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, 2019

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 incorporation or organization)	(I.R.S. Employer Identification No.)

Lilly Corporate Center, Indianapolis, Indiana 46285
(Address of principal executive offices)

Registrant's telephone number, including area code (317) 276-2000

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months and (2) has been subject to such filing requirements for the past 90 days.
Yes ☒ No ☐

Indicate by check mark whether the registrant 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 October 21, 2019:

Class	Number of Shares Outstanding
Common	960,130,771

Securities registered pursuant to Section 12(b) of the Exchange Act:

Title of Each Class	Trading Symbol	Name of Each Exchange On Which Registered
Common Stock (no par value)	LLY	New York Stock Exchange
1.000% Notes Due June 2, 2022	LLY22	New York Stock Exchange
7 1/8% Notes Due June 1, 2025	LLY25	New York Stock Exchange
1.625% Notes Due June 2, 2026	LLY26	New York Stock Exchange
2.125% Notes Due June 3, 2030	LLY30	New York Stock Exchange
6.77% Notes Due January 1, 2036	LLY36	New York Stock Exchange

Eli Lilly and Company

Form 10-Q
For the Quarter Ended September 30, 2019

Table of Contents

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, Section 21E of the Securities Exchange Act of 1934, and the Private Securities Litigation Reform Act of 1995. 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,” or similar 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:

- uncertainties in the pharmaceutical research and development process, including with respect to the timing of anticipated regulatory approvals and launches of new products;
- market uptake of recently launched products;
- competitive developments affecting current products and our pipeline;
- 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, misappropriation, or compromise 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, including the impact of U.S. tax reform legislation enacted in December 2017 and related guidance;
- 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; and
- the impact of global macroeconomic conditions.

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, 2018, particularly under the caption “Risk Factors”, our Form 8-K filed on October 24, 2019, which recasts the financial information in our Annual Report on Form 10-K for the year ended December 31, 2018, and our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2019 and June 30, 2019.

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 occurring after the date of this report.

PART I. Financial Information

Item 1. Financial Statements

Consolidated Condensed Statements of Operations
(Unaudited)
ELI LILLY AND COMPANY AND SUBSIDIARIES
(Dollars and shares in millions, except per-share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	**2018**	**2019**	**2018**
Revenue (Note 2)	**$ 5,476.6**	$ 5,306.9	**$ 16,205.5**	$ 15,855.7
Costs, expenses, and other:				
Cost of sales	**1,175.0**	1,152.9	**3,438.6**	3,551.8
Research and development	**1,380.9**	1,280.9	**4,013.6**	3,659.4
Marketing, selling, and administrative	**1,412.3**	1,457.2	**4,515.7**	4,281.5
Acquired in-process research and development (Note 3)	**77.7**	30.0	**239.6**	1,654.5
Asset impairment, restructuring, and other special charges (Note 6)	**—**	42.9	**423.9**	74.2
Other–net, (income) expense (Note 13)	**24.9**	1.9	**(28.7)**	(114.2)
	4,070.8	3,965.8	**12,602.7**	13,107.2
Income before income taxes	**1,405.8**	1,341.1	**3,602.8**	2,748.5
Income taxes (Note 9)	**151.9**	247.5	**460.6**	719.3
Net income from continuing operations	**1,253.9**	1,093.6	**3,142.2**	2,029.2
Net income from discontinued operations (Note 5)	**—**	55.9	**3,680.5**	77.8
Net income	**$ 1,253.9**	$ 1,149.5	**$ 6,822.7**	$ 2,107.0
Earnings per share:				
Earnings from continuing operations - basic	**$ 1.37**	$ 1.07	**$ 3.35**	$ 1.96
Earnings from discontinued operations - basic	**—**	0.06	**3.92**	0.08
Earnings per share - basic	**$ 1.37**	$ 1.13	**$ 7.27**	$ 2.04
Earnings from continuing operations - diluted	**$ 1.37**	$ 1.07	**$ 3.33**	$ 1.96
Earnings from discontinued operations - diluted	**—**	0.05	**3.91**	0.07
Earnings per share - diluted	**$ 1.37**	$ 1.12	**$ 7.24**	$ 2.03
Shares used in calculation of earnings per share:				
Basic	**913.9**	1,020.4	**938.2**	1,033.2
Diluted	**918.5**	1,026.3	**942.4**	1,037.8

See notes to consolidated condensed financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	**2018**	**2019**	**2018**
Net income	**$ 1,253.9**	$ 1,149.5	**$ 6,822.7**	$ 2,107.0
Other comprehensive income (loss) from continuing operations, net of tax (Note 12)	**(134.0)**	561.7	**(51.1)**	346.3
Other comprehensive income from discontinued operations, net of tax (Note 12) [(1)]	**—**	98.5	**56.8**	29.0
Other comprehensive income (loss), net of tax (Note 12)	**(134.0)**	660.2	**5.7**	375.3
Comprehensive income	**$ 1,119.9**	$ 1,809.7	**$ 6,828.4**	$ 2,482.3

[(1)] For the nine months ended September 30, 2019, other comprehensive income related to discontinued operations consisted of $45.8 million of accumulated other comprehensive income attributable to controlling interest and $11.0 million of accumulated other comprehensive income attributable to noncontrolling interest.

See notes to consolidated condensed financial statements.

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

	September 30, 2019	December 31, 2018
Assets	(Unaudited)	
Current Assets		
Cash and cash equivalents (Note 7)	**$ 1,563.8**	$ 7,320.7
Short-term investments (Note 7)	**89.2**	88.2
Accounts receivable, net of allowances of **$22.6 (2019)** and $24.1 (2018)	**4,441.7**	4,593.9
Other receivables	**1,096.2**	1,182.9
Inventories	**3,101.3**	3,098.1
Prepaid expenses and other	**2,369.6**	2,036.7
Current assets of discontinued operations (Note 5)	**—**	2,229.1
Total current assets	**12,661.8**	20,549.6
Investments (Note 7)	**1,825.3**	2,005.4
Goodwill	**3,772.5**	1,366.6
Other intangibles, net	**6,689.3**	1,068.0
Deferred tax assets	**2,412.8**	2,613.7
Sundry	**2,194.2**	1,824.9
Property and equipment, net of accumulated depreciation of **$9,055.3 (2019)** and $8,666.9 (2018)	**7,801.5**	7,996.1
Operating lease assets (Note 8)	**535.7**	—
Noncurrent assets of discontinued operations (Note 5)	**—**	6,484.1
Total assets	**$ 37,893.1**	$ 43,908.4
Liabilities and Equity		
Current Liabilities		
Short-term borrowings and current maturities of long-term debt	**$ 1,563.1**	$ 1,102.2
Accounts payable	**1,114.9**	1,207.1
Employee compensation	**704.5**	955.6
Sales rebates and discounts	**5,277.0**	4,849.5
Dividends payable	**—**	650.8
Income taxes payable	**180.7**	393.4
Other current liabilities	**1,988.4**	2,036.7
Current liabilities of discontinued operations (Note 5)	**—**	692.8
Total current liabilities	**10,828.6**	11,888.1
Other Liabilities		
Long-term debt	**13,662.2**	9,196.4
Noncurrent operating lease liabilities (Note 8)	**485.2**	—
Accrued retirement benefits (Note 10)	**2,414.2**	2,802.2
Long-term income taxes payable	**3,526.5**	3,700.0
Deferred tax liabilities	**2,413.7**	1,312.7
Other noncurrent liabilities	**1,100.4**	1,357.6
Noncurrent liabilities of discontinued operations (Note 5)	**—**	2,742.3
Total other liabilities	**23,602.2**	21,111.2
Commitments and Contingencies (Note 11)		
Eli Lilly and Company Shareholders' Equity		
Common stock	**600.4**	661.0
Additional paid-in capital	**6,608.7**	6,583.6
Retained earnings	**4,981.9**	11,395.9
Employee benefit trust	**(3,013.2)**	(3,013.2)
Accumulated other comprehensive loss (Note 12)	**(5,734.5)**	(5,729.2)
Cost of common stock in treasury	**(60.8)**	(69.4)
Total Eli Lilly and Company shareholders' equity	**3,382.5**	9,828.7
Noncontrolling interests	**79.8**	1,080.4
Total equity	**3,462.3**	10,909.1
Total liabilities and equity	**$ 37,893.1**	$ 43,908.4

See notes to consolidated condensed financial statements.

Consolidated Condensed Statements of Equity
(Unaudited)
ELI LILLY AND COMPANY AND SUBSIDIARIES

ELI LILLY AND COMPANY AND SUBSIDIARIES (Dollars in millions, except per-share data, and shares in thousands)	Equity of Eli Lilly and Company Shareholders								Noncontrolling Interest
	Common Stock		Additional Paid-in Capital	Retained Earnings	Employee Benefit Trust	Accumulated Other Comprehensive Loss	Common Stock in Treasury		
	Shares	Amount					Shares	Amount	
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 loss, net of tax						660.2			
Retirement of treasury shares	(10,191)	(6.4)		(993.7)			(10,191)	1,000.0	
Purchase of treasury shares							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			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
Balance at July 1, 2019	**965,957**	**$ 603.7**	**$ 6,534.5**	**$ 4,318.1**	**$ (3,013.2)**	**$ (5,600.5)**	**541**	**$ (62.1)**	**$ 76.8**
Net income				**1,253.9**					**4.6**
Other comprehensive income, net of tax						**(134.0)**			
Retirement of treasury shares	**(5,391)**	**(3.3)**		**(596.6)**			**(5,391)**	**600.0**	
Purchase of treasury shares [1]							**5,391**	**(600.0)**	
Issuance of stock under employee stock plans, net	**10**		**(1.3)**				**(11)**	**1.3**	
Stock-based compensation			**75.5**						
Other				**6.5**					**(1.6)**
Balance at September 30, 2019	**960,576**	**$ 600.4**	**$ 6,608.7**	**$ 4,981.9**	**$ (3,013.2)**	**$ (5,734.5)**	**530**	**$ (60.8)**	**$ 79.8**

[1] As of September 30, 2019, there was $1.80 billion remaining under our $8.00 billion share repurchase program authorized in June 2018.

See notes to consolidated condensed financial statements.

(Dollars in millions, except per-share data, and shares in thousands)	Equity of Eli Lilly and Company Shareholders								Noncontrolling Interests
	Common Stock		Additional Paid-in Capital	Retained Earnings	Employee Benefit Trust	Accumulated Other Comprehensive Loss	Common Stock in Treasury		
	Shares	Amount					Shares	Amount	
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 loss, 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							36,014	(3,050.7)	
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				2,584.4		(105.2)			
Sale of Elanco stock			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
Balance at January 1, 2019	**1,057,639**	**$ 661.0**	**$ 6,583.6**	**$ 11,395.9**	**$ (3,013.2)**	**$ (5,729.2)**	**604**	**$ (69.4)**	**$ 1,080.4**
Net income				**6,822.7**					**25.7**
Other comprehensive income, net of tax						**(5.3)**			**11.0**
Cash dividends declared per share: $1.29				**(1,171.6)**					
Retirement of treasury shares	**(100,018)**	**(62.4)**		**(12,065.1)**			**(100,018)**	**12,127.5**	
Purchase of treasury shares [1]							**35,017**	**(4,100.0)**	
Issuance of stock under employee stock plans, net	**2,955**	**1.8**	**(205.7)**				**(74)**	**8.6**	
Stock-based compensation			**230.8**						
Acquisition of common stock in exchange offer							**65,001**	**(8,027.5)**	
Deconsolidation of Elanco									**(1,028.9)**
Other									**(8.4)**
Balance at September 30, 2019	**960,576**	**$ 600.4**	**$ 6,608.7**	**$ 4,981.9**	**$ (3,013.2)**	**$ (5,734.5)**	**530**	**$ (60.8)**	**$ 79.8**

[1] As of September 30, 2019, there was $1.80 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,	
	2019	**2018**
Cash Flows from Operating Activities		
Net income	**$ 6,822.7**	$ 2,107.0
Adjustments to Reconcile Net Income to Cash Flows from Operating Activities:		
Gain related to disposition of Elanco (Note 5)	**(3,680.5)**	—
Depreciation and amortization	**891.9**	1,263.5
Change in deferred income taxes	**(23.4)**	161.6
Stock-based compensation expense	**230.8**	206.7
Acquired in-process research and development (Note 3)	**239.6**	1,654.5
Other changes in operating assets and liabilities, net of acquisitions and divestitures	**(1,763.7)**	(1,638.2)
Other non-cash operating activities, net	**155.5**	320.7
Net Cash Provided by Operating Activities	**2,872.9**	4,075.8
Cash Flows from Investing Activities		
Net purchases of property and equipment	**(707.4)**	(816.3)
Proceeds from sales and maturities of short-term investments	**116.3**	2,535.5
Purchases of short-term investments	**(34.1)**	(112.2)
Proceeds from sales of noncurrent investments	**498.4**	3,444.7
Purchases of noncurrent investments	**(196.7)**	(719.7)
Cash paid for acquisitions, net of cash acquired (Note 3)	**(6,917.7)**	—
Purchases of in-process research and development	**(319.6)**	(1,578.2)
Other investing activities, net	**(480.7)**	(188.8)
Net Cash (Used for) Provided by Investing Activities	**(8,041.5)**	2,565.0
Cash Flows from Financing Activities		
Dividends paid	**(1,822.6)**	(1,739.2)
Net change in short-term borrowings	**1,058.9**	(2,297.1)
Proceeds from issuance of long-term debt	**4,448.3**	2,477.7
Repayments of long-term debt	**(600.3)**	(1,001.5)
Purchases of common stock	**(4,100.0)**	(3,050.7)
Net proceeds from Elanco initial public offering	**—**	1,659.7
Other financing activities, net	**(195.2)**	(314.1)
Net Cash Used for Financing Activities	**(1,210.9)**	(4,265.2)
Effect of exchange rate changes on cash and cash equivalents	**(54.9)**	48.2
Net (decrease) increase in cash and cash equivalents	**(6,434.4)**	2,423.8
Cash and cash equivalents at January 1 (includes $677.5 (2019) and $324.4 (2018) of discontinued operations)	**7,998.2**	6,536.2
Cash and Cash Equivalents at September 30 (includes $575.0 (2018) of discontinued operations)	**$ 1,563.8**	$ 8,960.0

See notes to consolidated condensed financial statements.

