LILLY ELI & CO
Form 10-Q
May 02, 2019

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 MARCH 31, 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 ý No o
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 ý No o
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 ý	Accelerated filer o
Non-accelerated filer o	Smaller reporting company o
	Emerging growth company o

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. o
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).
Yes o No ý
The number of shares of common stock outstanding as of April 29, 2019:

Class	Number of Shares Outstanding
Common	970,830,868

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 March 31, 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 (Exchange Act), 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 United States 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.”

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

3

PART I. Financial Information
Item 1. Financial Statements
Consolidated Condensed Statements of Operations
(Unaudited)
ELI LILLY AND COMPANY AND SUBSIDIARIES
(Dollars and shares in millions, except per-share data)

	Three Months Ended March 31,	
	2019	2018
Revenue (Note 2)	$5,092.2	$4,963.8
Costs, expenses, and other:		
Cost of sales	1,138.7	1,164.6
Research and development	1,230.5	1,107.5
Marketing, selling, and administrative	1,517.1	1,338.7
Acquired in-process research and development (Note 3)	136.9	—
Asset impairment, restructuring, and other special charges (Note 6)	423.9	56.8
Other–net, (income) expense (Note 13)	(86.0)	(69.5)
	4,361.1	3,598.1
Income before income taxes	731.1	1,365.7
Income taxes (Note 9)	170.0	198.5
Net income from continuing operations	561.1	1,167.2
Net income from discontinued operations (Note 5)	3,680.5	50.2
Net income	$4,241.6	$1,217.4
Earnings per share:		
Earnings from continuing operations - basic	$0.57	$1.11
Earnings from discontinued operations - basic	3.76	0.05
Earnings per share - basic	$4.33	$1.16
Earnings from continuing operations - diluted	$0.57	$1.11
Earnings from discontinued operations - diluted	3.74	0.05
Earnings per share - diluted	$4.31	$1.16
Shares used in calculation of earnings per share:		
Basic	979.9	1,048.0
Diluted	984.0	1,049.8

See notes to consolidated condensed financial statements.

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

	Three Months Ended March 31,	
	2019	2018
Net income	$4,241.6	$1,217.4
Other comprehensive income (loss) from continuing operations, net of tax (Note 12)	(4.1)	295.6
Other comprehensive income from discontinued operations, net of tax (Note 12) [(1)]	56.8	90.7
Other comprehensive income, net of tax (Note 12)	52.7	386.3
Comprehensive income	$4,294.3	$1,603.7

[(1)] For the three months ended March 31, 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)

	March 31, 2019 (Unaudited)	December 31, 2018
Assets		
Current Assets		
Cash and cash equivalents (Note 7)	$ 2,036.4	$ 7,320.7
Short-term investments (Note 7)	100.7	88.2
Accounts receivable, net of allowances of $24.4 (2019) and $24.1 (2018)	4,200.5	4,593.9
Other receivables	977.5	1,182.9
Inventories	3,055.2	3,098.1
Prepaid expenses and other	2,227.2	2,036.7
Current assets of discontinued operations (Note 5)	—	2,229.1
Total current assets	12,597.5	20,549.6
Investments (Note 7)	2,111.4	2,005.4
Goodwill	3,855.9	1,366.6
Other intangibles, net	6,641.5	1,068.0
Deferred tax assets	2,511.0	2,613.7
Sundry	1,963.0	1,824.9
Property and equipment, net of accumulated depreciation of $8,792.0 (2019) and $8,666.9 (2018)	7,780.0	7,996.1
Operating lease assets (Note 8)	546.5	—
Noncurrent assets of discontinued operations (Note 5)	—	6,484.1
Total assets	$ 38,006.8	$ 43,908.4
Liabilities and Equity		
Current Liabilities		
Short-term borrowings and current maturities of long-term debt	$ 2,354.9	$ 1,102.2
Accounts payable	1,168.1	1,207.1
Employee compensation	511.7	955.6
Sales rebates and discounts	4,455.7	4,849.5
Dividends payable	—	650.8
Income taxes payable	491.4	393.4
Other current liabilities	2,254.3	2,036.7
Current liabilities of discontinued operations (Note 5)	—	692.8
Total current liabilities	11,236.1	11,888.1
Other Liabilities		
Long-term debt	13,610.2	9,196.4
Noncurrent operating lease liabilities (Note 8)	508.2	—
Accrued retirement benefits (Note 10)	2,757.6	2,802.2
Long-term income taxes payable	3,760.4	3,700.0
Deferred tax liabilities	2,399.5	1,312.7
Other noncurrent liabilities	1,169.8	1,357.6
Noncurrent liabilities of discontinued operations (Note 5)	—	2,742.3
Total other liabilities	24,205.7	21,111.2
Commitments and Contingencies (Note 11)		
Eli Lilly and Company Shareholders' Equity		
Common stock	607.1	661.0

Additional paid-in capital	5,756.6	6,583.6
Retained earnings	4,879.4	11,395.9
Employee benefit trust	(3,013.2)	(3,013.2)
Accumulated other comprehensive loss (Note 12)	(5,687.5)	(5,729.2)
Cost of common stock in treasury	(62.1)	(69.4)
Total Eli Lilly and Company shareholders' equity	2,480.3	9,828.7
Noncontrolling interests	84.7	1,080.4
Total equity	2,565.0	10,909.1
Total liabilities and equity	$ 38,006.8	$ 43,908.4

See notes to consolidated condensed financial statements.

