

LILLY ELI & CO  
Form 10-Q  
July 28, 2016

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, 2016

COMMISSION FILE NUMBER 001-6351

ELI LILLY AND COMPANY

(Exact name of Registrant as specified in its charter)

INDIANA 35-0470950

(State or other jurisdiction of (I.R.S. Employer  
incorporation or organization) 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 18, 2016:

Class	Number of Shares Outstanding
Common	1,103,843,444

Eli Lilly and Company  
 Form 10-Q  
 For the Quarter Ended June 30, 2016  
 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</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 Results of Operations and Financial Condition</u>	<u>33</u>
<u>Executive Overview</u>	<u>33</u>
<u>Revenue</u>	<u>39</u>
<u>Gross Margin, Costs, and Expenses</u>	<u>42</u>
<u>Financial Condition</u>	<u>43</u>
<u>Financial Expectations</u>	<u>43</u>
<u>Available Information on our Website</u>	<u>44</u>
<u>Item 4.</u>	
<u>Controls and Procedures</u>	<u>44</u>
<u>PART II. Other Information</u>	<u>45</u>
<u>Item 1.</u>	
<u>Legal Proceedings</u>	<u>45</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, 2015, particularly under the captions “Forward-Looking Statements” and “Risk Factors.”

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

## PART I. Financial Information

## Item 1. Financial Statements

## Consolidated Condensed Statements of Operations

(Unaudited)

## ELI LILLY AND COMPANY AND SUBSIDIARIES

(Dollars and shares in millions, except per-share data)

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2016	2015	2016	2015
Revenue	\$5,404.8	\$4,978.7	\$10,269.9	\$9,623.4
Costs, expenses, and other:				
Cost of sales	1,465.0	1,218.4	2,788.0	2,411.1
Research and development	1,335.9	1,169.5	2,556.9	2,208.8
Marketing, selling, and administrative	1,622.6	1,635.4	3,096.5	3,158.9
Acquired in-process research and development (Note 3)	—	80.0	—	336.0
Asset impairment, restructuring, and other special charges (Note 5)	58.0	72.4	189.4	180.4
Other—net, (income) expense (Note 12)	(21.2	) 123.3	127.8	30.6
	4,460.3	4,299.0	8,758.6	8,325.8
Income before income taxes	944.5	679.7	1,511.3	1,297.6
Income taxes (Note 8)	196.8	78.9	323.5	167.3
Net income	\$747.7	\$600.8	\$1,187.8	\$1,130.3
Earnings per share:				
Basic	\$0.71	\$0.57	\$1.12	\$1.06
Diluted	\$0.71	\$0.56	\$1.12	\$1.06
Shares used in calculation of earnings per share:				
Basic	1,057.7	1,061.7	1,058.8	1,063.0
Diluted	1,060.1	1,065.6	1,061.0	1,066.3
Dividends paid per share	\$0.51	\$0.50	\$1.02	\$1.00
See notes to consolidated condensed financial statements.				

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Net income	\$747.7	\$600.8	\$1,187.8	\$1,130.3
Other comprehensive income (loss), net of tax (Note 11)	(106.5 )	254.3	209.5	(411.4 )
Comprehensive income	\$641.2	\$855.1	\$1,397.3	\$718.9

See notes to consolidated condensed financial statements.

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

	June 30, 2016	December 31, 2015
Assets	(Unaudited)	
Current Assets		
Cash and cash equivalents (Note 6)	\$ 3,238.0	\$ 3,666.4
Short-term investments (Note 6)	696.8	785.4
Accounts receivable, net of allowances of \$39.3 (2016) and \$44.3 (2015)	3,947.9	3,513.0
Other receivables	545.2	558.6
Inventories	3,759.9	3,445.8
Prepaid expenses and other	789.5	604.4
Total current assets	12,977.3	12,573.6
Other Assets		
Investments (Note 6)	4,449.2	3,646.6
Goodwill	4,026.5	4,039.9
Other intangibles, net	4,806.3	5,034.8
Sundry	2,149.9	2,220.5
Total other assets	15,431.9	14,941.8
Property and Equipment		
Land, buildings, equipment, and construction in progress	16,927.6	16,660.9
Accumulated depreciation	(8,861.5 )	(8,607.4 )
Property and equipment, net	8,066.1	8,053.5
Total assets	\$ 36,475.3	\$ 35,568.9
Liabilities and Equity		
Current Liabilities		
Short-term borrowings and current maturities of long-term debt	\$ 645.8	\$ 6.1
Accounts payable	1,207.8	1,338.2
Employee compensation	622.5	967.0
Sales rebates and discounts	3,098.8	2,560.1
Dividends payable	537.5	539.0
Income taxes payable	88.0	358.9
Other current liabilities	2,200.6	2,460.3
Total current liabilities	8,401.0	8,229.6
Other Liabilities		
Long-term debt	8,685.5	7,972.4
Accrued retirement benefits (Note 9)	2,020.4	2,160.3
Long-term income taxes payable	805.1	868.9
Other noncurrent liabilities	1,907.1	1,747.4
Total other liabilities	13,418.1	12,749.0
Commitments and Contingencies (Note 10)		
Eli Lilly and Company Shareholders' Equity (Note 7)		
Common stock	690.3	691.3
Additional paid-in capital	5,587.8	5,552.1
Retained earnings	15,824.1	16,011.8
Employee benefit trust	(3,013.2 )	(3,013.2 )
Accumulated other comprehensive loss (Note 11)	(4,371.2 )	(4,580.7 )

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

Cost of common stock in treasury	(80.5	) (90.0	)
Total Eli Lilly and Company shareholders' equity	14,637.3	14,571.3	
Noncontrolling interests	18.9	19.0	
Total equity	14,656.2	14,590.3	
Total liabilities and equity	\$36,475.3	\$35,568.9	

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,	
	2016	2015
Cash Flows from Operating Activities		
Net income	\$1,187.8	\$1,130.3
Adjustments to Reconcile Net Income to Cash Flows from Operating Activities:		
Depreciation and amortization	759.2	726.0
Change in deferred income taxes	168.6	(666.5 )
Stock-based compensation expense	127.0	104.7
Net payments for terminations of interest rate swaps	(3.4 )	(186.1 )
Acquired in-process research and development	—	336.0
Other changes in operating assets and liabilities, net of acquisitions and divestitures	(1,399.9 )	(887.8 )
Other non-cash operating activities, net	235.6	307.2
Net Cash Provided by Operating Activities	1,074.9	863.8
Cash Flows from Investing Activities		
Net purchases of property and equipment	(399.7 )	(412.5 )
Proceeds from sales and maturities of short-term investments	925.4	1,285.3
Purchases of short-term investments	(265.3 )	(588.5 )
Proceeds from sales of noncurrent investments	919.3	1,750.5
Purchases of noncurrent investments	(2,269.2 )	(1,832.8 )
Restricted cash released for acquisition	—	5,405.6
Cash paid for acquisitions, net of cash acquired	(45.0 )	(5,276.7 )
Proceeds from sale of product rights	—	410.0
Purchase of in-process research and development	—	(336.0 )
Other investing activities, net	(31.8 )	(61.7 )
Net Cash Provided by (Used for) Investing Activities	(1,166.3 )	343.2
Cash Flows from Financing Activities		
Dividends paid	(1,079.5 )	(1,067.7 )
Net change in short-term borrowings	(1.4 )	(2,679.3 )
Proceeds from issuance of long-term debt	1,206.6	4,454.6
Repayment of long-term debt	(0.1 )	(1,949.2 )
Purchases of common stock	(300.1 )	(435.5 )
Other financing activities, net	(62.5 )	32.7
Net Cash Used for Financing Activities	(237.0 )	(1,644.4 )
Effect of exchange rate changes on cash and cash equivalents	(100.0 )	(118.7 )
Net decrease in cash and cash equivalents	(428.4 )	(556.1 )
Cash and cash equivalents at January 1	3,666.4	3,871.6
Cash and Cash Equivalents at June 30	\$3,238.0	\$3,315.5
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, 2015. We issued our financial statements by filing with the Securities and Exchange Commission and have evaluated subsequent events up to the time of the filing.

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

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

Note 2: Implementation of New Financial Accounting Pronouncements

The following table provides a brief description of accounting standards that have not yet been adopted and 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.	This standard is effective January 1, 2018, but we are permitted to adopt this standard one year earlier if we choose. We intend to adopt this standard on January 1, 2018.	We are in the process of evaluating the impact of the adoption of the standard, but do not yet have enough information to estimate the anticipated impact on our consolidated financial statements.

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

Standard	Description	Effective Date	Effect on the financial statements or other significant matters
Accounting Standards Update 2016-01, Financial Instruments - Overall: Recognition and Measurement of Financial Assets and Financial Liabilities	This standard will require entities to recognize changes in the fair value of equity investments with readily determinable fair values in net income (except for investments accounted for under the equity method of accounting or those that result in consolidation of the investee). An entity should apply the new standard through a cumulative effect adjustment to retained earnings as of the beginning of the fiscal year of adoption.	This standard is effective January 1, 2018. Early adoption of the majority of the amendments in this standard is not permitted, however, early application of certain amendments is permitted. We intend to fully adopt this standard on January 1, 2018.	We are unable to estimate the impact of adopting this standard as the significance of the impact will depend upon our equity investments as of the date of adoption.
Accounting Standards Update 2016-02, Leases	This standard was issued to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities, including leases classified as operating leases under current GAAP, on the balance sheet and requiring additional disclosures about leasing arrangements. This standard requires a modified retrospective approach to adoption.	This standard is effective January 1, 2019, with early adoption permitted. We intend to adopt this standard on January 1, 2019.	We are in the process of determining our approach to adopting the standard, as well as the anticipated impact on our consolidated financial statements.
Accounting Standards Update 2016-09, Compensation - Stock Compensation: Improvements to Employee Share-Based Payment Accounting	This standard will require entities to recognize all excess tax benefits and tax deficiencies in the statement of operations as a discrete item in the reporting period in which they occur. The standard also allows an employer to withhold up to the maximum statutory tax rate and still qualify for equity classification. Classification of excess tax benefits on the statement of cash flows should be classified as an operating activity, and employee taxes paid when an employer withholds shares for tax-withholding purposes should be classified as a financing activity. The provisions that affect the statement of operations will be effective prospectively in the year of adoption and the provisions that affect the statement of cash flows will be effective retrospectively.	This standard is effective January 1, 2017. Early adoption is permitted. We are evaluating our anticipated date of adoption.	We do not believe the impact of adopting this standard will have a material impact on our consolidated financial statements. We cannot predict the impact on our consolidated financial statements in future reporting periods following adoption as this will be dependent upon various factors including the number of shares issued and changes in the price of our stock between the grant date and settlement date.

Note 3: Acquisitions

On January 1, 2015, we completed the acquisition of Novartis Animal Health (Novartis AH). Additionally, on October 1, 2015, Bristol-Myers Squibb Company and E.R. Squibb (collectively, BMS) transferred to us their commercialization rights with respect to Erbitux<sup>®</sup> in the United States (U.S.) and Canada (collectively, North America) through a modification of our existing arrangement. We also had an immaterial acquisition of a business in April 2016. These transactions were accounted for as business combinations under the acquisition method of accounting. See Note 4 for additional information related to the Erbitux arrangement. 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 dates of acquisition.