Note 1: Basis of Presentation and Implementation of New Financial Accounting Standards

On March 11, 2019, we completed the disposition of our remaining 80.2 percent ownership of Elanco Animal Health (Elanco) common stock through a tax-free exchange offer. As a result, Elanco has been presented as discontinued operations in our consolidated condensed financial statements for all periods presented.

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 Form 8-K filed on October 24, 2019, which recasts the financial information in our Annual Report on Form 10-K for the year ended December 31, 2018. We issue our financial statements by filing them with the Securities and Exchange Commission 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.

Following the completion of the disposition of Elanco, we now operate as a single operating segment engaged in the discovery, development, manufacturing, marketing, and sales of pharmaceutical products worldwide. A global research and development organization and a supply chain organization are responsible for the discovery, development, manufacturing, and supply of our products. Regional commercial organizations market, distribute, and sell the products. The business is also supported by global corporate staff functions. Our determination that we operate as a single segment is consistent with the financial information regularly reviewed by the chief operating decision maker for purposes of evaluating performance, allocating resources, setting incentive compensation targets, and planning and forecasting for future periods.

On January 1, 2019 we adopted Accounting Standards Update 2016-02, *Leases,* using the modified retrospective approach, applied at the beginning of the period of adoption, and we elected the package of transitional practical expedients. The adoption of this standard resulted in recording of operating lease assets of approximately $530 million, which included reclassifying approximately $65 million of deferred rent and lease incentives, net of prepaid rent, as a component of the operating lease assets as of January 1, 2019. The adoption also resulted in recording operating lease liabilities of approximately $595 million as of January 1, 2019. Our accounting for finance leases remained substantially unchanged. The standard did not have an impact on our consolidated condensed statements of operations.

Note 2: Revenue

The following table summarizes our revenue recognized in our consolidated condensed statements of operations:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	**2018**	**2019**	**2018**
Net product revenue	**$ 4,982.0**	$ 4,909.5	**$ 14,843.0**	$ 14,644.8
Collaboration and other revenue [(1)]	**494.6**	397.4	**1,362.5**	1,210.9
Revenue	**$ 5,476.6**	$ 5,306.9	**$ 16,205.5**	$ 15,855.7

[(1)] Collaboration and other revenue associated with prior period transfers of intellectual property was $67.9 million and $163.0 million during the three and nine months ended September 30, 2019, respectively, and $76.2 million and $259.9 million during the three and nine months ended September 30, 2018, 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 Trajenta® 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.

Disaggregation of Revenue

The following table summarizes revenue by product:

	Three Months Ended September 30,					
	2019			2018		
	United States (U.S.) [1]	Outside U.S.	Total	U.S. [1]	Outside U.S.	Total
Revenue—to unaffiliated customers:						
Endocrinology:						
Trulicity®	**$ 755.5**	**$ 256.0**	**$ 1,011.5**	$ 645.9	$ 170.3	$ 816.2
Humalog® [2]	**356.2**	**292.6**	**648.9**	365.6	299.0	664.6
Forteo®	**175.1**	**195.7**	**370.7**	182.5	208.3	390.8
Humulin®	**218.2**	**103.6**	**321.8**	216.9	105.1	322.1
Basaglar®	**202.4**	**60.8**	**263.2**	157.3	43.9	201.2
Jardiance [3]	**140.6**	**100.1**	**240.7**	104.2	62.7	166.9
Trajenta [4]	**60.1**	**95.4**	**155.5**	50.3	85.3	135.7
Other Endocrinology	**78.9**	**53.2**	**132.1**	73.8	66.8	140.4
Total Endocrinology	**1,987.0**	**1,157.4**	**3,144.4**	1,796.5	1,041.4	2,837.9
Oncology:						
Alimta®	**282.4**	**225.9**	**508.2**	288.5	232.0	520.5
Cyramza®	**82.5**	**157.5**	**240.0**	67.0	131.4	198.4
Verzenio®	**124.8**	**32.4**	**157.2**	84.5	—	84.5
Erbitux®	**113.8**	**14.8**	**128.6**	132.6	26.9	159.5
Other Oncology	**36.7**	**76.6**	**113.4**	47.2	54.1	101.3
Total Oncology	**640.2**	**507.2**	**1,147.4**	619.8	444.4	1,064.2
Neuroscience:						
Cymbalta®	**10.3**	**168.3**	**178.6**	14.5	157.5	172.0
Zyprexa®	**11.2**	**94.2**	**105.4**	7.0	102.8	109.9
Strattera®	**8.7**	**43.3**	**52.1**	10.5	88.2	98.7
Emgality®	**45.8**	**1.9**	**47.7**	—	—	—
Other Neuroscience	**18.6**	**24.4**	**42.9**	23.8	23.0	46.6
Total Neuroscience	**94.6**	**332.1**	**426.7**	55.8	371.5	427.2
Immunology:						
Taltz®	**250.6**	**89.4**	**340.0**	210.6	53.3	263.9
Olumiant®	**12.1**	**102.5**	**114.6**	0.8	54.8	55.6
Total Immunology	**262.8**	**191.8**	**454.6**	211.4	108.1	319.5
Other:						
Cialis®	**30.9**	**153.4**	**184.3**	295.9	171.2	467.1
Other	**44.7**	**74.4**	**119.2**	91.1	99.8	191.0
Total Other	**75.6**	**227.8**	**303.5**	387.0	271.0	658.1
Revenue	**$ 3,060.2**	**$ 2,416.4**	**$ 5,476.6**	$ 3,070.5	$ 2,236.4	$ 5,306.9

Numbers may not add due to rounding.

[1] U.S. revenue includes revenue in Puerto Rico.

[2] Humalog revenue includes Insulin Lispro.

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

[4] Trajenta revenue includes Jentadueto®.

	Nine Months Ended September 30,					
	2019			2018		
	U.S. [1]	Outside U.S.	Total	U.S. [1]	Outside U.S.	Total
Revenue—to unaffiliated customers:						
Endocrinology:						
Trulicity	**$ 2,213.2**	**$ 706.5**	**$ 2,919.7**	$ 1,786.5	$ 487.8	$ 2,274.3
Humalog [2]	**1,201.0**	**856.3**	**2,057.3**	1,334.2	891.8	2,226.1
Forteo	**473.8**	**570.6**	**1,044.4**	529.7	608.8	1,138.5
Humulin	**639.6**	**302.5**	**942.1**	677.3	316.7	994.0
Basaglar	**632.8**	**172.6**	**805.4**	440.4	128.5	569.0
Jardiance [3]	**408.4**	**267.9**	**676.2**	284.8	180.3	465.1
Trajenta [4]	**171.9**	**269.5**	**441.4**	161.3	257.2	418.5
Other Endocrinology	**222.2**	**172.9**	**395.2**	199.4	206.9	406.1
Total Endocrinology	**5,962.9**	**3,318.8**	**9,281.7**	5,413.6	3,078.0	8,491.6
Oncology:						
Alimta	**905.8**	**679.3**	**1,585.1**	815.1	760.9	1,576.0
Cyramza	**247.4**	**432.7**	**680.1**	210.7	390.1	600.8
Erbitux	**364.1**	**42.3**	**406.4**	394.0	81.6	475.5
Verzenio	**323.5**	**77.0**	**400.6**	171.9	—	171.9
Other Oncology	**83.1**	**202.2**	**285.1**	149.5	157.1	306.7
Total Oncology	**1,923.9**	**1,433.5**	**3,357.3**	1,741.2	1,389.7	3,130.9
Neuroscience:						
Cymbalta	**38.7**	**491.2**	**529.9**	39.3	484.2	523.5
Zyprexa	**29.8**	**287.2**	**317.0**	27.6	332.8	360.4
Strattera	**31.4**	**169.4**	**200.8**	74.4	269.2	343.5
Emgality	**91.8**	**4.5**	**96.3**	—	—	—
Other Neuroscience	**58.5**	**70.1**	**128.6**	72.2	71.2	143.5
Total Neuroscience	**250.2**	**1,022.4**	**1,272.6**	213.5	1,157.4	1,370.9
Immunology:						
Taltz	**699.6**	**246.7**	**946.3**	495.3	135.1	630.4
Olumiant	**29.2**	**269.9**	**299.1**	2.5	130.0	132.5
Total Immunology	**728.8**	**516.6**	**1,245.4**	497.8	265.1	762.9
Other:						
Cialis	**209.3**	**483.4**	**692.7**	954.9	546.2	1,501.2
Other	**128.4**	**227.4**	**355.8**	287.5	310.9	598.2
Total Other	**337.7**	**710.9**	**1,048.5**	1,242.4	857.1	2,099.4
Revenue	**$ 9,203.5**	**$ 7,002.1**	**$ 16,205.5**	$ 9,108.5	$ 6,747.3	$ 15,855.7

Numbers may not add due to rounding.

[1] U.S. revenue includes revenue in Puerto Rico.

[2] Humalog revenue includes Insulin Lispro.

[3] Jardiance revenue includes Glyxambi and Synjardy.

[4] Trajenta revenue includes Jentadueto.

The following table summarizes revenue by geographical area:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenue—to unaffiliated customers [1]:				
United States [2]	**$ 3,060.2**	$ 3,070.5	**$ 9,203.5**	$ 9,108.5
Europe	**923.4**	890.3	**2,752.0**	2,725.1
Japan	**641.5**	589.0	**1,838.4**	1,766.2
Other foreign countries	**851.4**	757.1	**2,411.7**	2,255.9
Revenue	**$ 5,476.6**	$ 5,306.9	**$ 16,205.5**	$ 15,855.7

Numbers may not add due to rounding.

[1] Revenue is attributed to the countries based on the location of the customer.

[2] U.S. revenue includes revenue in Puerto Rico.

Adjustments to Revenue

Adjustments to revenue recognized as a result of changes in estimates for our most significant U.S. sales returns, rebates, and discounts liability balances for products shipped in previous periods were approximately 2 percent and 3 percent of U.S. revenue during the three and nine months ended September 30, 2019, respectively, and approximately 1 percent and 2 percent of U.S. revenue during the three and nine months ended September 30, 2018, respectively.

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 returns, rebates, and discounts. Changes in contract liabilities are generally due to either receipt of additional advance payments or our performance under the contract.

The following table summarizes contract liability balances:

	September 30, 2019	December 31, 2018
Contract liabilities	**$ 272.3**	$ 294.9

Revenue recognized from contract liabilities during the three and nine months ended September 30, 2019 and 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 3: Acquisitions and Divestiture

In February 2019, we completed the acquisition of Loxo Oncology, Inc. (Loxo). 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 condensed 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.

Additionally, we acquired assets in development 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 $77.7 million and $239.6 million for the three and nine months ended September 30, 2019, respectively, and $30.0 million and $1.65 billion for the three and nine months ended September 30, 2018, respectively.

Acquisition of a Business

Loxo Acquisition

Overview of Transaction

In February 2019, we acquired all shares of Loxo for a purchase price of $6.92 billion, net of cash acquired. The accelerated vesting of Loxo employee equity awards was recognized as transaction expense included in asset impairment, restructuring, and other special charges during the nine months ended September 30, 2019 (see Note 6).

Under the terms of the agreement, we acquired a pipeline of investigational medicines, including selpercatinib (LOXO-292), an oral RET inhibitor granted Breakthrough Therapy designation by the U.S. Food and Drug Administration, and LOXO-305, an oral BTK inhibitor.

Assets Acquired and Liabilities Assumed

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

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

Estimated Fair Value at February 15, 2019		
Acquired in-process research and development	$	4,670.0
Definite-lived intangibles [(1)]		1,020.0
Deferred income taxes		(1,146.9)
Other assets and liabilities - net		(31.4)
Total identifiable net assets		4,511.7
Goodwill [(2)]		2,406.0
Total consideration transferred - net of cash acquired	$	6,917.7

[(1)] Contract-based intangibles, 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 approximately 12 years from the acquisition date.