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

	Equity of Eli Lilly and Company Shareholders								
(Dollars in millions, shares in thousands)	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Retained Earnings	Employee Benefit Trust	Accumulated Other Comprehensive Loss	Common Stock in Treasury Shares	Common Stock in Treasury Amount	Noncontrolling Interests
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				1,217.4					0.4
Other comprehensive income (loss), net of tax						386.3			
Retirement of treasury shares	(14,088)	(8.8)		(1,091.2)			(14,088)	1,100.0	
Purchase of treasury shares							14,088	(1,100.0)	
Issuance of stock under employee stock plans, net	2,650	1.7	(127.8)				(60)	6.5	
Stock-based compensation			68.0						
Adoption of new accounting standards				2,584.4		(105.2)			
Other				3.5					(15.3)
Balance at March 31, 2018	1,089,234	$680.8	$5,758.0	$16,608.2	$(3,013.2)	$(5,437.5)	604	$(69.3)	$60.8
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				4,241.6					22.2
Other comprehensive income, net of tax						41.7			11.0
Retirement of treasury shares	(89,197)	(55.7)		(10,771.8)			(89,197)	10,827.5	
Purchase of treasury shares [1]			(700.0)				24,196	(2,800.0)	
Issuance of stock under employee stock plans, net	2,921	1.8	(202.8)				(63)	7.3	
Stock-based compensation			75.8						
							65,001	(8,027.5)	

Acquisition of common stock in exchange offer									(1,028.9)
Deconsolidation of Elanco									
Other				13.7					
Balance at March 31, 2019	971,363	$607.1	$5,756.6	$4,879.4	$(3,013.2)	$(5,687.5)	541	$(62.1)	$84.7

(1) As of March 31, 2019, there was $3.10 billion remaining under our $8.00 billion share repurchase program authorized in June 2018. Our share repurchases are facilitated through payments to a financial institution that purchases the shares on our behalf. As of March 31, 2019, we had paid $700 million to a financial institution for shares that are expected to be repurchased in the second quarter of 2019.

See notes to consolidated condensed financial statements.

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

	Three Months Ended March 31,	
	2019	2018
Cash Flows from Operating Activities		
Net income	$4,241.6	$1,217.4
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	356.5	422.8
Change in deferred income taxes	(72.4)	(22.7)
Stock-based compensation expense	75.8	68.0
Acquired in-process research and development (Note 3)	136.9	—
Other changes in operating assets and liabilities, net of acquisitions and divestitures	(714.3)	(1,270.0)
Other non-cash operating activities, net	(32.3)	21.0
Net Cash Provided by Operating Activities	311.3	436.5
Cash Flows from Investing Activities		
Net purchases of property and equipment	(203.7)	(236.5)
Proceeds from sales and maturities of short-term investments	35.9	450.7
Purchases of short-term investments	(33.7)	(112.2)
Proceeds from sales of noncurrent investments	83.6	310.5
Purchases of noncurrent investments	(60.6)	(561.6)
Cash paid for acquisitions, net of cash acquired (Note 3)	(6,917.7)	—
Purchase of in-process research and development	(196.9)	—
Other investing activities, net	(385.6)	(21.2)
Net Cash Used for Investing Activities	(7,678.7)	(170.3)
Cash Flows from Financing Activities		
Dividends paid	(637.2)	(587.3)
Net change in short-term borrowings	1,850.4	(1,202.5)
Proceeds from issuance of long-term debt	4,448.3	—
Repayments of long-term debt	(600.0)	(800.3)
Purchases of common stock	(3,500.0)	(1,100.0)
Other financing activities, net	(193.7)	(176.4)
Net Cash Provided by (Used for) Financing Activities	1,367.8	(3,866.5)
Effect of exchange rate changes on cash and cash equivalents	37.8	148.4
Net decrease in cash and cash equivalents	(5,961.8)	(3,451.9)
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 March 31 (includes $264.5 (2018) of discontinued operations)	$2,036.4	$3,084.3

See notes to consolidated condensed financial statements.

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

Note 1: Basis of Presentation and 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 Annual Report on Form 10-K for the year ended December 31, 2018. We issue our financial statements by filing with the Securities and Exchange Commission and have evaluated subsequent events up to the time of the filing.

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 asset 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 March 31,	
	2019	2018
Net product revenue	$4,692.3	$4,605.9
Collaboration and other revenue [1]	399.9	357.9
Revenue	$5,092.2	$4,963.8

[1] Collaboration and other revenue associated with prior period transfers of intellectual property was $35.5 million and $50.1 million during the three months ended March 31, 2019 and 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 and 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 March 31,					
	2019			2018		
	United States (U.S.) [1]	Outside U.S.	Total	U.S. [1]	Outside U.S.	Total
Revenue—to unaffiliated customers:						
Endocrinology:						
Trulicity®	$665.6	$214.1	$879.7	$528.2	$150.1	$678.3
Humalog®	448.6	282.2	730.8	504.1	287.6	791.7
Forteo®	125.9	187.0	312.9	122.1	191.1	313.2
Humulin®	201.3	96.4	297.7	221.6	104.3	325.9
Basaglar®	198.2	53.2	251.4	126.7	39.3	166.0
Jardiance	125.2	78.4	203.6	95.0	56.0	151.0
Trajenta	47.4	84.6	131.9	54.1	87.0	141.1
Other Endocrinology	61.7	60.3	122.1	64.1	67.5	131.5
Total Endocrinology	1,873.9	1,056.2	2,930.1	1,715.9	982.9	2,698.7
Oncology:						
Alimta®	281.8	217.4	499.2	245.3	254.3	499.6
Cyramza®	75.1	123.2	198.3	68.3	115.3	183.6
Erbitux®	113.3	5.1	118.4	121.3	28.3	149.6
Verzenio®	93.5	15.9	109.4	29.7	—	29.7
Other Oncology	30.2	57.3	87.4	45.6	48.4	94.1
Total Oncology	593.9	418.9	1,012.7	510.2	446.3	956.6
Neuroscience:						
Cymbalta®	10.3	153.8	164.1	12.2	157.3	169.6
Zyprexa®	9.3	97.9	107.2	8.8	113.8	122.6
Strattera®	1.5	64.7	66.2	46.9	83.7	130.7
Emgality®	12.2	2.1	14.2	—	—	—
Other Neuroscience	17.8	23.5	41.4	23.3	26.7	49.8
Total Neuroscience	51.1	342.0	393.1	91.2	381.5	472.7
Immunology:						
Taltz®	180.8	71.7	252.5	111.2	35.3	146.5
Other Immunology	6.4	75.7	82.2	—	32.2	32.2
Total Immunology	187.2	147.4	334.7	111.2	67.5	178.7
Other						
Cialis®	143.2	164.9	308.2	313.4	182.0	495.4
Other	41.5	72.0	113.4	53.7	108.0	161.7
Total Other	184.7	236.9	421.6	367.1	290.0	657.1

Revenue	$2,890.8	$2,201.4	$5,092.2	$2,795.6	$2,168.2	$4,963.8

Numbers may not add due to rounding.
(1) U.S. revenue includes revenue in Puerto Rico.