In addition to the acquisitions of businesses, we also acquired assets in development in the six months ended June 30, 2015, which are further discussed in this note below in Asset 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 six months ended June 30, 2016, we recorded no acquired IPR&D charges. There were acquired IPR&D charges of \$80.0 million and \$336.0 million for the three and six months ended June 30, 2015, respectively. The 2015 charges included the transactions discussed below in Asset Acquisitions and the upfront fee of \$200.0 million related to tanezumab. See Note 4 for additional information related to the tanezumab arrangement.

Acquisition of a Business

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 were exclusively related to the Novartis AH business in an all-cash transaction for a total purchase price of \$5.28 billion, \$5.41 billion of which was funded by cash held in escrow at December 31, 2014.

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

The acquired Novartis AH business consisted 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

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

## Estimated Fair Value at January 1, 2015

Inventories	\$380.2
Acquired in-process research and development	298.0
Marketed products <sup>(1)</sup>	1,953.0
Property and equipment	199.9
Assets held for sale (primarily the U.S. Sentinel rights)	422.7
Accrued retirement benefits	(108.7 )
Deferred income taxes	(60.1 )
Other assets and liabilities - net	(73.0 )
Total identifiable net assets	3,012.0
Goodwill <sup>(2)</sup>	2,271.1
Total consideration transferred - net of cash acquired	\$5,283.1

<sup>(1)</sup> These intangible assets, which are being amortized to cost of sales on a straight-line basis over their estimated useful lives, were 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 from combining the operations of Novartis AH with our legacy animal health business, future unidentified projects and products, and the assembled workforce of Novartis AH. Approximately \$1.0 billion of the goodwill associated with this acquisition will be deductible for tax purposes.

## Asset Acquisitions

The following table summarizes our asset acquisitions during the six months ended June 30, 2015 which are discussed in detail below. There were no asset acquisitions during the six months ended June 30, 2016.

Counterparty	Compound(s) or Therapy	Acquisition Month	Phase of Development <sup>(1)</sup>	Acquired IPR&D Expense
Innovent Biologics, Inc. (Innovent)	Monoclonal antibody targeting protein CD-20 Immuno-oncology molecules	March 2015	Pre-clinical <sup>(2)</sup>	\$ 56.0
Hanmi Pharmaceutical Co., Ltd. (Hanmi)	cMet monoclonal antibody BTK Inhibitor - HM71224	April 2015	Phase I	50.0
BioNTech AG (BioNTech)	Cancer immunotherapies	May 2015	Pre-clinical	30.0

<sup>(1)</sup> The phase of development presented is as of the date of the arrangement.

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

In connection with the arrangements described herein, 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 compounds through the development process.

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

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

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

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, which is included in revenue in the consolidated condensed statements of operations:

	Three Months		Six Months	
	Ended		Ended	
	June 30,		June 30,	
	2016	2015	2016	2015
Collaboration and other revenue	\$208.5	\$233.4	\$390.8	\$429.5

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.

## Boehringer Ingelheim Diabetes Collaboration

We and Boehringer Ingelheim have a global agreement to jointly develop and commercialize a portfolio of diabetes compounds. Currently, included in the collaboration are Boehringer Ingelheim's oral diabetes products: Trajenta®, Jentadueto®, Jardiance®, Glyxambi®, and Synjardy®, as well as our basal insulin: Basaglar®.

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

Product Family	Product Status			Milestones (Deferred) Capitalized (1)	
	U.S.	Europe	Japan	Year	Amount
Trajenta (2)	Launched 2011	Launched 2011	Launched 2011	2016	\$ —
				2015	—
				Cumulative (5)	446.4
Jardiance (3)	Launched 2014	Launched 2014	Launched 2015	2016	—
				2015	—
				Cumulative (5)	299.5
Basaglar	Approved (4)	Launched 2015	Launched 2015	2016	(187.5)
				2015	—
				Cumulative (5)	(250.0)

(1) In connection with the regulatory approvals of Basaglar in Europe and Japan, milestone payments received were recorded as deferred revenue and are being amortized through the term of the collaboration (2029) to collaboration and other revenue. In connection with the regulatory approvals of Trajenta and Jardiance, milestone payments made were capitalized as intangible assets and are being amortized to cost of sales.

(2) Jentadueto is included in the Trajenta family of product results.

(3) Glyxambi and Synjardy are included in the Jardiance family of product results.

(4) In September 2015, we entered into a settlement agreement to resolve patent infringement litigation filed by Sanofi-Aventis U.S. LLC, which markets Lantus® (insulin glargine). As part of the settlement agreement, the parties agreed that Basaglar can be launched in the U.S. beginning on December 15, 2016. Basaglar received U.S. Food and Drug Administration (FDA) approval in December 2015. As a result of receiving FDA approval, we received a \$187.5 million milestone payment from Boehringer Ingelheim in the first quarter of 2016, which was recorded as deferred revenue and, upon product launch, will be amortized through the term of the collaboration to collaboration and other revenue.

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

In the most significant markets, we and Boehringer Ingelheim share equally the ongoing development costs, commercialization costs and agreed upon gross margin for any product resulting from the collaboration. We record our portion of the gross margin associated with Boehringer Ingelheim's compounds as collaboration and other revenue. We record our sales of Basaglar to third parties as net product revenues with the payments made to Boehringer Ingelheim for their portion of the gross margin recorded as cost of sales. For all compounds under this collaboration, we record our portion of the development and commercialization costs as research and development expense and marketing, selling, and administrative expense, respectively. Each company will also be entitled to potential performance payments on sales of the molecules it contributes to the collaboration. These performance payments result in the owner of the molecule retaining a greater share of the agreed upon gross margin of that product. The following table summarizes our collaboration and other revenue recognized with respect to the Trajenta and Jardiance families of products:

Three Months Ended		Six Months Ended	
June 30, 2016	June 30, 2015	June 30, 2016	June 30, 2015

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

Trajenta \$121.0 \$80.0 \$215.4 \$162.4

Jardiance 40.1 11.1 78.3 30.3

Our revenue related to Basaglar was not significant for the three and six months ended June 30, 2016.

13

---

## Erbix

We have several collaborations with respect to Erbitux. The most significant collaborations are or, where applicable, were in Japan, and prior to the transfer of commercialization rights in the fourth quarter of 2015, the U.S. and Canada (Bristol-Myers Squibb Company); and worldwide except North America (Merck KGaA). Certain rights to Erbitux outside North America will remain with Merck KGaA (Merck) upon expiration of that agreement.

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

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2016	2015	2016	2015
Net product revenues - BMS	\$—	\$11.0	\$—	\$24.8
Net product revenues - third party	158.4	—	299.9	—
Collaboration and other revenue	22.2	123.6	48.7	198.0
Revenue	\$180.6	\$134.6	\$348.6	\$222.8

## Bristol-Myers Squibb Company

Pursuant to commercial agreements with BMS, we had been co-developing Erbitux in North America with BMS exclusively. A separate agreement grants co-exclusive rights among Merck, BMS, and us in Japan and expires in 2032. On October 1, 2015, BMS transferred their commercialization rights to us with respect to Erbitux in North America pursuant to a modification of our existing arrangement, and we began selling Erbitux at that time. This modification did not affect our rights with respect to Erbitux in other jurisdictions. In connection with the modification of terms, we will provide consideration to BMS based upon a tiered percentage of net sales of Erbitux in North America estimated to average 38 percent through September 2018. The transfer of the commercialization rights was accounted for as an acquisition of a business.

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

## Estimated Fair Value at October 1, 2015

Marketed products <sup>(1)</sup>	\$602.1
Deferred tax asset	232.2
Deferred tax liability	(228.2 )
Other assets and liabilities - net	57.2
Total identifiable net assets	\$663.3
Total consideration - contingent consideration liability <sup>(2)</sup>	\$(663.3)

<sup>(1)</sup> These intangible assets are being amortized to cost of sales using the straight-line method through the co-development period in North America as set forth in the original agreement, which was scheduled to expire in September 2018.

<sup>(2)</sup> See Note 6 for discussion on the estimation of the contingent consideration liability.

Including the Erbitux business as if we had acquired it on January 1, 2015, our combined consolidated unaudited pro forma revenue and total Erbitux revenue would have been approximately \$5.1 billion and \$230 million, respectively, for the three months ended June 30, 2015, and \$9.8 billion and \$405 million, respectively, for the six months ended June 30, 2015. This unaudited pro forma financial information adjusts the historical consolidated revenue to give effect to pro forma events that are directly attributable to the acquisition. There would have been no material change to our historical consolidated net income. The unaudited pro forma financial information is not necessarily indicative of what our consolidated revenues would have been had we completed the acquisition on January 1, 2015. In addition, the unaudited pro forma financial information does not attempt to project the future results of operations of our combined company.

Until the effective date of the transfer of the business, the arrangements between us and BMS were as set forth in this paragraph. Erbitux research and development and other costs were shared by both companies according to a predetermined ratio. Responsibilities associated with clinical and other ongoing studies were apportioned between the parties under the agreements. Collaborative reimbursements due to us for supply of clinical trial materials; for



research and development; and for a portion of marketing, selling, and administrative expenses were recorded as a reduction to the respective expense line items on the consolidated statement of operations. We received a distribution fee in the form of a royalty from BMS, based on a percentage of net sales in North America, which was

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

#### Merck KGaA

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

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

#### Effient®

We are in a collaborative arrangement with Daiichi Sankyo Co., Ltd. (Daiichi Sankyo) to develop, market, and promote Effient. Marketing rights for major territories are shown below. We and Daiichi Sankyo each have exclusive marketing rights in certain other territories.

Territory	Marketing Rights	Selling Party
U.S.	Co-promotion	Lilly
Major European markets	Co-promotion	Pre-January 1, 2016, Lilly
		Post-January 1, 2016, Daiichi Sankyo
Japan	Exclusive	Daiichi Sankyo

Beginning January 1, 2016, while major European markets continue to be a co-promotion territory under the terms of our arrangement, Daiichi Sankyo exclusively promotes Effient in these markets. The economic results for the major European markets continue to be shared in the same proportion as they were previously.

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 continue to produce the finished product for our exclusive and co-promotion territories, including the major European markets.

We record net product revenue in our exclusive and co-promotion territories where we are the selling party.

Profit-share payments due to Daiichi Sankyo for co-promotion countries where we are the selling party are recorded as marketing, selling, and administrative expenses. Beginning January 1, 2016, any profit-share payments due to us from Daiichi Sankyo for the major European markets are recorded as collaboration and other revenue. We also record our share of the expenses in these co-promotion territories as marketing, selling, and administrative expenses. In our exclusive territories, we pay Daiichi Sankyo a royalty specific to these territories. 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		Six Months	
	Ended		Ended	
	June 30,	June 30,	June 30,	June 30,
	2016	2015	2016	2015
Revenue	\$135.1	\$128.8	\$266.6	\$250.6

#### 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

15

---

up to percentages in the high twenties. In 2010, Incyte exercised its option to co-develop baricitinib in rheumatoid arthritis. The agreement calls for payments associated with certain development, success-based regulatory, and sales-based milestones. In the first quarter of 2016, we incurred milestone-related expenses of \$55.0 million in connection with regulatory submissions in the U.S. and Europe which were recorded as research and development expense. As of June 30, 2016, Incyte is eligible to receive up to \$360.0 million of additional payments from us contingent upon certain development and success-based regulatory milestones, of which \$180.0 million relates to regulatory decisions for a first indication. Incyte is also eligible to receive up to \$150.0 million of potential sales-based milestones.

