

LILLY ELI & CO
Form 10-Q
November 06, 2018

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, 2018
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 every Interactive Data File required to be submitted 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, a smaller reporting company, or an emerging growth company. See the definitions of a "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer Accelerated filer
Non-accelerated filer Smaller 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 November 2, 2018:

Class	Number of Shares Outstanding
Common	1,059,322,255

Eli Lilly and Company
 Form 10-Q
 For the Quarter Ended September 30, 2018
 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 Equity</u>	<u>7</u>
<u>Consolidated Condensed Statements of Cash Flows</u>	<u>9</u>
<u>Notes to Consolidated Condensed Financial Statements</u>	<u>10</u>
<u>Item 2.</u>	<u>41</u>
<u>Management's Discussion and Analysis of Results of Operations and Financial Condition</u>	<u>41</u>
<u>Executive Overview</u>	<u>41</u>
<u>Revenue</u>	<u>48</u>
<u>Gross Margin, Costs, and Expenses</u>	<u>52</u>
<u>Financial Condition</u>	<u>53</u>
<u>Financial Expectations</u>	<u>54</u>
<u>Available Information on our Website</u>	<u>54</u>
<u>Item 4.</u>	<u>54</u>
<u>Controls and Procedures</u>	<u>54</u>
<u>PART II. Other Information</u>	<u>55</u>
<u>Item 1.</u>	<u>55</u>
<u>Legal Proceedings</u>	<u>55</u>
<u>Item 1A.</u>	<u>56</u>
<u>Risk Factors</u>	<u>56</u>
<u>Item 2.</u>	<u>57</u>
<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	<u>57</u>
<u>Item 6.</u>	<u>57</u>
<u>Exhibits</u>	<u>57</u>
<u>Index to Exhibits</u>	<u>58</u>
<u>Signatures</u>	<u>58</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 Results of Operations and Financial Condition” 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. The following include some but not all of the factors that could cause actual results or events to differ materially from those anticipated:

- the timing of anticipated regulatory approvals and launches of new products;
 - market uptake of recently launched products;
 - competitive developments affecting current products;
 - the expiration of intellectual property protection for certain of our products;
 - our ability to protect and enforce patents and other intellectual property;
 - the impact of actions of governmental and private payers affecting pricing of, reimbursement for, and access to pharmaceuticals;
 - regulatory compliance problems or government investigations;
 - regulatory actions regarding currently marketed products;
 - unexpected safety or efficacy concerns associated with our products;
 - issues with product supply stemming from manufacturing difficulties or disruptions;
 - regulatory changes or other developments;
 - changes in patent law or regulations related to data-package exclusivity;
 - litigation involving past, current, or future products as we are largely self-insured;
 - unauthorized disclosure or misappropriation of trade secrets or other confidential data stored in our information systems, networks, and facilities, or those of third parties with whom we share our data;
 - changes in tax law;
 - changes in foreign currency exchange rates, interest rates, and inflation;
 - asset impairments and restructuring charges;
 - changes in accounting standards promulgated by the Financial Accounting Standards Board and the Securities and Exchange Commission (SEC);
 - acquisitions and business development transactions and related integration costs;
 - information technology system inadequacies or operating failures;
 - reliance on third-party relationships and outsourcing arrangements;
 - the impact of global macroeconomic conditions; and
- uncertainties and risks related to timing and potential value to both Elanco and Lilly of the planned separation of the Elanco animal health business, including business, industry, and market risks, as well as risks involving realizing the anticipated tax-free nature of the separation.

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 SEC, including our Annual Report on Form 10-K for the year ended December 31, 2017, particularly under the caption “Risk Factors”, and our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2018 and June 30, 2018.

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.

3

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,	
	2018	2017	2018	2017
Revenue	\$6,061.9	\$5,658.0	\$18,117.1	\$16,710.6
Costs, expenses, and other:				
Cost of sales	1,562.3	1,586.3	4,836.3	4,505.9
Research and development	1,343.3	1,340.0	3,853.3	3,870.4
Marketing, selling, and administrative	1,616.6	1,578.5	4,770.3	4,876.6
Acquired in-process research and development (Note 3)	30.0	205.0	1,654.5	1,062.6
Asset impairment, restructuring, and other special charges (Note 5)	83.3	406.5	236.0	670.4
Other—net, (income) expense (Note 11)	15.4	(49.9)	(90.1)	(188.6)
	4,650.9	5,066.4	15,260.3	14,797.3
Income before income taxes	1,411.0	591.6	2,856.8	1,913.3
Income taxes (Note 7)	261.5	36.0	749.8	460.5
Net income	\$1,149.5	\$555.6	\$2,107.0	\$1,452.8
Earnings per share:				
Basic	\$1.13	\$0.53	\$2.04	\$1.38
Diluted	\$1.12	\$0.53	\$2.03	\$1.37
Shares used in calculation of earnings per share:				
Basic	1,020.4	1,053.4	1,033.2	1,054.8
Diluted	1,026.3	1,056.0	1,037.8	1,057.0

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,	
	2018	2017	2018	2017
Net income	\$1,149.5	\$555.6	\$2,107.0	\$1,452.8
Other comprehensive income, net of tax (Note 10) ⁽¹⁾	660.2	167.7	375.3	651.2
Comprehensive income	\$1,809.7	\$723.3	\$2,482.3	\$2,104.0

⁽¹⁾ Other comprehensive income for the three and nine months ended September 30, 2018 was all attributable to controlling interest. Other comprehensive income for the three and nine months ended September 30, 2017 consisted of \$165.5 million and \$664.6 million, respectively, of other comprehensive income attributable to controlling interest and \$2.2 million and \$(13.4) million of other comprehensive income (loss) attributable to noncontrolling interest during the same periods.

See notes to consolidated condensed financial statements.

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

	September 30, 2018	December 31, 2017
	(Unaudited)	
Assets		
Current Assets		
Cash and cash equivalents (Note 6)	\$ 8,960.0	\$ 6,536.2
Short-term investments (Note 6)	76.1	1,497.9
Accounts receivable, net of allowances of \$34.0 (2018) and \$38.7 (2017)	4,859.4	4,546.3
Other receivables	793.2	715.9
Inventories	4,118.0	4,458.3
Prepaid expenses and other	1,879.2	1,447.5
Total current assets	20,685.9	19,202.1
Other Assets		
Investments (Note 6)	2,005.8	5,678.8
Goodwill	4,358.4	4,370.1
Other intangibles	3,619.4	4,029.2
Deferred tax assets	3,132.3	1,166.4
Sundry	2,009.2	1,707.9
Total other assets	15,125.1	16,952.4
Property and equipment, net of accumulated depreciation of \$9,671.7 (2018) and \$9,264.6 (2017)	8,814.1	8,826.5
Total assets	\$ 44,625.1	\$ 44,981.0
Liabilities and Equity		
Current Liabilities		
Short-term borrowings and current maturities of long-term debt	\$ 1,002.2	\$ 3,706.6
Accounts payable	1,281.2	1,410.7
Employee compensation	858.5	997.9
Sales rebates and discounts	5,129.4	4,465.1
Dividends payable	—	590.6
Income taxes payable	409.2	532.9
Other current liabilities	2,146.2	2,832.1
Total current liabilities	10,826.7	14,535.9
Other Liabilities		
Long-term debt	11,674.7	9,940.5
Accrued retirement benefits (Note 8)	2,684.5	3,513.9
Long-term income taxes payable	3,740.5	3,776.5
Other noncurrent liabilities	1,547.8	1,546.3
Total other liabilities	19,647.5	18,777.2
Commitments and Contingencies (Note 9)		
Eli Lilly and Company Shareholders' Equity		
Common stock	667.1	687.9
Additional paid-in capital	6,522.9	5,817.8
Retained earnings	14,408.7	13,894.1
Employee benefit trust	(3,013.2)	(3,013.2)
Accumulated other comprehensive loss (Note 10)	(5,439.5)	(5,718.6)
Cost of common stock in treasury	(69.4)	(75.8)

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

Total Eli Lilly and Company shareholders' equity	13,076.6	11,592.2
Noncontrolling interests (Note 3)	1,074.3	75.7
Total equity	14,150.9	11,667.9
Total liabilities and equity	\$ 44,625.1	\$ 44,981.0

See notes to consolidated condensed financial statements.

6

Consolidated Condensed Statements of Equity

(Unaudited)

ELI LILLY AND COMPANY AND SUBSIDIARIES

(Dollars in millions)

ELI LILLY AND COMPANY AND SUBSIDIARIES (Dollars in millions, shares in thousands)	Equity of Eli Lilly and Company Shareholders					Common Stock		Noncontrolling Interest	
	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Retained Earnings	Employee Benefit Trust	Accumulated Other Comprehensive Loss	in Treasury Shares		in Treasury Amount
Balance at July 1, 2017	1,101,646	\$ 688.5	\$ 5,686.1	\$ 15,590.1	\$(3,013.2)	\$(4,774.9)	664	\$(75.8)	\$ 68.9
Net income				555.6					0.3
Other comprehensive income, net of tax						165.5			2.2
Issuance of stock under employee stock plans, net	26		(1.2)						
Stock-based compensation			69.8						
Other				(0.2)					(1.1)
Balance at September 30, 2017	1,101,672	\$ 688.5	\$ 5,754.7	\$ 16,145.5	\$(3,013.2)	\$(4,609.4)	664	\$(75.8)	\$ 70.3
Balance at July 1, 2018	1,077,548	\$ 673.5	\$ 5,825.7	\$ 14,247.3	\$(3,013.2)	\$(6,108.7)	604	\$(69.4)	\$ 65.6
Net income (loss)				1,149.5					(5.2)
Other comprehensive income, net of tax						660.2			
Retirement of treasury shares	(10,191)	(6.4)		(993.7)			(10,191)	1,000.0	
Purchase of treasury shares ⁽¹⁾							10,191	(1,000.0)	
Issuance of stock under employee stock plans, net	17		(0.5)						
Stock-based compensation			68.5						
Sale of Elanco stock (Note 3)			629.2			9.0			1,017.2
Other				5.6					(3.3)
Balance at September 30, 2018	1,067,374	\$ 667.1	\$ 6,522.9	\$ 14,408.7	\$(3,013.2)	\$(5,439.5)	604	\$(69.4)	\$ 1,074.3

⁽¹⁾ As of September 30, 2018, there was \$7.00 billion remaining under our \$8.00 billion share repurchase program authorized in June 2018.

See notes to consolidated condensed financial statements.

Consolidated Condensed Statements of Equity (Continued)

(Unaudited)

ELI LILLY AND COMPANY AND SUBSIDIARIES

(Dollars in millions)

ELI LILLY AND COMPANY AND SUBSIDIARIES (Dollars in millions, shares in thousands)	Equity of Eli Lilly and Company Shareholders					Common Stock		Noncontrolling Interest	
	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Retained Earnings	Employee Benefit Trust	Accumulated Other Comprehensive Loss	in Treasury Shares		in Treasury Amount
Balance at January 1, 2017	1,101,586	\$ 688.5	\$ 5,640.6	\$ 16,046.3	\$(3,013.2)	\$(5,274.0)	711	\$(80.5)	\$ 72.8
Net income				1,452.8					14.3
Other comprehensive income (loss), net of tax						664.6			(13.4)
Cash dividends declared per share: \$1.04				(1,095.7)					
Retirement of treasury shares	(3,191)	(2.0)		(257.9)			(3,191)	259.9	
Purchase of treasury shares			60.0				3,191	(259.9)	
Issuance of stock under employee stock plans, net	3,277	2.0	(155.0)				(47)	4.7	
Stock-based compensation			209.1						
Other									(3.4)
Balance at September 30, 2017	1,101,672	\$ 688.5	\$ 5,754.7	\$ 16,145.5	\$(3,013.2)	\$(4,609.4)	664	\$(75.8)	\$ 70.3
Balance at January 1, 2018	1,100,672	\$ 687.9	\$ 5,817.8	\$ 13,894.1	\$(3,013.2)	\$(5,718.6)	664	\$(75.8)	\$ 75.7
Net income (loss)				2,107.0					(0.6)
Other comprehensive income, net of tax						375.3			
Cash dividends declared per share: \$1.13				(1,148.6)					
Retirement of treasury shares	(36,014)	(22.5)		(3,028.2)			(36,014)	3,050.7	
Purchase of treasury shares ⁽¹⁾							36,014	(3,050.7)	

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

Issuance of stock under employee stock plans, net	2,716	1.7	(130.8)			(60)	6.4
Stock-based compensation			206.7				
Adoption of new accounting standards (Note 2)			2,584.4			(105.2)	
Sale of Elanco stock (Note 3)			629.2			9.0	1,017.2
Other							(18.0)
Balance at September 30, 2018	1,067,374	\$667.1	\$6,522.9	\$14,408.7	\$(3,013.2)	\$(5,439.5)	604 \$(69.4) \$1,074.3

⁽¹⁾ As of September 30, 2018, there was \$7.00 billion remaining under our \$8.00 billion share repurchase program authorized in June 2018.

See notes to consolidated condensed financial statements.

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

	Nine Months Ended September 30,	
	2018	2017
Cash Flows from Operating Activities		
Net income	\$2,107.0	\$1,452.8
Adjustments to Reconcile Net Income to Cash Flows from Operating Activities:		
Depreciation and amortization	1,263.5	1,155.4
Change in deferred income taxes	161.6	151.7
Stock-based compensation expense	206.7	209.1
Acquired in-process research and development	1,654.5	1,062.6
Other changes in operating assets and liabilities, net of acquisitions	(1,638.2)	(525.2)
Other non-cash operating activities, net	320.7	365.7
Net Cash Provided by Operating Activities	4,075.8	3,872.1
Cash Flows from Investing Activities		
Net purchases of property and equipment	(816.3)	(633.3)
Proceeds from sales and maturities of short-term investments	2,535.5	2,320.2
Purchases of short-term investments	(112.2)	(2,973.8)
Proceeds from sales of noncurrent investments	3,444.7	1,686.9
Purchases of noncurrent investments	(719.7)	(3,739.6)
Cash paid for acquisitions, net of cash acquired (Note 3)	—	(882.1)
Purchase of in-process research and development (Note 3)	(1,578.2)	(1,036.8)
Other investing activities, net	(188.8)	(178.0)
Net Cash Provided by (Used for) Investing Activities	2,565.0	(5,436.5)
Cash Flows from Financing Activities		
Dividends paid	(1,739.2)	(1,643.8)
Net change in short-term borrowings	(2,297.1)	1,226.8
Proceeds from issuance of long-term debt	2,477.7	2,232.0
Repayments of long-term debt	(1,001.5)	(630.6)
Purchases of common stock	(3,050.7)	(199.9)
Net proceeds from Elanco initial public offering (Note 3)	1,659.7	—
Other financing activities, net	(314.1)	(299.6)
Net Cash Provided by (Used for) Financing Activities	(4,265.2)	684.9
Effect of exchange rate changes on cash and cash equivalents	48.2	21.7
Net increase (decrease) in cash and cash equivalents	2,423.8	(857.8)
Cash and cash equivalents at January 1	6,536.2	4,582.1
Cash and Cash Equivalents at September 30	\$8,960.0	\$3,724.3
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 and Revenue

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, 2017. We issue our financial statements by filing with the Securities and Exchange Commission (SEC) and have evaluated subsequent events up to the time of the filing.

