

LILLY ELI & CO
Form 10-Q
October 27, 2017

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
Form 10-Q
Quarterly Report Under Section 13 or 15(d) of the
Securities Exchange Act of 1934
FOR THE QUARTER ENDED SEPTEMBER 30, 2017
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 has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes No

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of 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

(Do not
check if a

Non-accelerated filer smaller reporting company

reporting
company)

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

Yes No

The number of shares of common stock outstanding as of October 23, 2017:

Class	Number of Shares Outstanding
Common	1,101,094,711

Eli Lilly and Company
 Form 10-Q
 For the Quarter Ended September 30, 2017
 Table of Contents

	Page
<u>PART I. Financial Information</u>	<u>4</u>
<u>Item 1.</u>	<u>4</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>35</u>
<u>Management's Discussion and Analysis of Results of Operations and Financial Condition</u>	<u>35</u>
<u>Executive Overview</u>	<u>35</u>
<u>Revenue</u>	<u>42</u>
<u>Gross Margin, Costs, and Expenses</u>	<u>46</u>
<u>Financial Condition</u>	<u>47</u>
<u>Financial Expectations</u>	<u>48</u>
<u>Available Information on our Website</u>	<u>48</u>
<u>Item 4.</u>	<u>48</u>
<u>Controls and Procedures</u>	<u>48</u>
<u>PART II. Other Information</u>	<u>49</u>
<u>Item 1.</u>	<u>49</u>
<u>Legal Proceedings</u>	<u>49</u>
<u>Item 1A.</u>	<u>50</u>
<u>Risk Factors</u>	<u>50</u>
<u>Item 2.</u>	<u>50</u>
<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	<u>50</u>
<u>Item 6.</u>	<u>50</u>
<u>Exhibits</u>	<u>50</u>
<u>Signatures</u>	<u>51</u>
<u>Index to Exhibits</u>	<u>52</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, 2016, 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		Nine Months Ended	
	September 30,		September 30,	
	2017	2016	2017	2016
Revenue	\$5,658.0	\$5,191.7	\$16,710.6	\$15,461.6
Costs, expenses, and other:				
Cost of sales	1,566.1	1,400.9	4,445.4	4,188.9
Research and development	1,319.4	1,236.4	3,808.6	3,793.3
Marketing, selling, and administrative	1,555.5	1,565.4	4,807.6	4,661.9
Acquired in-process research and development (Note 3)	205.0	—	1,062.6	—
Asset impairment, restructuring, and other special charges (Note 5)	406.5	45.5	670.4	234.9
Other—net, (income) expense (Note 12)	13.9	(27.2)	2.7	100.6
	5,066.4	4,221.0	14,797.3	12,979.6
Income before income taxes	591.6	970.7	1,913.3	2,482.0
Income taxes (Note 8)	36.0	192.7	460.5	516.2
Net income	\$555.6	\$778.0	\$1,452.8	\$1,965.8
Earnings per share:				
Basic	\$0.53	\$0.74	\$1.38	\$1.86
Diluted	\$0.53	\$0.73	\$1.37	\$1.85
Shares used in calculation of earnings per share:				
Basic	1,053.4	1,057.7	1,054.8	1,058.4
Diluted	1,056.0	1,060.8	1,057.0	1,061.1
Dividends paid per share	\$0.52	\$0.51	\$1.56	\$1.53
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		Nine Months	
	Ended		Ended	
	September 30,		September 30,	
	2017	2016	2017	2016
Net income	\$555.6	\$778.0	\$1,452.8	\$1,965.8
Other comprehensive income, net of tax (Note 11) ⁽¹⁾	167.7	113.5	651.2	323.0
Comprehensive income	\$723.3	\$891.5	\$2,104.0	\$2,288.8

⁽¹⁾ Other comprehensive income (loss) for the three and nine months ended September 30, 2017 consisted of \$165.5 million and \$664.6 million of other comprehensive income attributable to controlling interest, respectively, and \$2.2 million and \$(13.4) million of other comprehensive income (loss) attributable to non-controlling interest, respectively. Other comprehensive income (loss) for the three and nine months ended September 30, 2016 attributable to non-controlling interest is immaterial.

See notes to consolidated condensed financial statements.

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

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

	September 30, 2017	December 31, 2016
	(Unaudited)	
Assets		
Current Assets		
Cash and cash equivalents (Note 6)	\$ 3,724.3	\$ 4,582.1
Short-term investments (Note 6)	3,218.8	1,456.5
Accounts receivable, net of allowances of \$42.1 (2017) and \$40.3 (2016)	4,401.3	4,029.4
Other receivables	613.2	736.9
Inventories	4,406.9	3,561.9
Prepaid expenses and other	1,063.9	734.6
Total current assets	17,428.4	15,101.4
Other Assets		
Investments (Note 6)	6,148.7	5,207.5
Goodwill	4,365.6	3,972.7
Other intangibles	4,271.6	4,357.9
Sundry	2,197.6	1,913.8
Total other assets	16,983.5	15,451.9
Property and Equipment		
Land, buildings, equipment, and construction in progress	17,730.7	16,777.6
Accumulated depreciation	(9,132.2)	(8,525.0)
Property and equipment, net	8,598.5	8,252.6
Total assets	\$ 43,010.4	\$ 38,805.9
Liabilities and Equity		
Current Liabilities		
Short-term borrowings and current maturities of long-term debt	\$ 3,538.1	\$ 1,937.4
Accounts payable	1,200.1	1,349.3
Employee compensation	821.1	896.9
Sales rebates and discounts	4,332.7	3,914.9
Dividends payable	—	548.1
Income taxes payable	414.4	119.1
Other current liabilities	2,360.1	2,220.9
Total current liabilities	12,666.5	10,986.6
Other Liabilities		
Long-term debt	9,926.6	8,367.8
Accrued retirement benefits (Note 9)	2,458.1	2,453.9
Long-term income taxes payable	710.0	688.9
Other noncurrent liabilities	2,288.6	2,228.2
Total other liabilities	15,383.3	13,738.8
Commitments and Contingencies (Note 10)		
Eli Lilly and Company Shareholders' Equity (Note 7)		
Common stock	688.5	688.5
Additional paid-in capital	5,754.7	5,640.6
Retained earnings	16,145.5	16,046.3
Employee benefit trust	(3,013.2)	(3,013.2)
Accumulated other comprehensive loss (Note 11)	(4,609.4)	(5,274.0)

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

Cost of common stock in treasury	(75.8) (80.5)
Total Eli Lilly and Company shareholders' equity	14,890.3	14,007.7	
Noncontrolling interests	70.3	72.8	
Total equity	14,960.6	14,080.5	
Total liabilities and equity	\$ 43,010.4	\$ 38,805.9	

See notes to consolidated condensed financial statements.

6

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

	Nine Months Ended September 30,	
	2017	2016
Cash Flows from Operating Activities		
Net income	\$1,452.8	\$1,965.8
Adjustments to Reconcile Net Income to Cash Flows from Operating Activities:		
Depreciation and amortization	1,155.4	1,152.0
Change in deferred income taxes	151.7	350.8
Stock-based compensation expense	209.1	188.5
Acquired in-process research and development	1,062.6	—
Other changes in operating assets and liabilities, net of acquisitions	(525.2)	(1,110.8)
Other non-cash operating activities, net	365.7	298.2
Net Cash Provided by Operating Activities	3,872.1	2,844.5
Cash Flows from Investing Activities		
Net purchases of property and equipment	(633.3)	(627.2)
Proceeds from sales and maturities of short-term investments	2,320.2	1,245.9
Purchases of short-term investments	(2,973.8)	(425.7)
Proceeds from sales of noncurrent investments	1,686.9	1,606.8
Purchases of noncurrent investments	(3,739.6)	(3,640.7)
Cash paid for acquisitions, net of cash acquired (Note 3)	(882.1)	(45.0)
Purchase of in-process research and development (Note 3)	(1,036.8)	—
Other investing activities, net	(178.0)	(75.1)
Net Cash Used for Investing Activities	(5,436.5)	(1,961.0)
Cash Flows from Financing Activities		
Dividends paid	(1,643.8)	(1,617.4)
Net change in short-term borrowings	1,226.8	(1.7)
Proceeds from issuance of long-term debt	2,232.0	1,206.6
Repayments of long-term debt	(630.6)	(0.2)
Purchases of common stock	(199.9)	(300.1)
Other financing activities, net	(299.6)	(232.2)
Net Cash Provided by (Used for) Financing Activities	684.9	(945.0)
Effect of exchange rate changes on cash and cash equivalents	21.7	(115.9)
Net decrease in cash and cash equivalents	(857.8)	(177.4)
Cash and cash equivalents at January 1	4,582.1	3,666.4
Cash and Cash Equivalents at September 30	\$3,724.3	\$3,489.0
See notes to consolidated condensed financial statements.		

Notes to Consolidated Condensed Financial Statements
(Tables present dollars in millions, except per-share data)

Note 1: Basis of Presentation

We have prepared the accompanying unaudited consolidated condensed financial statements in accordance with the requirements of Form 10-Q and, therefore, they do not include all information and footnotes necessary for a fair presentation of financial position, results of operations, and cash flows in conformity with accounting principles generally accepted in the United States (GAAP). In our opinion, the financial statements reflect all adjustments (including those that are normal and recurring) that are necessary for a fair presentation of the results of operations for the periods shown. In preparing financial statements in conformity with GAAP, we must make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, 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, 2016. We issue 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. These reclassifications include \$110.4 million that increased net cash provided by operating activities and increased net cash used for financing activities on the consolidated condensed statements of cash flows as a result of our adoption in the fourth quarter of 2016 of Accounting Standards Update 2016-09, Compensation - Stock Compensation: Improvements to Employee Share-Based Payment Accounting as discussed in our Annual Report on Form 10-K for the year ended December 31, 2016.

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 and various other related updates, Revenue from Contracts with Customers	This standard will replace existing revenue recognition standards and will require entities to recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. 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. We plan to use the latter approach.	This standard is effective January 1, 2018, and we will adopt on that date.	We are in the process of completing our evaluation of the impact of adopting the standard. We have identified two revenue streams from our contracts with customers: 1) product sales, which represented 96 percent of our 2016 consolidated revenue and 2) licensing and other arrangements, which represented 4 percent of our 2016 consolidated revenue.
			Our evaluation of our contracts for product sales is substantially complete and, based upon the results of our work to date we currently do not expect the application of the new standard to these contracts to have a material impact to our consolidated statements of operations or balance sheets either at initial implementation or on an ongoing basis.
			While we have completed most of our reviews of arrangements in which we have licensed or sold intellectual property, we are not yet able to estimate the anticipated impact to our consolidated financial statements from the application of the new standard to these arrangements as we continue to interpret and apply the principles in the new standard to our arrangements.
			We are also evaluating the new disclosures required by the standard to determine what additional information will need to be disclosed.

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

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, and we will adopt on that date.	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.
---	--	---	--

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

Standard	Description	Effective Date	Effect on the financial statements or other significant matters
Accounting Standards Update 2016-02, 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 the impact on our consolidated financial statements.
Accounting Standards Update 2016-16, Income Taxes: Intra-Entity Transfers of Assets Other Than Inventory	This standard will require entities to recognize the income tax consequences of intra-entity transfers of assets other than inventory at the time of transfer. This standard requires a modified retrospective approach to adoption.	This standard is effective January 1, 2018, and we will adopt on that date.	We are continuing to assess the potential impact of this standard on our consolidated financial statements and currently estimate that the cumulative effect of initially applying the standard would result in an increase to deferred tax assets and the opening balance of retained earnings of approximately \$2 billion on January 1, 2018. This estimate is subject to change based upon intra-entity transfers of assets other than inventory over the remainder of 2017 and ongoing assessments of the future deductibility and realizability of the deferred tax assets that would result from implementation.
Accounting Standards Update 2017-07, Compensation-Retirement Benefits: Improving the Presentation of Net Periodic Pension Cost and Net Periodic Postretirement Benefit Cost	This standard was issued to improve the transparency and comparability among organizations by requiring entities to separate their net periodic pension cost and net periodic postretirement benefit cost into a service cost component and other components. Currently, the costs of the other components along with the service cost component are classified based upon the function of the employee. This standard will require entities to classify the service cost	This standard is effective January 1, 2018, and we will adopt this standard on that date.	Upon adoption of this standard, pension and postretirement benefit cost components other than service costs will be presented in other-net, (income) expense. We do not expect the application of the new standard to have a material impact on consolidated net income either at initial implementation or on an ongoing basis.

component in the same financial statement line item or items as other compensation costs arising from services rendered by pertinent employees. The other components of net benefit cost will be presented separately from the line items that include the service cost component. When applicable, the service cost component will be the only component eligible for capitalization. An entity should apply the new standard retrospectively for the classification of the service cost and other components and prospectively for the capitalization of the service cost component.