The following table summarizes revenue by geographical area:

	Three Months Ended March 31,	
	2019	2018
Revenue—to unaffiliated customers[1]:		
United States [2]	$2,890.8	$2,795.6
Europe	900.3	864.2
Japan	543.7	537.0
Other foreign countries	757.4	767.1
Revenue	$5,092.2	$4,963.8

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 during the three months ended March 31, 2019 and 2018 for products shipped in previous periods were approximately 3 percent of revenue and 4 percent of U.S. revenue, 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:

	March 31, 2019	December 31, 2018
Contract liabilities	$ 286.4	$ 298.7

Revenue recognized from contract liabilities during the three months ended March 31, 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.

In addition to the acquisition of Loxo, we acquired assets in development in the three months ended March 31, 2019, 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 $136.9 million for the three months ended March 31, 2019. There were no acquired IPR&D charges for the three months ended March 31, 2018.

Acquisition of a Business

Loxo Acquisition

Overview of Transaction

In February 2019, we acquired all shares of Loxo for a purchase price $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 three months ended March 31, 2019.

Under the terms of the agreement, we acquired a pipeline of investigational medicines, including LOXO-292, an oral RET inhibitor that has been 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, property and equipment, accrued expenses, and tax exposures. The final determination of these amounts will be completed as soon as possible but no later than one year from the acquisition date. The final determination may result in asset and liability fair values and tax bases that differ from the preliminary estimates and require changes to the preliminary amounts recognized.

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

Estimated Fair Value at February 15, 2019	
Acquired in-process research and development	$4,670.0
Definite-lived intangibles [1]	960.0
Deferred income taxes	(1,170.2)
Other assets and liabilities - net	(31.4)
Total identifiable net assets	4,428.4
Goodwill [2]	2,489.3
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, are expected to have a weighted average useful life of approximately 12 years.

[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 three months ended March 31, 2019. There were no asset acquisitions during the three months ended March 31, 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	Pre-clinical	$ 96.9
ImmuNext, Inc.	Novel immunometabolism target	March 2019	Pre-clinical	40.0

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

In connection with 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.

Subsequent Events

In April 2019, we entered into a license and research collaboration agreement with Avidity Biosciences, LLC for the discovery, development, and commercialization of potential new medicines in immunology and other select indications. Under terms of the agreement, we paid an upfront fee of $20.0 million and made an investment of $15.0 million. As a result of the transaction, we will record an acquired IPR&D expense of approximately $25 million in the second quarter of 2019.

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 will receive a deposit of $75.0 million, followed by 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 March 31,	
	2019	2018
Basaglar	$251.4	$166.0
Jardiance	203.6	151.0
Trajenta	131.9	141.1

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 March 31, 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 exercised its option to co-develop Olumiant in rheumatoid arthritis in 2010 and atopic dermatitis, alopecia areata, and SLE in 2017. In April 2019, Incyte opted-out of co-development of all indications as of January 1, 2019. As a result, we will solely fund all future development and pay a lower royalty rate to Incyte on future sales.

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 March 31, 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 presented Elanco as discontinued operations in our consolidated condensed financial statements for all periods presented.

We recognized a gain related to the disposition of approximately $3.7 billion, which was recorded in net income from discontinued operations in the consolidated condensed statement of operations for the three months ended March 31, 2019. 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. Net income from discontinued operations for the three months ended March 31, 2018 included Elanco's operating results.

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. The net cash flows of our discontinued operations for operating and investing activities were not material for either 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 the next 24 months. 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 March 11, 2019, the full 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 March 31,	
	2019	2018
Severance	$(3.6)	$7.3
Asset impairment and other special charges	427.5	49.5
Total asset impairment, restructuring, and other special charges	$423.9	$56.8

Asset impairment and other special charges recognized during the three months ended March 31, 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.

Asset impairment, restructuring, and other special charges recognized during the three months ended March 31, 2018 were primarily associated with asset impairment, exit costs, and severance costs related to the decision to end Posilac® (rbST) production at the Augusta, Georgia manufacturing site.

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 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 March 31, 2019, we had outstanding foreign currency forward commitments to purchase 1.22 billion U.S. dollars and sell 1.08 billion euro, commitments to purchase 1.97 billion euro and sell 2.23 billion U.S. dollars, commitments to purchase 356.8 million U.S. dollars and sell 39.58 billion Japanese yen, and commitments to purchase 309.7 million British pounds and sell 409.1 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 $3.33 billion and $3.40 billion as of March 31, 2019 and December 31, 2018, respectively, of which $2.33 billion and $2.38 billion have been designated as, and are effective as, economic hedges of net investments in certain of our euro-denominated foreign operations as of March 31, 2019 and December 31, 2018, respectively. At March 31, 2019, we had outstanding cross currency swaps with notional amounts of $1.86 billion swapping U.S. dollars to euro, $1.00 billion swapping Swiss francs to U.S. dollars, and $350.0 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 March 31, 2019, substantially all of our total long-term debt is at a fixed rate. We have converted approximately 15 percent of our long-term fixed-rate notes to floating rates through the use of interest rate swaps.

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

We also may enter into forward-starting interest rate swaps, which we designate as cash flow hedges, as part of any anticipated future debt issuances in order to reduce the risk of cash flow volatility from future changes in interest rates. Upon completion of a debt issuance and termination of the swap, the change in fair value of these instruments is recorded as part of other comprehensive income (loss) and is amortized to interest expense over the life of the underlying debt.

In 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 March 31,	
	2019	2018
Fair value hedges:		
Effect from hedged fixed-rate debt	$39.3	$(54.8)
Effect from interest rate contracts	(39.3)	54.8
Cash flow hedges:		
Effective portion of losses on interest rate contracts reclassified from accumulated other comprehensive loss	3.8	3.6
Net losses on foreign currency exchange contracts not designated as hedging instruments	48.9	16.7
Total	$52.7	$20.3

During the three months ended March 31, 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 were excluded from the assessment of effectiveness were not material.