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.

Adoption of Revenue Accounting Standard

Effective January 1, 2018, we adopted Accounting Standards Update 2014-09, Revenue from Contracts with Customers and other related updates (see Note 2 for additional discussion). The new standard has been applied to contracts for which performance was not substantially complete as of the date of adoption. For those contracts that were modified prior to the date of adoption, we reflected the aggregate effect of those modifications when determining the appropriate accounting under the new standard. We don't believe the effect of applying this practical expedient resulted in material differences. Revenue presented for periods prior to 2018 was accounted for under previous standards and has not been adjusted. Revenue and net income for the three and nine months ended September 30, 2018 do not differ materially from amounts that would have resulted from application of the previous standards. The following table summarizes our revenue recognized in our consolidated condensed statements of operations:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net product revenue	\$5,664.5	\$5,323.8	\$16,905.6	\$15,841.5
Collaboration and other revenue ⁽¹⁾	397.4	334.2	1,211.5	869.1
Revenue	\$6,061.9	\$5,658.0	\$18,117.1	\$16,710.6

⁽¹⁾ Collaboration and other revenue associated with prior year transfers of intellectual property was \$76.2 million and \$258.4 million during the three and nine months ended September 30, 2018, respectively, and \$36.7 million and \$105.5 million during the three and nine months ended September 30, 2017, respectively.

We recognize revenue primarily from two different types of contracts, product sales to customers (net product revenue) and collaborations and other arrangements. Revenue recognized from collaborations and other arrangements will include our share of profits from the collaboration, as well as royalties, upfront and milestone payments we receive under these types of contracts. See Note 4 for additional information related to our collaborations and other arrangements. Collaboration and other revenue disclosed above includes the revenue from the TrajentaTM and Jardiance[®] families of products resulting from our collaboration with Boehringer Ingelheim discussed in Note 4. Substantially all of the remainder of collaboration and other revenue is related to contracts accounted for as contracts with customers.

Net Product Revenue

Revenue from sales of products is recognized at the point where the customer obtains control of the goods and we satisfy our performance obligation, which generally is at the time we ship the product to the customer. Payment terms differ by jurisdiction and customer, but payment terms in most of our major jurisdictions typically range from 30 to 75

days from date of shipment. Revenue for our product sales has not been adjusted for the effects of a

10

financing component as we expect, at contract inception, that the period between when we transfer control of the product and when we receive payment will be one year or less. Any exceptions are either not material or we collect interest for payments made after the due date. Provisions for rebates and discounts, and returns are established in the same period the related sales are recognized. We generally ship product shortly after orders are received; therefore, we generally only have a few days of orders received but not yet shipped at the end of any reporting period. Shipping and handling activities are considered to be fulfillment activities and are not considered to be a separate performance obligation. We exclude from the measurement of the transaction price all taxes assessed by a governmental authority that are imposed on our sales of product and collected from a customer.

Significant judgments must be made in determining the transaction price for our sales of products related to anticipated rebates and discounts and returns. The following describe the most significant of these judgments:

Sales Rebates and Discounts - Background and Uncertainties

Most of our pharmaceutical products are sold to wholesalers that serve pharmacies, physicians and other health care professionals, and hospitals. Most of our animal health products are sold to wholesale distributors. We initially invoice our customers at contractual list prices. Contracts with direct and indirect customers may provide for various rebates and discounts that may differ in each contract. As a consequence, to determine the appropriate transaction price for our product sales at the time we recognize a sale to a direct customer, we must estimate any rebates or discounts that ultimately will be due to the direct customer and other customers in the distribution chain under the terms of our contracts. Significant judgments are required in making these estimates.

The rebate and discount amounts are recorded as a deduction to arrive at our net product revenue. Sales rebates and discounts that require the use of judgment in the establishment of the accrual include managed care, Medicare, Medicaid, chargebacks, long-term care, hospital, patient assistance programs, and various other programs. We estimate these accruals using an expected value approach.

The largest of our sales rebate and discount amounts are rebates associated with sales covered by managed care, Medicare, Medicaid, and chargeback contracts in the U.S. In determining the appropriate accrual amount, we consider our historical rebate payments for these programs by product as a percentage of our historical sales as well as any significant changes in sales trends (e.g., patent expiries and product launches), an evaluation of the current contracts for these programs, the percentage of our products that are sold via these programs, and our product pricing. Although we accrue a liability for rebates related to these programs at the time we record the sale, the rebate related to that sale is typically paid up to six months later. Because of this time lag, in any particular period our rebate adjustments may incorporate revisions of accruals for several periods.

Most of our rebates outside the U.S. are contractual or legislatively mandated and are estimated and recognized in the same period as the related sales. In some large European countries, government rebates are based on the anticipated budget for pharmaceutical payments in the country. An estimate of these rebates, updated as governmental authorities revise budgeted deficits, is recognized in the same period as the related sale.

Sales Returns - Background and Uncertainties

When product sales occur, to determine the appropriate transaction price for our sales, we estimate a reserve for future product returns related to those sales using an expected value approach. This estimate is based on several factors, including: historical return rates, expiration date by product (on average, approximately 24 months after the initial sale of a product to our customer), and estimated levels of inventory in the wholesale and retail channels, as well as any other specifically-identified anticipated returns due to known factors such as the loss of patent exclusivity, product recalls and discontinuances, or a changing competitive environment. We maintain a returns policy that allows U.S. pharmaceutical customers to return product for dating issues within a specified period prior to and subsequent to the product's expiration date. Following the loss of exclusivity for a patent-dependent product, we expect to experience an elevated level of product returns as product inventory remaining in the wholesale and retail channels expires.

Adjustments to the returns reserve have been and may in the future be required based on revised estimates to our assumptions. We record the return amounts as a deduction to arrive at our net product revenue. Once the product is returned, it is destroyed; we do not record a right of return asset. Our returns policies outside the U.S. are generally more restrictive than in the U.S. as returns are not allowed for reasons other than failure to meet product specifications in many countries. Our reserve for future product returns for product sales outside the U.S. is not material.

As a part of our process to estimate a reserve for product returns, we regularly review the supply levels of our significant products sold to major wholesalers in the U.S. and in major markets outside the U.S., primarily by reviewing periodic inventory reports supplied by our major wholesalers and available prescription volume information for our products, or alternative approaches. We attempt to maintain U.S. wholesaler inventory levels at an average of approximately one month or less on a consistent basis across our product portfolio. Causes of unusual wholesaler buying patterns include actual or anticipated product-supply issues, weather patterns, anticipated changes in the transportation network, redundant holiday stocking, and changes in wholesaler business operations. In the U.S., the current structure of our arrangements provides us with data on inventory levels at our wholesalers; however, our data on inventory levels in the retail channel is more limited. Wholesaler stocking and destocking activity historically has not caused any material changes in the rate of actual product returns.

Actual product returns have been less than 2 percent of our net revenue over each of the past three years and have not fluctuated significantly as a percentage of revenue, although fluctuations are more likely in periods following loss of patent exclusivity for major products in the U.S. market.

Adjustments to Revenue

Adjustments to revenue recognized as a result of changes in estimates for the judgments described above during the three and nine months ended September 30, 2018, for product shipped in previous years were not material.

Disaggregation of Revenue

Our disaggregated revenue is disclosed in Note 12.

Collaborations and Other Arrangements

We recognize several types of revenue from our collaborations and other arrangements, which we discuss in general terms immediately below and more specifically in Note 4 for each of our material collaborations and other arrangements. Our collaborations and other arrangements are not contracts with customers but are evaluated to determine whether any aspects of the arrangements are contracts with customers.

Revenue related to products we sell pursuant to these arrangements is included in net product revenue, while other sources of revenue (e.g., royalties and profit sharing from our partner) are included in collaboration and other revenue. Initial fees and developmental milestones we receive in collaborative and other similar arrangements from the partnering of our compounds under development are generally deferred and amortized into income through the expected product approval date.

Profit-sharing due from our collaboration partners, which is based upon gross margins reported to us by our partners, is recognized as collaboration and other revenue as earned.

Royalty revenue from licensees, which is based on sales to third parties of licensed products and technology, is recorded when the third-party sale occurs and the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). This royalty revenue is included in collaboration and other revenue. For arrangements involving multiple goods or services (e.g., research and development, marketing and selling, manufacturing, and distribution), each required good or service is evaluated to determine whether it is distinct. If a good or service does not qualify as distinct, it is combined with the other non-distinct goods or services within the arrangement and these combined goods or services are treated as a single performance obligation for accounting purposes. The arrangement's transaction price is then allocated to each performance obligation based on the relative standalone selling price of each performance obligation. For arrangements that involve variable consideration where we have sold intellectual property, we recognize revenue based on estimates of the amount of consideration we believe we will be entitled to receive from the other party, subject to a constraint. These estimates are adjusted to reflect the actual amounts to be collected when those facts and circumstances become known.

Significant judgments must be made in determining the transaction price for our sales of intellectual property.

Because of the risk that products in development will not receive regulatory approval, we generally do not recognize any contingent payments that would be due to us upon or after regulatory approval.

We have entered into arrangements whereby we transferred rights to products and committed to supply for a period of time. For those arrangements for which we concluded that the obligations were not distinct, any amounts received upfront are being amortized to revenue as net product revenue over the period of the supply arrangement as the performance obligation is satisfied.

Contract Liabilities

Our contract liabilities result from arrangements where we have received payment in advance of performance under the contract and do not include sales rebates, discounts, and returns. Changes in contract liabilities are generally due to either receipt of additional advance payments or our performance under the contract.

We have the following amounts recorded for contract liabilities:

	September 30, December 31,	
	2018	2017
Contract liabilities \$	308.6	\$ 335.2

The contract liabilities amount disclosed above as of September 30, 2018, is primarily related to:

- The remaining license period of symbolic intellectual property, and
- Obligations to supply product for a defined period of time.

Revenue recognized from contract liabilities as of January 1, 2018, during the three and nine months ended September 30, 2018, was not material. Revenue expected to be recognized in the future from contract liabilities as the related performance obligations are satisfied is not expected to be material in any one year.

Note 2: Implementation of New Financial Accounting Pronouncements

The following table provides a brief description of accounting standards that were effective January 1, 2018 and were adopted on that date:

Standard	Description	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 replaced existing revenue recognition standards and requires 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 applied the latter approach.	Application of the new standard to applicable contracts resulted in an increase of approximately \$5 million to retained earnings as of January 1, 2018. Disclosures required by the new standard are included in Note 1, Note 4, and Note 12.
Accounting Standards Update 2016-01, Financial Instruments - Overall: Recognition and Measurement of Financial Assets and Financial Liabilities	This standard requires 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.	Upon adoption, we reclassified from accumulated other comprehensive loss the after-tax amount of net unrealized gains resulting in an increase to retained earnings of approximately \$105 million. Adoption of this standard did not result in a material change in net income for the three and nine months ended September 30, 2018.

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

Standard	Description	Effect on the financial statements or other significant matters
Accounting Standards Update 2016-16, Income Taxes: Intra-Entity Transfers of Assets Other Than Inventory	This standard requires 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.	Upon adoption, the cumulative effect of applying the standard resulted in an increase to deferred tax assets and retained earnings of approximately \$2.5 billion. Adoption of this standard did not result in a material change in net income for the three and nine months ended September 30, 2018.
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. Previously, the costs of the other components along with the service cost component were classified based upon the function of the employee. This standard requires entities to classify the service cost 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 are now presented separately from the line items that include the service cost component. When applicable, the service cost component is now 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.	Upon adoption of this standard, pension and postretirement benefit cost components other than service costs are presented in other-net, (income) expense. The application of the new standard resulted in reclassification to other income of \$63.8 million for the three months ended September 30, 2017, while increasing cost of sales by \$20.2 million, marketing, selling, and administrative expenses by \$23.0 million, and research and development expenses by \$20.6 million for the same period. The application of the new standard resulted in reclassification to other income of \$191.3 million for the nine months ended September 30, 2017, while increasing cost of sales by \$60.5 million, marketing, selling, and administrative expenses by \$69.0 million, and research and development expenses by \$61.8 million for the same period. We do not expect application of the new standard to have a material impact on an ongoing basis.

The following table provides a brief description of the accounting standard that has 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 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. An entity can apply the new leases standard retrospectively to each prior reporting period	This standard is effective January 1, 2019, with early adoption permitted. We intend to adopt on that date.	We are in the process of determining the impact on our consolidated financial statements. We have selected a software solution to be compatible with our enterprise software system. Development of our selected solution is ongoing, as it is not yet fully compliant with the requirements of the standard. The

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.

timely readiness of the lease software system is critical to ensure an efficient and effective adoption of the standard.

Note 3: Divestiture and Acquisitions

Divestiture

Formation of Elanco and Initial Public Offering

On September 24, 2018, Elanco Animal Health Incorporated (Elanco) completed an initial public offering (the IPO) resulting in the issuance of 72.3 million shares of its common stock, which represents 19.8 percent of Elanco's outstanding shares, at \$24 per share. Elanco shares began trading on the New York Stock Exchange under the symbol "ELAN" in September 2018.

In connection with the completion of the IPO, through a series of equity and other transactions, we transferred to Elanco the animal health businesses that form its business going forward. In exchange, Elanco transferred to us, or will transfer to us, consideration of approximately \$4.2 billion, which consists primarily of the net proceeds from the IPO, the net proceeds from the debt offering completed by Elanco in August 2018, and the term loan facility entered into by Elanco during the period (see Note 6). The consideration that we receive is intended to be used for debt repayment, dividends, and/or share repurchases. The excess of the net proceeds from the IPO over the net book value of our divested interest was \$629.2 million and was recorded in additional paid-in capital. Of our consolidated cash and cash equivalents as of September 30, 2018, approximately \$300 million is retained by Elanco for working capital purposes.

We continue to consolidate Elanco, as we retain control over Elanco. The earnings attributable to the divested, noncontrolling interest for the period from IPO until September 30, 2018 were not material for the three and nine months ended September 30, 2018. As of September 30, 2018, the noncontrolling interest of \$1.02 billion associated with Elanco is reflected in noncontrolling interests in the consolidated condensed balance sheet.

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 have been included in our consolidated condensed financial statements from the date of acquisition.

In addition to the acquisition of BIVIVP, we acquired assets in development in the nine months ended September 30, 2018, 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. We incurred acquired IPR&D charges of \$30.0 million and \$1.65 billion for the three and nine months ended September 30, 2018, respectively, and \$205.0 million and \$1.06 billion for the three and nine months ended September 30, 2017, respectively.