**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 is eligible to 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.

**Tanezumab**

In October 2013, we entered into a collaboration agreement with Pfizer Inc. (Pfizer) to jointly develop and globally commercialize tanezumab for the treatment of osteoarthritis pain, chronic low back pain and cancer pain. Under the agreement, the companies share equally the ongoing development costs and, if successful, in gross margins and certain commercialization expenses. Following the FDA's decision in March 2015 to lift the partial clinical hold on tanezumab, certain Phase III trials resumed in July 2015. Upon the FDA's lifting of the partial clinical hold and the decision to continue the collaboration with Pfizer, we paid an upfront fee of \$200.0 million, which was expensed as acquired IPR&D in the first quarter of 2015. In addition to this fee, Pfizer is eligible to receive 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.

**BACE Inhibitor**

In September 2014, we entered into a collaboration agreement with AstraZeneca UK Limited (AstraZeneca) for the worldwide co-development and co-commercialization of AstraZeneca's AZD3293, an oral beta-secretase cleaving enzyme (BACE) inhibitor being investigated for the potential treatment of Alzheimer's disease. We are responsible for leading development efforts, while AstraZeneca will be responsible for manufacturing efforts. If successful, both parties will take joint responsibility for commercialization. Under the agreement, both parties share equally in the ongoing development costs and, if successful, in gross margins and certain other costs associated with commercialization of the molecule. As a result of the molecule moving into Phase III testing in April 2016, we incurred a \$100.0 million developmental milestone, which was recorded as research and development expense in the second quarter of 2016. AstraZeneca is eligible to receive up to an additional \$350.0 million contingent upon the achievement of certain development and success-based regulatory milestones.

**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,	
	2016	2015	2016	2015
Marketing, selling, and administrative	\$47.3	\$53.5	\$96.3	\$102.8

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

The components of the charges included in asset impairment, restructuring, and other special charges in our consolidated condensed statements of operations are described below.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Severance:				
Human pharmaceutical	\$—	\$8.2	\$—	\$16.9
Animal health	19.2	13.9	28.7	36.3
Total severance	19.2	22.1	28.7	53.2
Asset impairment and other special charges:				
Human pharmaceutical	—	17.2	—	17.2
Animal health	38.8	33.1	160.7	110.0
Total asset impairment and other special charges	38.8	50.3	160.7	127.2
Total asset impairment, restructuring, and other special charges	\$58.0	\$72.4	\$189.4	\$180.4

Severance costs recognized during the three months ended June 30, 2016 related primarily to the integration of Novartis AH. Severance costs recognized during the six months ended June 30, 2016 related primarily to the integration of Novartis AH, as well as our decision to close an animal health manufacturing plant in Ireland.

Severance costs recognized during the three and six months ended June 30, 2015 related primarily to the acquisition of Novartis AH, as well as severance costs for actions taken to reduce our cost structure.

Asset impairment and other special charges recognized during the three months ended June 30, 2016 related primarily to integration costs related to our acquisition of Novartis AH. Asset impairment and other special charges recognized during the six months ended June 30, 2016 resulted primarily from \$87.2 million of asset impairment and other charges related to our decision to close an animal health manufacturing plant in Ireland. The manufacturing plant was written down to its estimated fair value, which was based primarily on recent sales of similar assets. The remaining asset impairment and other special charges recognized during the six months ended June 30, 2016 consisted of integration costs related to our acquisition of Novartis AH. Asset impairment and other special charges recognized during the three and six months ended June 30, 2015 related primarily to integration costs and intangible asset impairments due to product rationalization resulting from our acquisition of Novartis AH.

## 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-science products account for a substantial portion of our 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 risk-management 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.

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 instruments 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 instruments that are designated and qualify as cash flow hedges, the effective portion of gains and losses is reported as a component of accumulated other comprehensive loss and reclassified into

earnings in the same period the hedged transaction affects earnings. For derivative and non-derivative instruments that are designated and qualify as net investment hedges, the effective portion of foreign currency translation gains or losses due to spot rate fluctuations are reported as a component of accumulated other comprehensive loss. 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, Japanese yen, and the Swiss franc). 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, 2016, we had outstanding foreign currency forward commitments to purchase 707.0 million U.S. dollars and sell 633.8 million euro, commitments to purchase 1.61 billion euro and sell 1.82 billion U.S. dollars, commitments to purchase 686.0 million U.S. dollars and sell 72.07 billion Japanese yen, commitments to purchase 246.4 million British pounds and sell 309.9 million euro, commitments to purchase 270.9 million U.S. dollars and sell 191.5 million British pounds, and commitments to purchase 228.6 million Swiss francs and sell 236.2 million U.S. dollars, which will all settle within 30 days.

Foreign currency exchange risk is also managed through the use of foreign currency debt and cross-currency interest rate swaps. Our foreign currency-denominated notes, which had carrying amounts of \$3.52 billion and \$2.27 billion as of June 30, 2016 and December 31, 2015, respectively, have been designated as, and are effective as, economic hedges of net investments in certain of our euro-denominated and Swiss franc-denominated operations. Our cross-currency interest rate swaps that convert a portion of our U.S. dollar-denominated floating rate debt to euro-denominated floating rate debt have also been designated as, and are effective as, economic hedges of net investments in certain of our euro-denominated foreign operations.

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, 2016, substantially all of our total long-term debt is at a fixed rate. We have converted approximately 30 percent of our long-term fixed-rate notes to floating rates through the use of interest rate swaps.

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

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

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

condensed statement of operations during the three and six months ended June 30, 2015.

In May 2016, we issued Swiss franc-denominated notes consisting of Fr.200.0 million of 0.00 percent fixed-rate notes due May 24, 2018, Fr.600.0 million of 0.15 percent fixed-rate notes due May 24, 2024, and Fr.400.0 million of 0.45 percent fixed-rate notes due May 24, 2028, with interest to be paid annually. We plan to use the net cash proceeds of the offering of \$1.21 billion for general corporate purposes, including the repayment or redemption prior to maturity of certain of our U.S. dollar denominated fixed-rate notes due March 2017.



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 our underlying U.S. dollar-denominated 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 June 2015 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, 2016		Six Months Ended June 30, 2015	
Fair value hedges:				
Effect from hedged fixed-rate debt	\$35.8	\$(99.2)	\$111.1	\$(40.3)
Effect from interest rate contracts	(35.8)	99.2	(111.1)	40.3
Cash flow hedges:				
Effective portion of losses on interest rate contracts reclassified from accumulated other comprehensive loss	3.7	3.6	7.4	6.3
Net (gains) losses on foreign currency exchange contracts not designated as hedging instruments	90.9	(1.2)	104.2	22.1

#### The Effect of Risk-Management Instruments on Other Comprehensive Income (Loss)

The effective portion of risk-management instruments that was recognized in other comprehensive income (loss) is as follows:

	Three Months Ended June 30, 2016		Six Months Ended June 30, 2015	
Net investment hedges:				
Foreign currency-denominated notes	\$34.8	\$(33.8)	\$(43.0)	\$(33.8)
Cross-currency interest rate swaps	7.5	—	6.3	—
Foreign currency exchange contracts	31.9	—	31.9	—

#### Cash flow hedges:

Forward-starting interest rate swaps (3.4) — (3.4) (56.7)

During the next 12 months, we expect to reclassify from accumulated other comprehensive loss to earnings \$15.2 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, 2016 and 2015, net losses related to ineffectiveness, as well as net losses related to the portion of our risk-management hedging instruments, fair value hedges, and cash flow hedges that were excluded from the assessment of effectiveness, were not material.



## Fair Value of Financial Instruments

The following tables summarize certain fair value information at June 30, 2016 and December 31, 2015 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:

	Carrying Amount	Cost <sup>(1)</sup>	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, 2016						
Cash equivalents	\$1,615.3	\$1,615.3	\$1,612.3	\$ 3.0	\$	—\$1,615.3
Short-term investments:						
U.S. government and agency securities	\$66.3	\$66.3	\$66.3	\$ —	\$	—\$66.3
Corporate debt securities	624.4	623.7	—	624.4	—	624.4
Asset-backed securities	3.4	3.4	—	3.4	—	3.4
Other securities	2.7	2.7	—	2.7	—	2.7
Short-term investments	\$696.8					
Noncurrent investments:						
U.S. government and agency securities	\$465.6	\$461.3	\$465.6	\$ —	\$	—\$465.6
Corporate debt securities	2,545.7	2,529.6	—	2,545.7	—	2,545.7
Mortgage-backed securities	197.2	194.8	—	197.2	—	197.2
Asset-backed securities	455.5	454.4	—	455.5	—	455.5
Other securities	155.7	105.5	12.5	7.1	136.1	155.7
Marketable equity securities	95.9	64.0	95.9	—	—	95.9
Cost and equity method investments <sup>(2)</sup>	533.6					
Noncurrent investments	\$4,449.2					
December 31, 2015						
Cash equivalents	\$1,644.4	\$1,644.4	\$1,637.0	\$ 7.4	\$	—\$1,644.4
Short-term investments:						
U.S. government and agency securities	\$153.2	\$153.4	\$153.2	\$ —	\$	—\$153.2
Corporate debt securities	625.8	626.9	—	625.8	—	625.8
Asset-backed securities	3.3	3.3	—	3.3	—	3.3
Other securities	3.1	3.1	—	3.1	—	3.1
Short-term investments	\$785.4					
Noncurrent investments:						
U.S. government and agency securities	\$284.5	\$286.0	\$283.5	\$ 1.0	\$	—\$284.5
Corporate debt securities	1,962.6	1,995.8	—	1,962.6	—	1,962.6
Mortgage-backed securities	153.3	154.7	—	153.3	—	153.3
Asset-backed securities	441.9	443.1	—	441.9	—	441.9

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

Other securities	137.1	97.3	—	4.1	133.0	137.1
Marketable equity securities	128.9	74.8	128.9	—	—	128.9
Cost and equity method investments <sup>(2)</sup>	538.3					
Noncurrent investments	\$3,646.6					

(1) For available-for-sale debt securities, amounts disclosed represent the securities' amortized cost.

(2) Fair value disclosures are not applicable for cost method and equity method investments.



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

Other current liabilities	(17.3 )	—	(17.3 )	—	(17.3 )
Contingent consideration liabilities <sup>(1)</sup> :					
Other current liabilities	(243.7 )	—	—	(243.7 )	(243.7 )
Other noncurrent liabilities	(427.2 )	—	—	(427.2 )	(427.2 )

<sup>(1)</sup> Contingent consideration liabilities primarily relate to the Erbitux arrangement with BMS discussed in Note 4.

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 our Level 1 and Level 2 fair value measurements 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. Level 3 fair value measurements for other investment securities are determined using unobservable inputs, including the investments' cost adjusted for impairments and price changes from orderly transactions. The fair value of cost and equity method investments is not readily available.