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

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

	Three Months Ended March 31,	
	2019	2018
Net investment hedges:		
Foreign currency-denominated notes	$53.7	$(107.7)
Cross-currency interest rate swaps	38.3	(31.5)
Cash flow hedges:		
Forward-starting interest rate swaps	(11.7)	—
Cross-currency interest rate swaps	(30.0)	—

During the next 12 months, we expect to reclassify $16.1 million of pretax net losses on cash flow hedges from accumulated other comprehensive loss to other–net, (income) expense. During the three months ended March 31, 2019, the amounts excluded from the assessment of hedge effectiveness recognized in other comprehensive income (loss) was not material.

Fair Value of Financial Instruments

The following tables summarize certain fair value information at March 31, 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:

	Carrying Amount	Cost [1]	Fair Value Measurements Using Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Fair Value
March 31, 2019						
Cash equivalents	$806.2	$806.2	$806.2	$—	$—	$806.2
Short-term investments:						
U.S. government and agency securities	$13.5	$13.6	$13.5	$—	$—	$13.5
Corporate debt securities	81.7	81.7	—	81.7	—	81.7
Asset-backed securities	4.0	4.0	—	4.0	—	4.0
Other securities	1.5	1.5	—	1.5	—	1.5
Short-term investments	$100.7					
Noncurrent investments:						
U.S. government and agency securities	$148.0	$150.0	$148.0	$—	$—	$148.0
Corporate debt securities	533.6	535.2	—	533.6	—	533.6
Mortgage-backed securities	118.7	119.9	—	118.7	—	118.7
Asset-backed securities	36.2	36.2	—	36.2	—	36.2
Other securities	82.4	29.7	—	—	82.4	82.4
Marketable equity securities	502.1	238.7	502.1	—	—	502.1
Equity investments without readily determinable fair values [2]	414.6					
Equity method investments [2]	275.8					
Noncurrent investments	$2,111.4					
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, investments accounted for under the measurement alternative for equity investments, and cost method investments that do not have readily determinable fair values.

	Carrying Amount	Fair Value Measurements Using Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Fair Value
Short-term commercial paper borrowings					
March 31, 2019	$(2,349.6)	$—	$(2,342.3)	$—	$(2,342.3)
December 31, 2018	(498.9)	—	(497.6)	—	(497.6)
Long-term debt, including current portion					
March 31, 2019	$(13,615.5)	$—	$(14,238.8)	$—	$(14,238.8)
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
March 31, 2019					
Risk-management instruments:					
Interest rate contracts designated as fair value hedges:					
Sundry	$ 30.9	$ —	$ 30.9	$ —	$30.9
Other current liabilities	(0.3)	—	(0.3)	—	(0.3)
Other noncurrent liabilities	(7.7)	—	(7.7)	—	(7.7)
Cross-currency interest rate contracts designated as net investment hedges:					
Other receivables	60.9	—	60.9	—	60.9
Sundry	26.9	—	26.9	—	26.9
Other current liabilities	(5.0)	—	(5.0)	—	(5.0)
Cross-currency interest rate contracts designated as cash flow hedges:					
Other noncurrent liabilities	(27.6)	—	(27.6)	—	(27.6)
Foreign exchange contracts not designated as hedging instruments:					
Other receivables	11.2	—	11.2	—	11.2
Other current liabilities	(28.8)	—	(28.8)	—	(28.8)
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 March 31, 2019:

		Maturities by Period			
	Total	Less Than 1 Year	1-5 Years	6-10 Years	More Than 10 Years
Fair value of debt securities	$935.7	$ 99.3	$539.9	$121.3	$ 175.2

The net unrealized gains and losses recognized in our consolidated condensed statements of operations for equity securities during the three months ended March 31, 2019 and 2018 were $149.6 million and $18.7 million, respectively.

We adjust our equity investments without readily determinable fair values are based upon changes in the equity instruments' values resulting from observable price changes in orderly transactions for an identical or similar investments 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 months ended March 31, 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:

	March 31, 2019	December 31, 2018
Unrealized gross gains	$ 5.2	$ 0.8
Unrealized gross losses	10.1	29.0
Fair value of securities in an unrealized gain position	338.9	84.3
Fair value of securities in an unrealized loss position	578.6	858.6

We periodically assess our investment in available-for-sale securities for other-than-temporary impairment losses. Other than temporary impairment losses were immaterial in the three months ended March 31, 2019. There were no other-than-temporary impairment losses in the three months ended March 31, 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 March 31, 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 60 percent of the fixed-rate debt securities in a loss position are investment-grade debt securities. As of March 31, 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 March 31,	
	2019	2018
Proceeds from sales	$93.7	$592.6
Realized gross gains on sales	2.5	2.1
Realized gross losses on sales	0.4	1.6

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 $638.3 million and $696.2 million of accounts receivable as of March 31, 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 months ended March 31, 2019 and 2018 was not material.

Note 8: Leases

We determine if an arrangement is a lease at inception. We have operating and finance leases for corporate offices, research and development facilities, vehicles, and equipment. Our leases have remaining lease terms of 1 to 14 years, some of which have options to extend the leases, and some of which include options to terminate the leases. 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 statements of operations, consolidated condensed balance sheets, and consolidated condensed statements of cash flows. Beginning January 1, 2019 operating leases are included in operating lease assets, other current liabilities, and noncurrent operating lease liabilities in our consolidated condensed balance sheet.

Operating lease assets represent our right to use an underlying asset for the lease term and 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. We use the implicit rate if it is readily determinable. The operating lease assets also include any lease payments made and excludes lease incentives. Our lease terms may include options to extend or terminate the lease when it is reasonably certain and there is a significant economic incentive to exercise that option.

Operating lease expense for operating lease assets is recognized on a straight-line basis over the lease term. Variable lease payments, which represent lease payments that 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 obligation for these payments was incurred. Variable lease expense recognized in the three months ended March 31, 2019 was not material.