Acquisition of a Business

Boehringer Ingelheim Vetmedica, Inc. Vaccine Portfolio Acquisition

Overview of Transaction

In 2017, 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 and 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

The following table summarizes the 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⁾	297.0
Property and equipment	148.2
Other assets and liabilities - net	8.2
Total identifiable net assets	562.0
Goodwill ⁽²⁾	320.1
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. The goodwill associated with this acquisition is deductible for tax purposes.

Asset Acquisitions

The following table and narrative summarize our asset acquisitions during the nine months ended September 30, 2018 and September 30, 2017.

Counterparty	Compound(s) or Therapy	Acquisition Month	Phase of Development ⁽¹⁾	Acquired IPR&D Expense
Sigilon Therapeutics (Sigilon)	Encapsulated cell therapies for the potential treatment of type 1 diabetes	April 2018	Pre-clinical	\$ 66.9
AurKa Pharma, Inc. (AurKa)	AK-01, an Aurora kinase A inhibitor	June 2018	Phase I	81.8
ARMO Biosciences, Inc. (ARMO)	Cancer therapy - pegilodecakin	June 2018	Phase III	1,475.8
Anima Biotech (Anima)	Translation inhibitors for selected neuroscience targets	July 2018	Pre-clinical	30.0
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 entered into a collaboration agreement with Sigilon to develop encapsulated cell therapies for the potential treatment of type 1 diabetes. Sigilon will create proprietary products comprised of induced pluripotent stem cells engineered into differentiated insulin-producing pancreatic beta cells and encapsulated using Sigilon's Afibromer technology. We will receive an exclusive worldwide license to Sigilon's Afibromer technology for islet cell encapsulation. Under the terms of the agreement, we paid an upfront fee of \$62.5 million and made an equity investment in Sigilon.

We acquired AK-01 through the acquisition of AurKa. Under the terms of the agreement, we acquired all shares of AurKa for a cash purchase price of \$81.3 million, net of cash acquired, plus net accrued liabilities assumed of \$0.5 million. Substantially all the value of AurKa was related to AK-01, its only significant asset. The acquired IPR&D expense was not tax deductible.

We acquired pegilodecakin through the acquisition of ARMO. Under the terms of the agreement, we acquired all shares of ARMO for a cash purchase price of \$1.40 billion, net of cash acquired, plus net accrued liabilities assumed of \$75.8 million. Substantially all of the value of ARMO was related to pegilodecakin, its only significant asset. The acquired IPR&D expense was not tax deductible.

We entered into a collaboration agreement with Anima for the discovery and development of translation inhibitors for several target proteins by using Anima's translation control therapeutics platform. Under the terms of the agreement, we paid an upfront fee of \$30.0 million. Anima will use its technology platform to discover lead candidates that are translation inhibitors of our selected neuroscience targets. We will be responsible for all clinical development and commercialization activities and costs related to the collaboration.

We acquired lasmiditan through the acquisition of 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 was 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.

In September 2018, we announced a license agreement with Chugai Pharmaceutical Company for OWL833, an oral non-peptidic GLP-1 receptor agonist. OWL833 is a preclinical asset that is being studied for the treatment of type 2 diabetes. Under the terms of the agreement, we will acquire worldwide development and commercialization rights to OWL833 for a cash purchase price of \$50.0 million and success-based milestones and royalties. The transaction is expected to close in the fourth quarter of 2018, subject to clearance under the Hart-Scott-Rodino Antitrust Improvements Act and other customary closing conditions. We expect an acquired IPR&D charge of \$50.0 million in the fourth quarter of 2018.

In October 2018, we announced a global license and research agreement with Dicerna Pharmaceuticals (Dicerna) for the discovery, development, and commercialization of potential new medicines in the areas of cardio-metabolic disease, neurodegeneration, and pain. Under terms of the agreement, we will pay an upfront fee of \$100.0 million and make an equity investment in Dicerna. The transaction is subject to clearance under the Hart-Scott-Rodino Antitrust Improvements Act and other customary closing conditions. Upon closing, we will record an acquired IPR&D expense of approximately \$135 million.

In October 2018, we acquired a Priority Review Voucher from SIGA Technologies, Inc. for a cash purchase price of \$80.0 million. We intend to utilize the voucher to fast track a product application for an existing R&D project, although the specific project has not yet been determined. As a result of this transaction, we will record an acquired IPR&D expense of \$80.0 million in the fourth quarter of 2018.

In November 2018, we entered into a collaboration agreement with NextCure, Inc. (NextCure) for the discovery and development of immuno-oncology cancer therapies. NextCure will apply its discovery platform technology to identify novel, functional immune-related targets and we will develop antibodies to these targets. The parties will be able to exclusively license antibodies resulting from the collaboration. Under terms of the agreement, we will pay an upfront fee of \$25.0 million and make an equity investment in NextCure. As a result of this transaction, we will record an acquired IPR&D expense of approximately \$30 million in the fourth quarter of 2018.

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. See Note 1 for amounts of collaboration and other revenue recognized from these types of arrangements.

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

Boehringer Ingelheim Diabetes Collaboration

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

The table below summarizes significant regulatory and commercialization events and milestones (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 2017	\$446.4
Jardiance ⁽³⁾	2014	2014	2015	Cumulative ⁽⁴⁾ - all prior to 2017	299.5
Basaglar	2016	2015	2015	Cumulative ⁽⁴⁾ - all prior to 2017	(250.0)

⁽¹⁾ In connection with the regulatory approvals of Basaglar in the U.S., Europe, and Japan, milestone payments received were recorded as contract liabilities 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 through the term of the collaboration.

⁽²⁾ Jentadueto is included in the Trajenta product family. The collaboration agreement with Boehringer Ingelheim for Trajenta ends upon expiration of the compound patent and any supplementary protection certificates or extensions thereto.

⁽³⁾ Glyxambi and Synjardy are included in the Jardiance product family. The collaboration agreement with Boehringer Ingelheim for Jardiance ends upon expiration of the compound patent and any supplementary protection certificates or extensions thereto.

⁽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,	
	2018	2017	2018	2017
Basaglar	\$201.2	\$145.7	\$569.0	\$278.3
Jardiance	166.9	127.2	465.1	304.3
Trajenta	135.7	153.3	418.5	408.2
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,	
	2018	2017	2018	2017
Net product revenue	\$133.7	\$137.6	\$397.0	\$403.3
Collaboration and other revenue	25.8	25.9	78.5	73.7
Revenue	\$159.5	\$163.5	\$475.5	\$477.0

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 provided 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.

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.

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 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, atopic dermatitis, alopecia areata, and systemic lupus erythematosus (SLE) in 2017. The

agreement calls for payments by us to Incyte associated with certain development, success-based regulatory, and sales-based milestones.

The following table summarizes our milestones achieved:

Year	Event	Classification	Amount
2016	Regulatory submissions in the U.S. and Europe	R&D expense	\$ 55.0
	Regulatory approval in Europe	Intangible asset	65.0
2017	Regulatory approval in Japan	Intangible asset	15.0
	Began Phase III testing for atopic dermatitis	R&D expense	30.0
	Regulatory approval in the U.S.	Intangible asset	100.0
2018	Began Phase III testing for SLE	R&D Expense	20.0

As of September 30, 2018, Incyte is eligible to receive up to \$130.0 million of additional payments from us contingent upon certain development and success-based regulatory milestones. Incyte is also eligible to receive up to \$150.0 million of potential sales-based milestones.

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	Daiichi Sankyo
Japan	Exclusive	Daiichi Sankyo

While major European markets are a co-promotion territory under the terms of our arrangement, Daiichi Sankyo exclusively promotes Effient in these markets.

The parties share approximately 50/50 in the profits, as well as in the costs of development and marketing in the co-promotion territories. A third party manufactures bulk product, and we produce the finished product for our exclusive and co-promotion territories, 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. 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,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenue	\$45.3	\$55.9	\$104.8	\$326.6
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. As of September 30, 2018, 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.

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		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Severance:				
Human pharmaceutical products	\$—	\$165.7	\$(24.7)	\$277.1
Animal health products	(5.4)	5.8	(0.6)	62.1
Total severance	(5.4)	171.5	(25.3)	339.2
Asset impairment and other special charges:				
Human pharmaceutical products	3.5	25.0	2.0	25.0
Animal health products	85.2	210.0	259.3	306.2
Total asset impairment and other special charges	88.7	235.0	261.3	331.2
Total asset impairment, restructuring, and other special charges	\$83.3	\$406.5	\$236.0	\$670.4

Severance charges recognized during the nine months ended September 30, 2018 primarily relate to severance adjustments recorded in the second quarter of 2018. Our severance charges recognized in the second half of 2017 as part of planned restructuring activities were based upon estimates for the number of employees that either lost or were going to lose their then current roles and would ultimately leave the company. During the second quarter of 2018, we determined that more displaced employees than expected were able to find other roles within the company, resulting in an immaterial reduction in the actual severance costs incurred. We expect the majority of the remaining severance payments to be made in the next 12 months.

Asset impairment and other special charges recognized during the three months ended September 30, 2018 resulted primarily from asset impairment and other restructuring charges related to the sale of the Posilac® (rbST) brand and the associated Augusta, Georgia manufacturing site. We also incurred expenses associated with the IPO and separation of Elanco. These expenses were offset by a gain recognized associated with the pension curtailment (see Note 8 for additional discussion).

In addition to the charges for the three months ended September 30, 2018, additional asset impairment and other special charges for the nine months ended September 30, 2018 included asset impairment, exit costs, and other charges related to the decision to end Posilac (rbST) production at the Augusta, Georgia manufacturing site, and charges related to the decision to suspend commercialization of Imrestor®, an animal health product. We also incurred expenses associated with the review of strategic alternatives for the Elanco animal health business.

Severance costs recognized during the three and 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). Substantially all of the asset impairment and other special charges recognized during the three months ended September 30, 2017 were related to lower projected revenue for Posilac (rbST). The assets associated with Posilac (rbST) were written down to their fair values, which were determined based upon a discounted cash flow valuation. 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 (rbST) impairment, integration costs of Novartis AH, as well as asset impairments due to site closures.

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 equity investments are accounted for using three different methods depending on the type of equity investment: Investments in companies over which we have significant influence but not a controlling interest are accounted for using the equity method, with our share of earnings or losses reported in other-net, (income) expense.

For equity investments that do not have readily determinable fair values, we measure these investments at cost, less any impairment, plus or minus changes resulting from observable price changes in orderly transactions for the identical or similar investment of the same issuer. Any change in recorded value is recorded in other-net, (income) expense.

Our public equity investments are measured and carried at fair value. Any change in fair value is recognized in other-net, (income) expense.

We review equity investments other than public equity investments for indications of impairment on a regular basis.

Our derivative activities are initiated within the guidelines of documented corporate risk-management policies and are intended to 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, 2018, we had outstanding foreign currency forward commitments to purchase 1.40 billion U.S. dollars and sell 1.19 billion euro, commitments to purchase 1.57 billion euro and sell 1.84 billion U.S. dollars, commitments to purchase 426.9 million U.S. dollars and sell 47.94 billion Japanese yen, commitments to purchase 234.1 million Swiss Francs and sell 243.2 million U.S. dollars, commitments to purchase 512.2 million U.S. dollars and sell 389.4 million British pounds, and commitments to purchase 466.4 million British pounds and sell 613.0 million U.S. dollars, which will all settle within 30 days.

Foreign currency exchange risk is also managed through the use of foreign currency debt and cross-currency interest rate swaps. Our foreign currency-denominated notes had carrying amounts of \$3.45 billion and \$3.70 billion as of September 30, 2018 and December 31, 2017, 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 foreign-denominated floating rate debt have also been designated as, and are effective as, economic hedges of net investments. At September 30, 2018, we had outstanding cross currency swaps with notional amounts of \$1.53 billion swapping euro to U.S. dollars and \$350.0 million swapping British pounds to U.S. dollars, which will all settle within 12 months.

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, 2018, substantially all of our total long-term debt is at a fixed rate. We have converted 20 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.

Elanco Debt Issuance

In August 2018, our wholly owned subsidiary, Elanco, issued \$2.00 billion of senior notes in a private placement. The senior notes are comprised of \$500.0 million of 3.91 percent senior notes due in August 2021, \$750.0 million of 4.27 percent senior notes due in August 2023, and \$750.0 million of 4.90 percent senior notes due in August 2028. Interest is to be paid semi-annually and the interest rate payable on each series of senior notes is subject to adjustment if certain bond rating agencies downgrade, or subsequently upgrade, their ratings on the respective series of senior notes. The indenture that governs the Elanco senior notes contains covenants, including limitations on the ability of Elanco and certain Elanco subsidiaries to incur liens or engage in sale-leaseback transactions. The indenture also contains restrictions on Elanco's ability to consolidate, merge or sell substantially all of their assets, in addition to other customary terms. Elanco was in compliance with all such covenants under the indentures governing the senior notes as of September 30, 2018.

Elanco has entered into an agreement that requires them to use commercially reasonable efforts to cause a registration statement to become effective with the SEC by August 28, 2019, relating to an offer to exchange the senior notes for registered senior notes having substantially identical terms, or in certain cases, to register the senior notes for resale. If they do not register or exchange the senior notes pursuant to the terms of the registration rights agreement, they will be required to pay additional interest to the holders of the senior notes under certain circumstances.

In September 2018, Elanco entered into a revolving credit agreement with a syndicate of banks providing for a five-year \$750.0 million senior revolving credit facility (Revolving Facility). The Revolving Facility bears interest at a variable rate plus specified margin as defined in the agreement and is payable quarterly. There were no borrowings

outstanding under the Revolving Facility at September 30, 2018. The Revolving Facility is payable in full at the end of the term.

In September 2018, Elanco also entered into a \$500.0 million three-year term loan under a term credit facility with a syndicate of banks (the Term Facility and collectively with the Revolving Facility, the Credit Facilities). The Term Facility bears interest at a variable rate plus margin as defined in the Term Facility and is payable quarterly. The Term Facility is payable in full at the end of the term.

The Credit Facilities are subject to various financial and other covenants including restrictions on Elanco's level of borrowings based on their consolidated leverage ratio and their consolidated interest coverage ratio. Elanco was in compliance with all such covenants as of September 30, 2018.

The aggregate net proceeds of the senior notes and Term Facility was \$2.48 billion. See Note 3 for a discussion of the use of the proceeds of the debt offerings as part of the formation of Elanco and their IPO process.