Note 3: Acquisitions

On January 3, 2017, we completed the acquisition of Boehringer Ingelheim Vetmedica, Inc.'s United States (U.S.) feline, canine, and rabies vaccine portfolio and other related assets (BIVIVP). This transaction, as further discussed in this note below in Acquisition of a Business, was accounted for as a business combination under the acquisition method of accounting. Under this method, 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 this acquisition are included in our consolidated condensed financial statements from the date of acquisition.

In addition to the acquisition of a business, we also acquired assets in development in the nine months ended September 30, 2017, which are further discussed in this note below in Asset Acquisitions. Upon acquisition, the acquired in-process research and development (IPR&D) charges related to these products were immediately expensed because the products had no alternative future use. There were acquired IPR&D charges of \$205.0 million and \$1.06 billion for the three and nine months ended September 30, 2017, respectively. There were no acquired IPR&D charges for the three and nine months ended September 30, 2016.

In October 2017, we entered into a global immuno-oncology collaboration agreement with CureVac AG (CureVac), to develop and commercialize up to five potential cancer vaccine products based on CureVac's proprietary RNActive® technology. This transaction is subject to clearance under the Hart-Scott-Rodino Antitrust Improvements Act and other customary closing conditions. Subject to the closing of this transaction, CureVac will receive from us an initial payment of \$50.0 million. CureVac will also be eligible to receive potential development and commercialization milestones, as well as tiered royalty payments based on future sales. We anticipate recording an acquired IPR&D charge of approximately \$50 million upon the closing of the transaction.

Acquisition of a Business

Boehringer Ingelheim Vetmedica, Inc. Vaccine Portfolio Acquisition

Overview of Transaction

We acquired BIVIVP in an all-cash transaction for \$882.1 million. Under the terms of the agreement, we acquired a manufacturing and research and development site, a U.S. vaccine portfolio, including vaccines used for the treatment of bordetella, Lyme disease, rabies, and parvovirus, among others.

Assets Acquired and Liabilities Assumed

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

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

Estimated Fair Value at January 3, 2017

Inventories	\$ 108.6
Marketed products ⁽¹⁾	298.0
Property and equipment	148.2
Other assets and liabilities - net	5.2
Total identifiable net assets	560.0
Goodwill ⁽²⁾	322.1
Total consideration transferred - net of cash acquired	\$882.1

⁽¹⁾ 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 10 years.

⁽²⁾ The goodwill recognized from this acquisition is attributable primarily to expected synergies from combining the operations of BIVIVP with our legacy animal health business, future unidentified projects and products, and the assembled workforce of BIVIVP. We anticipate that the goodwill associated with this acquisition will be deductible for tax purposes.

Our consolidated condensed statement of operations for the three and nine months ended September 30, 2017, includes BIVIVP revenue of \$61.2 million and \$180.2 million, respectively. BIVIVP has been integrated into our animal health products segment and, as a result of these integration efforts, certain parts of the animal health business were operating on a combined basis during these periods, and we could not distinguish the operations between BIVIVP and our legacy animal health products business.

Asset Acquisitions

The following table and narrative summarizes our asset acquisitions during the nine months ended September 30, 2017. There was no asset acquisition which resulted in acquired IPR&D expense during the nine months ended September 30, 2016.

Counterparty	Compound(s) or Therapy	Acquisition Month	Phase of Development ⁽¹⁾	Acquired IPR&D Expense
CoLucid Pharmaceuticals, Inc. (CoLucid)	Oral therapy for the acute treatment of migraine - lasmiditan	March 2017	Phase III	\$ 857.6
KeyBioscience AG (KeyBioscience)	Multiple molecules for treatment of metabolic disorders	July 2017	Phase II	\$ 55.0
Nektar Therapeutics (Nektar)	Immunological therapy - NKTR-358	August 2017	Phase I	\$ 150.0

⁽¹⁾ The phase of development presented is as of the date of the arrangement and represents the phase of development of the most advanced asset acquired, where applicable.

In connection with the arrangements described herein, our partners may be entitled to future royalties and/or commercial milestones 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.

We acquired lasmiditan by acquiring CoLucid. Under the terms of the agreement, we acquired all shares of CoLucid for a cash purchase price of \$831.8 million, net of cash acquired, plus net accrued liabilities assumed of \$25.8 million. Substantially all of the value of CoLucid was related to lasmiditan, its only significant asset. The acquired IPR&D expense is not tax deductible.

Our collaboration agreement with KeyBioscience provides us with access to KeyBioscience's Dual Amylin Calcitonin Receptor Agonists (DACRAs), a potential new class of treatments for metabolic disorders such as type 2 diabetes, along with multiple molecules. Prior to entering into the agreement, KeyBioscience had initiated Phase II development of the lead molecule. The other assets included in the collaboration range from pre-clinical to Phase I development. Under the terms of the agreement, we receive worldwide rights to develop and commercialize these molecules.

Our collaboration with Nektar is to co-develop Nektar's compound which has the potential to treat a number of autoimmune and other chronic inflammatory conditions. Under the terms of the agreement, we are responsible for all costs of global commercialization. Nektar will have an option to co-promote in the U.S. under certain conditions.

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. Revenue related to products we sell pursuant to these arrangements are included in net product revenue, 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 Ended September 30, 2017		Nine Months Ended September 30, 2017	
Collaboration and other revenue	\$334.2	\$216.5	\$869.1	\$607.3

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: TrajentaTM Jentadueto[®], Jardiance[®], Glyxambi[®], and Synjardy[®], as well as our basal insulin: Basaglar[®].

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

Product Family	Year Launched			Milestones (Deferred) Capitalized ⁽¹⁾	Amount
	U.S.	Europe	Japan	Year	
Trajenta ⁽²⁾	2011	2011	2011	Cumulative ⁽⁴⁾ - all prior to 2016	\$446.4
Jardiance ⁽³⁾	2014	2014	2015	Cumulative ⁽⁴⁾ - all prior to 2016	299.5
				2017	—
Basaglar	2016	2015	2015	2016	(187.5)
				Cumulative ⁽⁴⁾	(250.0)

⁽¹⁾ In connection with the regulatory approvals of Basaglar in the U.S., 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⁾ The cumulative amount represents the total initial amounts that were (deferred) or capitalized from the start of this collaboration through the end of the reporting period.

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 revenue 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 is entitled to potential performance payments depending on the 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. Subject to achieving these thresholds, in a given period, our reported revenue for Trajenta and Jardiance may be reduced by any performance payments we make related to these products. Similarly, performance payments we may receive related to Basaglar effectively reduce Boehringer Ingelheim's share of the gross margin, which reduces our cost of sales.

The following table summarizes our collaboration and other revenue recognized with respect to the Trajenta and Jardiance families of products and net product revenue recognized with respect to Basaglar:

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2017	2016	2017	2016
Trajenta	\$153.3	\$115.4	\$408.2	\$330.8
Jardiance	127.2	47.5	304.3	125.8
Basaglar	145.7	19.4	278.3	46.6
Erbitux®				

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 the U.S. and Canada (Merck KGaA). Certain rights to Erbitux outside the U.S. and Canada (collectively, North America) will remain with Merck KGaA (Merck) upon expiration of that agreement.

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2017	2016	2017	2016
Net product revenue	\$137.6	\$155.9	\$403.3	\$455.8
Collaboration and other revenue	25.9	28.7	73.7	77.5
Revenue	\$163.5	\$184.6	\$477.0	\$533.3

Bristol-Myers Squibb Company

Pursuant to commercial agreements with Bristol-Myers Squibb Company and E.R. Squibb (collectively, BMS), we had been co-developing Erbitux in North America exclusively with BMS. 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 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 consideration to be paid to BMS was accounted for as contingent consideration liability. See Note 6 for discussion regarding the estimation of this liability.

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.

14

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 the underlying sales occur. 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. Generic versions of Effient launched in the U.S. in the third quarter of 2017.

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

	Three Months Ended September 30, 2017		Nine Months Ended September 30, 2016	
Revenue	\$55.9	\$127.7	\$326.6	\$394.3

Olumiant®

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 (trade name Olumiant), and certain follow-on compounds, for the treatment of inflammatory and autoimmune diseases. Incyte has the right to receive tiered, double-digit royalty payments on future global sales with rates ranging up to 20 percent if the product is successfully commercialized. The agreement provides Incyte with options to co-develop these compounds on an indication-by-indication basis by funding 30 percent of the associated development costs from the initiation of a Phase IIb trial through regulatory approval in exchange for increased tiered royalties ranging up to percentages in the high twenties. Incyte exercised its option to co-develop Olumiant in rheumatoid arthritis in 2010 and psoriatic arthritis and atopic dermatitis in 2017. The agreement calls for payments by us to Incyte 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. We capitalized as intangible assets \$65.0 million in the first quarter of 2017 and \$15.0 million in the third quarter of 2017 of milestones in connection with regulatory approvals in Europe and Japan, respectively, which are being amortized to cost of sales over the term

of the collaboration. As of September 30, 2017, Incyte is eligible to receive up to \$280.0 million of additional payments from us contingent upon certain development and success-based regulatory milestones, of which \$100.0 million relates to the U.S. regulatory decision for a first indication. Incyte is also eligible to receive up to \$150.0 million of potential sales-based milestones.

Tanezumab

We have 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 U.S. Food and Drug Administration's (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. As of September 30, 2017, 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.

Lanabecestat

We have a collaboration agreement with AstraZeneca for the worldwide co-development and co-commercialization of AstraZeneca's lanabecestat, 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. In July 2017, as a result of the outcome of an interim analysis, we incurred a \$50.0 million developmental milestone, which was recorded as research and development expense in the third quarter of 2017. As of September 30, 2017, AstraZeneca is eligible to receive up to \$300.0 million of additional payments from us contingent upon the achievement of certain development and success-based regulatory milestones.

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 September 30, 2017		Nine Months Ended September 30, 2016	
Severance:				
Human pharmaceutical products	\$165.7	\$—	\$277.1	\$—
Animal health products	5.8	8.3	62.1	37.0
Total severance	171.5	8.3	339.2	37.0
Asset impairment and other special charges:				
Human pharmaceutical products	25.0	—	25.0	—
Animal health products	210.0	37.2	306.2	197.9
Total asset impairment and other special charges	235.0	37.2	331.2	197.9
Total asset impairment, restructuring, and other special charges	\$406.5	\$45.5	\$670.4	\$234.9

Severance costs recognized during the three months ended September 30, 2017 were incurred as a result of actions taken to reduce our cost structure. Severance costs recognized during the nine months ended September 30, 2017 were incurred as a result of actions taken to reduce our cost structure, as well as the integration of Novartis Animal Health (Novartis AH). Severance costs recognized during the three and nine months ended September 30, 2016 related primarily to the integration of Novartis AH. Severance costs recognized during the nine months ended September 30, 2016 also related to our decision to close an animal health manufacturing plant in Ireland. Substantially all of the severance costs incurred during the three and nine months ended September 30, 2017 are expected to be paid in the next 12 months.