We elected not to apply the recognition requirements of Accounting Standards Codification 842, Leases, to short-term leases, which are deemed to be leases with a lease term of 12 months or less. Instead, we recognized lease payments in the consolidated condensed statements of operations on a straight-line basis over the lease term and variable payments in the period in which the obligation for these payments was incurred. We elected this policy for all classes of underlying assets. Short-term lease expense recognized in the three months ended March 31, 2019 was not material.

The impact of operating leases to our consolidated condensed financial statements were as follows:

	Three Months Ended March 31, 2019
Lease cost	
Operating lease cost	$32.1
Other information	
Operating cash flows from operating leases	36.9
Right-of-use assets obtained in exchange for new operating lease liabilities	35.1
Weighted-average remaining lease term - operating leases	8 years
Weighted-average discount rate - operating leases	3.7 %

As of March 31, 2019, the annual minimum lease payments of our operating lease liabilities were as follows:

Year 1	$129.3
Year 2	111.7
Year 3	80.1
Year 4	69.5
Year 5	55.8
After Year 5	285.0
Total lease payments	731.4
Less imputed interest	(109.5)
Total	$621.9

Note 9: Income Taxes

The effective tax rates were 23.3 percent and 14.5 percent for the three months ended March 31, 2019 and 2018, respectively. The higher effective tax rate is primarily due to the non-deductibility of accelerated vesting of Loxo employee equity awards as part of the closing of the acquisition of Loxo, as well as tax expenses associated with the suspension of promotion of Lartruvo.

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 in 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 we believe it is reasonably possible that this examination could reach resolution within the next 12 months for the tax years 2013-2014 and certain matters under examination for tax year 2015, for which the examination remains ongoing. As a result, we currently estimate that gross uncertain tax positions may be reduced by approximately $450 million within the next 12 months. Additionally, we anticipate up to $150 million of cash payments will be due upon resolution.

Note 10: Retirement Benefits

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

	Defined Benefit Pension Plans Three Months Ended March 31,	
	2019	2018
Components of net periodic benefit cost:		
Service cost	$61.8	$77.6
Interest cost	120.7	112.0
Expected return on plan assets	(211.1)	(211.0)
Amortization of prior service cost	1.5	1.2
Recognized actuarial loss	69.6	89.9
Net periodic benefit cost	$42.5	$69.7

	Retiree Health Benefit Plans Three Months Ended March 31,	
	2019	2018
Components of net periodic benefit income:		
Service cost	$8.8	$10.7
Interest cost	14.6	13.9
Expected return on plan assets	(36.0)	(43.9)
Amortization of prior service benefit	(15.7)	(20.5)
Recognized actuarial loss	0.5	2.4
Net periodic benefit income	$(27.8)	$(37.4)

We contributed approximately $10 million required to satisfy minimum funding requirements to our defined benefit pension and retiree health benefit plans during the three months ended March 31, 2019. During the remainder of 2019, we expect to make contributions to our defined benefit pension and retiree health benefit plans of approximately $40 million to satisfy minimum funding requirements. There was no discretionary funding during the three months ended March 31, 2019, and none is planned for the remainder of 2019.

26

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. The remaining ANDA applicants have agreed to a preliminary injunction or stay pending the appeal of the inter partes review (IPR) described in the following sentence. In October 2017, the U.S. Patent and Trademark Office (USPTO) issued written decisions in our favor following 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.

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. in response to their applications to market alternative forms of pemetrexed (the active ingredient in Alimta) products, and we filed a similar lawsuit in the U.S. District Court for the District of Delaware against Eagle Pharmaceuticals, Inc. In June 2018, the U.S. District Court for the Southern District of Indiana ruled in our favor in two similar cases, finding Dr. Reddy's Laboratories' (Dr. Reddy) and Hospira, Inc.'s (Hospira) proposed products would infringe our patent. Dr. Reddy and Hospira have appealed those rulings. The lawsuit against Actavis has been stayed, pending a decision in Dr. Reddy’s appeal. The hearing on the appeal is scheduled for June 2019.

European Patent Litigation and Administrative Proceedings

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

Hexal AG, Stada Arzneimittel AG (Stada), and Fresenius Kabi Deutschland GmbH have each challenged the validity of our German vitamin regimen patent before the German Federal Patent Court. At a hearing in July 2018, the German Federal Patent Court held that our German vitamin regimen patent is invalid. We have appealed this decision to the German Supreme Court. Under German law, the patent remains in force pending appeal. A number of generic competitors have received approval to market generic versions of pemetrexed in Germany. Some of these companies, including Stada, have launched at risk or are preparing to do so. We are seeking injunctions and/or contesting the

lifting of previously granted injunctions against these companies while the appeal to the German Supreme Court is pending. While not material to our business, Alimta revenue in Germany has steadily decreased over the last few quarters and is down significantly for the first quarter of 2019 compared to the first quarter of 2018. The timing of further generic entry and full impact on market erosion in Germany is unpredictable and depends on

whether the existing injunctions remain in effect, the suspended injunctions are reinstated pending the appeal or further injunctions are granted, or whether additional generic competitors choose to launch at risk.

Additional legal proceedings are ongoing in various national courts throughout Europe. We are aware that several companies have received approval to market generic versions of pemetrexed in major European markets (including one generic product currently on the market in France) 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, 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 in the third quarter of 2019. We also anticipate decisions by the JPO with respect to another set of demands, brought by Hospira, in the third quarter of 2019. 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 Company) involving Cymbalta. The plaintiffs, purporting to represent a class of all persons within the U.S. who purchased and/or paid for Cymbalta, asserted claims under the consumer protection statutes of 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

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 medical insurance for the employees and contractors who worked at the Cosmopolis facility more than six months during the affected years and their children born during and after this period. We 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 500.0 million Brazilian real (approximately $130.0 million as of March 31, 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. We strongly disagree with the appeals court's decision. Lilly Brasil has taken an initial step in the appeal process by filing a Motion for Clarification; a decision on that motion is expected in the second quarter of 2019.

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.

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, 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, the court issued a written decision rejecting the plaintiff's appeal in the second lawsuit. The court's decision was procedurally based and was without a judgment on the merits, meaning that the plaintiffs are able to bring individual actions, notwithstanding the court's decision.

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

Adocia, S.A.