Contingent consideration liabilities primarily include contingent consideration related to Erbitux for which the fair value was estimated using a discounted cash flow analysis and Level 3 inputs, including projections representative of a market participant view for net sales in North America through September 2018 and an estimated discount rate. The amount to be paid is calculated as a tiered percentage of net sales (see Note 4) and will, therefore, vary directly with increases and decreases in net sales of Erbitux in North America. There is no cap on the amount that may be paid pursuant to this arrangement. The decrease in the fair value of the contingent consideration liabilities during the six months ended June 30, 2016 was due primarily to cash payments of \$111.6 million related to Erbitux. The change in the fair value of the contingent consideration liabilities recognized in earnings during the three and six months ended June 30, 2016 was not material.

The table below summarizes the contractual maturities of our investments in debt securities measured at fair value as of June 30, 2016:

	Maturities by Period				
	Total	Less Than 1 Year	2-5 Years	6-10 Years	More Than 10 Years
Fair value of debt securities	\$4,367.9	\$ 696.8	\$3,134.8	\$261.7	\$ 274.6

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, December 31,	
	2016	2015
Unrealized gross gains	\$ 79.8	\$ 68.0
Unrealized gross losses	23.2	52.5
Fair value of securities in an unrealized gain position	3,550.8	764.5
Fair value of securities in an unrealized loss position	769.9	2,933.4

We periodically assess our investment securities for other-than-temporary impairment losses. Other-than-temporary impairment losses recognized during the three and six months ended June 30, 2016 totaled \$15.9 million and \$41.6 million, respectively. Impairment losses recognized during the three months ended June 30, 2016 related primarily to our marketable equity securities, while impairment losses recognized during the six months ended June 30, 2016 related primarily to our cost and equity method investments. Other-than-temporary impairment losses recognized during the three and six months ended June 30, 2015 totaled \$6.2 million and \$9.8 million, respectively.

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

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

As of June 30, 2016, the securities in an unrealized loss position include primarily our marketable equity securities as well as fixed-rate debt securities of varying maturities. Marketable equity securities are sensitive to market price adjustments for general market conditions and industry or sector specific factors, and fixed-rate debt securities are sensitive to changes in the yield curve and other market conditions. Approximately 70 percent of the fixed-rate debt securities in a loss position are investment-grade debt securities. As of June 30, 2016, 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.

22

---



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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Proceeds from sales	\$850.7	\$1,900.1	\$1,577.1	\$2,869.9
Realized gross gains on sales	3.4	47.8	5.2	102.3
Realized gross losses on sales	3.1	1.7	10.4	2.4

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.

#### Accounts Receivable Factoring Arrangements

We have entered into accounts receivable factoring agreements with financial institutions to sell certain of our non-U.S. accounts receivable. These transactions are accounted for as sales and result in a reduction in accounts receivable because the agreements transfer effective control over and risk related to the receivables to the buyers. Our factoring agreements do not allow for recourse in the event of uncollectibility, and we do not retain interest in the underlying accounts receivable once sold. We derecognized \$731.9 million and \$670.6 million of accounts receivable as of June 30, 2016 and December 31, 2015, respectively, under these factoring arrangements. The cost of factoring such accounts receivable on our consolidated results of operations for the six months ended June 30, 2016 and 2015 was not material.

#### Note 7: Shareholders' Equity

During the six months ended June 30, 2016 and 2015, we repurchased \$300.1 million and \$435.5 million of shares, respectively, associated with our \$5.00 billion share repurchase program announced in October 2013. As of June 30, 2016, there were \$2.65 billion of shares remaining in that program.

#### Note 8: Income Taxes

The U.S. examination of tax years 2010-2012 commenced during the fourth quarter of 2013. In December 2015, we executed a closing agreement with the Internal Revenue Service which effectively settled certain matters for tax years 2010-2012. Accordingly, we reduced our gross uncertain tax positions by approximately \$320 million in 2015. During the first quarter of 2016, we effectively settled the remaining matters related to tax years 2010-2012. As a result of this resolution, our gross uncertain tax positions were further reduced by approximately \$140 million, and our consolidated results of operations benefited from an immaterial reduction in income tax expense. During the six months ended June 30, 2016, we made cash payments of approximately \$150 million related to tax years 2010-2012 after application of available tax credit carryforwards and carrybacks. We anticipate additional cash payments of approximately \$10 million in 2016 related to the settlement. The U.S. examination of tax years 2013-2014 commenced during the first quarter of 2016; we expect the U.S. examination of 2015 to begin in the third quarter of 2016.

## Note 9: Retirement Benefits

Net pension and retiree health benefit (income) cost included the following components:

	Defined Benefit Pension Plans			
	Three Months Ended June 30, 2016		Six Months Ended June 30, 2015	
Components of net periodic benefit cost:				
Service cost	\$70.6	\$85.5	\$142.0	\$162.5
Interest cost	105.1	117.2	210.2	234.3
Expected return on plan assets	(189.6)	(192.2)	(379.1)	(384.0)
Amortization of prior service (benefit) cost	(0.2)	2.6	5.7	5.1
Recognized actuarial loss	74.0	90.9	142.4	183.3
Net periodic benefit cost	\$59.9	\$104.0	\$121.2	\$201.2
	Retiree Health Benefit Plans			
	Three Months Ended June 30, 2016		Six Months Ended June 30, 2015	
Components of net periodic benefit income:				
Service cost	\$10.3	\$11.2	\$19.6	\$21.0
Interest cost	13.2	15.3	26.0	30.7
Expected return on plan assets	(37.6)	(37.1)	(75.1)	(74.2)
Amortization of prior service benefit	(21.5)	(21.6)	(42.8)	(43.2)
Recognized actuarial loss	5.2	9.5	10.3	18.9
Net periodic benefit income	\$(30.4)	\$(22.7)	\$(62.0)	\$(46.8)

We have contributed approximately \$25 million required to satisfy minimum funding requirements to our defined benefit pension and retiree health benefit plans during the six months ended June 30, 2016. Additional discretionary funding in the aggregate was not material during the six months ended June 30, 2016. During the remainder of 2016, we expect to make contributions to our defined benefit pension and retiree health benefit plans of approximately \$25 million to satisfy minimum funding requirements. Additional discretionary funding for the remainder of 2016 is not expected to be material.

## Note 10: 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 for the product in the relevant market.



#### U.S. Patent Litigation and Administrative Proceedings

We are engaged in various U.S. patent litigation matters involving Alimta brought pursuant to procedures set out in the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act). More than 10 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). A trial occurred in August 2013; the sole issue before the district court at that time was to determine patent validity. In March 2014, the court ruled that the asserted claims of the vitamin regimen patent are valid. The U.S. District Court for the Southern District of Indiana held a hearing on the issue of infringement in May 2015. In September 2015, the district court ruled that the vitamin regimen patent would be infringed by the generic challengers' proposed products. Teva and APP appealed all of the district court's substantive decisions. The U.S. Court of Appeals for the Federal Circuit has scheduled a hearing for September 2016.

From 2012 through 2016, we filed similar lawsuits against other ANDA defendants seeking a ruling that our patents are valid and infringed. Some 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. In February 2016, we filed a lawsuit alleging infringement against Dr. Reddy's Laboratories in response to its recently filed NDA for a salt form of pemetrexed product diluted in dextrose solution. Any remaining cases have been administratively closed.

In June 2016, the United States Patent and Trademark Office (USPTO) granted petitions by Neptune Generics, LLC and Sandoz Inc. seeking inter partes review (IPR) of our vitamin regimen patent. The final written IPR decisions are expected in mid-2017. Seven additional generic companies have filed petitions, seeking to join in these proceedings.

#### 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. In October 2015 the generic manufacturers withdrew the appeal. As a result, the original EPO decision upholding the patent is now final.

In addition, in the United Kingdom (U.K.), Actavis Group ehf and other Actavis companies (collectively, Actavis) filed litigation asking for a declaratory judgment that commercialization of certain salt forms of pemetrexed (the active ingredient in Alimta) diluted in saline solution would not infringe the vitamin regimen patents for Alimta 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's decision granting declarations of non-infringement over the Alimta vitamin regimen patents in those countries, ruling that the Alimta vitamin regimen patent would be indirectly infringed by commercialization of Actavis' products as proposed prior to the patent's expiration in June 2021. In February 2016, the U.K. Supreme Court granted our and Actavis' requests for permission to appeal different aspects of the judgment. A hearing is scheduled for April 2017.

In parallel proceedings, Actavis returned to the lower court seeking a declaration of non-infringement for a different proposed product diluted in dextrose solution. In February 2016, the trial court ruled that Actavis' commercialization of this product would not infringe the patent in the U.K., Italy, France, and Spain. We intend to appeal this ruling.

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 German Court of Appeal overturned the trial court and ruled that our vitamin regimen patent in Germany would not be infringed by a dipotassium salt form of pemetrexed. In June 2016, the German Federal Supreme Court granted our appeal, vacating the prior decision denying infringement, and returned the case to the Court of Appeal to reconsider infringement based on its judgment.

In separate proceedings, in May 2016 and June 2016, the German courts confirmed preliminary injunctions against Hexal AG (Hexal), which had stated its intention to launch a generic disodium salt product diluted in saline solution in

Germany, and ratiopharm GmbH, a subsidiary of Teva, which had stated its intention to launch a proposed alternative salt form of pemetrexed product diluted in dextrose solution. Hexal has separately filed a challenge to the validity of our vitamin regimen patent before the German Federal Patent court. We do not anticipate any generic

entry into the German market at least until the Court of Appeal proceedings against Actavis considers the issues remanded by the German Federal Supreme Court or the injunctions are lifted.

We are aware that at least one generic pemetrexed product has launched in a major European market.

#### Japanese Administrative Proceedings

Three separate demands for invalidation of our two vitamin regimen patents, involving several companies, have been filed with the Japanese Patent Office (JPO). In November 2015, the JPO issued written decisions in the invalidation trial initiated by Sawai Pharmaceutical Co., Ltd. (Sawai), which had been joined by three other companies, upholding both vitamin regimen patents. These patents provide intellectual property protection for Alimta until June 2021. Three companies, including Sawai, have filed appeals. The invalidation trials related to the other demands by Sawai are currently suspended.

Notwithstanding our patents, generic versions of Alimta were approved in Japan in February 2016. We filed for preliminary injunctions against the three generic competitors which received such approval, but we withdrew the requests for injunctions once those competitors agreed not to proceed to pricing approval.

We do not anticipate generic competitors to proceed to launch prior to the completion of the Sawai invalidation trial.

#### Effient Patent Litigation and Administrative Proceedings

We, along with Daiichi Sankyo, Daiichi Sankyo, Inc., and Ube Industries (Ube) are engaged in U.S. patent litigation involving Effient brought pursuant to procedures set out in the Hatch-Waxman Act. More than 10 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 2023) 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 April 2017 plus pediatric exclusivity for an additional six months) 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. These cases have been consolidated. Four generic companies have agreed to be bound by the outcome of the consolidated case.