Substantially all of the asset impairment and other special charges related to animal health products recognized during the three months ended September 30, 2017 related to lower projected revenue for Posilac® (rbST). The company is exploring strategic options for Posilac, including seeking a buyer for the molecule and its Augusta manufacturing site. The assets associated with Posilac were written down to their fair values, which were determined based upon a discounted cash flow valuation. The remaining book value of assets associated with Posilac subsequent to the impairment charge are not material. Other asset impairment and other special charges recognized during the three months ended September 30, 2017 related to exit costs associated with site closures. Asset impairment and other special charges recognized during the nine months ended September 30, 2017 resulted primarily from charges associated with the Posilac impairment, integration costs of Novartis AH, as well as asset impairments due to site closures. Asset impairment and other special charges recognized during the three months ended September 30, 2016 related primarily to integration costs related to our acquisition of Novartis AH. Asset impairment and other special charges recognized during the nine months ended September 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 nine months ended September 30, 2016 consisted of integration costs related to our acquisition of Novartis AH.

In September 2017, we announced plans to reduce our cost structure by streamlining our operations, including a U.S. voluntary early retirement program. In addition to the asset impairment, restructuring, and other special charges discussed above that were incurred during the three months ended September 30, 2017, we expect to incur additional charges of approximately \$800 million in the fourth quarter of 2017 related to these plans. The fourth quarter charge could vary depending on the composition of participants within the U.S. voluntary early retirement program, as well as other actions taken to improve our cost structure.

Note 6: Financial Instruments

Financial instruments that potentially subject us to credit risk consist principally of trade receivables and interest-bearing investments. Wholesale distributors of life-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, British pound, and the Japanese yen). Foreign currency derivatives used for hedging are put in place using the same or like currencies and duration as the underlying exposures. Forward and option contracts are principally used to manage exposures arising from subsidiary trade and loan payables and receivables denominated in foreign currencies. These contracts are recorded at fair value with the gain or loss recognized in other-net, (income) expense. We may enter into foreign currency forward and option contracts and currency swaps as fair value hedges of firm commitments. Forward contracts generally have maturities not exceeding 12 months. At September 30, 2017, we had outstanding foreign currency forward commitments to purchase 502.9 million U.S. dollars and sell 422.1 million euro, commitments to purchase 735.7 million euro and sell 878.1 million U.S. dollars, commitments to purchase 428.4 million U.S. dollars and sell 47.90 billion Japanese yen, commitments to purchase 295.9 million British pounds and sell 334.8 million euro, and commitments to purchase 287.3 million U.S. dollars and sell 212.2 million British pounds, 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 had carrying amounts of \$3.67 billion and \$3.34 billion as of September 30, 2017 and December 31, 2016, respectively, and have been designated as, and are effective as, economic hedges of net investments in certain of our euro-denominated and Swiss franc-denominated foreign 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 statements of cash flows. At September 30, 2017, 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.

We also 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.

In May 2017, we issued \$750.0 million of 2.35 percent fixed-rate notes due in May 2022, \$750.0 million of 3.10 percent fixed-rate notes due in May 2027, and \$750.0 million of 3.95 percent fixed-rate notes due in May 2047, with interest to be paid semi-annually. We are using the net proceeds of \$2.23 billion from the sale of these notes for general corporate purposes, which may include the repayment of notes due in 2018 and 2019. Prior to such uses, we may temporarily invest the net proceeds in investment securities.

In May 2016, we issued Swiss franc-denominated notes consisting of Fr.200.0 million of 0.00 percent fixed-rate notes due in May 2018, Fr.600.0 million of 0.15 percent fixed-rate notes due in May 2024, and Fr.400.0 million of 0.45 percent fixed-rate notes due in May 2028, with interest to be paid annually. We are using the net cash proceeds of the offering of \$1.21 billion for general corporate purposes, which included the repayment at maturity of certain of our

U.S. dollar denominated fixed-rate notes due March 2017.

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Fair value hedges:				
Effect from hedged fixed-rate debt	\$(4.0)	\$(18.8)	\$3.6	\$92.4
Effect from interest rate contracts	4.0	18.8	(3.6)	(92.4)
Cash flow hedges:				
Effective portion of losses on interest rate contracts reclassified from accumulated other comprehensive loss	3.7	3.8	11.1	11.2
Net losses on foreign currency exchange contracts not designated as hedging instruments	16.3	1.4	79.2	105.6

During the nine months ended September 30, 2017 and 2016, 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.

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 September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Net investment hedges:				
Foreign currency-denominated notes	\$(58.7)	\$(37.0)	\$(332.0)	\$(80.0)
Cross-currency interest rate swaps	(38.2)	(4.1)	(95.8)	2.2
Foreign currency exchange contracts	—	—	—	31.9
Cash flow hedges:				
Forward-starting interest rate swaps	—	—	13.0	(3.4)

During the next 12 months, we expect to reclassify \$14.7 million of pretax net losses on cash flow hedges from accumulated other comprehensive loss to other-net, (income) expense.

Fair Value of Financial Instruments

The following tables summarize certain fair value information at September 30, 2017 and December 31, 2016 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 ⁽¹⁾	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)	
September 30, 2017						
Cash equivalents	\$2,066.7	\$2,066.7	\$1,611.0	\$ 455.7	\$	—\$2,066.7
Short-term investments:						
U.S. government and agency securities	\$742.2	\$742.7	\$742.2	\$ —	\$	—\$742.2
Corporate debt securities	2,322.9	2,322.4	—	2,322.9	—	2,322.9
Asset-backed securities	149.8	149.8	—	149.8	—	149.8
Other securities	3.9	3.9	—	3.9	—	3.9
Short-term investments	\$3,218.8					
Noncurrent investments:						
U.S. government and agency securities	\$411.7	\$415.3	\$411.7	\$ —	\$	—\$411.7
Corporate debt securities	3,913.2	3,903.8	—	3,913.2	—	3,913.2
Mortgage-backed securities	165.1	166.0	—	165.1	—	165.1
Asset-backed securities	638.8	639.2	—	638.8	—	638.8
Other securities	130.7	75.5	—	—	130.7	130.7
Marketable equity securities	344.7	127.5	344.7	—	—	344.7
Cost and equity method investments ⁽²⁾	544.5					
Noncurrent investments	\$6,148.7					
December 31, 2016						
Cash equivalents	\$2,986.8	\$2,986.8	\$2,699.4	\$ 287.4	\$	—\$2,986.8
Short-term investments:						
U.S. government and agency securities	\$232.5	\$232.6	\$232.5	\$ —	\$	—\$232.5
Corporate debt securities	1,219.2	1,219.1	—	1,219.2	—	1,219.2
Asset-backed securities	4.3	4.3	—	4.3	—	4.3
Other securities	0.5	0.5	—	0.5	—	0.5
Short-term investments	\$1,456.5					
Noncurrent investments:						
U.S. government and agency securities	\$318.9	\$323.8	\$318.9	\$ —	\$	—\$318.9
Corporate debt securities	3,062.2	3,074.3	—	3,062.2	—	3,062.2
Mortgage-backed securities	183.1	185.4	—	183.1	—	183.1
Asset-backed securities	502.7	503.5	—	502.7	—	502.7

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

Other securities	153.7	77.6	—	—	153.7	153.7
Marketable equity securities	418.2	91.9	418.2	—	—	418.2
Cost and equity method investments ⁽²⁾	568.7					
Noncurrent investments	\$5,207.5					

(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.

	Carrying Amount	Fair Value Measurements Using Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Fair Value
Short-term commercial paper borrowings					
September 30, 2017	\$(2,526.0)	\$—	\$(2,523.7)	\$	—\$(2,523.7)
December 31, 2016	(1,299.3)	—	(1,299.3)	—	(1,299.3)
Long-term debt, including current portion					
September 30, 2017	\$(10,938.7)	\$—	\$(11,448.4)	\$	—\$(11,448.4)
December 31, 2016	(9,005.9)	—	(9,419.1)	—	(9,419.1)

	Carrying Amount	Active Markets for Identical Assets (Level 1)	Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Fair Value
September 30, 2017					
Risk-management instruments:					
Interest rate contracts designated as fair value hedges:					
Other receivables	\$ 2.0	\$ —	\$ 2.0	\$ —	\$ 2.0
Sundry	43.0	—	43.0	—	43.0
Other current liabilities	(0.4)	—	(0.4)	—	(0.4)
Other noncurrent liabilities	(1.8)	—	(1.8)	—	(1.8)
Cross-currency interest rate contracts designated as net investment hedges:					
Other current liabilities	(43.4)	—	(43.4)	—	(43.4)
Other noncurrent liabilities	(20.5)	—	(20.5)	—	(20.5)
Foreign exchange contracts not designated as hedging instruments:					
Other receivables	21.0	—	21.0	—	21.0
Other current liabilities	(13.9)	—	(13.9)	—	(13.9)
Contingent consideration liabilities ⁽¹⁾ :					
Other current liabilities	(201.8)	—	—	(201.8)	(201.8)
Other noncurrent liabilities	(92.2)	—	—	(92.2)	(92.2)
December 31, 2016					
Risk-management instruments:					
Interest rate contracts designated as fair value hedges:					
Other receivables	\$ 2.4	\$ —	\$ 2.4	\$ —	\$ 2.4
Sundry	37.0	—	37.0	—	37.0
Other noncurrent liabilities	(0.5)	—	(0.5)	—	(0.5)
Cross-currency interest rate contracts designated as net investment hedges:					
Sundry	31.4	—	31.4	—	31.4
Foreign exchange contracts not designated as hedging instruments:					
Other receivables	31.8	—	31.8	—	31.8
Other current liabilities	(21.7)	—	(21.7)	—	(21.7)
Contingent consideration liabilities ⁽¹⁾ :					
Other current liabilities	(215.9)	—	—	(215.9)	(215.9)
Other noncurrent liabilities	(242.6)	—	—	(242.6)	(242.6)

⁽¹⁾ 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 values of cost and equity method investments are 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 nine months ended September 30, 2017 was due primarily to cash payments of \$151.3 million related to Erbitux. The change in the fair value of the contingent consideration liabilities recognized in earnings during the three and nine months ended September 30, 2017 and 2016 due to changes in time value of money was not material.

The table below summarizes the contractual maturities of our investments in debt securities measured at fair value as of September 30, 2017:

	Maturities by Period				
	Total	Less Than 1 Year	1-5 Years	6-10 Years	More Than 10 Years
Fair value of debt securities	\$8,343.7	\$3,214.9	\$4,795.2	\$122.4	\$211.2

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

	September 30, December 31,	
	2017	2016
Unrealized gross gains	\$259.7	\$352.6
Unrealized gross losses	27.2	34.1
Fair value of securities in an unrealized gain position	3,400.7	1,869.7
Fair value of securities in an unrealized loss position	4,013.9	3,262.3

We periodically assess our investment securities for other-than-temporary impairment losses. There were no other-than-temporary impairment losses in the three and nine months ended September 30, 2017.

Other-than-temporary impairment losses recognized during the three and nine months ended September 30, 2016 were \$11.4 million and \$53.0 million, respectively.

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

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

As of September 30, 2017, the securities in an unrealized loss position include primarily fixed-rate debt securities of varying maturities, which are sensitive to changes in the yield curve and other market conditions. Approximately 95 percent of the fixed-rate debt securities in a loss position are investment-grade debt securities. As of September 30, 2017, we do not intend to sell, and it is not more likely than not that we will be required to sell the securities in a loss position before the market values recover or the underlying cash flows have been received, and there is no indication of default on interest or principal payments for any of our debt securities.

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

	Three Months Ended September 30, 2017		Nine Months Ended September 30, 2016	
Proceeds from sales	\$951.5	\$926.3	\$3,003.0	\$2,503.4
Realized gross gains on sales	9.0	12.8	82.9	18.0
Realized gross losses on sales	0.8	1.3	3.2	11.7

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 any interest in the underlying accounts receivable once sold. We derecognized \$678.9 million and \$661.6 million of accounts receivable as of September 30, 2017 and December 31, 2016, respectively, under these factoring arrangements. The cost of factoring such accounts receivable on our consolidated condensed results of operations for the nine months ended September 30, 2017 and 2016 was not material.

Note 7: Shareholders' Equity

During the nine months ended September 30, 2017 and 2016, we repurchased \$259.9 million and \$300.1 million of shares, respectively, associated with our \$5.00 billion share repurchase program announced in October 2013. A payment of \$60.0 million was made in the fourth quarter of 2016 for shares repurchased in 2017. As of September 30, 2017, there were \$2.15 billion of shares remaining in that program.