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		Nine Months Ended	
	September 30, 2018	September 30, 2017	September 30, 2018	September 30, 2017
Fair value hedges:				
Effect from hedged fixed-rate debt	\$(19.6)	\$(4.0)	\$(94.1)	\$3.6
Effect from interest rate contracts	19.6	4.0	94.1	(3.6)
Cash flow hedges:				
Effective portion of losses on interest rate contracts reclassified from accumulated other comprehensive loss	3.7	3.7	11.1	11.1
Net losses on foreign currency exchange contracts not designated as hedging instruments	0.7	16.3	76.5	79.2

During the nine months ended September 30, 2018 and 2017, 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		Nine Months Ended	
	September 30, 2018	September 30, 2017	September 30, 2018	September 30, 2017
Net investment hedges:				
Foreign currency-denominated notes	\$(47.8)	\$(58.7)	\$53.0	\$(332.0)
Cross-currency interest rate swaps	14.7	(38.2)	52.3	(95.8)
Cash flow hedges:				
Forward-starting interest rate swaps	—	—	—	13.0

During the next 12 months, we expect to reclassify \$15.0 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, 2018 and December 31, 2017 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 Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Fair Value
September 30, 2018						
Cash equivalents	\$6,646.3	\$6,646.3	\$6,646.3	\$ —	\$ —	—\$6,646.3
Short-term investments:						
U.S. government and agency securities	\$10.5	\$10.6	\$10.5	\$ —	\$ —	—\$10.5
Corporate debt securities	52.7	52.7	—	52.7	—	52.7
Asset-backed securities	11.5	11.6	—	11.5	—	11.5
Other securities	1.4	1.4	—	1.4	—	1.4
Short-term investments	\$76.1					
Noncurrent investments:						
U.S. government and agency securities	\$152.0	\$159.6	\$152.0	\$ —	\$ —	—\$152.0
Corporate debt securities	622.0	631.5	—	622.0	—	622.0
Mortgage-backed securities	109.5	114.1	—	109.5	—	109.5
Asset-backed securities	27.0	27.3	—	27.0	—	27.0
Other securities	137.4	39.3	—	—	137.4	137.4
Marketable equity securities	287.9	146.4	287.9	—	—	287.9
Equity investments without readily determinable fair values ⁽²⁾	394.7					
Equity method investments ⁽²⁾	275.3					
Noncurrent investments	\$2,005.8					
December 31, 2017						
Cash equivalents	\$4,763.9	\$4,763.9	\$4,712.4	\$ 51.5	\$ —	—\$4,763.9
Short-term investments:						
U.S. government and agency securities	\$217.8	\$218.2	\$217.8	\$ —	\$ —	—\$217.8
Corporate debt securities	1,182.3	1,183.2	—	1,182.3	—	1,182.3
Asset-backed securities	94.2	94.3	—	94.2	—	94.2
Other securities	3.6	3.6	—	3.6	—	3.6
Short-term investments	\$1,497.9					
Noncurrent investments:						
U.S. government and agency securities	\$360.0	\$365.0	\$360.0	\$ —	\$ —	—\$360.0
Corporate debt securities	3,464.3	3,473.5	—	3,464.3	—	3,464.3

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

Mortgage-backed securities	202.4	204.2	—	202.4	—	202.4
Asset-backed securities	653.9	656.0	—	653.9	—	653.9
Other securities	132.1	66.4	—	—	132.1	132.1
Marketable equity securities	281.3	131.0	281.3	—	—	281.3
Cost and equity method investments ⁽²⁾	584.8					
Noncurrent investments	\$5,678.8					

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

⁽²⁾ Fair value disclosures are not applicable for equity method investments and investments accounted for under the measurement alternative for equity investments that do not have readily determinable fair values.

	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, 2018	\$(399.7)	\$—	\$(398.4)	\$	—\$(398.4)
December 31, 2017	(2,696.8)	—	(2,690.6)	—	(2,690.6)
Long-term debt, including current portion					
September 30, 2018	\$(12,277.1)	\$—	\$(12,542.2)	\$	—\$(12,542.2)
December 31, 2017	(10,950.3)	—	(11,529.9)	—	(11,529.9)

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

	Fair Value Measurements			
	Using Quoted Prices in Active Markets for Identical Assets (Level 1)			Fair Value
	Carrying Amount	Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
September 30, 2018				
Risk-management instruments:				
Interest rate contracts designated as fair value hedges:				
Other current liabilities	\$ (2.7)	\$— (2.7)	\$ —	\$(2.7)
Other noncurrent liabilities	(66.5)	— (66.5)	—	(66.5)
Cross-currency interest rate contracts designated as net investment hedges:				
Other receivables	30.3	— 30.3	—	30.3
Sundry	6.9	— 6.9	—	6.9
Other current liabilities	(16.6)	— (16.6)	—	(16.6)
Foreign exchange contracts not designated as hedging instruments:				
Other receivables	6.3	— 6.3	—	6.3
Other current liabilities	(14.0)	— (14.0)	—	(14.0)
Contingent consideration liabilities:				
Other current liabilities	(62.0)	— —	(62.0)	(62.0)
Other noncurrent liabilities	(41.4)	— —	(41.4)	(41.4)
December 31, 2017				
Risk-management instruments:				
Interest rate contracts designated as fair value hedges:				
Other receivables	\$ 0.8	\$— 0.8	\$ —	\$0.8
Sundry	35.1	— 35.1	—	35.1
Other current liabilities	(0.2)	— (0.2)	—	(0.2)
Other noncurrent liabilities	(10.5)	— (10.5)	—	(10.5)
Cross-currency interest rate contracts designated as net investment hedges:				
Other current liabilities	(33.4)	— (33.4)	—	(33.4)
Other noncurrent liabilities	(26.0)	— (26.0)	—	(26.0)
Foreign exchange contracts not designated as hedging instruments:				
Other receivables	26.8	— 26.8	—	26.8
Other current liabilities	(36.0)	— (36.0)	—	(36.0)
Contingent consideration liabilities ⁽¹⁾ :				
Other current liabilities	(208.0)	— —	(208.0)	(208.0)
Other noncurrent liabilities	(45.2)	— —	(45.2)	(45.2)

⁽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 equity method investments and investments measured under the measurement alternative for equity investments that do not have readily determinable fair values are not readily available.

Contingent consideration liabilities at December 31, 2017 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, 2018 was due primarily to cash payments of \$155.4 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, 2018 and 2017 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, 2018:

	Maturities by Period				
	Total	Less Than 1 Year	1-5 Years	6-10 Years	More Than 10 Years
Fair value of debt securities	\$985.1	\$ 74.7	\$620.5	\$135.4	\$ 154.5

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, 2018	December 31, 2017
Unrealized gross gains	\$ 2.1	\$ 184.7
Unrealized gross losses	24.4	47.5
Fair value of securities in an unrealized gain position	164.0	1,434.2
Fair value of securities in an unrealized loss position	816.7	4,692.8

A summary of the unrealized gains and losses (pretax) recognized in our consolidated condensed statements of operations for equity securities held as of September 30, 2018 is as follows:

	Three Months Ended September 30,	Nine Months Ended September 30,
Unrealized gain (loss), net	\$ (40.8)	\$ (3.4)

We periodically assess our investment in available-for-sale securities for other-than-temporary impairment losses. There were no other-than-temporary impairment losses in the three or nine months ended September 30, 2018 or the three or nine months ended September 30, 2017.

We periodically assess our investments in equity securities other than public equity securities for impairment losses. Impairment losses recognized on these equity securities in the three and nine months ended September 30, 2018 were immaterial.

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 impairment losses include the financial condition and near term prospects of the issuer and general market conditions and industry specific factors.

As of September 30, 2018, the available-for-sale 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 60 percent of the fixed-rate debt securities in a loss position are investment-grade debt securities. As of September 30, 2018, 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 equity and available-for-sale securities, was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Proceeds from sales	\$52.0	\$951.5	\$5,598.4	\$3,003.0
Realized gross gains on sales	0.4	9.0	8.1	82.9
Realized gross losses on sales	0.7	0.8	49.7	3.2

Realized gains and losses on sales of available-for-sale 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.

Adjustments recorded to our equity investments without readily determinable fair values are based upon changes in the equity instrument's value resulting from observable price changes in orderly transactions for an identical or similar investment of the same issuer. Downward adjustments resulting from an impairment are recorded based upon the impairment considerations mentioned above. Adjustments recorded during the nine months ended September 30, 2018 were immaterial.

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 \$645.1 million and \$723.2 million of accounts receivable as of September 30, 2018 and December 31, 2017, 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, 2018 and 2017 was not material.

Note 7: Income Taxes

The effective tax rates were 18.5 percent and 26.2 percent for the three and nine months ended September 30, 2018, respectively, compared with 6.1 percent and 24.1 percent for the three and nine months ended September 30, 2017.

The increase in the effective tax rate for the third quarter of 2018 is primarily due to a higher income tax benefit in the third quarter of 2017 for acquired IPR&D charges and asset impairment, restructuring, and other special charges. The increase in the effective rate for the first nine months of 2018 is primarily due to the \$1.56 billion non-deductible acquired IPR&D charge related to the acquisitions of ARMO and AurKa. In December 2017, the President of the U.S. signed into law the Tax Cuts and Jobs Act (2017 Tax Act), which includes significant changes to the U.S. corporate income tax system, including a reduction in the corporate income tax rate, transition to a territorial tax system, and modifications to the international tax provisions. The changes that became effective January 1, 2018 resulted in a reduction to our tax expense for the three and nine months ended September 30, 2018 compared to the three and nine months ended September 30, 2017, respectively.

At September 30, 2018, our accounting for the 2017 Tax Act is incomplete; however, we expect to complete our accounting by December 2018. As discussed in our 2017 Annual Report on Form 10-K, we recorded provisional adjustments for effects that we were able to reasonably estimate. Those effects included the one-time repatriation transition tax (also known as the 'Toll Tax'), re-measurement of deferred tax assets and liabilities, unremitted earnings, executive compensation, and uncertain tax positions. At year-end, we were not able to make reasonable estimates for Global Intangible Low-Taxed Income (GILTI) deferred taxes or valuation allowances; therefore, we did not record provisional amounts. We are still evaluating the effects of the GILTI provisions and assessing our valuation allowances, and we have not yet determined our accounting policy election with respect to GILTI deferred taxes or the application of intra-entity transfers of inventory; therefore, the estimated annual effective tax rate reflects GILTI as a

period expense. For the three and nine months ended September 30, 2018, we increased our provisional amount of Toll Tax by an immaterial amount. We have not made any additional measurement-period adjustments related to the other provisional items as we are continuing to collect and analyze additional information as well as evaluate the interpretations and assumptions made. Updates to our calculations may result in material changes to the provisional adjustments recorded at year-end and the estimated annual effective tax rate.

The U.S. examination of tax years 2013-2015 began in 2016. While we believe it is reasonably possible that this audit could reach resolution within the next 12 months, the IRS examination of tax years 2013-2015 remains ongoing. Therefore, it is not possible to reasonably estimate the change to unrecognized tax benefits and the related future cash flows.

Note 8: 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, 2018	September 30, 2017	September 30, 2018	September 30, 2017
Components of net periodic benefit cost:				
Service cost	\$74.2	\$86.0	\$232.3	\$251.6
Interest cost	117.9	103.6	342.5	309.2
Expected return on plan assets	(212.7)	(196.4)	(636.3)	(585.7)
Amortization of prior service cost	1.1	1.4	3.6	4.3
Recognized actuarial loss	79.2	72.5	261.2	215.6
Curtailment loss	1.3	—	1.3	—
Net periodic benefit cost	\$61.0	\$67.1	\$204.6	\$195.0
Retiree Health Benefit Plans				
	Three Months Ended		Nine Months Ended	
	September 30, 2018	September 30, 2017	September 30, 2018	September 30, 2017
Components of net periodic benefit income:				
Service cost	\$10.1	\$11.6	\$31.7	\$34.8
Interest cost	14.9	13.2	42.3	39.6
Expected return on plan assets	(44.8)	(40.2)	(132.7)	(120.6)
Amortization of prior service benefit	(19.3)	(22.5)	(60.2)	(67.5)
Recognized actuarial loss	0.8	4.6	5.4	13.8
Curtailment gain	(29.3)	—	(29.3)	—
Net periodic benefit income	\$(67.6)	\$(33.3)	\$(142.8)	\$(99.9)

In July 2018, we announced that we would amend our defined benefit pension and retiree health benefit plans to freeze or reduce benefits for certain Elanco employees effective January 1, 2019. We remeasured the impacted pension and retiree health plans' benefit obligations as of July 31, 2018, which resulted in a net curtailment gain of \$28.0 million during the three and nine months ended September 30, 2018, which was recorded as a component of asset impairment, restructuring, and other special charges.

We contributed approximately \$35 million required to satisfy minimum funding requirements to our defined benefit pension and retiree health benefit plans during the nine months ended September 30, 2018. Additional discretionary funding totaled \$200.0 million during the nine months ended September 30, 2018. During the remainder of 2018, we expect to make contributions to our defined benefit pension and retiree health benefit plans of approximately \$15 million to satisfy minimum funding requirements. No additional discretionary funding for the remainder of 2018 is planned.

As discussed in Note 2, upon adoption of Accounting Standards Update 2017-07, Compensation-Retirement Benefits: Improving the Presentation of Net Periodic Pension Cost and Net Periodic Postretirement Benefit Cost, pension and retiree health benefit cost components other than service costs are presented in other-net, (income) expense.

Note 9: Contingencies

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

Alimta Patent Litigation and Administrative Proceedings

A number of generic manufacturers are seeking approvals in the U.S., Japan, and a number of countries in Europe 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

In the U.S., 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) pursuant to procedures set out in the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act). We have received favorable decisions from the U.S. Court of Appeals for the Federal Circuit (affirming the U.S. District Court for the Southern District of Indiana's decisions finding our U.S. vitamin regimen patent valid and infringed) against Teva, APP, and two other defendants' proposed products, and similar favorable judgments have been entered by the U.S. District Court for the Southern District of Indiana against five other companies. The remaining ANDA applicants have agreed to a preliminary injunction or stay pending the appeal of the inter partes review (IPR) described in the following sentence. In October 2017, the U.S. Patent and Trademark Office issued written decisions in our favor following IPR of our vitamin regimen patent, finding that the generic company petitioners failed to show that the claims in our patent are unpatentable. A number of these challengers have filed an appeal.

We currently have pending lawsuits in the U.S. District Court for the Southern District of Indiana alleging infringement against Actavis LLC (Actavis) and Apotex Inc. in response to their applications to market alternative forms of pemetrexed (the active ingredient in Alimta) products, and we filed a similar lawsuit in the U.S. District Court for Delaware against Eagle Pharmaceuticals, Inc. In June 2018, the U.S. District Court for the Southern District of Indiana ruled in our favor in two similar cases, finding Dr. Reddy's Laboratories' (Dr. Reddy) and Hospira, Inc.'s (Hospira) proposed products would infringe our patent. Dr. Reddy and Hospira have appealed those rulings. The lawsuit against Actavis has been stayed, pending a decision in the Dr. Reddy and Hospira appeals.

European Patent Litigation and Administrative Proceedings

In July 2017, the United Kingdom (U.K.) Supreme Court ruled that commercialization of certain salt forms of pemetrexed by Actavis Group ehf and other Actavis companies directly infringes our vitamin regimen patents in the U.K., Italy, France, and Spain. This litigation in the U.K. is now concluded.