In 2015, several generic pharmaceutical companies filed petitions with the USPTO, requesting IPR of the method patents. In September 2015, the USPTO granted the generic pharmaceutical companies' request. A hearing was held in May 2016, and a written decision is expected in the third quarter of 2016. In light of these petitions, the district court in the consolidated lawsuit stayed the case with respect to all parties.

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

#### Actos® Product Liability Litigation

We have been 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 (MDL) 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.

In April 2015, Takeda announced they would pay approximately \$2.4 billion to resolve the vast majority of the U.S. product liability lawsuits involving Actos, including the case of Allen, et al. v. Takeda Pharmaceuticals, et al., no. 6:12-md-00064, in which a judgment of approximately \$28 million was entered against Takeda and a judgment of approximately \$9 million was entered against us. In September 2015, Takeda announced that more than 96 percent of eligible claimants had opted into the resolution program that was announced in April 2015. As a result of the resolution program, the Allen case has been fully resolved. Accordingly, the appeals filed by Allen, Takeda, and us in the U.S. Court of Appeals for the Fifth Circuit have been dismissed with prejudice.

Although most U.S. product liability lawsuits involving Actos are included in the resolution program, there may be additional cases pending against Takeda and us following its completion. 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.

26

---

We believe we are entitled to full indemnification of our losses and expenses in these cases; however, there can be no guarantee we will ultimately be successful in obtaining full indemnification.

We are also named along with Takeda as a defendant in four purported product liability class actions in Canada related to Actos, including two in Ontario (Casseres et al. v. Takeda Pharmaceutical North America, Inc., et al. and Carrier et al. v. Eli Lilly 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 lawsuits are without merit, and we and Takeda are prepared to defend against them vigorously.

#### Byetta® Product Liability Litigation

We are named as a defendant in approximately 510 Byetta product liability lawsuits in the U.S. involving approximately 890 plaintiffs. Approximately 90 of these lawsuits, covering about 470 plaintiffs, are filed in California state court and coordinated in a Los Angeles Superior Court. Approximately 415 lawsuits, covering about 415 plaintiffs, are filed in federal court, the majority of which are coordinated in a multi-district litigation in the U.S. District Court for the Southern District of California. The remaining approximately five lawsuits, representing about five plaintiffs, are in various state courts. Approximately 465 of the lawsuits, involving approximately 700 plaintiffs, contain allegations that Byetta caused or contributed to the plaintiffs' cancer (primarily pancreatic cancer or thyroid cancer). The federal and state trial courts granted summary judgment in favor of us and co-defendants on the claims alleging pancreatic cancer; those rulings are being appealed by the plaintiffs. We are aware of approximately 10 additional claimants who have not yet filed suit. These additional claims allege damages for pancreatic cancer or thyroid cancer. We believe these lawsuits and claims are without merit and are prepared to defend against them vigorously.

#### Cymbalta® Product Liability Litigation

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, purporting to represent a class of all persons within the U.S. who purchased and/or paid for Cymbalta, asserted claims under the consumer protection statutes of four states, California, Massachusetts, Missouri, and New York, and sought declaratory, injunctive, and monetary relief for various alleged economic injuries arising from discontinuing treatment with Cymbalta. In December 2014, the district court denied the plaintiffs' motion for class certification. Plaintiffs filed a petition with the U.S. Court of Appeals for the Ninth Circuit requesting permission to file an interlocutory appeal of the denial of class certification, which was denied. Plaintiffs filed a second motion for certification under the consumer protection acts of New York and Massachusetts. The district court denied that motion for class certification in July 2015. The district court dismissed the suit and plaintiffs are appealing to the U.S. Court of Appeals for the Ninth Circuit.

Additionally, we have been named in approximately 140 lawsuits involving approximately 1,470 plaintiffs filed in various federal and state courts alleging injuries arising from discontinuation of treatment with Cymbalta. Counsel for plaintiffs in the federal court proceedings filed a petition seeking to have then-filed cases and an unspecified number of future cases coordinated into a federal MDL in the U.S. District Court for the Central District of California. In December 2014, the Judicial Panel on Multidistrict Litigation (JPML) denied the plaintiffs' petition for creation of an MDL. Plaintiffs' counsel subsequently filed a second petition seeking MDL consolidation, which petition was denied by the JPML in October 2015. There have been approximately 40 individual and multi-plaintiff cases filed in California state court. Most of those cases have been centralized in a California Judicial Counsel Coordination Proceeding pending in Los Angeles. The first individual product liability cases were tried in August 2015 and resulted in defense verdicts against four plaintiffs. The plaintiff in one of those cases is appealing the verdict. The other plaintiffs in those cases will not be appealing the judgment.

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 five 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 400 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 Limitada (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

27

---

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. We cannot currently estimate the range of reasonably possible financial losses that could arise if we do not ultimately prevail in the litigation. The judge has estimated the total financial impact of the ruling to be approximately 1.0 billion Brazilian real (approximately \$310 million as of June 30, 2016) 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 labor courts 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 11: 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, 2016 and 2015:

(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, 2016	\$ (1,085.4 )	\$ 17.9	\$ (2,981.1 )	\$ (216.1 )	\$ (4,264.7 )
Other comprehensive income (loss) before reclassifications	(187.6 )	8.8	24.6	(2.2 )	(156.4 )
Net amount reclassified from accumulated other comprehensive loss	—	10.1	37.4	2.4	49.9
Net other comprehensive income (loss)	(187.6 )	18.9	62.0	0.2	(106.5 )
Balance at June 30, 2016	\$ (1,273.0 )	\$ 36.8	\$ (2,919.1 )	\$ (215.9 )	\$ (4,371.2 )
(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, 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 )



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

The following tables summarize the activity related to each component of other comprehensive income (loss) during the six months ended June 30, 2016 and 2015:

(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, 2016	\$ (1,360.2 )	\$ 10.1	\$ (3,012.1 )	\$ (218.5 )	\$ (4,580.7 )
Other comprehensive income (loss) before reclassifications	12.7	13.0	20.5	(2.2 )	44.0
Net amount reclassified from accumulated other comprehensive loss	74.5	13.7	72.5	4.8	165.5
Net other comprehensive income (loss)	87.2	26.7	93.0	2.6	209.5
Balance at June 30, 2016	\$ (1,273.0 )	\$ 36.8	\$ (2,919.1 )	\$ (215.9 )	\$ (4,371.2 )
(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 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 )

The tax effects on the net activity related to each component of other comprehensive income (loss) were as follows:

	Three Months Ended June 30, 2016		Six Months Ended June 30, 2015	
Tax benefit (expense)				
Foreign currency translation gains (losses)	\$(26.0)	\$11.8	\$1.7	\$11.8
Unrealized net gains (losses) on securities	(10.2 )	18.6	(14.4 )	(11.4 )
Defined benefit pension and retiree health benefit plans	(21.8 )	(20.3 )	(47.5 )	(62.8 )
Effective portion of cash flow hedges	(0.1 )	(1.3 )	(1.4 )	17.2
Provision for income taxes allocated to other comprehensive income (loss) items	\$(58.1)	\$8.8	\$(61.6)	\$(45.2)

Except for the tax effects of foreign currency translation gains and losses related to our foreign currency-denominated notes, cross-currency interest rate swaps, and other foreign currency exchange contracts designated as net investment hedges (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 the consolidated condensed statements of operations.



Reclassifications out of accumulated other comprehensive loss were as follows:

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 June 30, 2016		Six Months Ended June 30, 2015		
Amortization of retirement benefit items:					
Prior service benefits, net	\$(21.7)	\$(19.0)	\$(37.1)	\$(38.1)	<sup>(1)</sup>
Actuarial losses	79.2	100.4	152.7	202.2	<sup>(1)</sup>
Total before tax	57.5	81.4	115.6	164.1	
Tax benefit	(20.1)	(27.0)	(43.1)	(56.0)	Income taxes
Net of tax	37.4	54.4	72.5	108.1	
Unrealized gains/losses on available-for-sale securities:					
Realized (gains) losses, net before tax	(0.3)	(46.1)	5.2	(64.4)	Other—net, (income) expense
Impairment losses	15.9	6.2	15.9	6.2	Other—net, (income) expense
Total before tax	15.6	(39.9)	21.1	(58.2)	
Tax (benefit) expense	(5.5)	14.0	(7.4)	20.4	Income taxes
Net of tax	10.1	(25.9)	13.7	(37.8)	
Other, net of tax <sup>(2)</sup>	2.4	2.3	79.3	4.7	Other—net, (income) expense
Total reclassifications for the period (net of tax)	\$49.9	\$30.8	\$165.5	\$75.0	

<sup>(1)</sup> These accumulated other comprehensive loss components are included in the computation of net periodic benefit (income) cost (see Note 9).

<sup>(2)</sup> Amount for the six months ended June 30, 2016 included primarily \$74.5 million of foreign currency translation losses.

Note 12: Other—Net, (Income) Expense

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

	Three Months Ended June 30, 2016		Six Months Ended June 30, 2015	
	2016	2015	2016	2015
Interest expense	\$43.2	\$36.8	\$86.6	\$77.7
Interest income	(23.5)	(20.6)	(47.7)	(42.0)
Venezuela charge	—	—	203.9	—
Debt extinguishment loss (Note 6)	—	166.7	—	166.7
Other income	(40.9)	(59.6)	(115.0)	(171.8)
Other—net, (income) expense	\$(21.2)	\$123.3	\$127.8	\$30.6

Due to the financial crisis in Venezuela and the significant deterioration of the bolívar, we changed the exchange rate used to translate the assets and liabilities of our subsidiaries in Venezuela which resulted in a first quarter of 2016 charge of \$203.9 million. Prior to this change, we used the Supplementary Foreign Currency Administration System (SICAD) rate; however, this official rate was discontinued in the first quarter of 2016. After considering several factors, including the future uncertainty of the Venezuelan economy, published exchange rates, and the limited amount of foreign currency exchanged, we changed to the Divisa Complementaria (DICOM) rate.



## Note 13: Segment Information

We have two operating segments—human pharmaceutical products and animal health. Our operating 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.