[(2)] The goodwill recognized from this acquisition is attributable primarily to future unidentified projects and products and the assembled workforce for Loxo and is not deductible for tax purposes.

Asset Acquisitions

The following table summarizes our asset acquisitions during the nine months ended September 30, 2019 and September 30, 2018:

Counterparty	Compound(s) or Therapy	Acquisition Month	Phase of Development [1]	Acquired IPR&D Expense
AC Immune SA	Tau aggregation inhibitor small molecules for the potential treatment of Alzheimer's disease and other neurodegenerative diseases	January 2019 & September 2019[2]	Pre-clinical	**$ 127.1**
ImmuNext, Inc.	Novel immunometabolism target	March 2019	Pre-clinical	**40.0**
Avidity Biosciences, Inc.	Potential new medicines in immunology and other select indications	April 2019	Pre-clinical	**25.0**
Centrexion Therapeutics Corporation	CNTX-0290, a novel, small molecule somatostatin receptor type 4 agonist	July 2019	Phase I	**47.5**
Sigilon Therapeutics	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	Translation inhibitors for selected neuroscience targets	July 2018	Pre-clinical	30.0

[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.

[2] We recognized acquired IPR&D expenses of $96.9 million in January 2019 upon entering into a license agreement and $30.2 million in September 2019 upon entering into an amendment to the license agreement.

In connection with these arrangements, our partners may be entitled to future royalties and/or commercial milestones based on sales should products be approved for commercialization and/or milestones based on the successful progress of compounds through the development process.

Divestiture

In April 2019, we announced an agreement to sell the rights in China for two legacy antibiotic medicines, as well as a manufacturing facility in Suzhou, China to Eddingpharm, a China-based specialty pharmaceutical company. Under terms of the agreement, we received a deposit of $75.0 million, and will receive a payment of $300.0 million upon successful closing of the transaction. The transaction is subject to customary closing conditions and regulatory approval.

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 2 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 milestones (deferred) capitalized for the compounds included in this collaboration:

Product Family	Milestones (Deferred) Capitalized [1]
Trajenta [2]	$ 446.4
Jardiance [3]	289.0
Basaglar	(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. This represents the cumulative amounts that have been (deferred) or capitalized from the start of this collaboration through the end of the reporting period.

[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.

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 products 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 its 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 net product revenue recognized with respect to Basaglar and collaboration and other revenue recognized with respect to the Trajenta and Jardiance families of products:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Basaglar	**$ 263.2**	$ 201.2	**$ 805.4**	$ 569.0
Jardiance	**240.7**	166.9	**676.2**	465.1
Trajenta	**155.5**	135.7	**441.4**	418.5

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 (JAK) 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. 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 significant milestones achieved:

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

As of September 30, 2019, 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.

The agreement provided 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 previously exercised its option to co-develop Olumiant in rheumatoid arthritis, atopic dermatitis, alopecia areata, and SLE. Incyte opted-out of co-development of all indications as of January 1, 2019. As a result, we will solely fund all further development and pay a lower royalty rate to Incyte on sales.

We record our sales of Olumiant to third parties as net product revenue with the royalty payments made to Incyte recorded as cost of sales. The following table summarizes our net product revenue recognized with respect to Olumiant:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Olumiant	**$ 114.6**	$ 55.6	**$ 299.1**	$ 132.5

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, 2019, 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: Discontinued Operations

On March 11, 2019, we completed the disposition of our remaining 80.2 percent ownership of Elanco common stock through a tax-free exchange offer. As a result, we have included the financial results of Elanco through March 11, 2019 and have presented Elanco as discontinued operations in our consolidated condensed financial statements for all periods presented.

The following table presents the revenue and net income from discontinued operations:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenue from discontinued operations	**$ —**	$ 755.0	**$ 580.0**	$ 2,261.4
Net income from discontinued operations	**—**	55.9	**3,680.5**	77.8

The operating results of Elanco were reported as net income from discontinued operations in the consolidated condensed statements of operations through March 11, 2019, the date of disposition, and were not material for all periods presented. For the nine months ended September 30, 2019, we recognized a gain related to the disposition of approximately $3.7 billion, which was also recorded in net income from discontinued operations in the consolidated condensed statement of operations.

In the consolidated condensed balance sheet as of December 31, 2018, the assets and liabilities associated with Elanco are classified as assets of discontinued operations and liabilities of discontinued operations, as appropriate. The following table presents the major classes of assets and liabilities from discontinued operations:

	December 31, 2018
Inventories	$ 1,013.7
Other current assets	1,215.4
Current assets of discontinued operations	$ 2,229.1
Goodwill	$ 2,980.9
Other intangibles, net	2,453.0
Property and equipment, net	923.4
Other assets	126.8
Noncurrent assets of discontinued operations	$ 6,484.1
Current liabilities of discontinued operations	$ 692.8
Long-term debt	$ 2,443.3
Other liabilities	299.0
Noncurrent liabilities of discontinued operations	$ 2,742.3

The gain related to the disposition of Elanco in the consolidated condensed statement of cash flows includes the operating results of Elanco, which were not material. Net cash provided by operating activities for our discontinued operations was approximately $450 million for the nine months ended September 30, 2018 and not material for the nine months ended September 30, 2019. The net cash flows of our discontinued operations for investing activities were not material for any period presented.

We entered into a transitional services agreement (TSA) with Elanco that is designed to facilitate the orderly transfer of various services to Elanco. The TSA relates primarily to administrative services, which are generally to be provided over 24 months from March 11, 2019, the disposition date. This agreement is not material and does not confer upon us the ability to influence the operating and/or financial policies of Elanco subsequent to the disposition date.

Note 6: Asset Impairment, Restructuring, and Other Special Charges

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Severance	**$ —**	$ (5.2)	**$ (3.6)**	$ (22.5)
Asset impairment and other special charges	**—**	48.1	**427.5**	96.7
Total asset impairment, restructuring, and other special charges	**$ —**	$ 42.9	**$ 423.9**	$ 74.2

Asset impairment and other special charges recognized during the three and nine months ended September 30, 2018 resulted primarily from asset impairment, exit costs, and other charges related to the sale of the Posilac® (rbST) brand and the associated Augusta, Georgia manufacturing site. These expenses were offset by a gain recognized associated with a pension curtailment (see Note 10 for additional discussion).

Asset impairment and other special charges recognized during the nine months ended September 30, 2019 consisted of $400.7 million related to the acquisition of Loxo, substantially all of which is associated with the accelerated vesting of Loxo employee equity awards.

We recorded severance charges in the second half of 2017 as part of planned restructuring activities 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 first nine months of 2018, we determined that more displaced employees than expected were able to find other roles within the company, resulting in a reduction in the actual severance costs incurred.

Note 7: 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. We seek to mitigate the risk associated with this concentration through 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.

We consider all highly liquid investments with a maturity of three months or less from the date of purchase to be cash equivalents. The cost of these investments approximates fair value.

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 and observable price changes 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, gains and losses are 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 foreign currency translation gains or losses due to spot rate fluctuations are reported as a component of accumulated other comprehensive loss. Derivative contracts that are not designated as hedging instruments are recorded at fair value with the gain or loss recognized in 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, 2019, we had outstanding foreign currency forward commitments to purchase 1.25 billion U.S. dollars and sell 1.13 billion euro, commitments to purchase 1.28 billion euro and sell 1.41 billion U.S. dollars, commitments to purchase 386.5 million U.S. dollars and sell 41.65 billion Japanese yen, and commitments to purchase 127.2 million British pounds and sell 158.4 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 $3.28 billion and $3.40 billion as of September 30, 2019 and December 31, 2018, respectively, of which $2.28 billion and $2.65 billion have been designated as, and are effective as, economic hedges of net investments in certain of our euro-denominated foreign operations as of September 30, 2019 and December 31, 2018, respectively. At September 30, 2019, we had outstanding cross currency swaps with notional amounts of $1.93 billion swapping U.S. dollars to euro, $1.00 billion swapping Swiss francs to U.S. dollars, and $268.0 million swapping U.S. dollars to British pounds, which have settlement dates ranging through 2028. Our cross-currency interest rate swaps, for which a majority 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.

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 seek to 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, 2019, all of our total long-term debt is at a fixed rate. We have converted approximately 12 percent of our long-term fixed-rate notes to floating rates through the use of interest rate swaps.

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. The change in fair value of these instruments is recorded as part of other comprehensive income (loss), and upon completion of a debt issuance and termination of the swap, is amortized to interest expense over the life of the underlying debt. As of September 30, 2019, the total notional amounts of forward-starting interest rate contracts in designated cash flow hedging instruments were $1.00 billion, which have settlement dates ranging between 2023 and 2025.

In February 2019, we issued $1.15 billion of 3.38 percent fixed-rate notes due in March 2029, $850.0 million of 3.88 percent fixed-rate notes due in March 2039, $1.50 billion of 3.95 percent fixed-rate notes due in March 2049, and $1.00 billion of 4.15 percent fixed-rate notes due in March 2059, with interest to be paid semi-annually. We used the net proceeds of $4.45 billion from the sale of these notes to fund the acquisition of Loxo and for general corporate purposes.

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Fair value hedges:				
Effect from hedged fixed-rate debt	**$ 49.5**	$ (19.6)	**$ 148.1**	$ (94.1)
Effect from interest rate contracts	**(49.5)**	19.6	**(148.1)**	94.1
Cash flow hedges:				
Effective portion of losses on interest rate contracts reclassified from accumulated other comprehensive loss	**2.8**	3.7	**10.6**	11.1
Net losses on foreign currency exchange contracts not designated as hedging instruments	**52.6**	0.7	**93.0**	76.5
Total	**$ 55.4**	$ 4.4	**$ 103.6**	$ 87.6

During the three and nine months ended September 30, 2019 and 2018, the amortization of losses related to the portion of our risk management hedging instruments, fair value hedges, and cash flow hedges that was excluded from the assessment of effectiveness was not material.

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Net investment hedges:				
Foreign currency-denominated notes	**$ 89.3**	$ (47.8)	**$ 112.6**	$ 53.0
Cross-currency interest rate swaps	**89.0**	14.7	**123.1**	52.3
Cash flow hedges:				
Forward-starting interest rate swaps	**(32.7)**	—	**(44.4)**	—
Cross-currency interest rate swaps	**16.6**	—	**(20.8)**	—

During the next 12 months, we expect to reclassify $16.3 million of pretax net losses on cash flow hedges from accumulated other comprehensive loss to other–net, (income) expense. During the three and nine months ended September 30, 2019, the amounts excluded from the assessment of hedge effectiveness recognized in other comprehensive income (loss) were not material.

Fair Value of Financial Instruments

The following tables summarize certain fair value information at September 30, 2019 and December 31, 2018 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:

			Fair Value Measurements Using			
	Carrying Amount	Cost [1]	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, 2019						
Cash equivalents	**$ 273.2**	**$ 273.2**	**$ 273.2**	**$ —**	**$ —**	**$ 273.2**
Short-term investments:						
U.S. government and agency securities	**$ 9.8**	**$ 9.8**	**$ 9.8**	**$ —**	**$ —**	**$ 9.8**
Corporate debt securities	**78.1**	**78.2**	**—**	**78.1**		**78.1**
Other securities	**1.3**	**1.4**	**—**	**1.3**	**—**	**1.3**
Short-term investments	**$ 89.2**					
Noncurrent investments:						
U.S. government and agency securities	**$ 76.3**	**$ 74.5**	**$ 76.3**	**$ —**	**$ —**	**$ 76.3**
Corporate debt securities	**348.8**	**345.1**	**—**	**348.8**	**—**	**348.8**
Mortgage-backed securities	**99.7**	**97.5**	**—**	**99.7**	**—**	**99.7**
Asset-backed securities	**32.9**	**32.5**	**—**	**32.9**	**—**	**32.9**
Other securities	**83.7**	**38.0**	**—**		**83.7**	**83.7**
Marketable equity securities	**483.8**	**235.1**	**483.8**	**—**	**—**	**483.8**
Equity investments without readily determinable fair values [2]	**427.0**					
Equity method investments [2]	**273.1**					
Noncurrent investments	**$ 1,825.3**					
December 31, 2018						
Cash equivalents	$ 5,727.1	$ 5,727.1	$ 5,727.1	$ —	$ —	$ 5,727.1
Short-term investments:						
U.S. government and agency securities	$ 16.9	$ 17.1	$ 16.9	$ —	$ —	$ 16.9
Corporate debt securities	62.2	62.6	—	62.2	—	62.2
Asset-backed securities	7.6	7.7	—	7.6	—	7.6
Other securities	1.5	1.5	—	1.5	—	1.5
Short-term investments	$ 88.2					
Noncurrent investments:						
U.S. government and agency securities	$ 149.1	$ 153.6	$ 149.1	$ —	$ —	$ 149.1
Corporate debt securities	568.0	587.8	—	568.0	—	568.0
Mortgage-backed securities	111.4	114.5	—	111.4	—	111.4
Asset-backed securities	27.7	27.9	—	27.7	—	27.7
Other securities	87.8	29.7	—	—	87.8	87.8
Marketable equity securities	357.5	238.3	357.5	—	—	357.5
Equity investments without readily determinable fair values [2]	414.7					
Equity method investments [2]	289.2					
Noncurrent investments	$ 2,005.4					

[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.