Hexal AG (Hexal) and Stada Arzneimittel AG (Stada) have each challenged the validity of our vitamin regimen patent before the German Federal Patent Court. At a hearing in July 2018, the German Federal Patent Court held that our vitamin regimen patent is invalid. We have appealed this decision. Under German law, the patent remains in force pending appeal. A number of generic competitors have received approval to market generic versions of pemetrexed in Germany and may choose to launch at risk. We will seek to remove any generic pemetrexed products launched at risk in Germany, seek damages in respect of such launches, and defend our patent. Injunctions are in place against four of these companies, including Hexal and ratiopharm GmbH (a subsidiary of Teva). Stada has recently launched at risk in Germany and we are seeking an injunction. Whether further injunctions are granted or the current injunctions are

maintained pending the appeal, or whether a generic competitor chooses to launch at risk, makes the timing of possible generic entry and market erosion in Germany unpredictable.

Additional legal proceedings are ongoing in various national courts throughout Europe. We are aware that several companies have received approval to market generic versions of pemetrexed in major European markets and that generic competitors may choose to launch at risk (including one generic product currently on the market in France). We will continue to seek to remove any generic pemetrexed products launched at risk in European markets, seek damages in respect of such launches, and defend our patents against validity challenges.

Japanese Administrative Proceedings

Three separate sets of demands for invalidation of our two vitamin regimen patents, involving several companies, have been filed with the Japanese Patent Office (JPO). In February 2017, the Japan Intellectual Property High Court confirmed the decisions of the JPO upholding the validity of both our Japanese vitamin regimen patents in the challenge initiated by Sawai Pharmaceutical Co., Ltd. and joined by three other companies. This decision is now final. In May 2017, the JPO resumed one of the two remaining sets of demands, brought by Nipro Corporation (Nipro) and in July 2018, the JPO issued written decisions dismissing Nipro's invalidation demands. Nipro filed an appeal and we anticipate decisions by the Japan Intellectual Property High Court in the third quarter of 2019. The other set of demands, brought by Hospira, that were previously suspended resumed in August 2018; we anticipate decisions by the JPO in the second quarter of 2019. 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.

Cymbalta® Product Liability Litigation

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. The district court denied the plaintiffs' motions for class certification. The district court dismissed the suits and plaintiffs appealed to the U.S. Court of Appeals for the Ninth Circuit. In November 2017, the U.S. Court of Appeals for the Ninth Circuit dismissed the suit. In July 2018, the U.S. District Court for the District of California denied plaintiffs' motion to reopen the case. Plaintiffs' appeal of this denial is currently pending before the U.S. Court of Appeals for the Ninth Circuit.

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 four plaintiffs. We believe all these Cymbalta lawsuits and claims are without merit. We have reached a settlement framework that provides for a comprehensive resolution of nearly all of these personal injury claims, filed or unfiled, alleging injuries from discontinuing treatment with Cymbalta.

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 the 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 Brasil manufacturing facility in Cosmopolis, Brazil, operated by the company between 1977 and 2003. The plaintiffs allege that some employees at the facility were exposed to benzene and heavy metals; however, Lilly Brasil maintains that these alleged contaminants were never used in the facility. In May 2014, the labor court judge ruled against Lilly Brasil. The judge's ruling orders Lilly Brasil to undertake several actions of unspecified financial impact, including paying lifetime medical insurance for the employees and contractors who worked at the Cosmopolis facility more than six months during the affected years and their children born during and after this period. We filed an appeal in May 2014. In July 2018, the appeals court affirmed the lower court's ruling with the total financial impact of the ruling estimated to be approximately 500 million Brazilian real (approximately \$125 million as of September 30, 2018). The appeals court restricted the broad health coverage awarded by the lower court to health problems that claimants could show arose

from exposure to the alleged contamination. We strongly disagree with the court's decision and plan to appeal. Lilly Brasil has taken an initial step in the appeal process by filing a Motion for Clarification; a decision on that motion is expected late in the fourth quarter of 2018 or in the first quarter of 2019.

We are also named in approximately 30 lawsuits filed in the same court by individual former employees making similar claims.

Lilly Brasil and Elanco Quimica Ltda. have been named in a lawsuit 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 the claims brought by all but the first named plaintiff. The plaintiffs are appealing that decision. Lilly Brasil and Elanco Quimica Ltda. have also been named in a separate lawsuit involving approximately 105 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 contractors and suppliers, and their dependents. In November 2017, the court dismissed the claims brought by all but the first named plaintiff. The plaintiffs are appealing that decision.

We believe all of these lawsuits are without merit and plan to defend against them vigorously.

Agri Stats, Inc.

During the third quarter, we sold Agri Stats, Inc., one of our subsidiaries. As a result of the sale, we no longer hold the liability for litigation in which Agri Stats is named as a party, including the approximately 25 antitrust suits filed in the U.S. District Court for the Northern District of Illinois and the District of Minnesota alleging that defendants engaged in a conspiracy to limit U.S. chicken and swine production and inflate prices.

Adocia, S.A.

We have been named a respondent in two arbitrations filed by Adocia, S.A. (Adocia), with which we entered into agreements for the co-development of an ultra-rapid insulin product. In the first arbitration, Adocia alleged that we failed to make a \$11.7 million milestone payment and, in August 2018, an arbitration panel ruled in favor of Adocia. In the second arbitration, Adocia alleged that we misappropriated and misused Adocia's confidential information and intellectual property and is seeking approximately \$1.8 billion in damages and other specific relief. We believe these claims are without merit and are defending against them vigorously. We have asserted several counterclaims relating to fraudulent misrepresentation and are seeking approximately \$188 million in damages.

Throughout the arbitrations described above, Adocia has made statements alleging that Adocia employees should be listed as inventors on two of our patents related to our ultra-rapid insulin product currently in development. We strongly contest this allegation. While inventorship of these two patents is not at issue in the arbitrations, in October 2018 we filed a declaratory judgment action against Adocia in the U.S. District Court for the Southern District of Indiana to confirm our inventorship.

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 10: 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, 2018 and 2017:

(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, 2018	\$ (1,671.5)	\$ (18.1)	\$ (4,190.6)	\$ (228.5)	\$ (6,108.7)
Other comprehensive income (loss) before reclassifications	60.6	1.1	548.6	—	610.3
Net amount reclassified from accumulated other comprehensive loss	—	(0.2)	47.2	2.9	49.9
Net other comprehensive income (loss)	60.6	0.9	595.8	2.9	660.2
Balance at September 30, 2018 ⁽⁴⁾	\$ (1,610.9)	\$ (17.2)	\$ (3,594.8)	\$ (225.6)	\$ (5,448.5)
(Amounts presented net of taxes)	Foreign Currency Translation Gains (Losses)	Unrealized Net Gains (Losses) on Securities	Defined Benefit Pension and Retiree Health Benefit Plans	Effective Portion of Cash Flow Hedges	Accumulated Other Comprehensive Loss
Balance at 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 ⁽¹⁾	\$ (1,205.5)	\$ 163.2	\$ (3,337.1)	\$ (195.2)	\$ (4,574.6)

The following tables summarize the activity related to each component of other comprehensive income (loss) during the nine months ended September 30, 2018 and 2017:

(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, 2018 ⁽²⁾	\$ (1,233.4)	\$ 113.5	\$ (4,340.7)	\$ (234.3)	\$ (5,694.9)
Reclassification due to adoption of new accounting standard ⁽³⁾	—	(128.9)	—	—	(128.9)
Other comprehensive income (loss) before reclassifications	(377.5)	31.0	581.0	—	234.5
Net amount reclassified from accumulated other comprehensive loss	—	(32.8)	164.9	8.7	140.8
Net other comprehensive income (loss)	(377.5)	(1.8)	745.9	8.7	375.3
Balance at September 30, 2018 ⁽⁴⁾	\$ (1,610.9)	\$ (17.2)	\$ (3,594.8)	\$ (225.6)	\$ (5,448.5)
(Amounts presented net of taxes)	Foreign Currency Translation Gains (Losses)	Unrealized Net Gains (Losses) on Securities	Defined Benefit Pension and Retiree Health Benefit Plans	Effective Portion of Cash Flow Hedges	Accumulated Other Comprehensive Loss
Balance at January 1, 2017 ⁽²⁾	\$ (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 ⁽¹⁾	\$ (1,205.5)	\$ 163.2	\$ (3,337.1)	\$ (195.2)	\$ (4,574.6)

⁽¹⁾ Accumulated other comprehensive loss as of September 30, 2017 consists of \$4.61 billion of accumulated other comprehensive loss attributable to controlling interest and \$34.8 million of accumulated other comprehensive income attributable to noncontrolling interest.

⁽²⁾ Accumulated other comprehensive loss as of January 1, 2018 consists of \$5.72 billion of accumulated other comprehensive loss attributable to controlling interest and \$23.7 million of accumulated other comprehensive income attributable to noncontrolling interest. Accumulated other comprehensive loss as of January 1, 2017 consists of \$5.27 billion of accumulated other comprehensive loss attributable to controlling interest and \$48.2 million of accumulated other comprehensive income attributable to noncontrolling interest.

⁽³⁾ This reclassification consists of \$104.8 million of accumulated other comprehensive loss attributable to controlling interest and \$24.1 million of accumulated other comprehensive loss attributable to noncontrolling interest. Refer to Note 2 for further details regarding the reclassification due to the adoption of Accounting Standards Update 2016-01, Financial Instruments - Overall: Recognition and Measurement of Financial Assets and Financial Liabilities.

⁽⁴⁾ Accumulated other comprehensive loss as of September 30, 2018 consists of \$5.44 billion of accumulated other comprehensive loss attributable to controlling interest and \$9.0 million of accumulated other comprehensive loss attributable to noncontrolling interest.

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Tax benefit (expense)				
Foreign currency translation gains/losses	\$7.0	\$33.9	\$(11.2)	\$149.7
Unrealized net gains/losses on securities	(0.2)	(4.2)	1.1	25.4
Defined benefit pension and retiree health benefit plans	(152.4)	(9.4)	(190.3)	(24.0)
Effective portion of cash flow hedges	(0.8)	(1.3)	(2.3)	(8.4)
Benefit/(provision) for income taxes allocated to other comprehensive income (loss) items	\$(146.4)	\$19.0	\$(202.7)	\$142.7

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

Reclassifications out of accumulated other comprehensive loss were as follows:

Details about Accumulated Other Comprehensive Loss Components	Three Months Ended		Nine Months Ended		Affected Line Item in the Consolidated Condensed Statements of Operations
	September 30, 2018	September 30, 2017	September 30, 2018	September 30, 2017	
Amortization of retirement benefit items:					
Prior service benefits, net	\$(18.2)	\$(21.1)	\$(56.6)	\$(63.2) ⁽¹⁾	
Actuarial losses, net	80.0	77.1	266.6	229.4 ⁽¹⁾	
Total before tax	61.8	56.0	210.0	166.2	
Tax benefit	(14.6)	(15.9)	(45.1)	(48.4)	Income taxes
Net of tax	47.2	40.1	164.9	117.8	
Unrealized gains/losses on available-for-sale securities:					
Realized (gains), losses, net	(0.3)	(36.7)	(41.6)	(108.2)	Other—net, (income) expense
Tax (benefit) expense	0.1	12.8	8.8	37.8	Income taxes
Net of tax	(0.2)	(23.9)	(32.8)	(70.4)	
Other, net of tax	2.9	10.5	8.7	15.4	Other—net, (income) expense
Total reclassifications for the period (net of tax)	\$49.9	\$26.7	\$140.8	\$62.8	

⁽¹⁾ These accumulated other comprehensive loss components are included in the computation of net periodic benefit (income) cost (see Note 8).

Note 11: Other–Net, (Income) Expense

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

	Three Months		Nine Months	
	Ended		Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Interest expense	\$69.4	\$61.9	\$193.9	\$162.1
Interest income	(32.1)	(45.1)	(118.8)	(114.6)
Retirement benefit	(62.9)	(63.8)	(174.2)	(191.3)
Other income	41.0	(2.9)	9.0	(44.8)
Other–net, (income) expense	\$15.4	\$(49.9)	\$(90.1)	\$(188.6)

As discussed in Note 2, upon adoption of Accounting Standards Update 2017-07, Compensation-Retirement Benefits: Improving the Presentation of Net Periodic Pension Cost and Net Periodic Postretirement Benefit Cost, pension and postretirement benefit cost components other than service costs are presented in other–net, (income) expense. Results for the three and nine months ended September 30, 2017 have been reclassified to reflect the adoption of this standard.

Note 12: 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			2017		
	September 30,					
	2018			U.S. (1)	Outside U.S.	Total
	U.S. (1)	Outside U.S.	Total	U.S. (1)	Outside U.S.	Total
Segment revenue—to unaffiliated customers:						
Human pharmaceutical products:						
Endocrinology:						
Trulicity®	\$645.9	\$170.3	\$816.2	\$412.9	\$114.8	\$527.7
Humalog®	365.6	299.0	664.6	414.9	281.3	696.2
Forteo®	182.5	208.3	390.8	234.1	207.6	441.7
Humulin®	216.9	105.1	322.1	203.0	97.5	300.5
Basaglar	157.3	43.9	201.2	115.2	30.5	145.7
Jardiance	104.2	62.7	166.9	83.8	43.4	127.2
Trajenta	50.3	85.3	135.7	68.4	84.9	153.3
Other Endocrinology	73.8	66.8	140.4	92.1	76.3	168.4
Total Endocrinology	1,796.5	1,041.4	2,837.9	1,624.4	936.3	2,560.7
Oncology:						
Alimta	288.5	232.0	520.5	260.3	254.2	514.5
Cyramza®	67.0	131.4	198.4	69.5	126.5	196.0
Erbix	132.6	26.9	159.5	136.0	27.4	163.5
Other Oncology	131.7	54.1	185.8	43.5	40.2	83.6
Total Oncology	619.8	444.4	1,064.2	509.3	448.3	957.6
Cardiovascular:						
Cialis®	295.9	171.2	467.1	319.6	245.3	564.9
Effient	30.2	15.1	45.3	42.7	13.1	55.9
Other Cardiovascular	39.7	31.7	71.4	4.9	37.3	42.1
Total Cardiovascular	365.8	218.0	583.8	367.2	295.7	662.9
Neuroscience:						
Cymbalta	14.5	157.5	172.0	19.6	163.5	183.2
Zyprexa®	7.0	102.8	109.9	12.6	128.0	140.6
Strattera®	10.5	88.2	98.7	52.9	84.1	137.1
Other Neuroscience	23.8	23.0	46.6	23.3	23.7	46.8
Total Neuroscience	55.8	371.5	427.2	108.4	399.3	507.7
Immunology:						
Taltz®	210.6	53.3	263.9	131.3	20.0	151.3
Other Immunology	0.8	54.8	55.6	—	16.3	16.3
Total Immunology	211.4	108.1	319.5	131.3	36.3	167.6
Other pharmaceuticals	13.4	43.2	56.6	10.7	50.2	60.9
Total human pharmaceutical products	3,062.7	2,226.5	5,289.2	2,751.3	2,166.1	4,917.4

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

Animal health products	383.9	388.8	772.7	353.0	387.6	740.6
Revenue	\$3,446.6	\$2,615.3	\$6,061.9	\$3,104.4	\$2,553.6	\$5,658.0