	Three Months Ended		Six Months Ended	
	June 30,	2015	June 30,	2015
Segment revenue—to unaffiliated customers:				
Human pharmaceutical products:				
Endocrinology:				
Humalog®	\$701.9	\$654.3	\$1,308.2	\$1,338.2
Humulin®	332.3	316.4	688.7	632.1
Forteo®	367.6	328.4	686.3	621.4
Trulicity®	201.3	44.3	344.9	62.6
Trajenta	121.0	80.0	215.4	162.4
Other Endocrinology	234.3	214.5	471.6	447.5
Total Endocrinology	1,958.4	1,637.9	3,715.1	3,264.2
Oncology:				
Alimta	607.1	664.3	1,171.3	1,237.4
Erbitux	180.6	134.6	348.6	222.8
Cyramza®	147.0	87.7	278.0	155.2
Other Oncology	35.8	36.0	67.1	66.2
Total Oncology	970.5	922.6	1,865.0	1,681.6
Cardiovascular:				
Cialis®	630.5	567.9	1,207.2	1,106.2
Effient	135.1	128.8	266.6	250.6
Other Cardiovascular	61.7	66.5	107.6	121.6
Total Cardiovascular	827.3	763.2	1,581.4	1,478.4
Neuroscience:				
Cymbalta	236.5	274.1	435.2	561.1
Zyprexa®	210.7	253.7	423.4	473.2
Strattera®	224.6	191.8	412.7	365.5
Other Neuroscience	45.9	44.3	90.0	89.4
Total Neuroscience	717.7	763.9	1,361.3	1,489.2
Other pharmaceuticals	71.1	50.3	132.7	119.5
Total human pharmaceutical products	4,545.0	4,137.9	8,655.5	8,032.9
Animal health	859.8	840.8	1,614.4	1,590.5
Revenue	\$5,404.8	\$4,978.7	\$10,269.9	\$9,623.4



	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2016	2015	2016	2015
Segment profits:				
Human pharmaceutical products	\$959.4	\$1,016.8	\$1,886.3	\$2,099.9
Animal health	211.7	188.3	359.4	303.3
Total segment profits	\$1,171.1	\$1,205.1	\$2,245.7	\$2,403.2
Reconciliation of total segment profits to consolidated income before taxes:				
Segment profits	\$1,171.1	\$1,205.1	\$2,245.7	\$2,403.2
Other profits (losses):				
Acquired in-process research and development (Note 3)	—	(80.0 )	—	(336.0 )
Amortization of intangible assets	(168.6 )	(151.9 )	(341.1 )	(304.6 )
Asset impairment, restructuring, and other special charges (Note 5)	(58.0 )	(72.4 )	(189.4 )	(180.4 )
Venezuela charge (Note 12)	—	—	(203.9 )	—
Debt repurchase charges, net <sup>(1)</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	\$944.5	\$679.7	\$1,511.3	\$1,297.6

<sup>(1)</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.

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 Results of Operations and Financial Condition

## Results of Operations

## Executive Overview

On July 27, 2016 we announced that David A. Ricks will assume the role of chief executive officer effective January 1, 2017, replacing John C. Lechleiter, who will retire at the end of 2016. Lechleiter will remain chairman of our board of directors through May 2017, and Ricks will assume the role of chairman effective June 1, 2017.

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

## Financial Results

The following table summarizes our key operating results:

	Three Months Ended			Percent Change from 2015	Six Months Ended		Percent Change from 2015
	June 30,				June 30,		
	2016	2015		2016	2015		
Revenue	\$5,404.8	\$4,978.7	9	\$10,269.9	\$9,623.4	7	
Gross margin	3,939.8	3,760.3	5	7,481.9	7,212.3	4	
Gross margin as a percent of revenue	72.9	% 75.5	%	72.9	% 74.9	%	
Operating expense <sup>(1)</sup>	\$2,958.5	\$2,804.9	5	\$5,653.4	\$5,367.7	5	
Acquired in-process research and development	—	80.0	NM	—	336.0	NM	
Asset impairment, restructuring, and other special charges	58.0	72.4	(20)	189.4	180.4	5	
Net income	747.7	600.8	24	1,187.8	1,130.3	5	
Earnings per share <sup>(2)</sup>	0.71	0.56	27	1.12	1.06	6	

<sup>(1)</sup> Operating expense consists of research and development and marketing, selling, and administrative expenses.

<sup>(2)</sup> Earnings per share benefited from a lower number of shares outstanding in 2016 compared with 2015.

NM - not meaningful

Revenue and gross margin increased for the three and six months ended June 30, 2016. The increase in operating expense for both periods was due to an increase in research and development expense, partially offset by a decrease in marketing, selling, and administrative expense. The increases in net income and EPS for the three months ended June 30, 2016 were driven by a higher gross margin, the 2015 charges related to the repurchase of debt, and lower acquired in-process research and development (IPR&D) charges, partially offset by higher operating expenses and higher income taxes. The increases in net income and EPS for the six months ended June 30, 2016 were driven by lower acquired IPR&D charges, a higher gross margin, and the 2015 charges related to the repurchase of debt, partially offset by higher operating expenses, the impact of the Venezuelan financial crisis, including the significant deterioration of the bolívar, and higher income taxes.

The following highlighted items affect comparisons of our financial results for the three and six months ended June 30, 2016 and 2015:

2016

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

We recognized charges of \$58.0 million (pretax), or \$0.04 per share, and \$189.4 million (pretax), or \$0.16 per share, for the three and six months ended June 30, respectively, related to the integration costs for our acquisition of Novartis Animal Health (Novartis AH), severance costs, and asset impairments. The charges for the six months ended June 30 also included charges related to the closure of an animal health manufacturing facility in Ireland.

Other-Net, (Income) Expense (Note 12)

We recognized charges of \$203.9 million (pretax), or \$0.19 per share, in the first quarter, related to the impact of the Venezuelan financial crisis, including the significant deterioration of the bolívar.

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 AH acquisition date inventory that was sold.

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

We recognized acquired IPR&D charges of \$80.0 million (pretax), or \$0.05 per share, and \$336.0 million (pretax), or \$0.20 per share, for the three and six months ended June 30, respectively, related to upfront fees paid in connection with the collaboration agreements with BioNTech AG (BioNTech) and Hanmi Pharmaceutical Co., Ltd. (Hanmi). The charges for the first six months ended June 30 also 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 12)

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.

### 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 45 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) were approved by regulatory authorities in at least one of the major geographies for use in the diseases described. The quarter in which each NME initially was approved in any major geography for any indication is shown in parentheses:

Ixekizumab\* (Taltz<sup>®</sup>) (Q1 2016)—a neutralizing monoclonal antibody to interleukin-17A for the treatment of moderate-to-severe plaque psoriasis and psoriatic arthritis.

Necitumumab\* (Portrazza<sup>®</sup>) (Q4 2015)—an anti-epidermal growth factor receptor monoclonal antibody for the treatment of metastatic squamous non-small cell lung cancer (NSCLC).

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

Baricitinib (Q1 2016)—a Janus tyrosine kinase inhibitor for the treatment of moderately-to-severely active rheumatoid arthritis (in collaboration with Incyte Corporation).

Olaratumab\* (Q1 2016)—a human IgG1 monoclonal antibody for the treatment of advanced soft tissue sarcoma. In the United States (U.S.), olaratumab is protected by a compound patent (2027, not including possible patent extension), and by biologics data package protection (2028).

The following NMEs and diagnostic agent are currently in Phase III clinical trial testing for potential use in the diseases described. The quarter in which each NME and diagnostic agent 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.

BACE inhibitor (Q2 2016)—an oral beta-secretase cleaving enzyme (BACE) inhibitor for the treatment of early Alzheimer's disease (in collaboration with AstraZeneca UK Limited).

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

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

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

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

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

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

\*\* Diagnostic agent

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

The following table reflects the status of each NME and diagnostic agent within our late-stage pipeline and recently approved products including developments since January 1, 2016:

Compound	Indication	U.S.	Europe	Japan	Developments
<b>Endocrinology</b>					
Nasal glucagon	Severe hypoglycemia	Phase III			Development of commercial manufacturing process is ongoing.
<b>Immunology</b>					
Baricitinib	Rheumatoid arthritis	Submitted			Submitted to regulatory authorities in the U.S., Europe, and Japan in first quarter of 2016.
Taltz	Psoriasis	Launched	Approved		Approved and launched in the U.S. in first and second quarters of 2016, respectively. Approved and launched in Europe in second and third quarters of 2016, respectively. Approved in Japan in third quarter of 2016.
	Psoriatic arthritis	Phase III	Approved		Phase III studies are ongoing. Approved in Japan in third quarter of 2016.
<b>Neuroscience</b>					
BACE inhibitor	Early Alzheimer's disease	Phase III			Moved into the Phase III portion of the Phase II/III seamless study in April 2016.
Galcanezumab	Cluster headache	Phase III			Phase III studies are ongoing.
	Migraine prevention	Phase III			Initiated first Phase III study in January 2016.
Solanezumab	Preclinical Alzheimer's disease	Phase III			Phase III study is ongoing.
	Mild Alzheimer's disease	Phase III			Announced change in primary endpoint for Phase III study in March 2016.
	Osteoarthritis pain	Phase III			
Tanezumab	Chronic low back pain	Phase III			Phase III studies are ongoing.
Tau imaging agent	Cancer pain	Phase III			
<b>Oncology</b>	Alzheimer's disease	Phase III			Phase III study is ongoing.
		Phase III			
	Metastatic breast cancer	Phase III			Phase III studies are ongoing.
	NSCLC	Phase III			Phase III study is ongoing. Received Breakthrough Therapy Designation <sup>(1)</sup> from the U.S. Food and Drug Administration (FDA) in 2015. Based on Phase II data, submitted to European regulatory authorities and completed rolling submission in the U.S. in first quarter of 2016. Granted Priority Review <sup>(2)</sup> from FDA in second quarter of 2016. Phase III study is ongoing.
Olaratumab	Soft tissue sarcoma	Submitted	Phase III		
Portrazza	Metastatic squamous NSCLC (first-line)	Launched	Phase Ib/II		Approved and launched in Europe in first and second quarters of 2016, respectively.

- (1) The Breakthrough Therapy Designation is designed to expedite the development and review of potential medicines that are intended to treat a serious condition where preliminary clinical evidence indicates that the treatment may demonstrate substantial improvement over available therapy on a clinically significant endpoint.
- (2) Priority Review is designed to expedite the review of potential medicines that, if approved, would be significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications.

## Other Matters

### Patent Matters

We depend on patents or other forms of intellectual-property protection for most of our revenues, cash flows, and earnings. We lost our data package protection for Cymbalta® in major European countries in 2014. In 2015, we saw the entry of generic competition in all major European markets. The loss of exclusivity for Cymbalta in the European markets has caused a rapid and severe decline in revenue for the product, which over time has, in the aggregate, had a material adverse effect on our consolidated results of operations and cash flows. We also lost patent exclusivity for the schizophrenia and bipolar mania indications in December 2015 and April 2016, respectively, for Zyprexa® in Japan. Generic versions of Zyprexa were launched in Japan in June 2016. We expect that the entry of generic competition for Zyprexa in Japan following the loss of effective patent protection will cause a rapid and severe decline in revenue for the product.

Additionally, as described in Note 10 to the consolidated condensed financial statements, the Alimta® vitamin regimen patents, which provide us with patent protection for Alimta through June 2021 in Japan and major European countries, and through May 2022 in the U.S., have been challenged in each of these jurisdictions. Our compound patent for Alimta will expire in the U.S. in January 2017, and expired in major European countries and Japan in December 2015. We expect that the entry of generic competition for Alimta following the loss of effective patent protection will cause a rapid and severe decline in revenue for the product, which will, in the aggregate, have a material adverse effect on our consolidated results of operations and cash flows. We are aware that at least one generic pemetrexed product has launched in a major European market. Notwithstanding our patents, generic versions of Alimta were also approved in Japan in February 2016. We filed for preliminary injunctions against the three generic competitors which received such approval. As described in Note 10 to the consolidated condensed financial statements, we withdrew the requests for injunctions once those competitors agreed not to proceed to pricing approval. We do not anticipate generic competitors to proceed to launch prior to the completion of the Sawai Pharmaceutical Co., Ltd. invalidation trial.