	Carrying Amount	Fair Value Measurements Using: Quoted Prices in Active Markets for Identical Assets (Level 1)	Fair Value Measurements Using: Significant Other Observable Inputs (Level 2)	Fair Value Measurements Using: Significant Unobservable Inputs (Level 3)	Fair Value
Short-term commercial paper borrowings					
September 30, 2019	**$ (1,557.8)**	**$ —**	**$ (1,550.1)**	**$ —**	**$ (1,550.1)**
December 31, 2018	(498.9)	—	(497.6)	—	(497.6)
Long-term debt, including current portion					
September 30, 2019	**$ (13,667.5)**	**$ —**	**$ (15,219.8)**	**$ —**	**$ (15,219.8)**
December 31, 2018	(9,799.7)	—	(9,970.0)	—	(9,970.0)

	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
September 30, 2019					
Risk-management instruments:					
Interest rate contracts designated as fair value hedges:					
Sundry	**$ 118.1**	**$ —**	**$ 118.1**	**$ —**	**$ 118.1**
Interest rate contracts designated as cash flow hedges:					
Other noncurrent liabilities	**(32.7)**	**—**	**(32.7)**	**—**	**(32.7)**
Cross-currency interest rate contracts designated as net investment hedges:					
Other receivables	**47.2**	**—**	**47.2**	**—**	**47.2**
Sundry	**76.3**	**—**	**76.3**	**—**	**76.3**
Cross-currency interest rate contracts designated as cash flow hedges:					
Other noncurrent liabilities	**(49.8)**	**—**	**(49.8)**	**—**	**(49.8)**
Foreign exchange contracts not designated as hedging instruments:					
Other receivables	**9.1**	**—**	**9.1**	**—**	**9.1**
Other current liabilities	**(10.8)**	**—**	**(10.8)**	**—**	**(10.8)**
December 31, 2018					
Risk-management instruments:					
Interest rate contracts designated as fair value hedges:					
Sundry	4.5	—	4.5	—	4.5
Other current liabilities	(22.3)	—	(22.3)	—	(22.3)
Other noncurrent liabilities	(19.0)	—	(19.0)	—	(19.0)
Cross-currency interest rate contracts designated as net investment hedges:					
Other receivables	69.2	—	69.2	—	69.2
Sundry	8.2	—	8.2	—	8.2
Other current liabilities	(9.2)	—	(9.2)	—	(9.2)
Cross-currency interest rate contracts not designated as hedging instruments					
Other noncurrent liabilities	(25.8)	—	(25.8)	—	(25.8)
Foreign exchange contracts not designated as hedging instruments:					
Other receivables	11.3	—	11.3	—	11.3
Other current liabilities	(16.3)	—	(16.3)	—	(16.3)

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.

The table below summarizes the contractual maturities of our investments in debt securities measured at fair value as of September 30, 2019:

		Maturities by Period			
	Total	Less Than 1 Year	1-5 Years	6-10 Years	More Than 10 Years
Fair value of debt securities	$ 645.6	$ 87.9	$ 377.9	$ 63.4	$ 116.4

The net unrealized gains (losses) recognized in our consolidated condensed statements of operations for equity securities were $26.4 million and $182.4 million for the three and nine months ended September 30, 2019, respectively, and $(40.8) million and $(3.4) million for the three and nine months ended September 30, 2018, respectively.

We adjust our equity investments without readily determinable fair values based upon changes in the equity instruments' values 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 impairment considerations, including the financial condition and near term prospects of the issuer, general market conditions, and industry specific factors. Adjustments recorded during the three and nine months ended September 30, 2019 and 2018 were not material.

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, 2019	December 31, 2018
Unrealized gross gains	**$ 12.2**	$ 0.8
Unrealized gross losses	**4.3**	29.0
Fair value of securities in an unrealized gain position	**476.4**	84.3
Fair value of securities in an unrealized loss position	**169.1**	858.6

We periodically assess our investment in available-for-sale securities for other-than-temporary impairment losses. Other than temporary impairment losses were not material in the three and nine months ended September 30, 2019. There were no other-than-temporary impairment losses in the three or nine months ended September 30, 2018.

For debt 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.

As of September 30, 2019, 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 39 percent of the fixed-rate debt securities in a loss position are investment-grade debt securities. As of September 30, 2019, 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,	
	2019	2018	2019	2018
Proceeds from sales	**$ 85.9**	$ 52.0	**$ 542.5**	$ 5,598.4
Realized gross gains on sales	**17.2**	0.4	**32.7**	8.1
Realized gross losses on sales	**0.1**	0.7	**6.9**	49.7

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.

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 $682.1 million and $696.2 million of accounts receivable as of September 30, 2019 and December 31, 2018, respectively, under these factoring arrangements. The costs of factoring such accounts receivable on our consolidated condensed results of operations for the three and nine months ended September 30, 2019 and 2018 were not material.

Note 8: Leases

We determine if an arrangement is a lease at inception. We have leases with terms up to 13 years for corporate offices, research and development facilities, vehicles, and equipment, including some of which have options to extend and/or early-terminate the leases. We determine the lease term by assuming the exercise of any renewal and/or early-termination options that are reasonably assured.

Beginning January 1, 2019, operating lease right-of-use assets have been presented in operating lease assets in our consolidated condensed balance sheet, and the current and long-term portions of operating lease liabilities are included in other current liabilities and noncurrent operating lease liabilities, respectively, in our consolidated condensed balance sheet. Short-term leases, which are deemed at inception to have a lease term of 12 months or less, are not recorded on the consolidated condensed balance sheet.

Operating lease assets represent our right to use an underlying asset for the lease term and operating lease liabilities represent our obligation to make lease payments arising from the lease. Operating lease assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. As most of our leases do not provide an implicit rate, we use our incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments.

Lease expense for operating lease assets, which is recognized on a straight-line basis over the lease term, was $38.2 million and $104.3 million, respectively, for the three and nine months ended September 30, 2019. Variable lease payments, which represent non-lease components such as maintenance, insurance and taxes, and which vary due to changes in facts or circumstances occurring after the commencement date other than the passage of time, are expensed in the period in which the payment obligation is incurred and were not material during the three and nine months ended September 30, 2019. Short-term lease expense was not material during the three and nine months ended September 30, 2019.

Supplemental balance sheet information related to operating leases as of September 30, 2019 was as follows:

Weighted-average remaining lease term	8 years
Weighted-average discount rate	3.7%

Supplemental cash flow information related to operating leases for the nine months ended September 30, 2019 was as follows:

Operating cash flows from operating leases	$	109.9
Right-of-use assets obtained in exchange for new operating lease liabilities		47.8

The annual minimum lease payments of our operating lease liabilities as of September 30, 2019 were as follows:

Year 1	$	144.6
Year 2		114.2
Year 3		78.3
Year 4		63.5
Year 5		56.0
After Year 5		262.2
Total lease payments		718.8
Less imputed interest		(107.3)
Total	$	611.5

Finance leases are included in property and equipment, short-term borrowings and current maturities of long-term debt, and long-term debt in our consolidated condensed balance sheets. Finance leases are not material to our consolidated condensed financial statements.

Note 9: Income Taxes

The effective tax rate was 10.8 percent for the three months ended September 30, 2019, driven by a net discrete tax benefit related to the settlement of certain tax matters as a result of statute of limitations expirations. The effective tax rate for the nine months ended September 30, 2019 was 12.8 percent, reflecting the non-deductibility of accelerated vesting of Loxo employee equity awards as part of the closing of the acquisition of Loxo, tax expenses associated with the suspension of promotion of Lartruvo®, as well as net discrete tax benefits resulting from the settlement of certain tax matters as a result of statute of limitations expirations and the resolution of certain global income tax audits. The effective tax rate for the three months ended September 30, 2018 was 18.5 percent, reflecting a net discrete tax detriment related to tax expenses resulting from U.S. tax reform and the Elanco separation. The effective tax rate for the nine months ended September 30, 2018 was 26.2 percent, as it also reflected these tax charges, as well as the non-deductible acquired IPR&D charges totaling $1.56 billion related to the acquisitions of ARMO and AurKa.

In 2017, the U.S. enacted the Tax Cuts and Jobs Act (2017 Tax Act), which significantly revised U.S. tax law. Guidance related to the 2017 Tax Act, including Notices, Proposed Regulations, and Final Regulations, has been issued, and we expect additional guidance will be issued by the end of 2019. This additional guidance could materially impact our assumptions and estimates used to record our U.S. federal and state income tax expense resulting from the 2017 Tax Act.

The U.S. examination of tax years 2013-2015 began in 2016, and certain matters were effectively settled during the second quarter of 2019. As a result, our gross uncertain tax positions were reduced by approximately $200 million, we made a cash payment of approximately $125 million, and our consolidated condensed results of operations were benefited by an immaterial reduction in tax expense. The examination for tax year 2015 remains ongoing, but we anticipate that the remaining matters will be effectively settled in the fourth quarter of 2019 and will result in an immaterial reduction in tax expense and gross uncertain tax positions. The U.S. examination of tax years 2016-2018 is expected to begin in the fourth quarter of 2019.

Note 10: Retirement Benefits

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

	Defined Benefit Pension Plans		Defined Benefit Pension Plans	
	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Components of net periodic benefit cost:				
Service cost	**$ 62.4**	$ 71.4	**$ 187.8**	$ 223.8
Interest cost	**121.0**	117.3	**364.4**	340.6
Expected return on plan assets	**(208.9)**	(211.2)	**(630.2)**	(632.1)
Amortization of prior service cost	**1.5**	1.1	**4.5**	3.5
Recognized actuarial loss	**70.9**	78.7	**213.6**	259.8
Curtailment loss	**—**	1.3	**—**	1.3
Net periodic benefit cost	**$ 46.9**	$ 58.6	**$ 140.1**	$ 196.9

	Retiree Health Benefit Plans		Retiree Health Benefit Plans	
	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Components of net periodic benefit income:				
Service cost	**$ 9.1**	$ 10.1	**$ 27.2**	$ 31.7
Interest cost	**14.5**	14.9	**43.5**	42.3
Expected return on plan assets	**(35.9)**	(44.8)	**(107.8)**	(132.6)
Amortization of prior service benefit	**(15.7)**	(19.3)	**(47.2)**	(60.2)
Recognized actuarial loss	**0.4**	0.8	**1.3**	5.4
Curtailment gain	**—**	(29.3)	**—**	(29.3)
Net periodic benefit income	**$ (27.6)**	$ (67.6)	**$ (83.0)**	$ (142.7)

We contributed approximately $30 million to satisfy minimum funding requirements to our defined benefit pension and retiree health benefit plans during the nine months ended September 30, 2019. Additional discretionary funding totaled $300 million during the nine months ended September 30, 2019. During the remainder of 2019, we expect to make contributions to our defined benefit pension and retiree health benefit plans of approximately $20 million to satisfy minimum funding requirements. No additional discretionary funding is planned for the remainder of 2019.

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 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.

Note 11: Contingencies

We are a party to various legal actions and government investigations. The most significant of these are described below. It is not possible to determine the outcome of these matters, and we cannot reasonably estimate the maximum potential exposure or the range of possible loss in excess of amounts accrued for any of these matters; however, we believe that, except as noted below with respect to the Alimta 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., a number of countries in Europe, and Japan 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 in the U.S. 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 in any of the below jurisdictions 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. In October 2017, the U.S. Patent and Trademark Office (USPTO) issued written decisions in our favor following *inter partes review* (IPR) of our U.S. vitamin regimen patent, finding that the generic company petitioners failed to show that the claims in our patent are unpatentable. In April 2019, the U.S. Court of Appeals for the Federal Circuit affirmed the written decisions of the USPTO IPR upholding our U.S. vitamin regimen patent. There were five remaining ANDA applicants who agreed to a preliminary injunction or stay pending the appeal of the IPR decision. In view of the Court of Appeals' affirmance, favorable judgments have been entered by the U.S. District Court for the Southern District of Indiana against all five of these remaining ANDA applicants.

We also 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. (Apotex) in response to their applications to market products using alternative forms of pemetrexed (the active ingredient in Alimta) products. Trial against Apotex is scheduled for January 2020. The lawsuit against Actavis has been stayed, pending the conclusion of the Dr. Reddy's Laboratories' (Dr. Reddy) and Hospira, Inc.'s (Hospira) appeals (described below). We filed a similar lawsuit in the U.S. District Court for the District of Delaware against Eagle Pharmaceuticals, Inc. (Eagle). Trial against Eagle is scheduled for late October 2019 and we expect a decision later in the fourth quarter of 2019 or the first quarter of 2020. 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 and Hospira's proposed products would infringe our method of use patent under the doctrine of equivalents. The district court also ruled that the use of Hospira's proposed product would literally infringe our method of use patent. In August 2019, the U.S. Court of Appeals for the Federal Circuit affirmed the district court's ruling that the use of Dr. Reddy's and Hospira's proposed products would infringe our patent under the doctrine of equivalents, but reversed the finding of literal infringement with respect to Hospira's product. Dr. Reddy and Hospira have petitioned for rehearing of the court's doctrine of equivalents ruling.