38

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

	Nine Months Ended			2017		
	September 30, 2018					
	U.S. ⁽¹⁾	Outside U.S.	Total	U.S. ⁽¹⁾	Outside U.S.	Total
Segment revenue—to unaffiliated customers:						
Human pharmaceutical products:						
Endocrinology:						
Trulicity	\$1,786.5	\$487.8	\$2,274.3	\$1,090.1	\$290.7	\$1,380.8
Humalog	1,334.2	891.8	2,226.1	1,254.3	828.6	2,083.0
Forteo	529.7	608.8	1,138.5	661.5	574.3	1,235.8
Humulin	677.3	316.7	994.0	634.9	337.9	972.8
Basaglar	440.4	128.5	569.0	196.7	81.6	278.3
Jardiance	284.8	180.3	465.1	198.3	105.9	304.3
Trajenta	161.3	257.2	418.5	174.2	234.1	408.2
Other Endocrinology	199.4	206.9	406.1	283.4	228.5	511.8
Total Endocrinology	5,413.6	3,078.0	8,491.6	4,493.4	2,681.6	7,175.0
Oncology:						
Alimta	815.1	760.9	1,576.0	761.9	775.4	1,537.3
Cyramza	210.7	390.1	600.8	204.3	349.2	553.5
Erbix	394.0	81.6	475.5	398.2	78.8	477.0
Other Oncology	321.4	157.1	478.6	128.4	104.3	232.7
Total Oncology	1,741.2	1,389.7	3,130.9	1,492.8	1,307.7	2,800.5
Cardiovascular:						
Cialis	954.9	546.2	1,501.2	997.3	728.5	1,725.7
Effient	59.4	45.3	104.8	290.8	35.8	326.6
Other Cardiovascular	143.7	96.3	239.7	20.5	99.6	120.2
Total Cardiovascular	1,158.0	687.8	1,845.7	1,308.6	863.9	2,172.5
Neuroscience:						
Cymbalta	39.3	484.2	523.5	100.8	463.6	564.4
Zyprexa	27.6	332.8	360.4	49.3	379.6	428.9
Strattera	74.4	269.2	343.5	276.9	243.0	519.9
Other Neuroscience	72.2	71.2	143.5	88.4	72.2	160.5
Total Neuroscience	213.5	1,157.4	1,370.9	515.4	1,158.4	1,673.7
Immunology:						
Taltz	495.3	135.1	630.4	343.6	43.1	386.7
Other Immunology	2.5	130.0	132.5	—	22.9	22.9
Total Immunology	497.8	265.1	762.9	343.6	66.0	409.6
Other pharmaceuticals	49.1	139.8	189.1	34.6	149.7	184.5
Total human pharmaceutical products	9,073.2	6,717.8	15,791.1	8,188.4	6,227.3	14,415.8
Animal health products	1,137.8	1,188.2	2,326.0	1,173.4	1,121.4	2,294.8
Revenue	\$10,211.0	\$7,906.1	\$18,117.1	\$9,361.8	\$7,348.7	\$16,710.6

Numbers may not add due to rounding.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Segment profits:				
Human pharmaceutical products	\$1,514.0	\$1,242.5	\$4,751.0	\$3,765.7
Animal health products	162.6	121.9	461.9	422.6
Total segment profits	\$1,676.7	\$1,364.4	\$5,213.0	\$4,188.3
Reconciliation of total segment profits to consolidated income before taxes:				
Segment profits	\$1,676.7	\$1,364.4	\$5,213.0	\$4,188.3
Other profits (losses):				
Acquired in-process research and development (Note 3)	(30.0)	(205.0)	(1,654.5)	(1,062.6)
Amortization of intangible assets	(153.4)	(155.8)	(458.7)	(510.0)
Asset impairment, restructuring, and other special charges (Note 5)	(83.3)	(406.5)	(236.0)	(670.4)
Other, net	1.0	(5.5)	(7.0)	(32.0)
Consolidated income before taxes	\$1,411.0	\$591.6	\$2,856.8	\$1,913.3

Numbers may not add due to rounding.

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 and global administrative services.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Geographic Information				
Revenue—to unaffiliated customers ⁽¹⁾ :				
United States	\$3,446.6	\$3,104.4	\$10,211.0	\$9,361.8
Europe	1,017.0	1,017.0	3,142.9	2,877.6
Japan	608.8	616.7	1,828.9	1,767.0
Other foreign countries	989.5	920.0	2,934.3	2,704.2
Revenue	\$6,061.9	\$5,658.0	\$18,117.1	\$16,710.6

Numbers may not add due to rounding.

⁽¹⁾ Revenue is attributed to the countries based on the location of the customer.

Refer to Note 3 for information regarding the IPO of Elanco.

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, 2017, may cause our actual results, financial position, 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,		
	2018	2017	Percent Change	2018	2017	Percent Change
Revenue	\$6,061.9	\$5,658.0	7	\$18,117.1	\$16,710.6	8
Gross margin	4,499.6	4,071.7	11	13,280.8	12,204.7	9
Gross margin as a percent of revenue	74.2	% 72.0	%	73.3	% 73.0	%
Operating expense ⁽¹⁾	\$2,959.9	\$2,918.5	1	\$8,623.6	\$8,747.0	(1)
Acquired in-process research and development (IPR&D)	30.0	205.0	(85)	1,654.5	1,062.6	56
Asset impairment, restructuring, and other special charges	83.3	406.5	(80)	236.0	670.4	(65)
Net income	1,149.5	555.6	NM	2,107.0	1,452.8	45
Earnings per share	1.12	0.53	NM	2.03	1.37	48

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

NM - not meaningful

Revenue increased for the three and nine months ended September 30, 2018 primarily driven by increased volume. For the three months ended September 30, 2018, the increase was partially offset by lower realized prices and, to a lesser extent, the unfavorable impact of foreign exchange rates. Operating expense remained relatively flat for the three and nine months ended September 30, 2018, reflecting previously-announced actions taken to reduce our cost structure. The following highlighted items also affect comparisons of our financial results for the three and nine months ended September 30, 2018 and 2017:

2018

Acquired IPR&D (Note 3 to the consolidated condensed financial statements)

We recognized acquired IPR&D charges of \$30.0 million (pretax), or \$0.02 per share, and \$1.65 billion, or \$1.57 per share, for the three and nine months ended September 30, 2018, respectively. The charge for the three months ended September 30, 2018 was related to upfront fees paid in connection with the collaboration agreement with Anima Biotech (Anima). The charges for the nine months ended September 30, 2018 also included charges associated with the acquisitions of ARMO Biosciences, Inc. (ARMO) and AurKa Pharma, Inc. (AurKa), and in connection with the collaborative agreement with Sigilon Therapeutics (Siglion). The charges for ARMO and AurKa totaling \$1.56 billion were not tax deductible.

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

We recognized charges of \$83.3 million (pretax), or \$0.07 per share, and \$236.0 million (pretax), or \$0.20 per share, for the three and nine months ended September 30, 2018, respectively. The charges for the three months ended September 30, 2018 resulted primarily from asset impairment and restructuring charges related to the sale of the Posilac® (rbST) brand and the October 2018 sale of the related Augusta, Georgia manufacturing site. We also incurred expenses associated with the initial public offering and separation of the Elanco animal health business. The charges for the nine months ended September 30, 2018 also included charges related to the decision to suspend commercialization of Imrestor®, an animal health product, expenses related to the decision to end Posilac (rbST) production, and expenses associated with the review of strategic alternatives for the Elanco animal health business.

2017

Acquired 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, 2017, 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, 2017 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, 2017, respectively. The charges for the three months ended September 30, 2017 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. The charges for the nine months ended September 30, 2017 were primarily due to severance costs incurred as a result of actions taken to reduce our cost structure, charges associated with the Posilac (rbST) 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.

The increases in net income and EPS for the three months ended September 30, 2018 were primarily driven by increased revenue and decreased acquired IPR&D and asset impairment, restructuring, and other special charges, partially offset by increased income tax expense. The increase in net income and EPS for the nine months ended September 30, 2018 were primarily driven by increased revenues and decreased asset impairment, restructuring, and other special charges, partially offset by increased acquired IPR&D charges and income tax expense.

42

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 40 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.

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

Galcanezumab* (Emgality[™]) (Q3 2018)—a once-monthly subcutaneously injected calcitonin gene-related peptide (CGRP) antibody for the treatment of migraine prevention. Refer to Item 1, "Legal Proceedings - Other Patent Matters" of Part II for discussion of the lawsuit filed by Teva Pharmaceuticals International GMBH.

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

The following NMEs have 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:

Nasal glucagon* (Q2 2018)—a glucagon nasal powder formulation for the treatment of severe hypoglycemia in patients with diabetes treated with insulin. In the United States (U.S.), nasal glucagon is protected by a delivery device patent (2034), with data protection (3.5 years) expected upon approval. In Europe, nasal glucagon is protected by a delivery device patent (2034), with data protection (6 years) expected upon approval.

The following NMEs and diagnostic agent are currently in Phase III clinical trial testing for potential use in the diseases described which have not yet been submitted for approval for any indication. The first quarter in which each NME and the diagnostic agent initially entered Phase III for any indication is shown in parentheses:

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.

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

Mirikizumab* (Q2 2018)—a human monoclonal antibody designed for the treatment of autoimmune diseases.

Pegilodecakin* (Q1 2017)—a PEGylated IL-10, which has demonstrated clinical benefit as a single agent, and in combination with both chemotherapy and checkpoint inhibitor therapy, across several tumor types.

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.).

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

* 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 the recently approved products, NMEs, and diagnostic agent set forth above, as well as certain other developments to our late-stage pipeline since January 1, 2018:

Compound	Indication	U.S.	Europe	Japan	Developments
Endocrinology					
Nasal glucagon	Severe hypoglycemia	Submitted		Phase III	Submitted to U.S. Food and Drug Administration (FDA) in second quarter of 2018. Submitted to European regulatory authorities in third quarter of 2018. In October 2018, announced Phase III trials met primary efficacy endpoint. Submission to regulatory authorities expected in 2019.
Ultra-rapid Lispro	Type 1 and 2 diabetes	Phase III			
Immunology					
Mirikizumab	Psoriasis	Phase III			Phase III trials were initiated during the second quarter of 2018.
	Ulcerative Colitis	Phase III			Phase III trial was initiated during the second quarter of 2018.
Olumiant	Rheumatoid arthritis	Launched			Granted approval of 2mg dose by FDA and launched in U.S. in second quarter of 2018.
	Atopic Dermatitis	Phase III			Phase III trials are ongoing.
	Systemic Lupus Erythematosus	Phase III			Phase III trials were initiated during the third quarter of 2018.
	Neuroscience				
Flortaucipir	Alzheimer's disease	Phase III			In the third quarter of 2018, announced Phase III trial met primary endpoints. In discussion with regulatory authorities to determine next steps.
	Cluster headache	Phase III			In the second quarter of 2018, announced Phase III trial met primary endpoint for episodic cluster headache. Received Breakthrough Therapy Designation ⁽¹⁾ in the third quarter of 2018. Submission to FDA expected in fourth quarter of 2018. A separate Phase III trial did not meet primary endpoint for chronic cluster headache. Approved and launched in the U.S. in the third and fourth quarters of 2018, respectively. Received positive opinion from the Committee for Medicinal Products for Human Use in Europe during the third quarter of 2018.
Emgality					
	Migraine prevention	Launched	Submitted	Phase III	
Lanabecestat	Early and mild Alzheimer's disease	Discontinued			Phase III trials discontinued in second quarter of 2018.
Lasmiditan	Migraine	Submitted	Phase III		In third quarter of 2017, announced Phase III trial met primary endpoint. Submitted to FDA in fourth quarter of 2018. See Note 3 to the consolidated condensed financial statements for information on the CoLucid acquisition.
Solanezumab	Preclinical Alzheimer's disease	Phase III			Phase III trial is ongoing.
Tanezumab	Osteoarthritis pain	Phase III			In third quarter of 2018, announced initial Phase III trial met primary endpoints. We anticipate additional readouts from the program to be available in 2019.
	Chronic low back pain	Phase III			Phase III trial is ongoing.

Cancer pain

Phase III

Phase III trial is ongoing.

44

Compound	Indication	U.S.	Europe	Japan	Developments
Oncology					
Pegilodecakin	Pancreatic cancer	Phase III			Acquired with ARMO in the second quarter of 2018. Phase III trial is ongoing. See Note 3 to the consolidated condensed financial statements for information on the acquisition.
Verzenio	Adjuvant breast cancer	Phase III			Phase III trial is ongoing.
	Metastatic breast cancer	Launched	Approved		In October 2018, approved in Europe and Japan.
Lartruvo	Soft tissue sarcoma	Launched		Phase III	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.

⁽¹⁾ The Breakthrough Therapy Designation is designed to expedite the development and review of potential medicines that are intended to treat a serious condition where preliminary clinical evidence indicates that the treatment may demonstrate substantial improvement over available therapy on a clinically significant endpoint.

⁽²⁾ 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 and ongoing. 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

Elanco Animal Health

On September 24, 2018, Elanco Animal Health Incorporated (Elanco) completed an initial public offering (the IPO) of 72.3 million shares of its common stock, which represents 19.8 percent of Elanco's outstanding shares, at \$24 per share. In addition, Elanco completed a debt offering and entered into a term loan facility during the third quarter of 2018. See Notes 3 and 6 to the consolidated condensed financial statements for additional information.

We intend to make a distribution to our shareholders of all or a portion of our remaining equity interest in Elanco, which may include one or more distributions effected as a dividend to all our shareholders, one or more distributions in exchange for our shares or other securities, or any combination thereof. We refer to any such potential distribution as the "Distribution". While we intend to effect the Distribution, we have no obligation to pursue or consummate any further dispositions of our ownership in Elanco, including through the Distribution, by any specified date or at all. If pursued, the Distribution may be subject to various conditions, including receipt of any necessary regulatory or other approvals, the existence of satisfactory market conditions, and the receipt of an opinion of counsel to the effect that the separation, together with such Distribution, would be tax-free to us and our shareholders for U.S. federal income tax purposes. The conditions of the Distribution may not be satisfied; we may decide not to consummate the Distribution even if the conditions are satisfied; or we may decide to waive one or more of these conditions and consummate the Distribution even if all of the conditions are not satisfied.

Patent Matters

We depend on patents or other forms of intellectual-property protection for most of our revenue, cash flows, and earnings. 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. Following a 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 in the aggregate have had a material adverse effect on our consolidated results of operations and cash flows.

Our compound patent protection for Cialis[®] (tadalafil) and Adcirca[®] (tadalafil) expired in major European markets and the U.S. in November 2017; however, in the U.S., we were granted pediatric exclusivity through May 2018.

Pursuant to a settlement agreement related to our unit dose patent in the U.S., generic tadalafil entered the U.S. market

in September 2018. We expect that the entry of generic competition into these markets following the loss of exclusivity will cause a significant 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.