Note 8: Income Taxes

The effective tax rates were 6.1 percent and 24.1 percent for the three and nine months ended September 30, 2017, respectively, compared with 19.9 percent and 20.8 percent for the same respective periods of 2016. The decrease in the effective tax rate for the third quarter of 2017 is primarily due to the income tax benefit of acquired IPR&D charges and asset impairment, restructuring, and other special charges. The increase in the effective tax rate for the first nine months of 2017 is primarily due to the non-tax deductible \$857.6 million acquired IPR&D charge for the acquisition of CoLucid, partially offset by the income tax benefit of acquired IPR&D charges and asset impairment, restructuring, and other special charges.

During the first quarter of 2016, we completed and effectively settled the U.S. examination of tax years 2010-2012. As a result of this resolution, our gross uncertain tax positions were reduced by approximately \$140 million, and our consolidated condensed results of operations benefited from an immaterial reduction in income tax expense. During 2016, we made cash payments of approximately \$150 million related to tax years 2010-2012 after application of available tax credit carryforwards and carrybacks. The U.S. examination of tax years 2013-2015 began in 2016 and is ongoing. The resolution of matters in this audit period will likely extend beyond the next 12 months.

Note 9: Retirement Benefits

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

	Defined Benefit Pension Plans			
	Three Months Ended		Nine Months Ended	
	September 30, 2017	September 30, 2016	September 30, 2017	September 30, 2016
Components of net periodic benefit cost:				
Service cost	\$86.0	\$70.2	\$251.6	\$212.2
Interest cost	103.6	104.2	309.2	314.4
Expected return on plan assets	(196.4)	(187.6)	(585.7)	(566.7)
Amortization of prior service cost	1.4	2.9	4.3	8.6
Recognized actuarial loss	72.5	71.0	215.6	213.4
Net periodic benefit cost	\$67.1	\$60.7	\$195.0	\$181.9
Retiree Health Benefit Plans				
	Three Months Ended		Nine Months Ended	
	September 30, 2017	September 30, 2016	September 30, 2017	September 30, 2016
Components of net periodic benefit income:				
Service cost	\$11.6	\$9.7	\$34.8	\$29.3
Interest cost	13.2	13.0	39.6	39.0
Expected return on plan assets	(40.2)	(37.6)	(120.6)	(112.7)
Amortization of prior service benefit	(22.5)	(21.5)	(67.5)	(64.3)
Recognized actuarial loss	4.6	5.2	13.8	15.5
Net periodic benefit income	\$(33.3)	\$(31.2)	\$(99.9)	\$(93.2)

We have contributed approximately \$30 million required to satisfy minimum funding requirements to our defined benefit pension and retiree health benefit plans during the nine months ended September 30, 2017. Additional discretionary funding in the aggregate was not material during the nine months ended September 30, 2017. During the remainder of 2017, we expect to make contributions to our defined benefit pension and retiree health benefit plans of approximately \$10 million to satisfy minimum funding requirements. No additional discretionary funding for the remainder of 2017 has been approved at this time.

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;

25

however, we believe that, except as noted below with respect to the Alimta® patent litigation and administrative proceedings, the resolution of all such matters will not have a material adverse effect on our consolidated financial position or liquidity, but could possibly be material to our consolidated results of operations in any one accounting period.

Alimta Patent Litigation and Administrative Proceedings

A number of generic manufacturers are seeking approvals in various countries to market generic forms of Alimta prior to the expiration of our vitamin regimen patents, alleging that those patents are invalid, not infringed, or both. We believe our Alimta vitamin regimen patents are valid and enforceable against these generic manufacturers. However, it is not possible to determine the ultimate outcome of the proceedings, and accordingly, we can provide no assurance that we will prevail. An unfavorable outcome could have a material adverse impact on our future consolidated results of operations, liquidity, and financial position. We expect that a loss of exclusivity for Alimta would result in a rapid and severe decline in future revenue 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 district 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. In January 2017, the U.S. Court of Appeals for the Federal Circuit affirmed the district court's decisions concerning validity and infringement. The defendants did not file for writ of certiorari with the U.S. Supreme Court, making the Court of Appeal's decision final.

From 2012 through 2017, we filed similar lawsuits against other ANDA defendants seeking a ruling that our patents are valid and infringed. As a result of the completion of the Teva/APP litigation, the U.S. District Court for the Southern District of Indiana has entered a judgment against five companies. Cases remain pending against an additional six ANDA defendants.

We have filed lawsuits in the U.S. District Court for the Southern District of Indiana alleging infringement against Dr. Reddy's Laboratories (Dr. Reddy's), Hospira, Inc. (Hospira), Apotex, and Actavis LLC in response to their alternative forms of pemetrexed products. In November 2017, the court is expected to hold a hearing on a motion for summary judgment filed by Dr. Reddy's. If that motion is denied, trial is expected in early 2018. We have also filed a lawsuit against Eagle Pharmaceuticals (Eagle) in the U.S. District Court for Delaware. Eagle has filed suit against us in U.S. District Court of New Jersey alleging violations of federal competition law relating to its application for an alternative salt form of pemetrexed (the active ingredient in Alimta).

In June 2016, the U.S. Patent and Trademark Office (USPTO) granted petitions by Neptune Generics, LLC and Sandoz Inc. seeking inter partes review (IPR) of our vitamin regimen patent. Several additional generic companies filed petitions and joined these proceedings. In October 2017, the USPTO ruled in our favor, finding that the claims of the vitamin regimen patent are valid. The generic companies which filed petitions with the USPTO may appeal these rulings to the U.S. Court of Appeals for the Federal Circuit.

European Patent Litigation and Administrative Proceedings

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 would not infringe the vitamin regimen patents for Alimta in the U.K., Italy, France, and Spain. In trial court and court of appeal decisions,

the alternative salt forms were found to indirectly infringe the Alimta vitamin regimen patent when reconstituted in saline, but not to directly infringe the patents as an equivalent. We appealed. In July 2017, the U.K. Supreme Court ruled that Actavis's products directly infringe our vitamin regimen patents in the U.K., Italy, France, and Spain. The U.K. Supreme Court also affirmed an earlier finding by the U.K. Court of Appeal that the Alimta vitamin regimen

patent would be indirectly infringed by commercialization of Actavis's products diluted in saline. We intend to pursue Actavis and others that launched at risk for damages.

Actavis sought a declaration of non-infringement from the U.K. High Court 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 are still seeking to appeal this ruling for procedural purposes, although it has now been superseded by the U.K. Supreme Court's recent decision.

We commenced separate infringement proceedings against certain Actavis companies in Germany. In April 2014, the German trial court ruled in our favor. The defendants appealed and 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 German Court of Appeal to reconsider issues relating to infringement.

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, and ratiopharm GmbH (ratiopharm), a subsidiary of Teva, which had stated its intention to launch a proposed alternative salt form of pemetrexed product diluted in dextrose solution. The German Court of Appeal affirmed the preliminary injunction against ratiopharm in May 2017. The preliminary injunctions against both Hexal and ratiopharm will remain in place pending the outcome of the cases on the merits.

In late 2016, the German courts issued preliminary injunctions against two other companies that had stated their intentions to launch a proposed alternative salt form of pemetrexed product diluted in dextrose solution.

Hexal and Stada Arzneimittel AG have separately challenged the validity of our vitamin regimen patent before the German Federal Patent court. The hearing will take place in mid-2018.

We do not anticipate any generic entry into the German market at least until the German Court of Appeal considers the issues remanded by the German Federal Supreme Court in the proceedings against Actavis, or if the injunctions are lifted.

Additional legal proceedings are ongoing in various national courts of other European countries. We are aware that generic competitors have received approval to market generic versions of pemetrexed in major European markets, and that a generic product is currently on the market in at least one major European market. In light of the U.K. Supreme Court's judgment finding infringement in the U.K., Italy, France, and Spain, Actavis has withdrawn its previously launched-at-risk generic products from these markets. We will continue to seek to remove any generic pemetrexed products launched at risk in other European markets.

Japanese Administrative Proceedings

Three separate sets of demands for invalidation of our two vitamin regimen patents, involving several companies, were filed with the Japanese Patent Office (JPO). In November 2015, the JPO issued written decisions in the invalidation trials initiated by Sawai Pharmaceutical Co., Ltd. (Sawai), which had been joined by three other companies, upholding both vitamin regimen patents. In February 2017, the Japan Intellectual Property High Court confirmed the decisions of the JPO and ruled in our favor in the invalidation trials initiated by Sawai. The Japan Intellectual Property High Court's decisions regarding the demands initiated by Sawai are now final. In May 2017, the JPO resumed one of the two remaining sets of demands, brought by Nipro Corporation. We expect a decision from the JPO on those demands in the first half of 2018. The other set of demands, brought by Hospira and Hospira Japan remain suspended. If upheld through all challenges, these patents provide intellectual property protection for Alimta until June 2021.

Notwithstanding our patents, generic versions of Alimta were approved in Japan starting in February 2016. We do not currently anticipate that generic versions of Alimta will proceed to pricing approval.

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 alleged that the compound patent for Effient (which expired in April 2017) was

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. Following the

27

settlement related to the compound patent challenge, generic products launched in the U.S. in the third quarter of 2017. The remaining cases have been consolidated and stayed. The entry of generic competition has caused a rapid and severe decline in revenue for the product.

In 2015, several generic pharmaceutical companies filed petitions with the USPTO, requesting IPR of the method-of-use patents. In September 2016, the USPTO determined that the method-of-use patents are invalid. Daiichi Sankyo and Ube have appealed these decisions to the U.S. Court of Appeals for the Federal Circuit. We expect a final decision in late 2017. The consolidated lawsuit is currently stayed with respect to all parties pending the outcome of this appeal.

We believe the Effient method-of-use 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.

Actos[®] Product Liability Litigation

We were named along with Takeda Chemical Industries, Ltd. and Takeda affiliates (collectively, Takeda) as a defendant in approximately 6,700 product liability cases in the U.S. related to the diabetes medication Actos, which we co-promoted with Takeda in the U.S. from 1999 until 2006. In general, plaintiffs in these actions alleged that Actos caused or contributed to their bladder cancer. Almost all of these cases were included as part of a resolution program announced by Takeda in April 2015 in which Takeda agreed to pay approximately \$2.4 billion to resolve the vast majority of the U.S. product liability lawsuits involving Actos. Although the vast majority of U.S. product liability lawsuits involving Actos are included in the resolution program, there may be additional cases pending against Takeda and us following completion of the resolution program.

We are also named along with Takeda as a defendant in three purported product liability class actions in Canada related to Actos, including one in Ontario (Casseres et al. v. Takeda Pharmaceutical North America, Inc., et al. 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.

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 (now called Strafford 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 suits and plaintiffs appealed to the U.S. Court of Appeals for the Ninth Circuit. In June 2017, we moved to dismiss the appeal for lack of jurisdiction based on the U.S. Supreme Court's recent decision in *Microsoft v. Baker*. In October 2017, the U.S. Court of Appeals for the Ninth Circuit granted our motion.

We are 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. These include approximately 40 individual and multi-plaintiff cases filed in California state court, 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 approximately five plaintiffs. We believe all these Cymbalta lawsuits and claims are without merit. We have reached a settlement framework which provides for a comprehensive resolution of nearly all of these personal injury claims, filed or unfiled, alleging injuries from discontinuing treatment with Cymbalta. There can be no assurances, however, that a final settlement will be reached.

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 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

28

exposed to benzene and heavy metals; however, Lilly Brasil maintains that these alleged contaminants were never used in the facility. In May 2014, the labor court judge ruled against Lilly Brasil. The judge's ruling orders Lilly Brasil to undertake several actions of unspecified financial impact, including paying lifetime medical insurance for the employees and contractors who worked at the Cosmopolis facility more than six months during the affected years and their children born during and after this period. While we cannot currently estimate the range of reasonably possible financial losses that could arise in the event we do not ultimately prevail in the litigation, the judge has estimated the total financial impact of the ruling to be approximately 1.0 billion Brazilian real (approximately \$315 million as of September 30, 2017) plus interest. We strongly disagree with the decision and filed an appeal in May 2014. We expect a ruling on this appeal before the end of the year.

