	)%
Other human pharmaceutical products	453.0	438.2	891.2	759.4	17	%
Animal health products	766.7	823.8	1,590.5	1,128.6	41	%
Total net product revenues	4,456.4	4,737.5	9,193.9	9,228.8	—	%
Collaboration and other revenue <sup>(2)</sup>	282.7	146.8	429.5	389.9	10	%
Revenue	\$4,739.1	\$4,884.3	\$9,623.4	\$9,618.7	—	%

(1) U.S. revenue includes revenue in Puerto Rico.

(2) Collaboration and other revenue consists primarily of royalties for Erbitux<sup>®</sup> and revenue associated with Trajenta<sup>®</sup>.

Revenues of Humalog, our injectable human insulin analog for the treatment of diabetes, decreased 3 percent in the U.S. during the second quarter of 2015, driven primarily by lower net effective selling prices. For the first six months of 2015, U.S. revenue increased 4 percent driven by wholesaler buying patterns and higher prices. Revenues outside the U.S. decreased 11 percent during the second quarter of 2015, driven by the unfavorable impact of foreign exchange rates, partially offset by increased volume and higher prices. For the first six months of 2015, revenue outside the U.S. decreased 8 percent, 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 second quarter and first six months of 2015, driven by higher prices. Revenues outside the U.S. decreased 14 percent and 16 percent during the second quarter and first six months of 2015, respectively, driven by the unfavorable impact of foreign exchange rates and, to a lesser extent, lower prices, partially offset by increased volume.

Revenues of Cialis, a treatment for erectile dysfunction and benign prostatic hyperplasia, increased 16 percent and 18 percent in the U.S. during the second quarter and first six months of 2015, respectively, driven by higher prices, partially offset by decreased volume. Revenues outside the U.S. decreased 14 percent and 13 percent during the second quarter and first six months of 2015, respectively, driven by the unfavorable impact of foreign exchange rates, partially offset by increased volume.

Revenues of Humulin, an injectable human insulin for the treatment of diabetes, increased 4 percent in the U.S. in the second quarter of 2015, driven primarily by increased demand and higher prices. For the first six months of 2015, U.S. revenue increased 9 percent, driven by higher prices and, to a lesser extent, increased volume. Revenues outside the U.S. decreased 25 percent and 20 percent in the second quarter and first six months of 2015, respectively, driven by decreased volume, primarily in Brazil and the unfavorable impact of foreign exchange rates.

Revenues of Forteo, an injectable treatment for osteoporosis in postmenopausal women and men at high risk for fracture and for glucocorticoid-induced osteoporosis in men and postmenopausal women, increased 13 percent and 17 percent in the U.S. in the second quarter and first six months of 2015, respectively, driven by higher prices, partially offset by lower demand. Revenues outside the U.S. increased 2 percent in the second quarter of 2015, as increased volume, primarily due to wholesaler buying patterns in Japan, was largely offset by the unfavorable impact of foreign exchange rates. For the first six months of 2015, revenue outside the U.S. decreased 7 percent due to the unfavorable impact of foreign exchange rates, partially offset by increased volume.

Revenues of Cymbalta, a product for the treatment of major depressive disorder, diabetic peripheral neuropathic pain, generalized anxiety disorder, and for the treatment of chronic musculoskeletal pain and the management of fibromyalgia, decreased 64 percent and 67 percent in the U.S. for the second quarter and first six months of 2015, respectively, due to the loss of U.S. patent exclusivity in December 2013. Revenues outside the U.S. decreased 19 percent and 21 percent in the second quarter and first six months of 2015, respectively, driven by the unfavorable impact of foreign exchange rates and the loss of exclusivity in 2014. For the second quarter of 2015, this decrease in revenues was partially offset by increased volume in Japan, primarily due to wholesaler buying patterns.

Revenues of Zyprexa, a treatment for schizophrenia, acute mixed or manic episodes associated with bipolar I disorder, and bipolar maintenance, increased 45 percent and 26 percent in the U.S. in the second quarter and first six months of 2015, respectively, driven by adjustments to the return reserve resulting from the expiration of the period to return expired product for credit. Revenues outside the U.S. decreased 4 percent in the second quarter of 2015, due to the unfavorable impact of foreign exchange rates, partially offset by increased volume in Japan, primarily due to wholesaler buying patterns. For the first six months of 2015, revenue outside the U.S. decreased 15 percent, due to the unfavorable impact of foreign exchange rates. We will lose patent exclusivity for Zyprexa in Japan in December 2015. Zyprexa revenues in Japan were \$200.3 million for the first six months of 2015, compared with \$227.1 million for the first six months of 2014. The revenue decrease in Japan was due to the unfavorable impact of foreign exchange rates.