We have been 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 alleges that we misappropriated and misused Adocia's confidential information and intellectual property and is seeking approximately $1.30 billion in damages and other specific relief. We have asserted several counterclaims relating to fraudulent misrepresentation and are seeking approximately $188 million in damages. An arbitration hearing was held on Adocia's claims and our counterclaims in December 2018, and we expect a decision in the third quarter of 2019. We believe Adocia's claims are without merit and have defended against them vigorously.

Throughout the dispute process, Adocia has made statements alleging that Adocia employees should be listed as inventors on two of our patents related to our ultra-rapid insulin product currently in development. We strongly contest this allegation. While inventorship of these two patents 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.

Insulin and Glucagon Pricing Litigation and Investigations

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). In February 2019, the court dismissed without prejudice the federal RICO Act claim as well as certain state consumer protection claims. Plaintiffs filed a second amended complaint in March 2019. Separately, we, along with Sanofi and Novo Nordisk, are named as defendants in a purported class action lawsuit, MSP Recovery Claims, Series, LLC et al. v. Sanofi Aventis U.S. LLC et al., in the same court, seeking damages under various state consumer protection laws, common law fraud, unjust enrichment, and the federal RICO Act. In March 2019, the court dismissed, without prejudice, the plaintiffs' federal RICO Act, unjust enrichment, and certain state consumer protection law claims. Finally, the Minnesota Attorney General's Office filed a complaint against us, Sanofi, and Novo Nordisk, State of Minnesota v. Sanofi-Aventis U.S. LLC et al., in the U.S. District Court of New Jersey, alleging unjust enrichment, and violations of various Minnesota state consumer protection laws and the federal RICO Act. We believe all of these claims are without merit and are defending against them vigorously.

We have received civil investigative demands from the Offices of the Attorney General from Washington and New Mexico relating to the pricing and sale of our insulin products. We are cooperating with these investigations. 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 are cooperating with these requests.

We received interrogatories from the California Attorney General's Office regarding our competition in the long-acting insulin market. We are cooperating with this investigation. Finally, we received a request from the House of Representatives' Committee on Oversight and Reform; two requests from its Committee on Energy and Commerce; as well as requests from the Senate's Committee on Finance and Committee on Health, Education, Labor, and Pensions, seeking certain information related to the pricing of insulin products, among other issues. We are cooperating with these investigations.

We, along with Novo Nordisk and various pharmacy benefit managers, were named as defendants in a lawsuit seeking class action status in the U.S. District Court of New Jersey relating to glucagon pricing. The lawsuit sought damages under various state consumer protection laws, the federal RICO Act, the Sherman Act, and other state and federal laws. In April 2019, the plaintiff voluntarily dismissed the case without prejudice.

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 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 March 31, 2019 and 2018:

(Amounts presented net of taxes)	Continuing Operations				Discontinued Operations	Accumulated Other Comprehensive Loss
	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		
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	(31.7)	16.8	(5.7)	(32.9)	(27.2)	(80.7)
Net amount reclassified from accumulated other comprehensive loss	—	1.7	44.7	3.0	84.0	133.4
Net other comprehensive income (loss)	(31.7)	18.5	39.0	(29.9)	56.8	52.7
Balance at March 31, 2019	$(1,601.4)	$ (3.6)	$ (3,813.7)	$ (268.8)	$ —	$ (5,687.5)

(Amounts presented net of taxes)	Continuing Operations				Discontinued Operations	Accumulated Other Comprehensive Loss
	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		
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	291.5	(36.0)	(20.8)	(0.1)	90.0	324.6
Net amount reclassified from accumulated other comprehensive loss	—	0.4	57.7	2.9	0.7	61.7
Net other comprehensive income (loss)	291.5	(35.6)	36.9	2.8	90.7	386.3
Balance at March 31, 2018	$(900.2)	$ (51.0)	$ (4,274.4)	$ (231.5)	$ 19.6	$ (5,437.5)

[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.

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

	Three Months Ended March 31,	
Tax benefit (expense)	2019	2018
Foreign currency translation gains/losses	$(19.3)	$40.1
Unrealized net gains/losses on securities	(4.8)	10.2
Defined benefit pension and retiree health benefit plans	(11.4)	(14.0)
Effective portion of cash flow hedges	8.0	(0.8)
Benefit/(provision) for income taxes allocated to other comprehensive income (loss) items	$(27.5)	$35.5

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 March 31,		Affected Line Item in the Consolidated Condensed Statements of Operations
	2019	2018	
Amortization of retirement benefit items:			
Prior service benefits, net	$(14.2)	$(19.3)	Other–net, (income) expense
Actuarial losses, net	70.1	92.3	Other–net, (income) expense
Total before tax	55.9	73.0	
Tax benefit	(11.2)	(15.3)	Income taxes
Net of tax	44.7	57.7	
Other, net of tax	4.7	3.3	Other–net, (income) expense
Reclassifications from continuing operations (net of tax)	49.4	61.0	
Reclassifications from discontinued operations (net of tax)	84.0	0.7	Net income from discontinued operations
Total reclassifications for the period (net of tax)	$133.4	$61.7	

Note 13: Other–Net, (Income) Expense

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

	Three Months Ended March 31,	
	2019	2018
Interest expense	$86.5	$61.2
Interest income	(30.6)	(45.5)
Retirement benefit	(55.9)	(56.0)
Other income	(86.0)	(29.2)
Other–net, (income) expense	$(86.0)	$(69.5)

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

Results of Operations

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

General

Management’s discussion and analysis of results of operations and financial condition is intended to assist the reader in understanding and assessing significant changes and trends related to the results of operations and financial position of our consolidated company. This discussion and analysis should be read in conjunction with the consolidated condensed financial statements and accompanying footnotes in Item 1 of Part I of this Quarterly Report on Form 10-Q. Certain statements in this Item 2 of Part I of this Quarterly Report on Form 10-Q constitute forward-looking statements. Various risks and uncertainties, including those discussed in "Forward-Looking Statements" and Item 1A, “Risk Factors,” of Part I of our Annual Report on Form 10-K for the year ended December 31, 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 March 31,		
	2019	2018	Percent Change
Revenue	$5,092.2	$4,963.8	3
Gross margin	3,953.5	3,799.2	4
Gross margin as a percent of revenue	77.6 %	76.5 %	
Operating expense	$2,747.6	$2,446.2	12
Acquired in-process research and development (IPR&D)	136.9	—	NM
Asset impairment, restructuring, and other special charges	423.9	56.8	NM
Net income from continuing operations	561.1	1,167.2	(52)
Net income from discontinued operations	3,680.5	50.2	NM
Net income	4,241.6	1,217.4	NM
EPS from continuing operations	0.57	1.11	
EPS from discontinued operations	3.74	0.05	
EPS	4.31	1.16	NM