We are also named in approximately 40 lawsuits filed in the same court by individual former employees making similar claims.

Lilly Brasil and Elanco Quimica Ltda. have also been named in a lawsuit in 15th Region in the Labor Court of Paulinia, State of Sao Paulo, involving approximately 305 individuals alleging that the companies failed to provide warnings regarding exposure to heavy metals or proper equipment at the former Cosmopolis facility, and that this alleged failure could result in possible harm to employees, former employees, and their dependents. In June 2017, the court denied the plaintiffs' request for a preliminary injunction. In September 2017, the court dismissed all claims except the one filed by the first named plaintiff. The other plaintiffs have filed a motion for clarification, which may lead to the filing of an appeal.

We believe all of 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 September 30, 2017 and 2016:

(Amounts presented net of taxes)	Foreign Currency Translation Gains (Losses)	Unrealized Net Gains (Losses) on Securities	Defined Benefit Pension and Retiree Health Benefit Plans	Effective Portion of Cash Flow Hedges	Accumulated Other Comprehensive Loss
Balance at July 1, 2017	\$ (1,349.4)	\$ 153.2	\$ (3,348.5)	\$ (197.6)	\$ (4,742.3)
Other comprehensive income (loss) before reclassifications	135.8	33.9	(28.7)	—	141.0
Net amount reclassified from accumulated other comprehensive loss	8.1	(23.9)	40.1	2.4	26.7
Net other comprehensive income (loss)	143.9	10.0	11.4	2.4	167.7
Balance at September 30, 2017 ⁽²⁾	\$ (1,205.5)	\$ 163.2	\$ (3,337.1)	\$ (195.2)	\$ (4,574.6)
(Amounts presented net of taxes)	Foreign Currency Translation Gains (Losses)	Unrealized Net Gains (Losses) on Securities	Defined Benefit Pension and Retiree Health Benefit Plans	Effective Portion of Cash Flow Hedges	Accumulated Other Comprehensive Loss
Balance at July 1, 2016	\$ (1,273.0)	\$ 36.8	\$ (2,919.1)	\$ (215.9)	\$ (4,371.2)
Other comprehensive income (loss) before reclassifications	5.8	48.9	18.7	—	73.4
Net amount reclassified from accumulated other comprehensive loss	—	(0.4)	38.0	2.5	40.1
Net other comprehensive income (loss)	5.8	48.5	56.7	2.5	113.5
Balance at September 30, 2016 ⁽²⁾	\$ (1,267.2)	\$ 85.3	\$ (2,862.4)	\$ (213.4)	\$ (4,257.7)

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 nine months ended September 30, 2017 and 2016:

(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, 2017 ⁽¹⁾	\$ (1,867.3)	\$ 224.0	\$ (3,371.6)	\$ (210.9)	\$ (5,225.8)
Other comprehensive income (loss) before reclassifications	653.7	9.6	(83.3)	8.4	588.4
Net amount reclassified from accumulated other comprehensive loss	8.1	(70.4)	117.8	7.3	62.8
Net other comprehensive income (loss)	661.8	(60.8)	34.5	15.7	651.2
Balance at September 30, 2017 ⁽²⁾	\$ (1,205.5)	\$ 163.2	\$ (3,337.1)	\$ (195.2)	\$ (4,574.6)
(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⁾	\$ (1,360.2)	\$ 10.1	\$ (3,012.1)	\$ (218.5)	\$ (4,580.7)
Other comprehensive income (loss) before reclassifications	18.5	61.9	39.2	(2.2)	117.4
Net amount reclassified from accumulated other comprehensive loss	74.5	13.3	110.5	7.3	205.6
Net other comprehensive income (loss)	93.0	75.2	149.7	5.1	323.0
Balance at September 30, 2016 ⁽²⁾	\$ (1,267.2)	\$ 85.3	\$ (2,862.4)	\$ (213.4)	\$ (4,257.7)

⁽¹⁾ Accumulated other comprehensive loss as of January 1, 2017 consists of \$5,274.0 million of accumulated other comprehensive loss attributable to controlling interest and \$48.2 million of accumulated other comprehensive income attributable to non-controlling interest. The accumulated other comprehensive loss attributable to non-controlling interest as of January 1, 2016 is immaterial.

⁽²⁾ Accumulated other comprehensive loss as of September 30, 2017 consists of \$4,609.4 million of accumulated other comprehensive loss attributable to controlling interest and \$34.8 million of accumulated other comprehensive income attributable to non-controlling interest. The accumulated other comprehensive loss attributable to non-controlling interest as of September 30, 2016 is immaterial.

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

	Three Months Ended September 30, 2017	Nine Months Ended September 30, 2016	Three Months Ended September 30, 2017	Nine Months Ended September 30, 2016
Tax benefit (expense)				
Foreign currency translation gains/losses	\$33.9	\$14.4	\$149.7	\$16.1
Unrealized net gains/losses on securities	(4.2)	(26.1)	25.4	(40.5)
Defined benefit pension and retiree health benefit plans	(9.4)	(9.5)	(24.0)	(57.0)
Effective portion of cash flow hedges	(1.3)	(1.3)	(8.4)	(2.7)
	\$19.0	\$ (22.5)	\$142.7	\$ (84.1)

Benefit/(provision) for income taxes allocated to other comprehensive income (loss)
items

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.

31

Reclassifications out of accumulated other comprehensive loss were as follows:

Details about Accumulated Other Comprehensive Loss Components	Three Months Ended		Nine Months Ended		Affected Line Item in the Consolidated Condensed Statements of Operations
	September 30, 2017	2016	September 30, 2017	2016	
Amortization of retirement benefit items:					
Prior service benefits, net	\$(21.1)	\$(18.6)	\$(63.2)	\$(55.7)	(1)
Actuarial losses, net	77.1	76.2	229.4	228.9	(1)
Total before tax	56.0	57.6	166.2	173.2	
Tax benefit	(15.9)	(19.6)	(48.4)	(62.7)	Income taxes
Net of tax	40.1	38.0	117.8	110.5	
Unrealized gains/losses on available-for-sale securities:					
Realized gains, net before tax	(36.7)	(12.0)	(108.2)	(6.8)	Other-net, (income) expense
Impairment losses	—	11.4	—	27.3	Other-net, (income) expense
Total before tax	(36.7)	(0.6)	(108.2)	20.5	
Tax (benefit) expense	12.8	0.2	37.8	(7.2)	Income taxes
Net of tax	(23.9)	(0.4)	(70.4)	13.3	
Other, net of tax (2)	10.5	2.5	15.4	81.8	Other-net, (income) expense
Total reclassifications for the period (net of tax)	\$26.7	\$40.1	\$62.8	\$205.6	

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

(2) Amount for the nine months ended September 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		Nine Months Ended	
	September 30, 2017	2016	September 30, 2017	2016
Interest expense	\$61.9	\$47.2	\$162.1	\$133.8
Interest income	(45.1)	(29.1)	(114.6)	(76.8)
Venezuela charge	—	—	—	203.9
Other income	(2.9)	(45.3)	(44.8)	(160.3)
Other-net, (income) expense	\$13.9	\$(27.2)	\$2.7	\$100.6

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 products. 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		Nine Months Ended	
	September 30, 2017	September 30, 2016	September 30, 2017	September 30, 2016
Segment revenue—to unaffiliated customers:				
Human pharmaceutical products:				
Endocrinology:				
Humalog®	\$696.2	\$640.8	\$2,083.0	\$1,949.0
Trulicity®	527.7	243.6	1,380.8	588.5
Forteo®	441.7	391.2	1,235.8	1,077.5
Humulin®	300.5	322.0	972.8	1,010.6
Trajenta	153.3	115.4	408.2	330.8
Other Endocrinology	441.3	262.8	1,094.4	734.5
Total Endocrinology	2,560.7	1,975.8	7,175.0	5,690.9
Oncology:				
Alimta	514.5	570.4	1,537.3	1,741.7
Cyramza®	196.0	159.0	553.5	437.0
Erbitux	163.5	184.6	477.0	533.3
Other Oncology	83.6	33.3	232.7	100.3
Total Oncology	957.6	947.3	2,800.5	2,812.3
Cardiovascular:				
Cialis®	564.9	588.2	1,725.7	1,795.3
Effient	55.9	127.7	326.6	394.3
Other Cardiovascular	42.1	57.6	120.2	165.4
Total Cardiovascular	662.9	773.5	2,172.5	2,355.0
Neuroscience:				
Cymbalta ⁽¹⁾	183.2	313.5	564.4	748.7
Strattera®	137.1	198.8	519.9	611.5
Zyprexa®	140.6	148.9	428.9	572.3
Other Neuroscience	46.8	47.3	160.5	137.4
Total Neuroscience	507.7	708.5	1,673.7	2,069.9
Immunology:				
Taltz®	151.3	32.5	386.7	51.9
Other Immunology	16.3	—	22.9	—
Total Immunology	167.6	32.5	409.6	51.9
Other pharmaceuticals	60.9	47.9	184.5	161.1
Total human pharmaceutical products	4,917.4	4,485.5	14,415.8	13,141.1
Animal health products	740.6	706.2	2,294.8	2,320.5
Revenue	\$5,658.0	\$5,191.7	\$16,710.6	\$15,461.6

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2017	2016	2017	2016
Segment profits:				
Human pharmaceutical products	\$1,242.5	\$1,089.0	\$3,765.7	\$2,975.3
Animal health products	121.9	104.9	422.6	464.3
Total segment profits	\$1,364.4	\$1,193.9	\$4,188.3	\$3,439.6
Reconciliation of total segment profits to consolidated income before taxes:				
Segment profits	\$1,364.4	\$1,193.9	\$4,188.3	\$3,439.6
Other profits (losses):				
Acquired in-process research and development (Note 3)	(205.0)	—	(1,062.6)	—
Amortization of intangible assets	(155.8)	(177.7)	(510.0)	(518.8)
Asset impairment, restructuring, and other special charges (Note 5)	(406.5)	(45.5)	(670.4)	(234.9)
Inventory fair value adjustment related to BIVIVP (Note 3)	(5.5)	—	(32.0)	—
Venezuela charge (Note 12)	—	—	—	(203.9)
Consolidated income before taxes	\$591.6	\$970.7	\$1,913.3	\$2,482.0

Numbers may not add due to rounding.

⁽¹⁾ Cymbalta revenues include reductions to the reserve for expected product returns of approximately \$145 million and \$175 million during the three and nine months ended September 30, 2016, respectively.

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

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

Results of Operations

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

General

Management's discussion and analysis of results of operations and financial condition, is intended to assist the reader in understanding and assessing significant changes and trends related to the results of operations and financial position of our consolidated company. This discussion and analysis should be read in conjunction with the consolidated condensed financial statements and accompanying footnotes in Item 1 of Part I of this Quarterly Report on Form 10-Q. Certain statements in this Item 2 of Part I of this Quarterly Report on Form 10-Q constitute forward-looking statements. Various risks and uncertainties, including those discussed in "Forward-Looking Statements" and Item 1A, "Risk Factors," of Part I of our Annual Report on Form 10-K for the year ended December 31, 2016, may cause our actual results and cash generated from operations to differ materially from these forward-looking statements.

Executive Overview

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 September 30,			Nine Months Ended September 30,		
	2017	2016	Percent Change	2017	2016	Percent Change
Revenue	\$5,658.0	\$5,191.7	9	\$16,710.6	\$15,461.6	8
Gross margin	4,091.9	3,790.8	8	12,265.2	11,272.7	9
Gross margin as a percent of revenue	72.3	% 73.0	%	73.4	% 72.9	%
Operating expense ⁽¹⁾	\$2,874.9	\$2,801.8	3	\$8,616.2	\$8,455.2	2
Acquired in-process research and development	205.0	—	NM	1,062.6	—	NM
Asset impairment, restructuring, and other special charges	406.5	45.5	NM	670.4	234.9	185
Net income	555.6	778.0	(29)	1,452.8	1,965.8	(26)
Earnings per share	0.53	0.73	(27)	1.37	1.85	(26)

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

NM - not meaningful

In September 2017, we announced plans to reduce our cost structure by streamlining our operations. Global workforce reductions, including those from a U.S. voluntary early retirement program, are expected to impact approximately 3,500 positions. These plans are expected to result in charges of approximately \$1.2 billion (pretax). In addition to the asset impairment, restructuring, and other special charges of \$406.5 million that were incurred during the three months ended September 30, 2017, which are discussed further below, we expect to incur additional charges of approximately \$800 million in the fourth quarter of 2017 related to these plans. The fourth quarter charge could vary depending on the composition of participants within the United States (U.S.) voluntary early retirement program, as well as other actions taken to improve our cost structure.