European Patent Litigation

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. 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 (including generics currently on the market at risk in France,

Germany, and the Netherlands) and that additional generic competitors may choose to launch at risk. We will continue to seek to remove any generic pemetrexed products launched at risk in European markets, including Germany, France, and the Netherlands, seek damages with respect to such launches, and defend our patents against validity challenges.

Japanese Administrative Proceedings

Three separate sets of demands for invalidation of our two Japanese vitamin regimen patents, involving several companies, have been filed with the Japanese Patent Office (JPO). The JPO rejected a demand for invalidation by Sawai Pharmaceutical Co., Ltd., which was affirmed on appeal in 2017. In July 2018, the JPO issued written decisions dismissing demands brought by Nipro Corporation (Nipro) for invalidation of our two Japanese vitamin regimen patents. Nipro filed an appeal, and we anticipate decisions by the Japan Intellectual Property High Court later in the fourth quarter of 2019. We also anticipate the JPO will schedule a hearing with respect to the third set of demands, brought by Hospira, after the Nipro decision is handed down. If upheld through all challenges, these patents would provide intellectual property protection for Alimta until June 2021. Notwithstanding our patents, generic versions of Alimta received regulatory approval 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 Com*pany) 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 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 and dismissed the suits. The plaintiffs subsequently 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.

Brazil Litigation – Cosmopolis Facility

Labor Attorney 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. In May 2014, the labor court judge ruled against Lilly Brasil, ordering it to undertake several actions of unspecified financial impact, including paying lifetime health coverage 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 appealed this decision. In July 2018, the appeals court affirmed the labor court's ruling with the total financial impact of the ruling estimated to be approximately 500 million Brazilian real (approximately $120 million as of September 30, 2019). The appeals court restricted the broad health coverage awarded by the labor court to health problems that claimants could show arose from exposure to the alleged contamination. In August 2019, Lilly Brasil filed an appeal to the superior labor court. In September 2019, the appeals court stayed a number of elements of its prior decision, including the obligation to provide health coverage for contractors, their children, and children of employees who worked at the Cosmopolis facility, pending the determination of Lilly Brasil's appeal to the superior labor court.

In June 2019, the Labor Attorney filed an application in the labor court for enforcement of the healthcare coverage granted by the appeals court in its July 2018 ruling and requested restrictions on Lilly Brasil's assets in Brazil. In July 2019, the labor court issued a ruling requiring either a freeze of Lilly Brasil's immovable property or, alternatively, a security deposit of 500 million Brazilian real (approximately $120 million as of September 30, 2019). Lilly Brasil filed a writ of mandamus challenging this ruling and we expect a decision later in the fourth quarter of 2019. In the meantime, the labor court stayed the Labor Attorney's application to enforce the previous healthcare coverage ruling until after the appeals court ruled on the various motions pending before it. Given the appeals court's stay in September 2019 of a number of elements of its prior decision described above, we intend to file a motion to strike the Labor Attorney's application to enforce the previous healthcare coverage.

Individual Former Employee Litigation

We are also named in approximately 30 lawsuits filed in the same labor court by individual former employees making similar claims. These lawsuits are each at various stages in the litigation process, with judgments being handed down in approximately half of the lawsuits, nearly all of which are on appeal in the labor courts.

Mental Anguish Litigation

Lilly Brasil and Elanco Quimica Ltda. have been named in two similar lawsuits in the same labor court involving approximately 410 individual plaintiffs. We agreed to indemnify Elanco Quimica Ltda. in this litigation as part of the divestiture of Elanco. In the first lawsuit (involving approximately 305 plaintiffs), plaintiffs alleged harm to employees and former employees, and their dependents. In the second lawsuit (involving approximately 105 plaintiffs), plaintiffs alleged harm to contractors and suppliers, and their dependents. The plaintiffs' claims in these two lawsuits relate only to mental anguish attributable to the possibility of illness due to alleged exposure to heavy metals or other contaminants. In 2017, the labor court dismissed the claims brought by all but the first named plaintiff in each of the lawsuits. The plaintiffs in both lawsuits appealed. In April 2019 and July 2019, the appeals court issued written decisions rejecting the plaintiffs' appeals in both of these lawsuits. The appeals court's decisions were procedurally based and were without a judgment on the merits, meaning that the plaintiffs are able to bring individual actions, notwithstanding the court's rulings.

We believe all of these lawsuits are without merit and are defending against them vigorously.

Adocia, S.A.

We were named as a respondent in an arbitration filed by Adocia, S.A. (Adocia), with which we entered into agreements for the co-development of an ultra-rapid insulin product. Adocia alleged that we misappropriated and misused Adocia's confidential information and intellectual property and sought approximately $1.39 billion in damages and other specific relief. We asserted several counterclaims relating to fraudulent misrepresentation and sought approximately $188 million in damages. In August 2019, the arbitration panel ruled that we did not misappropriate or misuse Adocia's intellectual property or confidential information and denied Adocia's claims for damages. The arbitration panel also denied our counterclaims.

Throughout the dispute process, Adocia 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. While inventorship of these two patents was not at issue in the arbitration proceedings, 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. In September 2019, a consent judgment was entered in our favor confirming that inventorship is correct for the relevant patents and dismissing with prejudice all of Adocia's counterclaims, which improperly asserted that certain Adocia employees should be named as inventors.

Insulin Pricing Litigation and Investigations

Litigation

We, along with Sanofi and Novo Nordisk, are 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 Racketeer Influenced and Corrupt Organization Act (federal RICO Act). Separately, we, along with Sanofi and Novo Nordisk, are named as defendants in *MSP Recovery Claims, Series, LLC et al. v. Sanofi Aventis U.S. LLC et al.*, in the same court, seeking damages under various state consumer protection laws, common law fraud, unjust enrichment, and the federal RICO Act. Also in the same court, we, along with Sanofi and Novo Nordisk, have been named as defendants in a purported class action lawsuit, *Prof'l Drug Co., Inc. & FWK Holdings, LLC v. Novo Nordisk Inc. et al.*, seeking damages under the federal and New Jersey RICO Acts.

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. Additionally, the Kentucky Attorney General's Office filed a complaint against us, Sanofi, and Novo Nordisk, *Commonwealth of Kentucky v. Novo Nordisk, Inc. et al.*, in Kentucky state court, alleging violations of the Kentucky consumer protection law, false advertising, and unjust enrichment.

We believe all of these claims are without merit and are defending against them vigorously.

Investigations, Subpoenas, and Inquiries

We have received a subpoena from the New York Attorney General's Office and civil investigative demands from the Washington and New Mexico Attorney General Offices relating to the pricing and sale of our insulin products. The Offices of the Attorney General in Mississippi, Washington D.C., California, Florida, Hawaii, and Nevada have requested information relating to the pricing and sale of our insulin products. We also received interrogatories from the California Attorney General's Office regarding our competition in the long-acting insulin market. We received two requests from the House of Representatives' Committee on Energy and Commerce and a request from the Senate's Committee on Health, Education, Labor, and Pensions, seeking certain information related to the pricing of insulin products, among other issues. We also received a request from the House of Representatives' Committee on Oversight and Reform and one from the Senate's Committee on Finance, both of which seek detailed commercial information and business records. We are cooperating with all of these aforementioned requests and investigations.

Product Liability Insurance

Because of the nature of pharmaceutical products, it is possible that we could become subject to large numbers of additional 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 and previously marketed products.

Note 12: Other Comprehensive Income (Loss)

The following tables summarize the activity related to each component of other comprehensive income (loss) during the three months ended September 30, 2019 and 2018:

	Continuing Operations					
(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**	**Discontinued Operations**	**Accumulated Other Comprehensive Loss**
Balance at July 1, 2019	**$ (1,570.0)**	**$ 4.5**	**$ (3,763.3)**	**$ (271.7)**	**$ —**	**$ (5,600.5)**
Other comprehensive income (loss) before reclassifications	**(192.0)**	**1.5**	**21.3**	**(12.7)**	**—**	**(181.9)**
Net amount reclassified from accumulated other comprehensive loss	**—**	**0.6**	**45.1**	**2.2**	**—**	**47.9**
Net other comprehensive income (loss)	**(192.0)**	**2.1**	**66.4**	**(10.5)**	**—**	**(134.0)**
Balance at September 30, 2019	**$ (1,762.0)**	**$ 6.6**	**$ (3,696.9)**	**$ (282.2)**	**$ —**	**$ (5,734.5)**

	Continuing Operations					
(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**	**Discontinued Operations**	**Accumulated Other Comprehensive Loss**
Balance at July 1, 2018	$ (1,561.5)	$ (18.1)	$ (4,160.0)	$ (228.5)	$ (140.6)	$ (6,108.7)
Other comprehensive income (loss) before reclassifications	(23.1)	1.1	532.6	—	99.7	610.3
Net amount reclassified from accumulated other comprehensive loss	—	(0.2)	48.4	2.9	(1.2)	49.9
Net other comprehensive income (loss)	(23.1)	0.9	581.0	2.9	98.5	660.2
Balance at September 30, 2018[4]	$ (1,584.6)	$ (17.2)	$ (3,579.0)	$ (225.6)	$ (42.1)	$ (5,448.5)

The following tables summarize the activity related to each component of other comprehensive income (loss) during the nine months ended September 30, 2019 and 2018:

	Continuing Operations					
(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**	**Discontinued Operations**	**Accumulated Other Comprehensive Loss**
Balance at January 1, 2019 [1]	**$ (1,569.7)**	**$ (22.1)**	**$ (3,852.7)**	**$ (238.9)**	**$ (56.8)**	**$ (5,740.2)**
Other comprehensive income (loss) before reclassifications	**(192.3)**	**26.7**	**19.0**	**(51.7)**	**(27.2)**	**(225.5)**
Net amount reclassified from accumulated other comprehensive loss	**—**	**2.0**	**136.8**	**8.4**	**84.0**	**231.2**
Net other comprehensive income (loss)	**(192.3)**	**28.7**	**155.8**	**(43.3)**	**56.8**	**5.7**
Balance at September 30, 2019	**$ (1,762.0)**	**$ 6.6**	**$ (3,696.9)**	**$ (282.2)**	**$ —**	**$ (5,734.5)**

	Continuing Operations					
(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**	**Discontinued Operations**	**Accumulated Other Comprehensive Loss**
Balance at January 1, 2018 [2]	$ (1,191.7)	$ 113.5	$ (4,311.3)	$ (234.3)	$ (71.1)	$ (5,694.9)
Reclassification due to adoption of new accounting standard [3]	—	(128.9)	—	—	—	(128.9)
Other comprehensive income (loss) before reclassifications	(392.9)	31.0	567.6	—	28.8	234.5
Net amount reclassified from accumulated other comprehensive loss	—	(32.8)	164.7	8.7	0.2	140.8
Net other comprehensive income (loss)	(392.9)	(1.8)	732.3	8.7	29.0	375.3
Balance at September 30, 2018[4]	$ (1,584.6)	$ (17.2)	$ (3,579.0)	$ (225.6)	$ (42.1)	$ (5,448.5)

[1] Accumulated other comprehensive loss as of January 1, 2019 consists of $5.73 billion of accumulated other comprehensive loss attributable to controlling interest and $11.0 million of accumulated other comprehensive loss 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.

[3] This reclassification consists of $105.2 million of accumulated other comprehensive loss attributable to controlling interest and $23.7 million of accumulated other comprehensive loss attributable to noncontrolling interest.