NM - not meaningful

Revenue increased for the three months ended March 31, 2019 driven by increased volume, partially offset by lower realized prices and the unfavorable impact of foreign exchange rates. Operating expense increased for the three months ended March 31, 2019, reflecting additional investments in recently launched products and late-stage assets. The increase in net income and EPS for the three months ended March 31, 2019 were driven by the gain recognized on the disposition of Elanco Animal Health (Elanco).

The following highlighted items also affect comparisons of our financial results for the three months ended March 31, 2019 and 2018:

2019

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

- We recognized acquired IPR&D charges of $136.9 million, or $0.12 per share, related to collaborations with AC Immune SA (AC Immune) and ImmuNext, Inc. (ImmunNext).

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

- We recognized charges of $423.9 million (pretax), or $0.44 per share, 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

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

- We recognized charges of $56.8 million (pretax), or $0.04 per share, primarily associated with asset impairment, exit costs, and severance costs related to the decision to end Posilac® (rbST) production at the 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 45 potential new drugs in human testing or under regulatory review and a larger number of projects in preclinical research.

The following new molecular entity (NME) has 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 NME initially was 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 for discussion of the lawsuit filed by Teva Pharmaceuticals International GMBH and Teva Pharmaceuticals USA, Inc.

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

Lasmiditan (Q4 2018)—an oral 5-HT1F agonist for the acute treatment of migraine. In the United States (U.S.), lasmiditan is protected by a compound patent (2025, including possible extension upon approval).

Nasal glucagon* (Q2 2018)—a glucagon nasal powder formulation for the treatment of severe hypoglycemia in patients with diabetes treated with insulin. In the U.S., nasal glucagon is protected by a delivery device patent (2034), a formulation patent (2036), and data protection (3.5 years) expected upon approval. In Europe, nasal glucagon is protected by a delivery device patent (2034).

Ultra-rapid Lispro* (Q1 2019)—an ultra-rapid insulin for the treatment of type 1 and type 2 diabetes. In Europe, ultra-rapid lispro is protected by a formulation patent (2035). In Japan, ultra-rapid lispro is protected by a formulation patent (2035, including possible patent extension) 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 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:

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

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.).

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					
Nasal glucagon	Severe hypoglycemia	Submitted		Phase III	In April 2019, the U.S. Food and Drug Administration (FDA) extended the review time by up to three months to allow for review of information requested late in the review cycle. The submission of the additional information constituted a Major Amendment.
Tirzepatide	Type 2 diabetes	Phase III			Phase III trials are ongoing.
Ultra-rapid Lispro	Type 1 and 2 diabetes	Phase III	Submitted		Submitted to regulatory authorities in Europe and Japan in first quarter of 2019.
Immunology					
Mirikizumab	Psoriasis	Phase III			Phase III trials are ongoing.
	Ulcerative colitis	Phase III			Phase III trial is ongoing.
Neuroscience					
Emgality	Cluster headache	Submitted		Phase III	Submitted to FDA in fourth quarter of 2018 and to European regulatory authorities in first quarter of 2019 in episodic cluster headache. Granted Priority Review(1) from FDA in first quarter of 2019.
	Migraine prevention	Launched		Phase III	Launched in Europe in the first quarter 2019.
Flortaucipir	Alzheimer's disease	Phase III			In discussion with regulatory authorities to determine next steps following Phase III trial met primary endpoints in the third quarter of 2018.
Lasmiditan	Migraine	Submitted	Phase III		Phase III trials are ongoing.
Solanezumab	Preclinical Alzheimer's disease	Phase III			Phase III trial is ongoing.

Compound	Indication	U.S.	Europe	Japan	Developments
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. We are analyzing these findings in the context of the recent Phase III study results and plan to review the totality of data from our clinical development program with regulatory authorities.
	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. We anticipate an additional readout from the program to be available in 2019.
	Cancer pain	Phase III			Phase III trial is ongoing.
Oncology					
Lartruvo®	Soft tissue sarcoma	Withdrawing		Not Submitting	In the first quarter of 2019, announced confirmatory phase III trial did not meet primary endpoint. As trial did not confirm clinical benefit, we have suspended promotion and in April 2019, announced our intention to globally withdraw from the market.
Pegilodecakin	Pancreatic cancer	Phase III			Phase III trial is ongoing.

(1) Priority Review is designed to expedite the review of potential medicines that, if approved, would be significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications.

Other Matters

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 expect that the entry of additional generic competition into these markets following the loss of exclusivity will continue to cause a rapid and severe decline in revenue, which will, in the aggregate, have a material adverse effect on our consolidated results of operations and cash flows.

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

35

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 and France) and that additional generic competitors may choose to launch at risk. Although we will continue to seek to remove any such products, their 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 first quarter of 2019, we announced we will introduce 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

United States

In the U.S., public concern over access to and affordability of pharmaceuticals continues to drive the regulatory and legislative debate. These policy and political issues increase the risk that taxes, fees, rebates, or other cost control measures may be enacted to manage federal and state budgets. Key health policy proposals affecting biopharmaceuticals include a reduction in biologic data exclusivity, modifications to Medicare Parts B and D, language that would allow the Department of Health and Human Services to negotiate prices for biologics and drugs in Medicare, proposals 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 January 2019, the Department of Health and Human Services released a proposed rule to reform the system of rebates paid to Medicare Part D plans, Medicaid Managed Care organizations, and pharmacy benefit managers. In

April 2019, the White House signed into law significant, targeted amendments to the Medicaid Drug Rebate Program statute. We are currently reviewing the new statute and proposed rule, the impact of both 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 in 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 $6.92 billion, net of cash acquired. Under the terms of the agreement, we acquired a pipeline of investigational medicines, including 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 March 31,		
	2019	2018	Percent Change
U.S. [1]	$2,890.8	$2,795.6	3
Outside U.S.	2,201.4	2,168.2	2
Revenue	$5,092.2	$4,963.8	3

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 March 31, 2019 vs. 2018		
	U.S.	Outside U.S.	Consolidated
Volume	6 %	9 %	7 %
Price	(3)	(2)	(3)
Foreign exchange rates	—	(5)	(2)
Percent change	3 %	2 %	3 %

Numbers may not add due to rounding.