We are reviewing strategic alternatives for Elanco Animal Health (our animal health segment), including an initial public offering, merger, sale, or retention of the business, and will provide an update no later than the middle of 2018.

Revenue increased for the three and nine months ended September 30, 2017 primarily driven by increased volume for Trulicity®, Taltz®, Basaglar®, and other new pharmaceutical products. Operating expense increased for the three months ended September 30, 2017, driven by an increase in research and development expense. Operating expense increased for the nine months ended September 30, 2017 driven by an increase in marketing, selling, and administrative expense. The following highlighted items also affect comparisons of our financial results for the three and nine months ended September 30, 2017 and 2016:

2017

Acquired in-process research and development (IPR&D) (Note 3 to the consolidated condensed financial statements)
We recognized acquired IPR&D charges of \$205.0 million (pretax), or \$0.13 per share, and \$1.06 billion (pretax), or \$0.94 per share, for the three and nine months ended September 30, respectively, related to upfront fees paid in connection with the collaboration agreements with Nektar Therapeutics (Nektar) and KeyBioscience AG (KeyBioscience). The charges for the nine months ended September 30 also included the charge associated with the acquisition of CoLucid Pharmaceuticals, Inc. (CoLucid) which was not tax-deductible.

Asset Impairment, Restructuring, and Other Special Charges (Note 5 to the consolidated condensed financial statements)

We recognized charges of \$406.5 million (pretax), or \$0.29 per share, and \$670.4 million (pretax), or \$0.48 per share, for the three and nine months ended September 30, respectively. The charges for the third quarter were partially associated with asset impairments related to lower projected revenue for Posilac® (rbST), as well as severance costs incurred as a result of actions taken to reduce the company's cost structure as discussed above. The charges for the nine months ended September 30 were primarily due to severance costs incurred as a result of actions taken to reduce our cost structure, charges associated with the Posilac impairment, integration costs related to the acquisition of Novartis Animal Health (Novartis AH), asset impairments and other charges related to animal health assets, as well as exit costs due to site closures.

2016

Asset Impairment, Restructuring, and Other Special Charges (Note 5 to the consolidated condensed financial statements)

We recognized charges of \$45.5 million (pretax), or \$0.03 per share, and \$234.9 million (pretax), or \$0.19 per share, for the three and nine months ended September 30, respectively, related to the integration costs for our acquisition of Novartis AH and severance costs. The charges for the nine months ended September 30 also included asset impairment charges related to the closure of an animal health manufacturing facility in Ireland.

Other-Net, (Income) Expense (Note 12 to the consolidated condensed financial statements)

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.

The decreases in net income and EPS for the third quarter of 2017 were due to higher asset impairment, restructuring, and other special charges, higher acquired IPR&D charges, and, to a lesser extent, higher operating expenses, partially offset by a higher gross margin and lower income taxes. The decreases in net income and EPS for the nine months ended September 30, 2017, were due to higher acquired IPR&D charges and, to a lesser extent, asset impairment, restructuring, and other special charges, and higher operating expenses, partially offset by a higher gross margin and, to a lesser extent, the 2016 charge related to the Venezuelan financial crisis, including the significant deterioration of the bolívar.

Late-Stage Pipeline

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

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

Abemaciclib (Verzenio)[™](Q3 2017)—a small molecule cell-cycle inhibitor, selective for cyclin-dependent kinases 4 and 6 for the treatment of metastatic breast cancer. In the U.S., abemaciclib is protected by a compound patent (2029, not including possible patent extension).

Baricitinib (Olumiant[®]) (Q1 2017)—a Janus tyrosine kinase inhibitor for the treatment of moderate-to-severe active rheumatoid arthritis (in collaboration with Incyte Corporation).

Olaratumab* (Lartruvo)[™](Q4 2016)—a human IgG1 monoclonal antibody for the treatment of advanced soft tissue sarcoma.

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

Galcanezumab* (Q3 2017)—a once-monthly subcutaneously injected calcitonin gene-related peptide (CGRP) antibody for the treatment of migraine prevention. In the U.S., galcanezumab is protected by a compound patent (2033). Refer to Item 1, "Legal Proceedings—Other Patent Matters" for discussion of the lawsuit filed by Teva Pharmaceuticals International GMBH.

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

Ultra-rapid insulin* (Q3 2017)—an ultra-rapid insulin for the treatment of type 1 and type 2 diabetes.

Flortaucipir** (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.

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

Lasmiditan (Q2 2015)—an oral 5-HT_{1F} agonist for the acute treatment of migraine.

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 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 Inc.).

* 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, 2017:

Compound	Indication	U.S.	Europe	Japan	Developments
Endocrinology					
Nasal glucagon	Severe hypoglycemia	Phase III			Development of commercial manufacturing process is ongoing.
Ultra-rapid insulin	Type 1 diabetes	Phase III			Initiated Phase III study in third quarter of 2017.
Immunology					
Olumiant	Rheumatoid arthritis	See Developments	Launched		Approved and launched in Europe in first quarter of 2017. Received complete response letter from the U.S. Food and Drug Administration (FDA) in second quarter of 2017. After discussions with FDA, resubmission in the U.S. is expected before the end of January 2018. Approved and launched in Japan in third quarter of 2017.
Neuroscience					
Flortaucipir	Alzheimer's disease	Phase III			Phase III trial is ongoing.
Galcanezumab	Cluster headache	Phase III			Phase III trials are ongoing.
	Migraine prevention	Submitted	Phase III		Three Phase III trials met primary endpoints. Submitted to FDA in third quarter of 2017.
Lanabecestat	Early and mild Alzheimer's disease	Phase III			Phase III trials are ongoing.
Lasmiditan	Migraine	Phase III			Acquired from CoLucid in first quarter of 2017. In third quarter of 2017, announced Phase III trial met primary endpoint. Submission to FDA expected in second half of 2018. See Note 3 to the consolidated condensed financial statements for information on the acquisition.
Solanezumab	Preclinical Alzheimer's disease	Phase III			Phase III trial is ongoing.
Tanezumab	Osteoarthritis pain	Phase III			Granted Fast Track designation ⁽¹⁾ from the FDA in second quarter of 2017.
	Chronic low back pain	Phase III			
	Cancer pain	Phase III			Phase III trial is ongoing.

Compound	Indication	U.S.	Europe	Japan	Developments
	Oncology				
	Adjuvant breast cancer	Phase III			Initiated Phase III study in third quarter of 2017.
Verzenio	Metastatic breast cancer	Launched	Submitted		Two Phase III trials met primary endpoints. Approved and launched in the U.S. in the third and fourth quarters of 2017, respectively. Submitted to regulatory authorities in Europe and Japan in third quarter of 2017.
	KRAS-mutant non-small cell lung cancer	Terminated			In fourth quarter of 2017, announced Phase III trial did not meet primary endpoint and further development of monotherapy in this indication has been discontinued. Granted accelerated approval ⁽²⁾ by the FDA in fourth quarter of 2016 based on phase II data. Launched in the U.S. in the fourth quarter of 2016. Granted conditional approval ⁽³⁾ and launched in Europe in fourth quarter of 2016. Phase III trial is ongoing.
Lartruvo	Soft tissue sarcoma	Launched		Phase III	

⁽¹⁾ The FDA's fast track program is designed to expedite the development and review of new therapies to treat serious conditions and address unmet medical needs.

⁽²⁾ Continued approval for this indication may be contingent on verification and description of clinical benefit in a confirmatory Phase III trial.

⁽³⁾ As part of a conditional marketing authorization, results from an ongoing Phase III study will need to be provided. This study is fully enrolled. Until availability of the full data, the Committee for Medicinal Products for Human Use will review the benefits and risks of Lartruvo annually to determine whether the conditional marketing authorization can be maintained.

Other Matters

Patent Matters

We depend on patents or other forms of intellectual-property protection for most of our revenue, cash flows, and earnings. We lost patent exclusivity for the schizophrenia and bipolar mania indications for Zyprexa[®] in Japan in December 2015 and April 2016, respectively. Generic versions of Zyprexa were launched in Japan in June 2016. The loss of exclusivity for Zyprexa in Japan has caused a rapid and severe decline in revenue for the product. We lost our patent exclusivity for Strattera[®] in the U.S. in May 2017, and generic versions of Strattera were approved in the same month. As described in Note 10 to the consolidated condensed financial statements, following the settlement related to the compound patent challenge for Effient[®], generic products launched in the U.S. in the third quarter of 2017. The entry of generic competition for these products has caused a rapid and severe decline in revenue, which will, in the aggregate, have a material adverse effect on our consolidated results of operations and cash flows. We will lose our compound patent protection for Cialis[®] (tadalafil) and Adcirca[®] (tadalafil) in major European markets in November 2017. We will also lose compound patent protection for Cialis and Adcirca in the U.S. in November 2017; however, we now expect U.S. exclusivity for Cialis to end in late September 2018 at the earliest. We expect that the entry of generic competition into these markets following the loss of exclusivity 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.

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 vitamin regimen patents have also been challenged in other smaller European jurisdictions. Our compound patent for Alimta expired 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. While the U.S. Patent and Trademark Office recently ruled in our favor regarding the validity of the vitamin regimen patent, the generic companies which filed petitions seeking inter partes review of our vitamin regimen patent may appeal these rulings as further described in Note 10 to the consolidated condensed financial statements. We are aware that generic competitors have received approval to market generic versions of pemetrexed in major European markets, and that a generic product is currently on the market in at least one major European market. In light of the United Kingdom (U.K.) Supreme Court's judgment finding infringement in the U.K., Italy, France, and Spain, Actavis has withdrawn its previously launched-at-risk generic products from these markets. We will continue to seek to remove any generic pemetrexed products launched at risk in other European markets. Notwithstanding our patents, generic versions of Alimta were also approved in Japan starting in February 2016. As described in Note 10 to the consolidated condensed financial statements, we do not currently anticipate that generic versions of Alimta will proceed to pricing approval.

The compound patent for Humalog[®] (insulin lispro) has expired in major markets. 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 insulin lispro. A similar version of insulin lispro has received tentative approval in the U.S. and could launch soon. We are also aware that a competitor's insulin lispro product has launched in certain European markets. Other manufacturers have efforts underway to bring to market a similar version of insulin lispro in the U.S. and Europe. While it is difficult to estimate the severity of the impact of similar insulin lispro products entering the market, we do not expect a rapid and severe decline in revenue; however, we expect competitive pressure and some loss of market share initially that would continue over time.

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, and British pound; and the British pound against the euro. While we manage a portion of these exposures through hedging and other risk management techniques, significant fluctuations in currency rates can have a substantial impact, either positive or negative, on our revenue, cost of sales, and operating expenses. Over the past 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 and cash flows.

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. As of September 30, 2017, our Venezuelan subsidiaries represented a de minimis portion of our consolidated assets and liabilities. We continue to monitor other deteriorating economies and 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 access to and affordability of 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 in Medicare, proposals that would require biopharmaceutical manufacturers to disclose proprietary drug pricing information, and state-level proposals related to

prescription drug prices and reducing the cost of pharmaceuticals purchased by government health care programs. Several states enacted legislation in 2017 related to prescription drug pricing transparency. 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 private sector, consolidation and integration among healthcare providers is also a major factor in the competitive marketplace for human pharmaceuticals. Health plans, pharmaceutical benefit managers, wholesalers, and other supply chain stakeholders 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 formulary 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 and cash flows.