[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 noncontrolling interest.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
Tax benefit (expense)	**2019**	**2018**	**2019**	**2018**
Foreign currency translation gains/losses	**$ (5.1)**	$ 7.0	**$ (17.1)**	$ (11.2)
Unrealized net gains/losses on securities	**(0.5)**	(0.2)	**(7.4)**	1.1
Defined benefit pension and retiree health benefit plans	**(17.4)**	(152.4)	**(42.2)**	(190.3)
Effective portion of cash flow hedges	**2.7**	(0.8)	**11.4**	(2.3)
Benefit/(provision) for income taxes allocated to other comprehensive income (loss) items	**$ (20.3)**	$ (146.4)	**$ (55.3)**	$ (202.7)

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 7), 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 September 30,		Nine Months Ended September 30,		Affected Line Item in the Consolidated Condensed Statements of Operations
	2019	**2018**	**2019**	**2018**	
Amortization of retirement benefit items:					
Prior service benefits, net	**$ (14.2)**	$ (18.2)	**$ (42.7)**	$ (56.7)	Other–net, (income) expense
Actuarial losses, net	**71.3**	79.5	**214.9**	265.2	Other–net, (income) expense
Total before tax	**57.1**	61.3	**172.2**	208.5	
Tax benefit	**(12.0)**	(12.9)	**(35.4)**	(43.8)	Income taxes
Net of tax	**45.1**	48.4	**136.8**	164.7	
Other, net of tax	**2.8**	2.7	**10.4**	(24.1)	Other–net, (income) expense
Reclassifications from continuing operations (net of tax)	**47.9**	51.1	**147.2**	140.6	
Reclassifications from discontinued operations (net of tax)	**—**	(1.2)	**84.0**	0.2	Net income from discontinued operations
Total reclassifications for the period (net of tax)	**$ 47.9**	$ 49.9	**$ 231.2**	$ 140.8	

Note 13: Other–Net, (Income) Expense

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	**2018**	**2019**	**2018**
Interest expense	**$ 107.4**	$ 60.8	**$ 304.7**	$ 185.3
Interest income	**(17.3)**	(32.1)	**(67.2)**	(118.8)
Retirement benefit plans	**(52.2)**	(62.5)	**(157.9)**	(173.3)
Other income	**(13.0)**	35.7	**(108.3)**	(7.4)
Other–net, (income) expense	**$ 24.9**	$ 1.9	**$ (28.7)**	$ (114.2)

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" of this Quarterly Report on Form 10-Q and Item 1A, "Risk Factors," of Part I of our Annual Report on Form 10-K for the year ended December 31, 2018, 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,		
	2019	2018	Percent Change	2019	2018	Percent Change
Revenue	**$ 5,476.6**	$ 5,306.9	3	**$ 16,205.5**	$ 15,855.7	2
Gross margin	**4,301.6**	4,154.0	4	**12,766.9**	12,303.9	4
Gross margin as a percent of revenue	**78.5%**	78.3%		**78.8%**	77.6%	
Operating expenses	**$ 2,793.2**	$ 2,738.1	2	**$ 8,529.3**	$ 7,940.9	7
Acquired in-process research and development (IPR&D)	**77.7**	30.0	NM	**239.6**	1,654.5	(86)
Asset impairment, restructuring, and other special charges	**—**	42.9	NM	**423.9**	74.2	NM
Net income from continuing operations	**1,253.9**	1,093.6	15	**3,142.2**	2,029.2	55
Net income from discontinued operations	**—**	55.9	NM	**3,680.5**	77.8	NM
Net income	**1,253.9**	1,149.5	9	**6,822.7**	2,107.0	NM
EPS from continuing operations	**1.37**	1.07		**3.33**	1.96	
EPS from discontinued operations	**—**	0.05		**3.91**	0.07	
EPS	**1.37**	1.12	22	**7.24**	2.03	NM

NM - not meaningful

Revenue increased for the three and nine months ended September 30, 2019 driven by increased volume, partially offset by lower realized prices and the unfavorable impact of foreign exchange rates. Operating expenses increased for the three and nine months ended September 30, 2019, reflecting additional investments in recently launched products and late-stage assets. The increase in net income for the three months ended September 30, 2019 was primarily driven by higher gross margin and, to a lesser extent, lower tax expense and asset impairment, restructuring and other special charges, partially offset by higher operating expenses and acquired IPR&D charges. EPS for the three months ended September 30, 2019 also significantly benefited as a result of the retirement of shares in the Elanco Animal Health (Elanco) exchange offer and other share repurchases. The increase in net income and EPS for the nine months ended September 30, 2019 was driven primarily by the gain recognized on the disposition of Elanco.

The following highlighted items also affect comparisons of our financial results for the three and nine months ended September 30, 2019 and 2018:

2019

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

- We recognized acquired IPR&D charges of $77.7 million and $239.6 million for the three and nine months ended September 30, 2019, respectively. The charge for the three months ended September 30, 2019 was related to collaborations with Centrexion Therapeutics Corporation (Centrexion) and AC Immune SA (AC Immune). The charges for the nine months ended September 30, 2019 also included charges related to collaborations with ImmuNext, Inc. (ImmuNext) and Avidity Biosciences, Inc (Avidity).

Asset Impairment, Restructuring, and Other Special Charges (Note 6 to the consolidated condensed financial statements)

- We recognized charges of $423.9 million for the nine months ended September 30, 2019, primarily associated with the accelerated vesting of Loxo Oncology, Inc. (Loxo) employee equity awards as a result of the closing of the acquisition of Loxo.

2018

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

- We recognized acquired IPR&D charges of $30.0 million and $1.65 billion 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 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 collaboration with Sigilon Therapeutics (Sigilon). The charges for ARMO and AurKa totaling $1.56 billion were not tax deductible.

Asset Impairment, Restructuring, and Other Special Charges (Note 6 to the consolidated condensed financial statements)

- We recognized charges of $42.9 million and $74.2 million for the three and nine months ended September 30, 2018, primarily related to the sale of Posilac® (rbST) brand and the associated Augusta, Georgia manufacturing site.

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 condition described. The first quarter in which the NMEs initially were approved in any major geography for any indication is shown in parentheses:

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 on our Quarterly Report on Form 10-Q for the quarter ended March 31, 2019 for discussion of the legal proceedings involving Teva Pharmaceuticals International GMBH and Teva Pharmaceuticals USA, Inc.

Lasmiditan (REYVOW™) (Q4 2019)—an oral 5-HT1F agonist for the acute treatment of migraine.

Nasal glucagon* (Baqsimi®) (Q3 2019)—a glucagon nasal powder formulation for the treatment of severe hypoglycemia in patients with diabetes ages four years and above.

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

Flortaucipir (Q3 2019)**—a positron emission tomography (PET) tracer intended to image tau (or neurofibrillary) tangles in the brain, which are an indicator of Alzheimer's disease. In the United States (U.S.), flortaucipir is protected by compound patents (2029).

Ultra-rapid Lispro* (Q1 2019)—an ultra-rapid insulin for the treatment of type 1 and type 2 diabetes. In the U.S., ultra-rapid lispro is protected by formulation patents (2035 and 2036). In Europe, ultra-rapid lispro is protected by a formulation patent (2035). In Japan, ultra-rapid lispro is protected by a formulation patent (2035 and 2036, plus possible patent extensions) and data protection (4 years) expected upon approval.

The following NMEs and diagnostic agent are currently in Phase III clinical trial testing for potential use in the conditions described below but have not yet been submitted for regulatory 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:

Mirikizumab* (Q2 2018)—a 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. (Pfizer)).

Tirzepatide* (Q4 2018)—a long-acting, combination therapy of glucose-dependent insulinotropic polypeptide (GIP) and glucagon-like peptide 1 for the treatment of type 2 diabetes.

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

** Diagnostic agent

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, 2019:

Compound	Indication	U.S.	Europe	Japan	Developments
Endocrinology					
Baqsimi	Severe hypoglycemia	Launched	Submitted	Phase III	Launched in the U.S. in third quarter of 2019. In October 2019, the European regulatory authority issued a positive opinion recommending approval.
Tirzepatide	Type 2 diabetes	Phase III			Phase III trials are ongoing.
Ultra-rapid Lispro	Type 1 and 2 diabetes	Submitted			Submitted to regulatory authorities in Europe and Japan in first quarter of 2019. Submitted to the U.S. Food and Drug Administration (FDA) in the third quarter of 2019.
Immunology					
Mirikizumab	Crohn's Disease	Phase III			Phase III trials began in third quarter of 2019.
	Psoriasis	Phase III			Phase III trials are ongoing.
	Ulcerative colitis	Phase III			Phase III trials are ongoing.
Neuroscience					
Emgality	Cluster headache	Launched	Submitted	Phase III	Submitted to European regulatory authorities in first quarter of 2019. Approved and launched in the U.S. in the second quarter of 2019.
	Migraine prevention	Launched		Phase III	Launched in Europe in the first quarter of 2019.

Compound	Indication	U.S.	Europe	Japan	Developments
Flortaucipir	Alzheimer's disease diagnostic	Submitted	Phase III		Submitted to the FDA in the third quarter of 2019.
REYVOW	Acute treatment of migraine	Approved	Phase III		Approved by the FDA in October 2019. Recommended controlled substance classification is under review by the Drug Enforcement Administration and is expected within 90 days of the FDA approval.
Solanezumab	Preclinical Alzheimer's disease	Phase III			Phase III trial is ongoing.
Tanezumab	Osteoarthritis pain	Phase III			In the third quarter of 2018 and January 2019, announced multiple Phase III trials met several primary endpoints. In April 2019, announced the results of the long-term Phase III study in which the 5mg dose met two of the three co-primary endpoints and the 2.5mg dose did not meet any of the three co-primary endpoints. In partnership with Pfizer, we are pursuing U.S. submission by the first quarter of 2020, followed by submission in Europe and Japan.
	Chronic low back pain	Phase III			In the first quarter of 2019, announced Phase III trial met primary endpoint for the 10mg dose and did not meet primary endpoint on the 5mg dose. In the third quarter of 2019, announced results from a Phase 3 study evaluating long-term safety and efficacy in Japan. In partnership with Pfizer, announced in the third quarter of 2019 that we are not planning regulatory submission. We will maintain an open dialogue with regulatory authorities on potential future regulatory pathways.
	Cancer pain	Phase III			Phase III trial is ongoing.
Oncology					
Lartruvo®	Soft tissue sarcoma	Withdrawn	Withdrawing	Not Submitting	In the first quarter of 2019, announced confirmatory phase III trial did not meet primary endpoint. As this trial did not confirm clinical benefit, we suspended promotion globally and withdrew in the U.S. in the third quarter of 2019. For countries in Europe, we have withdrawn or are in the process of withdrawing.
Pegilodecakin	Pancreatic cancer	Phase III			In October 2019, announced phase III trial did not meet primary endpoint of overall survival. Phase II trials for other indications are ongoing.

In addition to the developments discussed above, we intend to submit a new drug application to the FDA based on currently-available data from Phase II clinical trials for selpercatinib, also known as LOXO-292, an oral RET inhibitor granted Breakthrough Therapy designation by the FDA. The Breakthrough Therapy designation is intended to expedite the development and review of drugs for serious or life threatening conditions where preliminary clinical evidence demonstrates that the drug may have substantial improvement on at least one clinically significant endpoint over available therapy. The submission to the FDA is expected to occur by the end of 2019.

Other Matters

Elanco

On March 11, 2019, we completed the disposition of our remaining 80.2 percent ownership of Elanco common stock through a tax-free exchange offer. As a result, we recognized a gain on the disposition of approximately $3.7 billion in the first quarter of 2019. See Note 5 to the consolidated condensed financial statements for further discussion.

As a result of the disposition, we now operate as a single segment. See Note 1 to the consolidated condensed financial statements for further discussion.

Patent Matters

We depend on patents or other forms of intellectual-property protection for most of our revenue, cash flows, and earnings.

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 have faced and remain exposed to generic competition following the loss of exclusivity, which has rapidly and severely eroded revenue and is likely to continue to erode revenue.

Our formulation patents for Forteo® expired in December 2018, and our use patents expired in August 2019 in major European markets and the U.S. Both the formulation patent and the use patent expired in August 2019 in Japan. While it is difficult to estimate the severity of the impact and timing of generic and/or biosimilar competition, we expect a rapid and severe decline in revenue in the U.S. as a result of generic competition. Outside the U.S., we expect a decline in revenue following a recent biosimilar launch; 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.

The Alimta® vitamin regimen patents, which we expect to 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 are aware that several companies have received approval to market generic versions of pemetrexed in major European markets (including Germany France, and the Netherlands) and that additional generic competitors may choose to launch at risk. Although we will continue to seek to remove any such products, generic product entry is resulting in some loss in revenue. We expect that further 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 11 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 patents.

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 competitor launched a similar version of insulin lispro in certain European markets in 2017 and in the U.S. in the second quarter of 2018. While it is difficult to estimate the severity of the impact of 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. Additionally, in the second quarter of 2019, we launched our own insulin lispro authorized generic.

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 expense. 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

U.S.

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 related to Medicaid prescription drug coverage and manufacturer drug rebates, 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 effect this legislation will have on our business. The Bipartisan Budget Act, enacted in February 2018, requires manufacturers of brand-name drugs, biologics, and biosimilars to pay a 70 percent discount in the Medicare Part D Coverage Gap, up from the previous 50 percent discount. This increase in coverage gap discounts became effective at the beginning of 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 proposed policy changes. We believe the effect of certain of these proposals would be positive for our business while others 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 April 2019, the White House signed into law targeted amendments to the Medicaid Drug Rebate Program statute. We do not believe this will have a material impact to our business. In September 2019, the White House signed into law the Fair and Accurate Medicaid Pricing Act. We are currently reviewing the new statute, the impact of which is uncertain at this time. Several states passed importation legislation, including Colorado, Florida, Maine, and Vermont. Specifically, the state of Florida is working with the Administration to implement an importation program from Canada as early as 2020. We are currently reviewing the state legislation, as well as corresponding proposed federal rulemaking and guidance recently announced by the Department of Health and Human Services and the FDA, the impact of which is uncertain at this time.

In the private sector, consolidation and integration among healthcare providers is also a major factor in the competitive marketplace for human pharmaceuticals. Health plans, pharmacy 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. Value-based agreements are another tool which may be utilized between payers and pharmaceutical companies as formulary placement and pricing are negotiated. 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 continue to negatively affect future consolidated results of operations and cash flows. In addition to formulary placement, changes in insurance designs continue to drive greater consumer cost sharing through high deductible plans and higher co-insurance or co-pays (including co-pay accumulator and maximizer programs). We continue to invest in patient affordability solutions (resulting in lower revenue) in an effort to assist patients in affording their medicines.