Revenues of Strattera, a treatment for attention-deficit hyperactivity disorder, decreased 7 percent in the U.S. in the second quarter of 2015, driven by lower net effective selling prices. For the first six months of 2015, U.S. revenue increased 8 percent, primarily driven by higher prices and, to a lesser extent, increased demand. Revenues outside the U.S. increased 4 percent during the second quarter of 2015 driven by increased volume, primarily due to wholesaler buying patterns in Japan, partially offset by the unfavorable impact of foreign exchange rates. For the first six months

of 2015, revenue outside the U.S. decreased 2 percent, driven by the unfavorable impact of foreign exchange rates, largely offset by increased volume.

Revenues of Effient, a product for the reduction of thrombotic cardiovascular events (including stent thrombosis) in patients with acute coronary syndrome who are managed with an artery-opening procedure known as percutaneous

coronary intervention, including patients undergoing angioplasty, atherectomy, or stent placement, increased 2 percent in the U.S. in the second quarter of 2015, as higher prices were largely offset by decreased demand. For the first six months of 2015, U.S. revenue increased 5 percent driven by higher prices, partially offset by decreased demand.

Revenue outside the U.S. decreased 19 percent and 17 percent in the second quarter and first six months of 2015, respectively, driven by the unfavorable impact of foreign exchange rates.

Revenues of Evista, a product for the prevention and treatment of osteoporosis in postmenopausal women and for reduction of risk of invasive breast cancer in postmenopausal women with osteoporosis and postmenopausal women at high risk for invasive breast cancer, decreased 75 percent in the U.S. in the second quarter and first six months of 2015, due to the loss of U.S. patent exclusivity in March 2014. Revenues outside the U.S. decreased 14 percent and 16 percent in the second quarter and first six months of 2015, respectively, driven by the unfavorable impact of foreign exchange rates.

Revenues of animal health products increased 24 percent and 60 percent in the U.S. and outside the U.S., respectively, in the second quarter of 2015. For the first six months of 2015, revenue increased 20 percent and 68 percent in the U.S. and outside the U.S., respectively. The increases for the second quarter and first six months of 2015 were primarily driven by the inclusion of revenue from Novartis AH. For the first six months of 2015, the increase also benefited from the inclusion of revenue from Lohmann SE (Note 3).

On a pro forma basis, which reflects the 2014 revenues of Novartis AH as described in Note 3, revenues of animal health products in the U.S. would have increased 1 percent in the second quarter of 2015, driven by increased volume in companion animal products and to a lesser extent higher prices, partially offset by decreased volume in food animal products. For the first six months of 2015, revenue in the U.S. would have decreased 1 percent, primarily driven by decreased volume in food animal products, partially offset by higher prices, primarily for food animal products.

Revenues outside the U.S. would have decreased 9 percent in the second quarter of 2015, driven by the unfavorable impact of foreign exchange rates, partially offset by increased volume, primarily in food animal products, and to a lesser extent higher prices. Revenues outside the U.S. would have decreased 7 percent in the the first six months of 2015, driven by the unfavorable impact of foreign exchange rates and, to a lesser extent decreased volume in companion animal products, partially offset by increased volume for food animal products and to a lesser extent higher prices, primarily for food animal products.

#### Gross Margin, Costs, and Expenses

Gross margin as a percent of revenue decreased 0.4 percentage points to 75.5 percent for the second quarter of 2015 and remained essentially flat at 74.9 percent for the first six months of 2015. For the second quarter of 2015, the decrease was primarily due to the inclusion of Novartis AH and inventory step-up and amortization costs, largely offset by the favorable impact of foreign exchange rates on international inventories sold. For the first six months of 2015, the favorable impact of foreign exchange rates on international inventories sold was offset by the inclusion of Novartis AH and inventory step-up and amortization costs.

Research and development expenses decreased 2 percent to \$1.17 billion for the second quarter of 2015 and decreased 4 percent to \$2.21 billion for the first six months of 2015. For the second quarter of 2015, the decrease was primarily driven by the favorable impact of foreign exchange rates, partially offset by expenses of Novartis AH. For the first six months of 2015, the decrease was driven by the favorable impact of foreign exchange rates and lower late-stage clinical development costs, partially offset by expenses of Novartis AH.