The main coverage expansion provisions of the Affordable Care Act (ACA) are currently in effect through both state-based exchanges and the expansion of Medicaid. A 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. Repealing and replacing the ACA remains a priority for President Trump and Congress. Provisions included in final legislation could have a material adverse effect on our consolidated results of operations and cash flows. At the same time, the broader paradigm shift towards performance-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 and biosimilars only and reduce current and future access to branded 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 Trump administration has stated that one of its top priorities is comprehensive tax reform. The tax rates and the manner in which U.S. companies are taxed could be altered by any such potential tax reform and could have a material adverse effect on our consolidated results of operations and cash flows. 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. Other institutions have also become more active regarding tax-related matters, including the European Commission, the United Nations, the Group of Twenty, and the European Parliament. 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 results of operations and cash flows.

Acquisitions

See Note 3 to the consolidated condensed financial statements for discussion regarding our recent acquisitions of businesses and assets, including:

• Our acquisition of Boehringer Ingelheim Vetmedica, Inc.'s U.S. feline, canine, and rabies vaccine portfolio and other related assets (BIVIVP), completed on January 3, 2017, in an all-cash transaction for \$882.1 million.

• Our acquisition of CoLucid, completed on March 1, 2017, for a cash purchase price of \$831.8 million, net of cash acquired.

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 region:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2017	2016	Percent Change	2017	2016	Percent Change
U.S. ⁽¹⁾	\$3,104.4	\$2,837.6	9	\$9,361.8	\$8,283.1	13
Outside U.S.	2,553.6	2,354.1	8	7,348.7	7,178.5	2
Revenue	\$5,658.0	\$5,191.7	9	\$16,710.6	\$15,461.6	8

Numbers may not add due to rounding.

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

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

	Three Months Ended September 30, 2017 vs. 2016			Nine Months Ended September 30, 2017 vs. 2016		
	U.S.	Outside U.S.	Consolidated	U.S.	Outside U.S.	Consolidated
Volume	6%	8%	7%	8%	5%	7%
Price	3	—	2	5	(1)	2
Foreign exchange rates	—	—	—	—	(1)	(1)
Percent change	9%	8%	9%	13%	2%	8%

Numbers may not add due to rounding

In the U.S., for the three and nine months ended September 30, 2017, the volume increase was primarily driven by new pharmaceutical products, including Trulicity, Taltz, Basaglar, Lartruvo, and Jardiance[®], as well as increased volume for companion animal products from the acquisition of BIVIVP, partially offset by decreased volume for several established pharmaceutical products, including Cialis due to decreased demand as well as Strattera due to the loss of exclusivity. The U.S. increase in realized prices for the three and nine months ended September 30, 2017 was driven by several pharmaceutical products, primarily Forteo[®], Cialis, and Humalog. For the three and nine months ended September 30, 2017, Cymbalta[®] revenue declined as the third quarter of 2016 included an increase in revenue due to a reduction to the return reserve of approximately \$145 million.

Outside the U.S., for the three and nine months ended September 30, 2017, the volume increase was driven by sales of several new pharmaceutical products, including Trulicity and Cyramza[®]. For the nine months ended September 30, 2017, the volume increase was partially offset by the loss of exclusivity for several established products, including Zyprexa in Japan, Cymbalta in Canada and Europe, and Alimta in several countries.

The following tables summarize our revenue activity by product:

Product	Three Months Ended September 30, 2017			2016	Percent Change
	U.S. ⁽¹⁾	Outside U.S.	Total	Total	
Humalog	\$414.9	\$281.3	\$696.2	\$640.8	9
Cialis	319.6	245.3	564.9	588.2	(4)
Trulicity	412.9	114.8	527.7	243.6	117
Alimta	260.3	254.2	514.5	570.4	(10)
Forteo	234.1	207.6	441.7	391.2	13
Humulin [®]	203.0	97.5	300.5	322.0	(7)
Cyramza	69.5	126.5	196.0	159.0	23
Cymbalta	19.6	163.5	183.2	313.5	(42)
Erbix [®]	136.0	27.4	163.5	184.6	(11)
Trajenta [™] ⁽²⁾	68.4	84.9	153.3	115.4	33
Taltz	131.3	20.0	151.3	32.5	NM
Basaglar	115.2	30.5	145.7	19.4	NM
Zyprexa	12.6	128.0	140.6	148.9	(6)
Strattera	52.9	84.1	137.1	198.8	(31)
Jardiance ⁽³⁾	83.8	43.4	127.2	47.5	168
Effient	42.7	13.1	55.9	127.7	(56)
Other human pharmaceutical products	174.6	243.9	418.1	382.0	9
Animal health products	353.0	387.6	740.6	706.2	5
Revenue	\$3,104.4	\$2,553.6	\$5,658.0	\$5,191.7	9

Product	Nine Months Ended September 30, 2017			2016	Percent Change
	U.S. ⁽¹⁾	Outside U.S.	Total	Total	
Humalog	\$1,254.3	\$828.6	\$2,083.0	\$1,949.0	7
Cialis	997.3	728.5	1,725.7	1,795.3	(4)
Alimta	761.9	775.4	1,537.3	1,741.7	(12)
Trulicity	1,090.1	290.7	1,380.8	588.5	135
Forteo	661.5	574.3	1,235.8	1,077.5	15
Humulin	634.9	337.9	972.8	1,010.6	(4)
Cymbalta	100.8	463.6	564.4	748.7	(25)
Cyramza	204.3	349.2	553.5	437.0	27
Strattera	276.9	243.0	519.9	611.5	(15)
Erbix	398.2	78.8	477.0	533.3	(11)
Zyprexa	49.3	379.6	428.9	572.3	(25)
Trajenta ⁽²⁾	174.2	234.1	408.2	330.8	23
Taltz	343.6	43.1	386.7	51.9	NM
Effient	290.8	35.8	326.6	394.3	(17)
Jardiance ⁽³⁾	198.3	105.9	304.3	125.8	142
Basaglar	196.7	81.6	278.3	46.6	NM
Other human pharmaceutical products	555.3	677.2	1,232.6	1,126.3	9
Animal health products	1,173.4	1,121.4	2,294.8	2,320.5	(1)
Revenue	\$9,361.8	\$7,348.7	\$16,710.6	\$15,461.6	8

Numbers may not add due to rounding.

NM - not meaningful

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

⁽²⁾ Trajenta revenue includes Jentaducto[®].

⁽³⁾ Jardiance revenue includes Glyxambi[®] and Synjardy[®].

Revenue of Humalog, our injectable human insulin analog for the treatment of diabetes, increased 10 percent and 8 percent in the U.S. during the three and first nine months of 2017, respectively, driven by higher realized prices due to changes in estimates to rebates and discounts and, to a lesser extent, increased volume. For the first nine months of 2017, the increase in realized prices primarily resulted from decreased revenue in the first quarter of 2016 resulting from changes in estimates for rebates and discounts. Revenue outside the U.S. increased 7 percent and 5 percent during the three and nine months ended September 30, 2017, respectively, driven by increased volume and, to a lesser extent, higher realized prices. The increase in revenue for the nine months ended September 30, 2017 was partially offset by the unfavorable impact of foreign exchange rates. A similar version of insulin lispro has received tentative approval in the U.S. and could launch soon. We are also aware that a competitor's insulin lispro product has launched in certain European markets. While it is difficult to estimate the severity of the impact of similar insulin lispro products entering the market, we do not expect a rapid and severe decline in revenue; however, we expect competitive pressure and some loss of market share initially that would continue over time. See "Other Matters—Patent Matters" for more information.

Revenue of Cialis, a treatment for erectile dysfunction and benign prostatic hyperplasia, decreased 8 percent and 6 percent in the U.S. during the three and nine months ended September 30, 2017, respectively, driven by decreased demand, partially offset by higher realized prices. Revenue outside the U.S. increased 2 percent in the third quarter of 2017, driven by higher realized prices and, to a lesser extent, the favorable impact of foreign exchange rates, partially offset by decreased volume. For the first nine months of 2017, revenue outside the U.S. decreased 2 percent, driven by decreased volume and, to a lesser extent, the unfavorable impact of foreign exchange rates, partially offset by higher realized prices. We will lose our compound patent protection for Cialis in major European markets in November 2017 and now expect U.S. exclusivity for Cialis to end in late September 2018 at the earliest. See "Other Matters—Patent Matters" for more information regarding our U.S. exclusivity. In addition to potential competition from generic tadalafil, we also currently face competition from generic sildenafil, which we expect to accelerate during 2018. We expect that the entry of generic competition following the loss of exclusivity will cause a rapid and severe decline in revenue.

Revenue of Alimta, a treatment for various cancers, decreased 6 percent and 8 percent in the U.S. during the three and nine months ended September 30, 2017, respectively, driven by decreased demand due to competitive pressure. Revenue outside the U.S. decreased 13 percent and 15 percent during the three and nine months ended September 30, 2017, respectively, driven by competitive pressure, lower realized prices, and the loss of exclusivity in several countries. We have faced and remain exposed to generic entry in multiple countries that has eroded revenue and is likely to continue to erode revenue from current levels.

Revenue of Trulicity, a treatment for type 2 diabetes, increased 119 percent and 132 percent in the U.S. during the three and nine months ended September 30, 2017, respectively, driven by increased share of market for Trulicity and growth in the GLP-1 market. Revenue outside the U.S. increased 109 percent and 144 percent during the three and nine months ended September 30, 2017, respectively, primarily driven by uptake in Europe and Japan.

Revenue of Forteo, an injectable treatment for osteoporosis in postmenopausal women and men at high risk for fracture and for glucocorticoid-induced osteoporosis in men and postmenopausal women, increased 13 percent and 22 percent in the U.S. during the three and nine months ended September 30, 2017, respectively, driven by higher realized prices. Revenue outside the U.S. increased 13 percent and 7 percent during the third quarter of 2017 and the first nine months of 2017, respectively, driven by increased volume. Revenue for the first nine months of 2017 was partially offset by lower realized prices and the unfavorable impact of foreign exchange rates.

Revenue of Humulin, an injectable human insulin for the treatment of diabetes, increased 4 percent in the U.S. during the third quarter of 2017, driven by increased volume, partially offset by lower realized prices. For the first nine months of 2017, revenue decreased 1 percent in the U.S., primarily resulting from a change in estimate in the first quarter of 2016 for a government rebate, which increased revenue in that period, partially offset by increased volume. Revenue outside the U.S. decreased 23 percent during the third quarter of 2017, driven by decreased volume, primarily due to buying patterns in China. For the first nine months of 2017, revenue decreased 9 percent outside the U.S., driven by lower realized prices and, to a lesser extent, the unfavorable impact of foreign exchange rates, and decreased volume.

Revenue 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, was \$19.6 million and \$100.8 million in the U.S. during the three and nine months ended September 30, 2017, respectively, compared to \$162.3 million and \$246.2 million during the three and nine months ended September 30, 2016, respectively. The decreases were driven by reductions to the reserve for expected product returns, which increased revenue by approximately \$145 million and \$175 million in the third quarter and first nine months of 2016, respectively. Revenue increased 8 percent outside the U.S. during the third quarter of 2017, primarily driven by increased volume in Japan. Revenue decreased 8 percent outside the U.S. during the nine months ended September 30, 2017, primarily driven by the loss of exclusivity in Canada and Europe, partially offset by increased volume in Japan.

Revenue of Cyramza, a treatment for various cancers, increased 4 percent in the U.S. during the third quarter of 2017, driven by increased volume. For the first nine months of 2017, revenue decreased 1 percent in the U.S., driven by lower realized prices and decreased demand due to competitive pressure. Revenue outside the U.S. increased 38

percent and 52 percent during the three and nine months ended September 30, 2017, respectively, primarily due to strong volume growth in Japan, partially offset by lower realized prices and the unfavorable impact of foreign exchange rates.

Revenue of Strattera, a treatment for attention-deficit hyperactivity disorder, decreased 56 percent and 27 percent in the U.S. during the three and nine months ended September 30, 2017, respectively, driven by the loss of exclusivity in the second quarter of 2017, partially offset by higher realized prices. We lost our patent protection for Strattera in the U.S. in May 2017. The entry of generic competition following the loss of effective patent protection has caused a rapid and severe decline in revenue. Revenue outside the U.S. increased 6 percent and 5 percent during the three and nine months ended September 30, 2017, respectively, driven by increased volume in Japan, partially offset by lower realized prices and the unfavorable impact of foreign exchange rates.