We will lose our patent protection for Strattera® in the U.S. in May 2017 and Cialis® in the U.S. and major European markets in November 2017. We expect that the entry of generic competition into these markets following the loss of effective patent protection will cause a rapid and severe decline in revenue for the affected products, which will, in the aggregate, have a material adverse effect on our consolidated results of operations and cash flows.

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

### Foreign Currency Exchange Rates

As a global company with substantial operations outside the U.S., we face foreign currency risk exposure from fluctuating currency exchange rates, primarily the U.S. dollar against the euro, Japanese yen, British pound, and Swiss franc, 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 two years, we have seen significant foreign currency rate fluctuations between the U.S. dollar and several other foreign currencies, including the euro, British pound, and 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.

The impact of the Venezuelan financial crisis, including the significant deterioration of the bolívar, resulted in a charge of \$203.9 million in the first quarter of 2016. See Note 12 to the consolidated condensed financial statements for additional information related to the charge. We anticipate that the revenue from Venezuela for the remainder of 2016 will be de minimis. As of June 30, 2016, our Venezuelan subsidiaries represented less than 0.2 percent of our consolidated assets and liabilities. We continue to monitor Venezuela's economy and other deteriorating economies. It is possible that additional charges may be recorded in the future. Any additional charges are not expected to have a material adverse effect on our future consolidated results of operations.





## Trends Affecting Pharmaceutical Pricing, Reimbursement, and Access

### United States

In the U.S., public concern over prices for specialty and brand name pharmaceuticals continues to drive the regulatory and legislative debate. These policy and political issues increase the risk that taxes, fees, rebates or other federal and state measures may be enacted. Key health policy proposals affecting biopharmaceuticals include a reduction in biologic data exclusivity, modifications to Medicare Parts B and D, language that would allow the Department of Health and Human Services to negotiate prices for biologics and drugs on the specialty tier in Part D, and state-level proposals to reduce the cost of pharmaceuticals purchased by government health care programs. Savings projected under these proposals are targeted as a means to fund both health care expenditures and non-health care initiatives, or to manage federal and state budgets.

In the U.S. private sector, consolidation and integration among U.S. healthcare providers is also a major factor in the competitive marketplace for human pharmaceuticals. Health plans and pharmaceutical benefit managers have been consolidating into fewer, larger entities, thus enhancing their purchasing strength and importance. Payers typically maintain formularies which specify coverage (the conditions under which drugs are included on a plan's formulary) and reimbursement (the associated out-of-pocket cost to the consumer). Formulary placement can lead to reduced usage of a drug for the relevant patient population due to coverage restrictions, such as prior authorizations and formulary exclusions, or due to reimbursement limitations which result in higher consumer out-of-pocket cost, such as non-preferred co-pay tiers, increased co-insurance levels and higher deductibles. Consequently, pharmaceutical companies compete for formula placement not only on the basis of product attributes such as greater efficacy, fewer side effects, or greater patient ease of use, but also by providing rebates. Price is an increasingly important factor in formulary decisions, particularly in treatment areas in which the payer has taken the position that multiple branded products are therapeutically comparable. These downward pricing pressures could negatively affect future consolidated results of operations.

The main coverage expansion provisions of the Affordable Care Act (ACA) are now in effect through both the launch of state-based exchanges and the expansion of Medicaid. An emerging trend has been the prevalence of benefit designs containing high out-of-pocket costs for patients, particularly for pharmaceuticals. In addition to the coverage expansions, many employers in the commercial market, driven in part by ACA changes such as the 2020 implementation of the excise tax on employer-sponsored health care coverage for which there is an excess benefit (the so-called "Cadillac tax"), continue to evaluate strategies such as private exchanges and wider use of consumer-driven health plans to reduce their healthcare liabilities over time. At the same time, the broader paradigm shift towards quality-based reimbursement and the launch of several value-based purchasing initiatives have placed demands on the pharmaceutical industry to offer products with proven real-world outcomes data and a favorable economic profile.

### International

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

### Tax Matters

We are subject to income taxes in the U.S. and numerous foreign jurisdictions. Changes in the relevant tax laws, regulations, administrative practices, principles, and interpretations could adversely affect our future effective tax rates. The U.S. and a number of other countries are actively considering or enacting changes in this regard. For example, the Obama administration proposed changes to the manner in which the U.S. would tax the international income of U.S.-based companies, including unremitted earnings of foreign subsidiaries. Other tax proposals under discussion or introduced in the U.S. Congress could change the tax rate and manner in which U.S. companies would be taxed. Additionally, the Organisation for Economic Co-operation and Development issued its final recommendations of international tax reform proposals to influence international tax policy in major countries in

which we operate. While outcomes of these initiatives continue to develop and remain uncertain, changes to key elements of the U.S. or international tax framework could have a material adverse effect on our consolidated operating results and cash flows.

## Legal Matters

Information regarding contingencies relating to certain legal proceedings can be found in Note 10 to the consolidated condensed financial statements and is incorporated here by reference.

## Revenue

The following tables summarize our revenue activity by jurisdiction:

	Three Months		
	Ended		Percent Change from
	June 30,		2015
	2016	2015	2015
U.S. <sup>(1)</sup>	\$2,889.9	\$2,527.8	14
Outside U.S.	2,514.9	2,450.9	3
Revenue	\$5,404.8	\$4,978.7	9
	Six Months Ended		
	June 30,		Percent Change from
	2016		2015
	2016	2015	2015
U.S. <sup>(1)</sup>	\$5,445.5	\$4,739.1	15
Outside U.S.	4,824.4	4,884.3	(1)
Revenue	\$10,269.9	\$9,623.4	7

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

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

	Three Months Ended			Six Months Ended		
	June 30,			June 30,		
	2016 vs. 2015			2016 vs. 2015		
	U.S.	Outside U.S.	Consolidated	U.S.	Outside U.S.	Consolidated
Volume	11%	6%	8%	12%	4%	8%
Price	3%	(3)%	—%	3%	(2)%	—%
Foreign exchange rates	—%	—%	—%	—%	(3)%	(1)%
Percent change	14%	3%	9%	15%	(1)%	7%

Numbers may not add due to rounding

In the U.S., for the three and six months ended June 30, 2016, the volume increase was driven by several pharmaceutical products, primarily Trulicity<sup>®</sup>, Erbitux<sup>®</sup>, and Humalog.

Outside the U.S., for the three and six months ended June 30, 2016, the volume increase was driven by several pharmaceutical products, primarily Cyramza<sup>®</sup>, Trulicity, and Humalog, partially offset by the loss of exclusivity for Cymbalta in Europe.

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

The following tables summarize our revenue activity by product:

Product	Three Months Ended			Three Months Ended	Percent Change from 2015
	June 30, 2016			June 30, 2015	
	U.S. <sup>(1)</sup>	Outside U.S.	Total	Total	
	(Dollars in millions)				
Humalog	\$420.0	\$281.9	\$701.9	\$654.3	7
Cialis	383.2	247.3	630.5	567.9	11
Alimta	291.0	316.1	607.1	664.3	(9)
Forteo <sup>®</sup>	186.4	181.2	367.6	328.4	12
Humulin <sup>®</sup>	204.3	128.0	332.3	316.4	5
Cymbalta	60.5	176.0	236.5	274.1	(14)
Strattera	143.5	81.1	224.6	191.8	17
Zyprexa	14.5	196.2	210.7	253.7	(17)
Trulicity	161.4	39.9	201.3	44.3	NM
Erbitux	156.8	23.8	180.6	134.6	34
Cyramza	67.9	79.1	147.0	87.7	68
Effient <sup>®</sup>	116.8	18.3	135.1	128.8	5
Trajenta <sup>®</sup>	48.6	72.4	121.0	80.0	51
Other human pharmaceutical products	190.5	258.3	448.8	411.6	9
Animal health products	444.5	415.3	859.8	840.8	2
Revenue	\$2,889.9	\$2,514.9	\$5,404.8	\$4,978.7	9
Product	Six Months Ended			Six Months Ended	Percent Change from 2015
	June 30, 2016			June 30, 2015	
	U.S. <sup>(1)</sup>	Outside U.S.	Total	Total	
	(Dollars in millions)				
Humalog	\$781.6	\$526.6	\$1,308.2	\$1,338.2	(2)
Cialis	707.2	500.0	1,207.2	1,106.2	9
Alimta	554.1	617.2	1,171.3	1,237.4	(5)
Humulin	444.4	244.3	688.7	632.1	9
Forteo	334.5	351.8	686.3	621.4	10
Cymbalta	83.8	351.4	435.2	561.1	(22)
Zyprexa	52.4	371.0	423.4	473.2	(11)
Strattera	260.1	152.6	412.7	365.5	13
Erbitux	297.1	51.5	348.6	222.8	56
Trulicity	280.8	64.1	344.9	62.6	NM
Cyramza	139.5	138.5	278.0	155.2	79
Effient	226.4	40.2	266.6	250.6	6
Trajenta	87.0	128.4	215.4	162.4	33
Other human pharmaceutical products	359.7	509.3	869.0	844.2	3
Animal health products	836.9	777.5	1,614.4	1,590.5	1
Revenue	\$5,445.5	\$4,824.4	\$10,269.9	\$9,623.4	7

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

NM - not meaningful

40

---

Revenues of Humalog, our injectable human insulin analog for the treatment of diabetes, increased 5 percent in the U.S. during the second quarter of 2016 driven by increased demand, partially offset by lower realized prices. For the first six months of 2016, U.S. revenue decreased 5 percent driven by lower realized prices, partially offset by increased demand. The decrease in realized prices for the first six months of 2016 primarily resulted from a first quarter change in estimate for rebates and discounts. Revenues outside the U.S. increased 11 percent during the second quarter primarily driven by increased volume, partially offset by the unfavorable impact of foreign exchange rates. For the first six months of 2016, revenues outside the U.S. increased 2 percent driven by increased volume, largely offset by the unfavorable impact of foreign exchange rates.

Revenues of Cialis, a treatment for erectile dysfunction and benign prostatic hyperplasia, increased 24 percent and 27 percent in the U.S. during the second quarter and first six months of 2016, respectively, driven primarily by higher realized prices, and to a lesser extent, increased volume. Revenues outside the U.S. decreased 4 percent and 9 percent during the second quarter and first six months of 2016, respectively, primarily driven by the unfavorable impact of foreign exchange rates and decreased volume.

Revenues of Alimta, a treatment for various cancers, decreased 12 percent and 5 percent in the U.S. during the second quarter and first six months of 2016, respectively, driven primarily by decreased demand due to competitive pressure. For the first six months of 2016, the decrease in demand was partially offset by wholesaler buying patterns. Revenues outside the U.S. decreased 5 percent during the second quarter of 2016, driven by decreased volume and lower realized prices, partially offset by the favorable impact of foreign exchange rates. For the first six months of 2016, revenues outside the U.S. decreased 6 percent, driven by lower realized prices, decreased volume, and the unfavorable impact of foreign exchange rates. We are exposed to generic entry in multiple countries during 2016 that may erode revenues from current levels.

Revenues of Humulin, an injectable human insulin for the treatment of diabetes, increased 9 percent in the U.S. in the second quarter of 2016, driven by increased volume. For the first six months of 2016, revenues increased 21 percent in the U.S., driven by higher realized prices and, to a lesser extent, increased volume. The increase in our realized prices resulted from a first quarter change in estimate of a government rebate. Revenues outside the U.S. remained relatively flat in the second quarter of 2016. For the first six months of 2016, revenues outside the U.S. decreased 8 percent, driven by the unfavorable impact of foreign exchange rates and decreased volume.