Marketing, selling, and administrative expenses decreased 2 percent to \$1.64 billion for the second quarter of 2015 and remained essentially flat at \$3.16 billion for the first six months of 2015. For the second quarter of 2015, the decrease was due to the favorable impact of foreign exchange rates and ongoing cost-containment measures, partially offset by expenses of Novartis AH and marketing and selling expenses related to new product launches. For the first six months of 2015, the expenses of Novartis AH and marketing and selling expenses related to new product launches were largely offset by the favorable impact of foreign exchange rates and ongoing cost-containment measures.

Acquired in-process research and development charges of \$80.0 million were recognized in the second quarter of 2015 and \$336.0 million in the first six months of 2015, compared to no charges for the same periods in 2014. The charges for the second quarter of 2015 included a \$50.0 million payment to Hanmi related to an exclusive license and collaboration agreement for Hanmi's oral Bruton's tyrosine kinase inhibitor and a \$30.0 million payment to BioNTech

related to the research collaboration to discover novel cancer immunotherapies. In addition, the first six months of 2015 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 second quarter of 2015, we recognized \$72.4 million of asset impairment, restructuring, and other special charges, compared to no charges for the second quarter of 2014. The charges primarily relate to integration costs for Novartis AH, asset impairments, and severance costs. For the first six months of 2015 and 2014, we recognized asset impairment, restructuring, and other special charges of \$180.4 million and \$31.4 million, respectively. The 2015 charges were related primarily to integration costs and intangible asset impairments due to product rationalization resulting from our 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 an expense of \$123.3 million and \$30.6 million for the second quarter and first six months of 2015, respectively, compared with income of \$53.8 million and \$109.8 million for the same respective periods in 2014. Other expense in the second quarter and first six months of 2015 was driven by a net charge of \$152.7 million related to the repurchase of \$1.65 billion of debt. See Notes 6 and 13 for additional information.

The effective tax rates were 11.6 percent and 12.9 percent for the second quarter and first six months of 2015, respectively, compared with 22.0 percent and 20.2 percent for the same respective periods in 2014. The decrease in the effective tax rate for the second quarter and first six months of 2015 is primarily due to the tax impact of the net charge related to the repurchase of debt, acquired in-process research and development charges, and asset impairment, restructuring and other special charges. The 2015 effective tax rates also reflected a discrete tax benefit of approximately \$24 million in the second quarter. The effective tax rate for the first six months 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 research and development (R&D) tax credit.

#### Financial Condition

Cash and cash equivalents decreased to \$3.32 billion as of June 30, 2015, compared with \$3.87 billion as of December 31, 2014. Refer to the consolidated condensed statements of cash flows for additional details on the significant sources and uses of cash for the six months ended June 30, 2015 and 2014.

In addition to our cash and cash equivalents, we held total investments of \$5.01 billion and \$5.52 billion as of June 30, 2015 and December 31, 2014, respectively. See Note 6 for additional details.

Total debt decreased to \$8.00 billion as of June 30, 2015, compared with \$8.02 billion as of December 31, 2014 primarily due to \$2.68 billion of net repayments of commercial paper borrowings, the repayment of \$1.78 billion of fixed-rate notes in connection with the purchase and redemption, and, to a lesser extent, the decrease in fair value of our hedged debt. These decreases were largely offset by the issuance of \$4.45 billion of fixed-rate notes. At June 30, 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 six months ended June 30, 2015, we purchased \$435.5 million of shares associated with our previously announced \$5.00 billion share repurchase program.

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

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

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

#### Financial Expectations for 2015

We have revised certain elements of our 2015 financial guidance. Full-year 2015 EPS are now expected to be in the range of \$2.20 to \$2.30. We now anticipate that 2015 revenue will be between \$19.7 billion and \$20.0 billion, reflecting solid underlying performance for the first six months of the year, including the launch trajectories of Jardiance, Trulicity, and Cyramza.

We still expect that gross margin as a percent of revenue will be approximately 74.5 percent. 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 still expected to be in the range of \$6.4 billion to \$6.7 billion. Other—net, (income) expense is now expected to be in a range between \$50 million of expense and no income due to the net charge related to the repurchase of debt.