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, litigation, 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 tax laws, regulations, administrative practices, and interpretations could adversely affect our future effective tax rates. In 2017, the U.S. enacted the Tax Cuts and Jobs Act (2017 Tax Act) significantly revising U.S. tax law, and other countries are actively considering or enacting tax law changes. Further, 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.

Subsequent to the enactment of the 2017 Tax Act, several items of additional guidance have been issued, including Notices, Proposed Regulations, and Final Regulations. We expect that additional guidance will be issued by the end of 2019 which could materially affect the assumptions and estimates used to record our U.S. federal and state income tax expense resulting from the 2017 Tax Act.

Acquisitions

We strategically invest in external research and technologies that we believe to complement and strengthen our own efforts. These investments can take many forms, including licensing arrangements, collaborations, and acquisitions. We view our business development activity as an important way to achieve our strategies, as we seek to bolster our pipeline and enhance shareholder value. We continue to evaluate business development transactions that have the potential to strengthen our business.

In February 2019, we acquired all shares of Loxo for a purchase price of $6.92 billion, net of cash acquired. Under the terms of the agreement, we acquired a pipeline of investigational medicines, including selpercatinib (LOXO-292), an oral RET inhibitor that has been granted Breakthrough Therapy designation by the FDA, and LOXO-305, an oral BTK inhibitor. See Note 3 to the consolidated condensed financial statements for further discussion regarding our recent acquisitions of businesses and assets.

Legal Matters

Information regarding contingencies relating to certain legal proceedings can be found in Item 1. "Legal Proceedings" of Part II of this Quarterly Report on Form 10-Q and is incorporated here by reference.

Revenue

The following table summarizes our revenue activity by region:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2019	2018	Percent Change	2019	2018	Percent Change
U.S. [1]	**$ 3,060.2**	$ 3,070.5	—	**$ 9,203.5**	$ 9,108.5	1
Outside U.S.	**2,416.4**	2,236.4	8	**7,002.1**	6,747.3	4
Revenue	**$ 5,476.6**	$ 5,306.9	3	**$ 16,205.5**	$ 15,855.7	2

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, 2019 vs. 2018			Nine Months Ended September 30, 2019 vs. 2018		
	U.S.	Outside U.S.	Consolidated	U.S.	Outside U.S.	Consolidated
Volume	5 %	12 %	8 %	5 %	10 %	7 %
Price	(5)	(2)	(4)	(4)	(2)	(3)
Foreign exchange rates	—	(2)	(1)	—	(4)	(2)
Percent change	— %	8 %	3 %	1 %	4 %	2 %

Numbers may not add due to rounding.

In the U.S. for the three and nine months ended September 30, 2019, the volume increase was primarily driven by Trulicity®, Taltz®, Emgality, Jardiance®, Verzenio®, and Basaglar®, partially offset by decreased volume for products that have lost exclusivity, including Cialis, as well as the impact from the withdrawal of Lartruvo. The decrease in realized prices for the three and nine months ended September 30, 2019 was primarily due to increased coverage gap funding requirements in Medicare Part D. The decrease in realized prices for the three months ended September 30, 2019 was also due to higher contracted rebates.

Outside the U.S. for the three and nine months ended September 30, 2019, the volume increase was primarily driven by Trulicity, Olumiant®, Jardiance, Taltz, and Verzenio, partially offset by the unfavorable impact of foreign exchange rates and, to a lesser extent, lower realized prices.

The following table summarizes our revenue activity by product:

	Three Months Ended September 30,				
	2019			2018	
Product	**U.S. [1]**	**Outside U.S.**	**Total**	**Total**	**Percent Change**
Trulicity	**$ 755.5**	**$ 256.0**	**$ 1,011.5**	$ 816.2	24
Humalog [2]	**356.2**	**292.6**	**648.9**	664.6	(2)
Alimta	**282.4**	**225.9**	**508.2**	520.5	(2)
Forteo	**175.1**	**195.7**	**370.7**	390.8	(5)
Taltz	**250.6**	**89.4**	**340.0**	263.9	29
Humulin®	**218.2**	**103.6**	**321.8**	322.1	—
Basaglar	**202.4**	**60.8**	**263.2**	201.2	31
Jardiance [3]	**140.6**	**100.1**	**240.7**	166.9	44
Cyramza®	**82.5**	**157.5**	**240.0**	198.4	21
Cialis	**30.9**	**153.4**	**184.3**	467.1	(61)
Cymbalta®	**10.3**	**168.3**	**178.6**	172.0	4
Verzenio	**124.8**	**32.4**	**157.2**	84.5	86
Trajenta® [4]	**60.1**	**95.4**	**155.5**	135.7	15
Erbitux®	**113.8**	**14.8**	**128.6**	159.5	(19)
Olumiant	**12.1**	**102.5**	**114.6**	55.6	NM
Zyprexa®	**11.2**	**94.2**	**105.4**	109.9	(4)
Strattera®	**8.7**	**43.3**	**52.1**	98.7	(47)
Emgality	**45.8**	**1.9**	**47.7**	—	NM
Other products	**179.0**	**228.6**	**407.6**	479.3	(15)
Revenue	**$ 3,060.2**	**$ 2,416.4**	**$ 5,476.6**	$ 5,306.9	3

Numbers may not add due to rounding.

NM - not meaningful

[1] U.S. revenue includes revenue in Puerto Rico.

[2] Humalog revenue includes Insulin Lispro.

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

[4] Trajenta revenue includes Jentadueto®.

	Nine Months Ended September 30,				
	2019			2018	
Product	U.S. [1]	Outside U.S.	Total	Total	Percent Change
Trulicity	**$ 2,213.2**	**$ 706.5**	**$ 2,919.7**	$ 2,274.3	28
Humalog [2]	**1,201.0**	**856.3**	**2,057.3**	2,226.1	(8)
Alimta	**905.8**	**679.3**	**1,585.1**	1,576.0	1
Forteo	**473.8**	**570.6**	**1,044.4**	1,138.5	(8)
Taltz	**699.6**	**246.7**	**946.3**	630.4	50
Humulin	**639.6**	**302.5**	**942.1**	994.0	(5)
Basaglar	**632.8**	**172.6**	**805.4**	569.0	42
Cialis	**209.3**	**483.4**	**692.7**	1,501.2	(54)
Cyramza	**247.4**	**432.7**	**680.1**	600.8	13
Jardiance [3]	**408.4**	**267.9**	**676.2**	465.1	45
Cymbalta	**38.7**	**491.2**	**529.9**	523.5	1
Trajenta [4]	**171.9**	**269.5**	**441.4**	418.5	5
Erbitux	**364.1**	**42.3**	**406.4**	475.5	(15)
Verzenio	**323.5**	**77.0**	**400.6**	171.9	NM
Zyprexa	**29.8**	**287.2**	**317.0**	360.4	(12)
Olumiant	**29.2**	**269.9**	**299.1**	132.5	NM
Strattera	**31.4**	**169.4**	**200.8**	343.5	(42)
Emgality	**91.8**	**4.5**	**96.3**	—	NM
Other products	**492.2**	**672.6**	**1,164.7**	1,454.5	(20)
Revenue	**$ 9,203.5**	**$ 7,002.1**	**$ 16,205.5**	$ 15,855.7	2

Numbers may not add due to rounding.

NM - not meaningful

[1] U.S. revenue includes revenue in Puerto Rico.

[2] Humalog revenue includes Insulin Lispro.

[3] Jardiance revenue includes Glyxambi and Synjardy.

[4] Trajenta revenue includes Jentadueto.

Revenue of Trulicity, a treatment for type 2 diabetes, increased 17 percent and 24 percent in the U.S. during the three and nine months ended September 30, 2019, respectively, primarily driven by increased demand, partially offset by lower realized prices resulting from the following negative price dynamics: higher contracted rebates, changes in segment mix, and increased coverage gap funding requirements in Medicare Part D. We expect these negative price dynamics to moderate by the end of 2019 and into 2020. Revenue outside the U.S. increased 50 percent and 45 percent during the three and nine months ended September 30, 2019, respectively, primarily driven by increased volume.

Revenue of Humalog, our injectable human insulin analog for the treatment of diabetes, decreased 3 percent in the U.S. during the three months ended September 30, 2019, driven by decreased demand and lower realized prices. Revenue decreased 10 percent during the nine months ended September 30, 2019 driven by lower realized prices and decreased demand. Revenue outside the U.S. decreased 2 percent and 4 percent during the three and nine months ended September 30, 2019, respectively. The decrease during the three months ended September 30, 2019 was driven by the unfavorable impact of foreign exchange rates, partially offset by higher realized prices. The decrease during the nine months ended September 30, 2019 was primarily driven by the unfavorable impact of foreign exchange rates, partially offset by increased volume. A competitor launched a similar version of insulin lispro in certain European markets in 2017 and in the U.S. in the second quarter of 2018. 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, due to the impact of competition and due to pricing pressure in the U.S. and some international markets, we expect some price declines and loss of market share to continue over time. Additionally, in the second quarter of 2019, we launched our own insulin lispro authorized generic.

Revenue of Alimta, a treatment for various cancers, decreased 2 percent in the U.S. during the three months ended September 30, 2019, driven by lower realized prices and the impact of buying patterns, partially offset by increased demand. Revenue increased 11 percent in the U.S. during the nine months ended September 30, 2019, driven by increased demand. Revenue outside the U.S. decreased 3 percent in the three months ended September 30, 2019, primarily driven by lower realized prices and, to a lesser extent, the unfavorable impact of foreign exchange rates, partially offset by increased volume. Revenue decreased 11 percent in the nine months ended September 30, 2019, driven by decreased volume resulting from the entry of generic pemetrexed in Germany and the unfavorable impact of foreign exchange rates and lower realized prices. 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 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 4 percent and 11 percent in the U.S. during the three and nine months ended September 30, 2019, respectively, primarily due to decreased demand. The decrease in demand during the three months ended September 30, 2019 was partially offset by higher realized prices. Revenue outside the U.S. decreased 6 percent during the three months ended September 30, 2019, driven by decreased volume and, to a lesser extent, the unfavorable impact of foreign exchange rates. Revenue decreased 6 percent during the nine months ended September 30, 2019 driven by the unfavorable impact of foreign exchange rates and decreased volume. Our formulation patents for Forteo expired in December 2018, and our use patents expired in August 2019 in major European markets and the U.S. Both the formulation patent and the use patent expired in August 2019 in Japan. While it is difficult to estimate the severity of the impact and timing of generic and/or biosimilar competition, we expect a rapid and severe decline in revenue in the U.S. as a result of generic competition. Outside the U.S., we expect a decline in revenue following a recent biosimilar launch; however the decline may not be rapid and severe.

Revenue of Taltz, a treatment for moderate-to-severe plaque psoriasis and active psoriatic arthritis, increased 19 percent and 41 percent in the U.S. during the three and nine months ended September 30, 2019, respectively, driven by increased demand, partially offset by lower realized prices primarily due to changes in estimates for rebates and discounts. Revenue outside the U.S. increased 68 percent and 83 percent during the three and nine months ended September 30, 2019, respectively, primarily driven by increased volume from recent launches.

Revenue of Humulin, an injectable human insulin for the treatment of diabetes, increased 1 percent in the U.S. during the three months ended September 30, 2019, driven by higher realized prices, partially offset by decreased volume. Revenue decreased 6 percent in the U.S. during the nine months ended September 30, 2019, driven primarily by lower realized prices due to changes in estimates to rebates and discounts, changes in segment mix, and increased coverage gap funding in Medicare Part D. Revenue outside the U.S. decreased 1 percent during the three months ended September 30, 2019, due to the unfavorable impact of foreign exchange rates, partially offset by higher realized prices and increased volume. Revenue decreased 4 percent during the nine months ended September 30, 2019, respectively, due to the unfavorable impact of foreign exchange rates, partially offset by increased volume.

Revenue of Basaglar, a long-acting human insulin analog for the treatment of diabetes, increased 29 percent and 44 percent in the U.S. during the three and nine months ended September 30, 2019, respectively, primarily driven by increased demand and higher realized prices. Revenue outside the U.S. increased 39 percent and 34 percent during the three and nine months ended September 30, 2019, respectively, primarily driven by increased volume. See Note 4 to the consolidated condensed financial statements for information regarding our collaboration with Boehringer Ingelheim involving Basaglar.

Revenue of Cialis, a treatment for erectile dysfunction and benign prostatic hyperplasia, decreased 90 percent and 78 percent in the U.S. during the three and nine months ended September 30, 2019, respectively, driven by decreased demand due to generic competition. Revenue outside the U.S. decreased 10 percent during the three months ended September 30, 2019 driven by decreased demand due to generic competition and, to a lesser extent, lower realized prices and the unfavorable impact of foreign exchange rates. Revenue decreased 11 percent during the nine months ended September 30, 2019 driven by the unfavorable impact of foreign exchange rates, decreased demand due to generic competition and, to a lesser extent, lower realized prices. We have faced and remain exposed to generic competition following the loss of exclusivity, which has eroded revenue and is likely to continue to rapidly and severely erode revenue from current levels. See "Executive Overview - Other Matters - Patent Matters" for more information.