Revenues of Forteo, an injectable treatment for osteoporosis in postmenopausal women and men at high risk for fracture and for glucocorticoid-induced osteoporosis in men and postmenopausal women, increased 29 percent and 25 percent in the U.S. in the second quarter and first six months of 2016, respectively, driven by higher realized prices. Revenues outside the U.S. decreased 1 percent in the second quarter of 2016, driven by lower realized prices, largely offset by increased volume and the favorable impact of foreign exchange rates. For the first six months of 2016, revenues outside the U.S. decreased 1 percent, as lower realized prices were essentially 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, increased 49 percent and decreased 12 percent in the U.S. in the second quarter and first six months of 2016, respectively. The revenue increase in the second quarter of 2016 was 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 25 percent outside the U.S. in the second quarter and first six months of 2016, driven by the loss of exclusivity in Europe in 2014.

Revenues of Zyprexa, a treatment for schizophrenia, acute mixed or manic episodes associated with bipolar I disorder, and bipolar maintenance, remained flat outside the U.S. in the second quarter of 2016 as lower realized prices and decreased volume were essentially offset by the favorable impact of foreign exchange rates. For the first six months of 2016, revenues outside the U.S. decreased 5 percent, due to lower realized prices and decreased volume, partially offset by the favorable impact of foreign exchange rates. We lost patent exclusivity for Zyprexa in Japan in December 2015 and generic competition launched in June 2016. Zyprexa revenues in Japan were \$114.6 million and \$208.2 million for the second quarter and first six months of 2016, respectively, compared with \$106.4 million and \$200.3 million for the second quarter and first six months of 2015, respectively.

Revenues of Strattera, a treatment for attention-deficit hyperactivity disorder, increased 19 percent and 13 percent in the U.S. in the second quarter and first six months of 2016, driven by higher realized prices and, to a lesser extent, increased demand. Revenues outside the U.S. increased 15 percent and 12 percent during the second quarter and first six months of 2016, respectively, driven by increased volume.

Revenues of Erbitux, a treatment for various cancers, increased 36 percent and 67 percent in the U.S. in the second quarter and first six months of 2016, respectively, due to the transfer of commercialization rights in the U.S. and Canada (collectively, North America) that occurred on October 1, 2015.

Revenues of Trulicity, a treatment for type 2 diabetes, were \$161.4 million and \$280.8 million in the U.S. during the second quarter and first six months of 2016, respectively, driven by growth in the GLP-1 market and increased share of market for Trulicity. Revenues of Trulicity outside the U.S. were \$39.9 million and \$64.1 million during the second quarter and first six months of 2016, respectively.

Revenues of animal health products increased 8 percent and 9 percent in the U.S. in the second quarter and first six months of 2016, respectively, due to wholesaler buying patterns and uptake of new companion animal products. The increase in revenues for companion animal products was partially offset by decreased revenues for food animal products in the second quarter of 2016. Revenues outside the U.S. decreased 3 percent and 5 percent in the second quarter and first six months of 2016, respectively, primarily due to the unfavorable impact of foreign exchange rates.

#### Gross Margin, Costs, and Expenses

Gross margin as a percent of revenue decreased 2.6 percentage points to 72.9 percent for the second quarter of 2016 compared with the second quarter of 2015 and decreased 2.0 percentage points to 72.9 percent for the first six months of 2016 compared with the first six months of 2015. The decline was primarily due to a lower benefit from foreign exchange rates on international inventories sold and, to a lesser extent, the transfer of Erbitux commercialization rights in North America, partially offset by 2015 inventory step-up costs related to the acquisition of Novartis AH. Research and development expenses increased 14 percent to \$1.34 billion for the second quarter of 2016 and increased 16 percent to \$2.56 billion for the first six months of 2016. The increase was driven primarily by higher late-stage clinical development costs, including a \$100.0 million charge related to a development milestone for AZD3293, a BACE inhibitor, in development with AstraZeneca UK Limited. The first six months of 2016 also included a charge of \$55.0 million for milestone payments to Incyte Corporation for the regulatory submissions of baricitinib in the U.S. and Europe. See Note 4 to the consolidated condensed financial statements for additional information.

Marketing, selling, and administrative expenses decreased 1 percent to \$1.62 billion for the second quarter of 2016 and decreased 2 percent to \$3.10 billion for the first six months of 2016. The decrease was primarily due to lower litigation expenses and reduced spending on late life-cycle products, partially offset by expenses related to new products. For the first six months of 2016, the favorable impact of foreign exchange rates also contributed to the decrease.

There were no acquired IPR&D charges recognized in the second quarter and first six months of 2016, compared with charges of \$80.0 million and \$336.0 million for the second quarter of 2016 and first six months ended June 30, 2015, respectively. 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. The first six months of 2015 also 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 to the consolidated condensed financial statements for additional information.

We recognized asset impairment, restructuring, and other special charges of \$58.0 million and \$72.4 million in the second quarters of 2016 and 2015, respectively, related to integration costs for Novartis AH, severance costs, and asset impairments. For the first six months of 2016 and 2015, we recognized asset impairment, restructuring, and other special charges of \$189.4 million and \$180.4 million, respectively. The charges for the first six months of 2016 were associated with asset impairments related to the closure of an animal health manufacturing facility in Ireland as well as integration and severance costs related to the acquisition of Novartis AH. The 2015 charges primarily related to integration costs and intangible asset impairments due to product rationalization resulting from the acquisition of Novartis AH. See Note 5 to the consolidated condensed financial statements for additional information.

Other-net, (income) expense was income of \$21.2 million and expense of \$127.8 million for the second quarter and first six months of 2016, respectively, compared with expense of \$123.3 million and \$30.6 million for the same respective periods in 2015. Other expense during the first six months of 2016 was driven by a \$203.9 million charge





related to the impact of the Venezuelan financial crisis, including the significant deterioration of the bolívar. Other expense during 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 Note 12 to the consolidated condensed financial statements for additional information.

The effective tax rates were 20.8 percent and 21.4 percent for the second quarter and first six months of 2016, respectively, compared with 11.6 percent and 12.9 percent for the same respective periods in 2015. The increase in the effective tax rates for the second quarter and first six months of 2016 as compared with the same respective periods of 2015 is primarily due to the tax impact of 2015 charges, including acquired IPR&D charges; asset impairment, restructuring, and other special charges; and a net charge related to the repurchase of debt.

#### Financial Condition

Cash and cash equivalents decreased to \$3.24 billion as of June 30, 2016, compared with \$3.67 billion as of December 31, 2015. 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, 2016 and 2015.

In addition to our cash and cash equivalents, we held total investments of \$5.15 billion and \$4.43 billion as of June 30, 2016 and December 31, 2015, respectively. See Note 6 to the consolidated condensed financial statements for additional details.

Total debt increased to \$9.33 billion as of June 30, 2016, compared with \$7.98 billion as of December 31, 2015. The increase was primarily due to the issuance of \$1.21 billion of fixed-rate notes. See Note 6 to the consolidated condensed financial statements for additional details. At June 30, 2016, we had approximately \$1.2 billion available to us under our corporate credit facility, which is 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, 2016, we purchased \$300.1 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 "Other Matters—Patent Matters" for information regarding recent and upcoming losses of patent protection for Cymbalta (Europe), Alimta (U.S., Europe, and Japan), Zyprexa (Japan), Strattera (U.S.), and Cialis (U.S. and Europe). 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 health care legislation; various international government funding levels; and changes in foreign currency exchange rates (see "Other Matters—Foreign Currency Exchange Rates").

#### Financial Expectations

We have confirmed our 2016 financial guidance. Full-year 2016 EPS is still expected to be in the range of \$2.68 to \$2.78. We still expect 2016 revenue of between \$20.6 billion and \$21.1 billion.

Gross margin as a percent of revenue is still expected to be approximately 73 percent. Research and development expenses are still expected to be in the range of \$4.9 billion to \$5.1 billion. Marketing, selling, and administrative expenses are still expected to be in the range of \$6.1 billion to \$6.3 billion. Other—net, (income) expense is still expected to be in a range between \$125 million and \$200 million of expense.

The 2016 tax rate is still expected to be approximately 21 percent.

Capital expenditures are still expected to be approximately \$1.1 billion.

Our financial expectations through the remainder of the decade include at least 5 percent average annual revenue growth driven by volume, along with an increase in gross margin as a percent of revenue, both on a constant currency basis. We also plan to return to annual dividend increases for shareholders and reaffirmed our commitment to achieve an operating expense-to-revenue ratio of 50 percent or less in 2018.

Various risks and uncertainties, including those discussed in "Forward-Looking Statements" may cause our actual results to differ materially from these forward-looking statements.

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 (a) evaluate the company's "disclosure controls and procedures," which are defined generally as controls and other procedures of a reporting company designed to ensure that information required to be disclosed by the reporting company in its periodic reports filed with the SEC (such as this Form 10-Q) is recorded, processed, summarized, and reported on a timely basis.

Our management, with the participation of John C. Lechleiter, Ph.D., chairman, president, and chief executive officer, and Derica W. Rice, executive vice president, global services, and chief financial officer, evaluated our disclosure controls and procedures as of June 30, 2016, and concluded that they are effective.

Changes in Internal Controls. During the second quarter of 2016, there were no changes in our internal control over (b) financial reporting that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II. Other Information

### Item 1. Legal Proceedings

See "Notes to Consolidated Condensed Financial Statements—Note 10, 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>, Cymbalta, 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, 2015 (Part I, Item 3).

We are engaged in U.S. patent litigation involving Forteo brought pursuant to procedures set out in the Drug Price Competition and Patent Term Restoration Act of 1984. Teva Pharmaceuticals USA, Inc. has filed an Abbreviated New Drug Application with the FDA seeking approval to market generic versions of Forteo and has filed a notice alleging that a number of our patents covering various formulations and methods of use for Forteo are invalid and/or not infringed. In March 2016, we filed a patent infringement suit against Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. asserting six different patents with expiration dates ranging from December 2018 to August 2019.

We have received a civil investigative demand from the U.S. Attorney's Office for the Southern District of New York requesting documents and information relating to our contracts with, services performed by and payments to pharmacy benefit managers. We are cooperating with this investigation.

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, 2015. 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

There were no share repurchases during the three months ended June 30, 2016.

Item 6. Exhibits

The following documents are filed as exhibits to this Report:

EXHIBIT 3.1 Amended Articles of Incorporation

EXHIBIT 3.2 By-laws, as amended

EXHIBIT 12. Statement re: Computation of Ratio of Earnings to Fixed Charges

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

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

EXHIBIT 32. Section 1350 Certification

EXHIBIT 101. Interactive Data File

46

---

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 28, 2016 /s/Bronwen L. Mantlo  
Bronwen L. Mantlo  
Corporate Secretary

Date: July 28, 2016 /s/Donald A. Zakrowski  
Donald A. Zakrowski  
Vice President, Finance and Chief Accounting Officer

Index to Exhibits

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

Exhibit

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