The 2015 tax rate is now expected to be approximately 14.5 percent, primarily due to the tax impact of the net charge related to the repurchase of debt. 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.

(a) 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 June 30, 2015, and concluded that they are effective.

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



## Part II. Other Information

### Item 1. Legal Proceedings

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

- The patent litigation and administrative proceedings involving Alimta and Effient.
- The product liability litigation involving Acto<sup>®</sup>, Byetta<sup>®</sup>, and Prozac<sup>®</sup>.
- 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. Plaintiffs have filed a second motion for certification under the consumer protection acts of two states.

Additionally, we have been named in approximately 65 lawsuits filed in various federal and state courts by claimants alleging injuries arising from discontinuation of treatment with Cymbalta. Counsel for plaintiffs filed a petition seeking to have then-filed cases and an unspecified number of future cases coordinated into a federal multi-district litigation (MDL) in the Central District of California. In December 2014, the Judicial Panel on Multidistrict Litigation denied the plaintiffs' petition for creation of an MDL. A few cases have been coordinated in Los Angeles Superior Court. The first individual product liability cases are scheduled for trial in August 2015.

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 185 U.S. product liability lawsuits involving Axiron<sup>®</sup>. 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 Patent Litigation

We have filed applications with the FDA and regulators in Europe, Japan, and other countries seeking approval to market our new insulin glargine product following the expiration of the compound patent for insulin glargine (generally May 2015). In January 2014, Sanofi-Aventis U.S. LLC (Sanofi) filed a lawsuit against us in the U.S. District Court for the District of Delaware alleging patent infringement with respect to our product. Sanofi asserts infringement of three U.S. patents relating to pen injector devices and two U.S. patents relating to insulin glargine formulations. Under the Drug Price Competition and Patent Term Restoration Act of 1984, the initiation of the lawsuit automatically invoked a stay of final FDA approval for a period of 30 months (until June 2016), which may be shortened in the event of an earlier court decision in our favor. In August 2014, we received tentative FDA approval for our insulin glargine product under the trade name Basaglar<sup>®</sup>, with final approval subject to the stay described above. A trial date has been scheduled in the District of Delaware for September 2015. In July 2014, Sanofi filed a second lawsuit against us in the same court alleging infringement of patents relating to the use of our insulin glargine formulation in a cartridge; however, we are no longer seeking approval of a cartridge, and this second lawsuit has been dismissed.

Legal proceedings are also underway in France, Japan, and Canada related to various patents asserted by Sanofi against our insulin glargine product. Sanofi has also asserted certain device patents against Humalog and Humulin pen devices in France and Japan in these proceedings. Proceedings brought in the United Kingdom, which were related to device patents, were resolved in December 2014 with a declaration of non-infringement in our favor.

We do not believe our insulin glargine product infringes any valid claim of the asserted patents, and we believe we will prevail in the various proceedings related to the patents.

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 June 30, 2015:

Period	Total Number of Shares Purchased (in thousands)	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs (in thousands)	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs (in millions)
April 2015	1,664.7	\$75.01	1,664.7	\$3,264.5
May 2015	—	—	—	—
June 2015	—	—	—	—
Total	1,664.7	75.01	1,664.7	

In October 2013, we announced a \$5.00 billion share repurchase program. During the second quarter of 2015, we purchased \$124.9 million of shares under the program.

Item 6. Exhibits

The following documents are filed as exhibits to this Report:

- |              |   |
|--------------|---|
| EXHIBIT 3.1  | Amended Articles of Incorporation   |
| EXHIBIT 3.2  | By-laws, as amended   |
| EXHIBIT 4.1  | 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: July 30, 2015     /s/James B. Lootens  
James B. Lootens  
Corporate Secretary

Date: July 30, 2015     /s/Donald A. Zakrowski  
Donald A. Zakrowski  
Vice President, Finance and Chief Accounting Officer

Index to Exhibits

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

Exhibit

- |              |   |
|--------------|---|
| EXHIBIT 3.1  | Amended Articles of Incorporation are incorporated by reference to Exhibit 3.1 to the Company's Report on Form 10-K for the year ended December 31, 2013.   |
| EXHIBIT 3.2  | By-laws, as amended, are incorporated by reference to Exhibit 99 to the Company's Report on Form 8-K filed February 27, 2012.   |
| EXHIBIT 4.1  | 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   |