Our formulation patent and use patent for Forteo[®] expire in December 2018 and August 2019, respectively, in major European markets and the U.S. Both the formulation patent and the use patent expire in 2019 in Japan. While it is difficult to estimate the severity of the impact of generic and/or biosimilar competition in these markets, we expect a rapid and severe decline in revenue in the U.S. as a result of the U.S. patent expirations. Outside the U.S., we expect a decline in revenue as a result of patent expirations, however the decline may not be rapid and severe. In the aggregate, we expect that the decline in revenue will have a material adverse effect on our consolidated results of operations and cash flows.

Additionally, as described in Note 9 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. See Note 9 to the consolidated condensed financial statements for a more detailed account of the legal proceedings currently pending in the U.S., Europe, and Japan regarding our Alimta patent.

The compound patent for Humalog[®] (insulin lispro) has expired in major markets. Global regulators have different legal pathways to approve similar versions of insulin lispro. A similar version of insulin lispro launched in the U.S. in the second quarter of 2018 and in certain European markets in 2017. While it is difficult to estimate the severity of the impact of similar insulin lispro products entering the market, we do not expect and have not experienced a rapid and severe decline in revenue; however, we expect additional pricing pressure and some loss of market share 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 and Japanese yen. 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. While there is uncertainty in the future movements in foreign exchange rates, fluctuations in these rates could negatively impact our future consolidated results of operations and cash flows.

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 cost control measures may be enacted to manage federal and state budgets. 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. California and several other states have enacted legislation related to prescription drug pricing transparency and it is unclear the affect this legislation will have on our business. The Bipartisan Budget Act, enacted on February 9, 2018, will require manufacturers of brand-name drugs, biologics, and biosimilars to pay a 70 percent discount in the Medicare Part D Coverage Gap, up from the current 50 percent discount. This increase in Coverage Gap discounts will be effective beginning in 2019. In May 2018, the White House released "American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs" (Blueprint). The Administration's corresponding request for information included more than 30 policy changes. We believe some proposals would be positive and other proposals would have negative consequences to our business. The effect of these proposals, and those that extend beyond the Blueprint, will depend on the details and timing of the final legislation, regulation, or guidance and could lead to a wide range of outcomes. Some of these outcomes could have a material adverse effect on our consolidated results of operations and cash flows.

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, increasingly through vertical integration, 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 that 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 2022 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. Federal legislation or administrative actions to repeal or modify some or all of the provisions of the ACA 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. As additional reforms are finalized, we will assess their impact on future revenues. 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. recently enacted tax reform legislation significantly revising U.S. tax law, and a number of other countries are actively considering or enacting tax changes. Other organizations, such as the Organisation for Economic Co-operation and Development and the European Commission, are active regarding tax-related matters, which could influence international tax policy in countries in which we operate. While outcomes of these initiatives continue to develop and remain uncertain, modifications 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.

Our accounting for the Tax Cuts and Jobs Act (2017 Tax Act), signed into law in December 2017, is incomplete; however, we expect to complete our accounting by December 2018. In the fourth quarter of 2017, we recorded provisional adjustments for effects that we were able to reasonably estimate. Refer to Note 7 to the consolidated condensed financial statements for further information related to the 2017 Tax Act.

Acquisitions

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

• Our collaboration with Sigilon, completed in April 2018, for an upfront fee of \$62.5 million and an equity investment in Sigilon.

• Our acquisition of AurKa, completed in June 2018, for a cash purchase price of \$81.3 million, net of cash acquired, plus net accrued liabilities assumed of \$0.5 million.

Our acquisition of ARMO, completed in June 2018, for a cash purchase price of \$1.40 billion, net of cash acquired, plus net accrued liabilities assumed of \$75.8 million.

Our collaboration with Anima, completed in July 2018, for an upfront fee of \$30.0 million.

Legal Matters

Information regarding contingencies relating to certain legal proceedings can be found in Item 1. Legal Proceedings of Part II 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,		
	2018	2017	Percent Change	2018	2017	Percent Change
U.S. ⁽¹⁾	\$3,446.6	\$3,104.4	11	\$10,211.0	\$9,361.8	9
Outside U.S.	2,615.3	2,553.6	2	7,906.1	7,348.7	8
Revenue	\$6,061.9	\$5,658.0	7	\$18,117.1	\$16,710.6	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, 2018 vs. 2017			Nine Months Ended September 30, 2018 vs. 2017		
	U.S.	Outside U.S.	Consolidated	U.S.	Outside U.S.	Consolidated
Volume	16 %	8 %	12 %	8 %	7 %	7 %
Price	(5)	(3)	(4)	1 (2)	—	—
Foreign exchange rates	—	(2)	(1)	—	4	2
Percent change	11 %	2 %	7 %	9 %	8 %	8 %

Numbers may not add due to rounding.

In the U.S., for the three and nine months ended September 30, 2018, the volume increase was primarily driven by increased volume for new pharmaceutical products, including Trulicity[®], Basaglar[®], Taltz[®], and Verzenio, partially offset by decreased volume for products that have lost exclusivity, including Cialis, Strattera, and Effient. The decrease in realized prices for the three months ended September 30, 2018 was primarily driven by Basaglar, Humalog, and Taltz.

Outside the U.S., for the three and nine months ended September 30, 2018, the volume increase was primarily driven by increased volume for new pharmaceutical products, including Trulicity, Olumiant, and Taltz, partially offset by decreased volume for Cialis due to loss of exclusivity in several markets. The decrease in realized prices was due to several pharmaceutical products.

The following tables summarize our revenue activity by product:

Product	Three Months Ended September 30, 2018			2017	Percent Change
	U.S. ⁽¹⁾	Outside U.S.	Total	Total	
Trulicity	\$645.9	\$170.3	\$816.2	\$527.7	55
Humalog	365.6	299.0	664.6	696.2	(5)
Alimta	288.5	232.0	520.5	514.5	1
Cialis	295.9	171.2	467.1	564.9	(17)
Forteo	182.5	208.3	390.8	441.7	(12)
Humulin [®]	216.9	105.1	322.1	300.5	7
Taltz	210.6	53.3	263.9	151.3	74
Basaglar	157.3	43.9	201.2	145.7	38
Cyramza [®]	67.0	131.4	198.4	196.0	1
Cymbalta [®]	14.5	157.5	172.0	183.2	(6)
Jardiance ^{® (2)}	104.2	62.7	166.9	127.2	31
Erbitux [®]	132.6	26.9	159.5	163.5	(2)
Trajenta ^{™ (3)}	50.3	85.3	135.7	153.3	(12)
Zyprexa [®]	7.0	102.8	109.9	140.6	(22)
Strattera	10.5	88.2	98.7	137.1	(28)
Other human pharmaceutical products	313.4	288.6	601.7	474.0	27
Animal health products	383.9	388.8	772.7	740.6	4
Revenue	\$3,446.6	\$2,615.3	\$6,061.9	\$5,658.0	7

Product	Nine Months Ended September 30, 2018			2017	
	U.S. ⁽¹⁾	Outside U.S.	Total	Total	Percent Change
Trulicity	\$1,786.5	\$487.8	\$2,274.3	\$1,380.8	65
Humalog	1,334.2	891.8	2,226.1	2,083.0	7
Alimta	815.1	760.9	1,576.0	1,537.3	3
Cialis	954.9	546.2	1,501.2	1,725.7	(13)
Forteo	529.7	608.8	1,138.5	1,235.8	(8)
Humulin	677.3	316.7	994.0	972.8	2
Taltz	495.3	135.1	630.4	386.7	63
Cyramza	210.7	390.1	600.8	553.5	9
Basaglar	440.4	128.5	569.0	278.3	NM
Cymbalta	39.3	484.2	523.5	564.4	(7)
Erbix	394.0	81.6	475.5	477.0	—
Jardiance ⁽²⁾	284.8	180.3	465.1	304.3	53
Trajenta ⁽³⁾	161.3	257.2	418.5	408.2	3
Zyprexa	27.6	332.8	360.4	428.9	(16)
Strattera	74.4	269.2	343.5	519.9	(34)
Other human pharmaceutical products	847.7	846.7	1,694.3	1,559.2	9
Animal health products	1,137.8	1,188.2	2,326.0	2,294.8	1
Revenue	\$10,211.0	\$7,906.1	\$18,117.1	\$16,710.6	8

Numbers may not add due to rounding.

NM - not meaningful

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

⁽²⁾ Jardiance revenue includes Glyxambi[®] and Synjardy[®].

⁽³⁾ Trajenta revenue includes Jentaducto[®].

Revenue of Trulicity, a treatment for type 2 diabetes, increased 56 percent and 64 percent in the U.S. during the three and nine months ended September 30, 2018, respectively, primarily driven by increased demand. Revenue outside the U.S. increased 48 percent and 68 percent during the three and nine months ended September 30, 2018, respectively, primarily driven by increased volume. The increase during the nine months ended September 30, 2018 was also, to a lesser extent, driven by the favorable impact of foreign exchange rates, partially offset by lower realized prices.

Revenue of Humalog, our injectable human insulin analog for the treatment of diabetes, decreased 12 percent in the U.S. during the three months ended September 30, 2018 driven by lower realized prices primarily due to changes in segment mix and the impact of patient affordability programs. Revenue increased 6 percent in the U.S. during the nine months ended September 30, 2018 driven by increased volume and higher realized prices due to changes in estimates to rebates and discounts and changes in segment mix. Revenue outside the U.S. increased 6 percent and 8 percent during the three and nine months ended September 30, 2018, respectively. The increase during the three months ended September 30, 2018 was driven by increased volume, partially offset by lower realized prices and the unfavorable impact of foreign exchange rates. The increase during the nine months ended September 30, 2018 was driven by increased volume, and to a lesser extent, the favorable impact of foreign exchange rates, partially offset by lower realized prices. A similar version of insulin lispro launched in the U.S. in the second quarter of 2018 and in certain European markets in 2017. While it is difficult to estimate the severity of the impact of similar insulin lispro products entering the market, we do not expect and have not experienced a rapid and severe decline in revenue; however, we expect additional pricing pressure and some loss of market share that would continue over time. See "Executive Overview - Other Matters - Patent Matters" for more information.

Revenue of Alimta, a treatment for various cancers, increased 11 percent and 7 percent in the U.S. during the three and nine months ended September 30, 2018, respectively, driven by increased demand, and to a lesser extent, higher realized prices. Revenue outside the U.S. decreased 9 percent and 2 percent during the three and nine months ended September 30, 2018, respectively, primarily driven by decreased volume due to competitive pressure and loss of exclusivity in several countries. The decrease during the nine months ended September 30, 2018 was partially offset by the favorable impact of foreign exchange rates. We have faced and remain exposed to generic entry in multiple countries, which has eroded revenue and is likely to continue to erode revenue from current levels.

Revenue of Cialis, a treatment for erectile dysfunction and benign prostatic hyperplasia, decreased 7 percent and 4 percent in the U.S. during the three and nine months ended September 30, 2018, respectively, driven by decreased demand due to the entry of generic products, partially offset by higher realized prices. Revenue outside the U.S. decreased 30 percent and 25 percent during the three and nine months ended September 30, 2018, respectively, primarily driven by the loss of exclusivity in Europe. We lost our compound patent protection for Cialis in major European markets in November 2017 and U.S. exclusivity ended in late September 2018. See "Executive Overview - Other Matters - Patent Matters" for more information. In addition to competition from generic tadalafil, we also currently face competition from generic sildenafil, which has accelerated during 2018. We expect that the entry of generic competition due to the loss of exclusivity will continue to cause a rapid and severe decline in revenue.

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, decreased 22 percent and 20 percent in the U.S. during the three and nine months ended September 30, 2018, respectively, primarily due to decreased demand and, to a lesser extent, lower realized prices. Revenue outside the U.S. remained flat during the three months ended September 30, 2018 driven by increased volume, offset by lower realized prices and the unfavorable impact of foreign exchange rates. Revenue increased 6 percent during the nine months ended September 30, 2018 driven by increased volume and the favorable impact of foreign exchange rates, partially offset by lower realized prices. Our formulation patent and use patent for Forteo expire in December 2018 and August 2019, respectively, in major European markets and the U.S. Both the formulation patent and the use patent expire in 2019 in Japan. While it is difficult to estimate the severity of the impact of generic and/or biosimilar competition in these markets, we expect a rapid and severe decline in revenue in the U.S. as a result of the U.S. patent expirations. Outside the U.S., we expect a decline in revenue as a result of patent expirations, however the decline may not be rapid and severe. See "Executive Overview - Other Matters - Patent Matters" for more information.

Revenue of Humulin, an injectable human insulin for the treatment of diabetes, increased 7 percent in the U.S. during the three and nine months ended September 30, 2018, primarily driven by increased volume. Revenue outside the U.S. increased 8 percent during the three months ended September 30, 2018 primarily due to buying patterns in China, partially offset by the unfavorable impact of foreign exchange rates. Revenue decreased 6 percent during the nine months ended September 30, 2018 driven by decreased volume, primarily in China, partially offset by the favorable impact of foreign exchange rates.

Revenue of Taltz, a product for the treatment of moderate-to-severe plaque psoriasis and active psoriatic arthritis, increased 60 percent and 44 percent in the U.S. during the three and nine months ended September 30, 2018, respectively, driven by higher demand, partially offset by lower realized prices. Revenue outside the U.S. increased \$33.3 million and \$92.0 million during the three and nine months ended September 30, 2018, respectively, driven by increased volume from new launches.

Revenue of Cyramza, a treatment for various cancers, decreased 4 percent in the U.S. during the three months ended September 30, 2018 driven by lower realized prices. Revenue increased 3 percent in the U.S. during the nine months ended September 30, 2018 driven by increased volume. Revenue outside the U.S. increased 4 percent and 12 percent during the three and nine months ended September 30, 2018, respectively, driven by increased volume, partially offset by lower realized prices. The increase during the nine months ended September 30, 2018 was also driven by the favorable impact of foreign exchange rates.

Revenue of Basaglar, a long-acting human insulin analog for the treatment of diabetes, which launched in the U.S. in late 2016, increased \$42.1 million and \$243.7 million in the U.S. during the three and nine months ended September 30, 2018, primarily driven by increased demand, partially offset by lower realized prices due to increased

volume in Medicare Part D and, to a lesser extent, changes to estimates for rebates and discounts. Revenue outside the U.S. increased \$13.4 million and \$46.9 million during the three and nine months ended September 30, 2018, primarily driven by increased demand. The increase during the nine months ended September 30, 2018 was also partially driven by the favorable impact of foreign exchange rates. See Note 4 to the consolidated condensed financial statements for information regarding our collaboration with Boehringer Ingelheim involving Basaglar.

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, decreased 26 percent and 61 percent in the U.S. during the three and nine months ended September 30, 2018, respectively, driven by decreased demand, partially offset by higher realized prices. Revenue decreased 4 percent outside the U.S. during the three months ended September 30, 2018, primarily driven by lower realized prices, and to a lesser extent, the unfavorable impact of foreign exchange rates, partially offset by increased volume in Japan. Revenue increased 4 percent outside the U.S. during the nine months ended September 30, 2018, primarily driven by increased volume in Japan, and to a lesser extent, the favorable impact of foreign exchange rates, partially offset by lower realized prices.