Revenue of Erbitux, a treatment for various cancers, decreased 12 percent in the U.S. during both the third quarter and first nine months of 2017, due to competitive pressure from immuno-oncology products.

Worldwide food animal revenue decreased 6 percent during the third quarter of 2017, driven by market access and competitive pressures in U.S. cattle. Worldwide food animal revenue decreased 8 percent during the nine months ended September 30, 2017, driven by market access and competitive pressures in cattle and swine. Worldwide companion animal revenue increased 35 percent during the three months ended September 30, 2017, driven by the inclusion of \$61.2 million in revenue from the BIVIVP acquisition and wholesaler buying patterns in the U.S. in the third quarter of 2016. The increase in revenue during the third quarter of 2017 was partially offset by competitive pressure and lower realized prices. Worldwide companion animal revenue increased 13 percent during the nine months ended September 30, 2017, driven by the inclusion of \$180.2 million in revenue from the BIVIVP acquisition, partially offset by competitive pressure. We expect these pressures for both companion animal and food animal to continue.

Gross Margin, Costs, and Expenses

Gross margin as a percent of revenue decreased 0.7 percentage points to 72.3 percent and increased 0.5 percentage points to 73.4 percent for the three and nine months ended September 30, 2017, respectively. The decrease in gross margin percent for the third quarter of 2017 was primarily due to the effect of foreign exchange rates on international inventories sold and negative product mix, partially offset by manufacturing efficiencies. The increase in gross margin percent for the nine months ended September 30, 2017 was primarily due to manufacturing efficiencies and higher realized prices, partially offset by the effect of foreign exchange rates on international inventories sold and negative product mix.

Research and development expenses increased 7 percent to \$1.32 billion and remained relatively flat at \$3.81 billion for the three and nine months ended September 30, 2017, respectively. The increase for the third quarter of 2017 was primarily due to a \$50.0 million milestone payment related to lanabecestat as part of our collaboration with AstraZeneca and, to a lesser extent, higher late-stage clinical development costs. For the nine months ended September 30, 2017, higher late-stage clinical development costs were essentially offset by lower milestone payments in 2017 as compared with 2016. See Note 4 to the consolidated condensed financial statements for additional information regarding our collaboration with AstraZeneca.

Marketing, selling, and administrative expenses decreased 1 percent to \$1.56 billion and increased 3 percent to \$4.81 billion for the three and nine months ended September 30, 2017, respectively. The decrease for the third quarter of 2017 was due to decreased expenses related to late life-cycle products, partially offset by increased expenses related to new pharmaceutical products. The increase for the first nine months of 2017 was due to increased expenses related to new pharmaceutical products, partially offset by decreased expenses related to late life-cycle products.

We recognized \$205.0 million and \$1.06 billion of acquired IPR&D charges for the three and nine months ended September 30, 2017, respectively, compared with no charges for the three and nine months ended September 30, 2016. The charges during the third quarter of 2017 relate to the upfront payments associated with our collaborations with Nektar and KeyBioscience. The charges during the first nine months of 2017, also include the acquired IPR&D charges associated with the acquisition of CoLucid. See Note 3 to the consolidated condensed financial statements for additional information.

We recognized asset impairment, restructuring, and other special charges of \$406.5 million and \$670.4 million for the three and nine months ended September 30, 2017, respectively, compared with charges of \$45.5 million and \$234.9 million for the three and nine months ended September 30, 2016, respectively. The charges for the third quarter of 2017 were partially associated with asset impairments related to lower projected revenue for Posilac, severance costs incurred as a result of actions taken to reduce our cost structure, as well as exit costs due to site closures. See "Executive Overview—Financial Results" for more information on the actions taken to reduce our cost structure. The charges for the first nine months of 2017 were due to severance costs incurred as a result of actions taken to reduce our cost structure, charges associated with the Posilac impairment, integration costs related to the acquisition of Novartis AH, asset impairments and other charges related to animal health assets, as well as exit costs due to site closures. We are exploring strategic options for Posilac, including seeking a buyer for the molecule and its Augusta manufacturing site. The charges for the third quarter of 2016 related to integration and severance costs for Novartis AH. The charges for the first nine months of 2016 were primarily associated with integration costs related to our acquisition of Novartis AH, asset impairments related to the closure of an animal health manufacturing facility in Ireland, as well as severance costs for Novartis AH. See Note 5 to the consolidated condensed financial statements for additional information.

Other-net, (income) expense was expense of \$13.9 million and expense of \$2.7 million for the third quarter and first nine months of 2017, respectively, compared with income of \$27.2 million and expense of \$100.6 million for the third quarter and first nine months of 2016. The increase in expense during the third quarter of 2017 was driven by higher net gains on investments in the third quarter of 2016 as compared to 2017. Other expense during the first nine 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. See Note 12 to the consolidated condensed financial statements for additional information.

The effective tax rates were 6.1 percent and 24.1 percent for the three and nine months ended September 30, 2017, respectively, compared with 19.9 percent and 20.8 percent for the same respective periods of 2016. The decrease in the effective tax rate for the third quarter of 2017 is primarily due to the income tax benefit of acquired IPR&D charges and asset impairment, restructuring, and other special charges. The increase in the effective tax rate for the first nine months of 2017 is primarily due to the non-tax deductible \$857.6 million acquired IPR&D charge for the acquisition of CoLucid, partially offset by the income tax benefit of acquired IPR&D charges and asset impairment, restructuring, and other special charges.

Financial Condition

Cash and cash equivalents decreased to \$3.72 billion as of September 30, 2017, compared with \$4.58 billion as of December 31, 2016. Refer to the consolidated condensed statements of cash flows for additional details on the significant sources and uses of cash for the nine months ended September 30, 2017 and 2016.

In addition to our cash and cash equivalents, we held total investments of \$9.37 billion and \$6.66 billion as of September 30, 2017 and December 31, 2016, respectively. See Note 6 to the consolidated condensed financial statements for additional details.

Total debt increased to \$13.46 billion as of September 30, 2017, compared with \$10.31 billion as of December 31, 2016. The increase was primarily due to the cash proceeds of \$2.23 billion from the issuance of fixed-rate notes and, to a lesser extent, the net increase in the balance of commercial paper outstanding of \$1.23 billion, partially offset by the repayment of \$630.6 million of long term debt. See Note 6 to the consolidated condensed financial statements for additional details regarding the May 2017 debt issuance. At September 30, 2017, we had a total of \$5.17 billion of committed bank credit facilities, \$5.00 billion of 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 nine months ended September 30, 2017, we repurchased \$259.9 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.

See "Other Matters—Patent Matters" for information regarding recent and upcoming losses of patent protection.

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

Full-year 2017 EPS is now anticipated to be in the range of \$1.73 to \$1.83 reflecting charges associated with recently announced streamlining initiatives. We now expect 2017 revenue of between \$22.4 billion and \$22.7 billion, primarily due to uptake trends for new pharmaceutical products and, to a lesser extent, the positive impact of the Euro.

Excluding the impact of foreign exchange rates, we expect revenue growth from new pharmaceutical products including Trulicity, Taltz, Basaglar, Cyramza, Jardiance, and Lartruvo, as well as a number of established pharmaceutical products including Trajenta, Forteo, and Humalog.

Gross margin as a percent of revenue is still expected to be approximately 72.5 percent. Research and development expenses are now expected to be in the range of \$5.1 billion to \$5.2 billion. Marketing, selling, and administrative expenses are still expected to be in the range of \$6.4 billion to \$6.6 billion. Other—net, (income) expense is still expected to be income of up to \$100 million.

The 2017 tax rate is now expected to be approximately 20.0 percent.

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

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 David A. Ricks, chairman, president, and chief executive officer, and Derica W. Rice, executive vice president, global services, and chief financial officer, evaluated our disclosure controls and procedures as of September 30, 2017, and concluded that they are effective.

Changes in Internal Controls. During the third quarter of 2017, 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[®] and Cymbalta.
- 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, 2016 (Part I, Item 3) and our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2017 and June 30, 2017 (Part II, Item 1).

Other Product Liability Litigation

We are named as a defendant in approximately 505 Byetta[®] product liability lawsuits in the U.S. involving approximately 770 plaintiffs. Approximately 60 of these lawsuits, covering about 320 plaintiffs, are filed in California state court and coordinated in a Los Angeles Superior Court. Approximately 440 lawsuits, covering about 445 plaintiffs, are filed in federal court, the majority of which are coordinated in a multidistrict litigation (MDL) in the U.S. District Court for the Southern District of California. The remaining three lawsuits, representing approximately five plaintiffs, are in various state courts. Approximately 495 of the lawsuits, involving approximately 730 plaintiffs, contain allegations that Byetta caused or contributed to the plaintiffs' cancer (primarily pancreatic cancer or thyroid cancer); most others allege Byetta caused or contributed to pancreatitis. The federal and state trial courts granted summary judgment in favor of us and our co-defendants on the claims alleging pancreatic cancer. The plaintiffs appealed those rulings. In October 2017, oral argument was held in the U.S. Court of Appeals for the Ninth Circuit for the federal court decision. No oral argument date has been set for appeal of the state court decision. We are aware of approximately 20 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.

We are named as a defendant in approximately 135 Cialis product liability lawsuits in the U.S. These cases, originally filed in various federal courts, contain allegations that Cialis caused or contributed to the plaintiffs' cancer (melanoma). In December 2016, the Judicial Panel on Multidistrict Litigation (JPML) granted the plaintiffs' petition to have the filed cases and an unspecified number of future cases coordinated into a federal MDL in the U.S. District Court for the Northern District of California, alongside an existing coordinated proceeding involving Viagra[®]. The JPML ordered the transfer of the existing cases to the now-renamed MDL In re: Viagra (Sildenafil Citrate) and Cialis (Tadalafil) Products Liability Litigation. We believe these lawsuits and claims are without merit and are prepared to defend against them vigorously.

Other Patent Matters

In Canada, several generic companies previously challenged the validity of our Zyprexa patent. In September 2012, the Canadian Court of Appeals affirmed the lower court's decision that the patent was invalid for lack of utility. In 2013, our petition for leave to appeal the decision to the Supreme Court of Canada was denied. Two of the generic companies, Apotex Inc. (Apotex) and Teva Canada Limited (Teva Canada), pursued claims for damages arising from our enforcement of the patent under Canadian regulations. In April 2014, the Supreme Court of Canada dismissed Apotex's damages suit. Teva Canada's claim for damages remains, and a separate trial to determine the total amount of damages that may be awarded to Teva Canada concluded in May 2016. In January 2017, the court issued a ruling that Teva Canada is entitled to damages. We have appealed this decision and a hearing is expected in late 2017.

In October 2017, Teva Pharmaceuticals International GMBH filed a lawsuit against us in U.S. District Court for the District of Massachusetts seeking a ruling that various patents would be infringed if we launch galcanezumab. We believe these patents are invalid and that this lawsuit is without merit. We are prepared to vigorously defend against this lawsuit.

Other Matters

We, along with Sanofi, Novo Nordisk, and various pharmacy benefit managers, are named as defendants in a purported class action lawsuit in the U.S. District Court of Western District of Texas, MSP Recovery Claims, Series, LLC et al. v. CVS Health Corp., et al., relating to insulin pricing. The complainants are seeking damages under common law fraud, unjust enrichment, and the federal Racketeer Influenced and Corrupt Organizations Act. We believe this lawsuit and these claims are without merit and are prepared to defend against them vigorously.

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, 2016. 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 September 30, 2017.

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 David A. Ricks, 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 Files

Signatures

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned thereunto duly authorized.

ELI LILLY AND COMPANY
(Registrant)

Date: October 27, 2017 /s/Bronwen L. Mantlo
Bronwen L. Mantlo
Corporate Secretary

Date: October 27, 2017 /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 99.1 to the Company's Report on Form 8-K dated August 29, 2017.
- EXHIBIT 12. Statement re: Computation of Ratio of Earnings to Fixed Charges
- EXHIBIT 31.1 Rule 13a-14(a) Certification of David A. Ricks, 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 Files