Revenue of Cyramza, a treatment for various cancers, increased 23 percent and 17 percent in the U.S. during the three and nine months ended September 30, 2019, respectively, driven by increased demand and, to a lesser extent, higher realized prices. Revenue outside the U.S. increased 20 percent and 11 percent during the three and nine months ended September 30, 2019, driven by increased volume. The increase in revenue during the nine months ended September 30, 2019 was partially offset by the unfavorable impact of foreign exchange rates and higher realized prices.

Revenue of Jardiance, a treatment for type 2 diabetes and to reduce the risk of cardiovascular death in adult patients with type 2 diabetes and established cardiovascular disease, increased 35 percent and 43 percent in the U.S. during the three and nine months ended September 30, 2019, respectively, driven by increased demand. Revenue outside the U.S. increased 60 percent and 49 percent during the three and nine months ended September 30, 2019, respectively, driven by increased volume, partially offset by the unfavorable impact of foreign exchange rates. See Note 4 to the consolidated condensed financial statements for information regarding our collaboration with Boehringer Ingelheim involving Jardiance.

Gross Margin, Costs, and Expenses

Gross margin as a percent of revenue increased 0.2 percentage points to 78.5 percent and increased 1.2 percentage points to 78.8 percent for the three and nine months ended September 30, 2019, respectively. The increase in gross margin percent for the three months ended September 30, 2019 was primarily due to the favorable effect of foreign exchange rates on international inventories sold, lower intangibles amortization expense, and greater manufacturing efficiencies, partially offset by unfavorable product mix primarily as a result of the loss of patent exclusivity for Cialis, and the impact of lower realized prices on revenue. The increase in gross margin percent for the nine months ended September 30, 2019 was primarily due to the favorable effect of foreign exchange rates on international inventories sold and lower intangibles amortization expense, partially offset by unfavorable product mix primarily as a result of the loss of patent exclusivity for Cialis, the impact of lower realized prices on revenue, and charges resulting from the suspension of promotion of Lartruvo.

Research and development expenses increased 8 percent to $1.38 billion and 10 percent to $4.01 billion for the three and nine months ended September 30, 2019, respectively, driven by higher development expenses for late-stage assets.

Marketing, selling, and administrative expenses decreased 3 percent to $1.41 billion for the three months ended September 30, 2019, as lower spending on late life-cycle products, lower litigation charges, and ongoing cost containment measures were partially offset by increased expenses for recently launched products. Marketing, selling, and administrative expenses increased 5 percent to $4.52 billion for the nine months ended September 30, 2019, respectively, primarily due to increased marketing expenses to support the recent U.S. launch of Emgality, as well as other recent product launches.

We recognized $77.7 million and $239.6 million of acquired IPR&D charges for the three and nine months ended September 30, 2019, respectively. The charge for the three months ended September 30, 2019 was related to the collaborations with Centrexion and AC Immune. The nine months ended September 30, 2019 also included charges related to collaborations with ImmuNext and Avidity. 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. See Note 3 to the consolidated condensed financial statements for additional information.

There were no asset impairment, restructuring, and other special charges recognized during the three months ended September 30, 2019. We recognized asset impairment, restructuring, and other special charges of $423.9 million for the nine months ended September 30, 2019, which included $400.7 million related to the acquisition of

Loxo, substantially all of which is associated with the accelerated vesting of Loxo employee equity awards. We recognized asset impairment, restructuring, and other special charges of $42.9 million and $74.2 million during the three and nine months ended September 30, 2018, respectively, primarily due to asset impairments, exit costs, and other charges related to the sale of the Posilac (rbST) brand and the associated Augusta, Georgia manufacturing site, partially offset with a gain recognized associated with a pension curtailment.

Other–net, (income) expense was expense of $24.9 million and income of $28.7 million for the three and nine months ended September 30, 2019, respectively, compared with expense of $1.9 million and income of $114.2 million for the three and nine months ended September 30, 2018, respectively. See Note 13 to the consolidated condensed financial statements for additional information.

The effective tax rate was 10.8 percent for the three months ended September 30, 2019, driven by a net discrete tax benefit related to the settlement of certain tax matters as a result of statute of limitations expirations. The effective tax rate for the nine months ended September 30, 2019 was 12.8 percent, reflecting the non-deductibility of accelerated vesting of Loxo employee equity awards as part of the closing of the acquisition of Loxo, tax expenses associated with the suspension of promotion of Lartruvo, as well as net discrete tax benefits resulting from the settlement of certain tax matters as a result of statute of limitations expirations and the resolution of certain global income tax audits. The effective tax rate for the three months ended September 30, 2018 was 18.5 percent, reflecting a net discrete tax detriment related to tax expenses for U.S. tax reform and the Elanco separation. The effective tax rate for the nine months ended September 30, 2018 was 26.2 percent, as it also reflected these tax charges, as well as the non-deductible acquired IPR&D charges totaling $1.56 billion related to the acquisitions of ARMO and AurKa.

Financial Condition

Cash and cash equivalents decreased to $1.56 billion as of September 30, 2019, compared with $7.32 billion as of December 31, 2018. Refer to the consolidated condensed statements of cash flows for additional information on the significant sources and uses of cash for the nine months ended September 30, 2019 and 2018.

In addition to our cash and cash equivalents, we held total investments of $1.91 billion and $2.09 billion as of September 30, 2019 and December 31, 2018, respectively. See Note 7 to the consolidated condensed financial statements for additional information.

Total debt increased to $15.23 billion as of September 30, 2019, compared with $10.30 billion as of December 31, 2018. The increase primarily related to the net proceeds of $4.45 billion from the issuance of senior notes in February 2019. The proceeds from these notes were used to fund the acquisition of Loxo and for general corporate purposes. See Note 7 to the consolidated condensed financial statements for additional information.

We have commenced a tender offer to purchase for cash approximately $2.00 billion aggregate principal amount of certain of our outstanding series of notes, subject to certain specified conditions, including the completion of an offering of debt securities. We plan to use the proceeds of such offering, together with cash on hand, to pay the consideration for any tendered notes that we accept for purchase. Holders of the notes subject to the tender offer are not obligated to tender their notes to us pursuant to the tender offer. Accordingly, there can be no assurance that any of the notes will be tendered and accepted for purchase in the tender offer.

As of September 30, 2019, we had a total of $5.42 billion of committed bank credit facilities, $5.00 billion of which is available to support our commercial paper program. In January 2019, we entered into a $4.00 billion credit facility to support our commercial paper program, which was terminated upon closing of the February 2019 debt offering. We believe that amounts accessible through existing commercial paper markets should be adequate to fund short-term borrowing needs.

During the nine months ended September 30, 2019, we repurchased $4.10 billion of shares under our $8.00 billion share repurchase program authorized in June 2018. As of September 30, 2019, we had $1.80 billion remaining under this program.

We believe that cash generated from operations, along with available cash and cash equivalents, will be sufficient to fund our normal operating needs, including dividends, share repurchases under our share repurchase program, and capital expenditures.

On March 11, 2019, we completed the disposition of our remaining 80.2 percent ownership of Elanco common stock through a tax-free exchange offer, which resulted in a reduction in shares of our common stock outstanding by approximately 65 million as of that date.

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 2019 EPS is now anticipated to be in the range of $8.59 to $8.69. We still expect 2019 revenue of between $22.0 billion and $22.5 billion. Revenue growth is expected to be driven by volume from Trulicity, Taltz, Basaglar, Jardiance, Verzenio, Cyramza, Olumiant, and Emgality. Revenue growth is also expected to benefit from the recent launch of Baqsimi. Revenue growth is expected to be partially offset by lower revenue for Cialis and other products that have lost patent exclusivity. Revenue growth is also expected to be partially offset by the negative impact of foreign exchange rates, a mid-single digit net price decline in the U.S. driven primarily by rebates and legislated increases to Medicare Part D cost sharing, patient affordability programs, price declines in some international markets, and the impact of the product withdrawal of Lartruvo.

Gross margin as a percent of revenue is still expected to be approximately 79.0 percent. Research and development expenses are still expected to be in the range of $5.5 billion to $5.7 billion. Marketing, selling, and administrative expenses are still expected to be in the range of $5.9 billion to $6.1 billion. Other—net, (income) expense is now expected to be between income of $50 million and expense of $100 million.

The 2019 tax rate is now expected to be in the range of 13 percent to 14 percent.

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**. The information contained in, or that can be accessed through, our website is not a part of, or incorporated by reference in, this quarterly report.

Item 4. Controls and Procedures

(a) *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, 2019, and concluded that they were effective.

(b) *Changes in Internal Controls*. During the third quarter of 2019, there were no changes in our internal control over financial reporting that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. Other Information

Item 1. Legal Proceedings

See Note 11 to Consolidated Condensed Financial Statements 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 litigation in Brazil regarding the Cosmopolis facility;
- The proceedings involving Adocia; and
- The insulin pricing litigation and investigations.

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, 2018 (Part I, Item 3) and our Quarterly Report on Form 10-Q for the quarter ended March 31, 2019 and June 30, 2019 (See Part II, Item 1).

Other Product Liability Litigation

We are named as a defendant in approximately 250 Axiron personal injury/product liability lawsuits in the U.S. involving approximately 250 plaintiffs. In some of the cases, other manufacturers of testosterone are named as co-defendants. Nearly all of these lawsuits have been consolidated in a federal multi-district litigation 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. While we are in the process of settling these cases, there can be no assurances, however, that a final settlement of all cases will be reached. We have also been engaged in litigation with Medical Mutual of Ohio (“MMO”), which filed a class action complaint against multiple manufacturers of testosterone products, including us, in the U.S. District Court for the Northern District of Illinois, on behalf of third-party payers who paid for those products and is seeking damages under the Federal Racketeer Influenced and Corrupt Organizations Act. MMO's motion for class certification was denied, and in February 2019, the District Court granted summary judgment in favor of defendants, dismissing MMO's lawsuit with prejudice. MMO’s appeal of this dismissal is currently pending before the U.S. Court of Appeals for the Seventh Circuit, and an oral argument is scheduled for November 2019. We continue to believe all of these lawsuits are without merit and are defending against them vigorously.

Other Patent Matters

We have been named as a defendant in litigation filed by Genentech, Inc. (Genentech) in the U.S. District Court for the Southern District of California seeking a ruling that Genentech’s patent would be infringed by our continued sales of Taltz. We believe this lawsuit is without merit and are defending against it vigorously. Separately, the U.S. Patent and Trademark Office (USPTO) has granted our request to initiate a post grant review to examine the validity of Genentech’s patent asserted against us in the litigation. We expect USPTO’s decision on the merits in the fourth quarter of 2020.

Other Matters

We are named as a defendant in a lawsuit in the U.S. District Court for the Eastern District of Texas seeking damages under the federal anti-kickback statute and state and federal false claims acts for certain patient support programs related to our products Humalog, Humulin, and Forteo. In September 2019, the U.S. District Court granted the Department of Justice's motion to dismiss the relator’s second amended complaint.

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, 2018. 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, 2019:

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 2019	267	$ 109.51	267	$ 2,370.8
August 2019	4,195	111.39	4,195	1,903.5
September 2019	929	111.43	929	1,800.0
Total	5,391	111.30	5,391	

During the three months ended September 30, 2019, we repurchased $600.0 million 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	Bylaws, as amended
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	Bylaws, as amended, are incorporated by reference to Exhibit 99.1 to the Company's Report on Form 8-K dated on December 18, 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 (embedded within the Inline XBRL document)
EXHIBIT 104.	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

Signatures

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

ELI LILLY AND COMPANY
(Registrant)

Date: October 25, 2019

/s/Bronwen L. Mantlo
Bronwen L. Mantlo
Corporate Secretary

Date: October 25, 2019

/s/Donald A. Zakrowski
Donald A. Zakrowski
Vice President, Finance and Chief Accounting Officer

EXHIBIT 31.1 Rule 13a-14(a) Certification of David A. Ricks, Chairman, President, and Chief Executive Officer

CERTIFICATIONS

I, David A. Ricks, certify that:

1. I have reviewed this report on Form 10-Q of Eli Lilly and Company;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and

5. The registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s Board of Directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize, and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: October 25, 2019

By: /s/David A. Ricks

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

CERTIFICATIONS

I, Joshua L. Smiley, certify that:

1. I have reviewed this report on Form 10-Q of Eli Lilly and Company;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and

5. The registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s Board of Directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize, and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: October 25, 2019

By: /s/Joshua L. Smiley

Joshua L. Smiley

Senior Vice President and Chief Financial Officer

EXHIBIT 32. Section 1350 Certification

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of Eli Lilly and Company, an Indiana corporation (the “Company”), does hereby certify that, to the best of their knowledge:

The Quarterly Report on Form 10-Q for the quarter ended September 30, 2019 (the “Form 10-Q”) of the Company fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 and information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: October 25, 2019

/s/David A. Ricks

David A. Ricks

Chairman, President, and Chief Executive Officer

Date: October 25, 2019

/s/Joshua L. Smiley

Joshua L. Smiley

Senior Vice President and Chief Financial Officer