Worldwide animal health revenue increased 4 percent during the three months ended September 30, 2018 driven by higher realized prices and increased volume, partially offset by the negative impact of foreign exchange rates. The overall increase in revenue included increased revenue in the companion animal prevention, ruminants and swine, and companion animal therapeutics product categories, partially offset by decreased revenue of products that are being exited. Worldwide animal health revenue increased 1 percent during the nine months ended September 30, 2018 driven by higher realized prices, and to a lesser extent, the favorable impact of foreign exchange rates, partially offset by decreased volume. The overall increase in revenue included increased revenue in the companion animal prevention, future protein and health products, companion animal therapeutics, and ruminants and swine product categories, partially offset by decreased revenue of products that are being exited.

Gross Margin, Costs, and Expenses

Gross margin as a percent of revenue increased 2.2 percentage points to 74.2 percent and increased 0.3 percentage points to 73.3 percent for the three and nine months ended September 30, 2018, respectively. The increase in gross margin percent for the three months ended September 30, 2018 was primarily due to manufacturing efficiencies, and to a lesser extent, the effect of foreign exchange rates on international inventories sold and favorable impact of product mix, partially offset by the negative impact of price on revenue. The increase in gross margin percent for the nine months ended September 30, 2018 was primarily due to manufacturing efficiencies largely offset by the effect of foreign exchange rates on international inventories sold.

Research and development expenses remained flat at \$1.34 billion and \$3.85 billion for the three and nine months ended September 30, 2018, respectively, primarily due to additional late-stage development expenditures, offset by lower development milestone payments compared to the prior year periods.

Marketing, selling, and administrative expenses increased 2 percent to \$1.62 billion for the three months ended September 30, 2018 primarily due to increased expenses related to new pharmaceutical product launches, partially offset by reduced expenses on late life-cycle products. Marketing, selling, and administrative expenses decreased 2 percent to \$4.77 billion for the nine months ended September 30, 2018 due to decreased expenses related to late life-cycle products, partially offset by increased expenses related to new pharmaceutical products.

Both research and development expenses and marketing, selling, and administrative expenses benefited during the three and nine months ended September 30, 2018 from actions taken in 2017 to reduce our cost structure.

We recognized \$30.0 million and \$1.65 billion of acquired IPR&D charges for the three and nine months ended September 30, 2018, respectively. The charge for the three months ended September 30, 2018 was related to the collaboration with Anima. The nine months ended September 30, 2018 also included charges related to the acquisitions of ARMO and AurKa, as well as the collaboration with Sigilon. 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. The charges for the three months ended September 30, 2017 related to the upfront payments associated with our collaborations with Nektar and KeyBioscience. The charges for the nine months ended September 30, 2017 also included 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 \$83.3 million and \$236.0 million for the three and nine months ended September 30, 2018, respectively, compared with charges of \$406.5 million and \$670.4 million for the three and nine months ended September 30, 2017, respectively. The charges for the third quarter of 2018 were primarily associated with asset impairment and restructuring charges related to the sale of the Posilac (rbST) brand and the October 2018 sale of the Augusta, Georgia manufacturing site. The charges also include expenses associated with the IPO and separation of the Elanco animal health business. In addition to these charges, the charges for the first nine months of 2018 also included charges for contractual commitments related to the suspension of commercial activities for Imrestor, as well as expenses associated with the review of strategic alternatives for the Elanco animal health business. The charges for the third quarter of 2017 were primarily associated with asset impairments related to lower projected revenue for Posilac (rbST), severance costs incurred as a result of actions taken to reduce our cost structure, as well as exit costs due to site closures. The charges for the first nine months of 2017 also include integration costs related to the acquisition of Novartis AH. See Note 5 to the consolidated condensed financial statements for additional information.

Other-net, (income) expense was expense of \$15.4 million and income of \$90.1 million for the three and nine months ended September 30, 2018, respectively, compared with income of \$49.9 million and \$188.6 million for the three and nine months ended September 30, 2017. See Note 11 to the consolidated condensed financial statements for additional information.

The effective tax rate was 18.5 percent for the three months ended September 30, 2018, compared with 6.1 percent for the three months ended September 30, 2017, primarily due to a higher income tax benefit in the third quarter of 2017 for acquired IPR&D charges, asset impairment, restructuring, and other special charges. The effective tax rate for the nine months ended September 30, 2018 was 26.2 percent as it reflects non-deductible acquired IPR&D charges totaling \$1.56 billion from the acquisitions of ARMO and AurKa. The effective tax rate for the nine months ended September 30, 2017 was 24.1 percent as it reflected the non-deductible acquired IPR&D charge of \$857.6 million related to the acquisition of CoLucid, in addition to the items discussed for the third quarter. See Note 7 to the consolidated condensed financial statements for additional information.

Financial Condition

Cash and cash equivalents increased to \$8.96 billion as of September 30, 2018, compared with \$6.54 billion as of December 31, 2017. 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, 2018 and 2017. Approximately \$4.2 billion of the cash and cash equivalents as of September 30, 2018 is intended to be used for debt repayment, dividends, and/or share repurchases. See Note 3 to the consolidated condensed financial statements for additional details.

In addition to our cash and cash equivalents, we held total investments of \$2.08 billion and \$7.18 billion as of September 30, 2018 and December 31, 2017, respectively. See Note 6 to the consolidated condensed financial statements for additional details.

Total debt decreased to \$12.68 billion as of September 30, 2018, compared with \$13.65 billion as of December 31, 2017. The decrease was primarily due to the net decrease in the balance of commercial paper outstanding of \$2.30 billion and the repayment of \$1.00 billion of long term debt, partially offset by an increase due to the debt offering and credit facilities entered into by Elanco totaling \$2.48 billion. See Note 6 to the consolidated condensed financial statements for additional details.

Excluding Elanco, as of September 30, 2018, we had a total of \$5.57 billion of committed bank credit facilities, \$5.00 billion of which is available to support our commercial paper program. \$3.80 billion of the committed bank credit facilities will expire before the end of 2018. We believe that amounts accessible through existing commercial paper markets should be adequate to fund short-term borrowing needs.

In September 2018, Elanco entered into a revolving credit agreement providing for a five-year \$750.0 million senior unsecured revolving credit facility, which expires September 2023. See Note 6 to the consolidated condensed financial statements for additional details.

During the nine months ended September 30, 2018, we repurchased \$3.05 billion of shares. We completed the \$5.00 billion share repurchase program announced in October 2013, and the board authorized a new \$8.00 billion share

repurchase program. There were \$1.00 billion of shares repurchased under the \$8.00 billion program during the nine months ended September 30, 2018.

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 "Executive Overview - 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 "Executive Overview - Other Matters - Foreign Currency Exchange Rates").

Financial Expectations

Full-year 2018 EPS is now anticipated to be in the range of \$3.04 to \$3.09. We now expect 2018 revenue of between \$24.3 billion and \$24.5 billion, with the increase in the low end of the revenue range from prior guidance due to strong performance across the pharmaceutical portfolio, particularly in diabetes. We still expect revenue growth to be driven by new pharmaceutical products including Trulicity, Taltz, Basaglar, Jardiance, Verzenio, Cyramza, Olumiant, and Lartruvo.

Gross margin as a percent of revenue is still expected to be approximately 73.5 percent. Research and development expenses are still expected to be in the range of \$5.2 billion to \$5.4 billion. Marketing, selling, and administrative expenses are now expected to be in the range of \$6.3 billion to \$6.5 billion. Other—net, (income) expense is still expected to be income between \$75 million and \$200 million.

The 2018 tax rate is still expected to be approximately 22.5 percent. The 2018 effective tax rate benefits from a lower corporate income tax rate, partially offset by the changes to certain business exclusions, deductions, credits, and international tax provisions as a result of the 2017 Tax Act. The 2018 effective tax rate is subject to change based upon changes in our interpretations of the tax laws, along with subsequent regulations, interpretations, guidance, and accounting policy elections that we continue to evaluate.

Capital expenditures are still expected to be approximately \$1.2 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 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 Joshua L. Smiley, senior vice president and chief financial officer, evaluated our disclosure controls and procedures as of September 30, 2018, and concluded that they are effective.

Changes in Internal Controls. During the third quarter of 2018, 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 9, Contingencies" for information on various legal proceedings, including but not limited to:

- The patent litigation and administrative proceedings involving Alimta.
- The product liability litigation involving Cymbalta.
- The employee litigation in Brazil.
- Antitrust litigation involving Agri Stats, Inc.
- The arbitration filed by Adocia, S.A.

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, 2017 (Part I, Item 3) and our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2018 and June 30, 2018 (Part II, Item 1).

Other Product Liability Litigation

We are named as a defendant in approximately 550 Axiron product liability lawsuits in the U.S. involving approximately 550 plaintiffs. In about one-third of the cases, other manufacturers of testosterone are named as co-defendants. Nearly all of these lawsuits have been consolidated in a federal multidistrict litigation (MDL) in the U.S. District Court for the Northern District of Illinois. A small number of lawsuits have been filed in state courts. The cases generally allege cardiovascular and related injuries. We have reached agreement on a settlement framework that provides for a comprehensive resolution of nearly all of these personal injury claims alleging cardiovascular and related injuries from Axiron treatment. There can be no assurances, however, that a final settlement will be reached. Medical Mutual of Ohio ("MMO") has filed a class action complaint against multiple manufacturers of testosterone products, including us, in the Northern District of Illinois, on behalf of third-party payers who paid for those products. MMO's motion for class certification was denied, but MMO continues to pursue its individual claims and seek damages under the federal Racketeer Influenced and Corrupt Organizations Act (the federal RICO Act). We believe all of these lawsuits and claims are without merit and plan to defend against them vigorously.

We are named as a defendant in approximately 270 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 plan to defend against them vigorously.

Other Patent Matters

Boehringer Ingelheim, our partner in marketing and development of Jardiance, is engaged in various U.S. patent litigation in the U.S. District Court for the District of Delaware involving Jardiance, Glyxambi, and Synjardy in accordance with the procedures set out in the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act). Several companies submitted Abbreviated New Drug Applications (ANDA) seeking approval to market generic versions of Jardiance prior to the expiration of the relevant patents, alleging certain patents, including in some allegations the compound patent, are invalid or would not be infringed.

Boehringer Ingelheim, our partner in marketing and development of Trajenta, is engaged in various U.S. patent litigation matters in the U.S. District Court for the District of New Jersey involving Trajenta and Jentadueto in accordance with the procedures set out in the Hatch-Waxman Act. Eleven groups of companies submitted ANDAs seeking approval to market generic versions of Trajenta prior to the expiration of the relevant patents, alleging certain patents, including in some allegations the compound patent, are invalid or would not be infringed. In October 2018, the District Court held that some of the secondary patents were invalid; however, the challenge to the compound patent, which runs through 2025, was withdrawn.

We are named as a defendant in litigation filed by Research Corporation Technologies, Inc. (RCT) in the U.S. District Court for the District of Arizona. RCT is seeking damages for breach of contract, trade secret misappropriation, unjust enrichment, and conversion related to processes used to manufacture certain products, including Humalog and Humulin. A trial date has not been set. We believe this lawsuit is without merit, and are vigorously defending ourselves against these claims.

In October 2017, Teva Pharmaceuticals International GMBH filed a lawsuit against us in the U.S. District Court for the District of Massachusetts seeking a ruling that various patents would be infringed if we launched Emgality for the prevention of migraine in adults. Teva Pharmaceuticals USA, Inc. (collectively with Teva Pharmaceuticals International GMBH, Teva) was added as a plaintiff in January 2018. In February 2018, Teva filed another lawsuit in the same court seeking a ruling that two recently granted Teva patents would also be infringed if we launched Emgality for the prevention of migraine in adults. While those lawsuits were dismissed without prejudice in September 2018, Teva subsequently refiled their complaint, alleging infringement of the same patents asserted in the previous suits. We believe this newly filed lawsuit is without merit and we plan to defend against it vigorously. In Canada, several generic companies previously challenged the validity of our Zyprexa compound patent. In September 2012, the Canadian Federal 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 in January 2017, the court issued a ruling that Teva Canada is entitled to damages. We appealed the ruling, and in February 2018 the Canadian Federal Court of Appeal affirmed the lower court ruling. In April 2018, we filed a petition for leave to appeal the decision to the Supreme Court of Canada and expect a decision on the petition in the fourth quarter of 2018.

Other Matters

We, along with Sanofi and Novo Nordisk, were named as defendants in a consolidated purported class action lawsuit, *In re. Insulin Pricing Litigation*, in the U.S. District Court of New Jersey relating to insulin pricing. Plaintiffs seek damages under various state consumer protection laws and the federal RICO Act. Separately, we, along with Sanofi and Novo Nordisk, were named as defendants in a purported class action lawsuit, *MSP Recovery Claims, Series, LLC et al. v. Sanofi Aventis U.S. LLC et al.*, in the the same court seeking damages under various state consumer protection laws, common law fraud, unjust enrichment, and the federal RICO Act. Finally, the Minnesota Attorney General's Office filed a complaint against us, Sanofi and Novo Nordisk, *State of Minnesota v. Sanofi-Aventis U.S. LLC et al.*, in the U.S. District Court of New Jersey, alleging unjust enrichment, and violations of various Minnesota state consumer protection laws and the federal RICO Act. We believe these claims are without merit and plan 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, 2017. There have been no material changes from the risk factors previously disclosed in our Annual Report.

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

The following table summarizes the activity related to repurchases of our equity securities during the three months ended September 30, 2018:

Period	Total Number of Shares Purchased (in thousands)	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs (in thousands)	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs (in millions)
July 2018	8,471	\$ 96.93	8,471	\$ 7,178.8
August 2018	1,719	103.96	1,719	7,000.0
September 2018	—	—	—	7,000.0
Total	10,191	98.12	10,191	

Numbers may not add due to rounding.

During the three months ended September 30, 2018, we repurchased \$1.00 billion of shares under the \$8.00 billion share repurchase program authorized in June 2018.

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 10.1 Master Separation Agreement

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 Joshua L. Smiley, Senior Vice President and Chief Financial Officer

EXHIBIT 32. Section 1350 Certification

EXHIBIT 101. Interactive Data Files

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 10.1 Master Separation Agreement, dated September 24, 2018, between Eli Lilly and Company and Elanco Animal Health Incorporated, is incorporated by reference to Exhibit 10.1 to Elanco Animal Health Incorporated's Report on Form 8-K dated September 26, 2018.
- 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 Joshua L. Smiley, Senior Vice President 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: 11/6/2018/s/Bronwen L. Mantlo
Bronwen L. Mantlo
Corporate Secretary
- Date: 11/6/2018/s/Donald A. Zakrowski
Donald A. Zakrowski
Vice President, Finance and Chief Accounting Officer