In the U.S. for the three months ended March 31, 2019, the volume increase was primarily driven by Trulicity®, Taltz®, Verzenio®, and Basaglar®, partially offset by decreased volume for products that have lost exclusivity, including Cialis and Strattera®. The decrease in realized prices was primarily related to Trulicity.

Outside the U.S. for the three months ended March 31, 2019, the volume increase was primarily driven by Trulicity, Olumiant®, and Taltz. The decrease in realized prices was related to most products.

The following table summarizes our revenue activity by product:

	Three Months Ended March 31,				
	2019			2018	
Product	U.S. [1]	Outside U.S.	Total	Total	Percent Change
Trulicity	$665.6	$214.1	$879.7	$678.3	30
Humalog	448.6	282.2	730.8	791.7	(8)
Alimta	281.8	217.4	499.2	499.6	—
Forteo	125.9	187.0	312.9	313.2	—
Cialis	143.2	164.9	308.2	495.4	(38)
Humulin®	201.3	96.4	297.7	325.9	(9)
Taltz	180.8	71.7	252.5	146.5	72
Basaglar	198.2	53.2	251.4	166.0	51
Jardiance® [2]	125.2	78.4	203.6	151.0	35
Cyramza®	75.1	123.2	198.3	183.6	8
Cymbalta®	10.3	153.8	164.1	169.6	(3)
Trajenta® [3]	47.4	84.6	131.9	141.1	(6)
Erbitux®	113.3	5.1	118.4	149.6	(21)
Verzenio	93.5	15.9	109.4	29.7	NM
Zyprexa®	9.3	97.9	107.2	122.6	(13)
Strattera	1.5	64.7	66.2	130.7	(49)
Emgality®	12.2	2.1	14.2	—	NM
Other products	157.6	288.8	446.5	469.3	(5)
Revenue	$2,890.8	$2,201.4	$5,092.2	$4,963.8	3

Numbers may not add due to rounding.

NM - not meaningful

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

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

[3] Trajenta revenue includes Jentadueto®.

Revenue of Trulicity, a treatment for type 2 diabetes, increased 26 percent in the U.S. during the three months ended March 31, 2019, driven by increased demand, partially offset by realized prices and changes in estimates to rebates and discounts. Revenue outside the U.S. increased 43 percent during the three months ended March 31, 2019, driven by increased volume, partially offset by the unfavorable impact of foreign exchange rates and, to a lesser extent, lower realized prices.

Revenue of Humalog, an injectable human insulin analog for the treatment of diabetes, decreased 11 percent in the U.S. during the three months ended March 31, 2019, driven by decreased demand and, to a lesser extent, lower realized prices primarily due to the impact of patient affordability programs. Revenue outside the U.S. decreased 2 percent during the three months ended March 31, 2019, driven primarily by the unfavorable impact of foreign exchange rates, largely 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 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 to continue over time. Additionally, in the first quarter of 2019, we announced we will introduce our own insulin lispro authorized generic.

Revenue of Alimta, a treatment for various cancers, increased 15 percent in the U.S. during the three months ended March 31, 2019, primarily driven by increased demand. Revenue outside the U.S. decreased 15 percent during the three months ended March 31, 2019, driven by decreased volume resulting from the entry of generic pemetrexed in Germany and, to a lesser extent, 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, increased 3 percent in the U.S. during the three months ended March 31, 2019, primarily due to higher realized prices, partially offset by decreased demand. Revenue outside the U.S. decreased 2 percent during the three months ended March 31, 2019, primarily driven by the unfavorable impact of foreign exchange rates, partially offset by increased volume. Our formulation patents for Forteo expired in December 2018, and our use patents will expire in August 2019 in major European markets and the U.S. Both the formulation patent and the use patent expire in 2019 in Japan. While it is difficult to estimate the severity of the impact of generic and/or biosimilar competition in these markets, we expect a rapid and severe decline in revenue in the U.S. as a result of generic competition when the U.S. patents expire. Outside the U.S., we expect a decline in revenue following patent expirations; however the decline may not be rapid and severe.

Revenue of Cialis, a treatment for erectile dysfunction and benign prostatic hyperplasia, decreased 54 percent in the U.S. during the three months ended March 31, 2019, driven by decreased demand due to generic competition, partially offset by higher realized prices. Revenue outside the U.S. decreased 9 percent during the three months ended March 31, 2019, primarily driven by the unfavorable impact of foreign exchange rates. We lost our compound patent protection for Cialis in the U.S. in September 2018. See "Executive Overview - Other Matters - Patent Matters" for more information. We expect that generic competition due to the loss of exclusivity will continue to cause a rapid and severe decline in revenue.

Revenue of Humulin, an injectable human insulin for the treatment of diabetes, decreased 9 percent in the U.S. during the three months ended March 31, 2019, driven by lower realized prices due to changes in estimates to rebates and discounts and, to a lesser extent, decreased volume. Revenue outside the U.S. decreased 8 percent during the three months ended March 31, 2019, primarily due to the unfavorable impact of foreign exchange rates.

Revenue of Taltz, a product for the treatment of moderate-to-severe plaque psoriasis and active psoriatic arthritis, increased 63 percent in the U.S. during the three months ended March 31, 2019, driven by increased demand, partially offset by lower realized prices. Revenue outside the U.S. increased $36.4 million during the three months ended March 31, 2019, driven by increased volume from recent launches, partially offset by the unfavorable impact of foreign exchange rates.

Revenue of Basaglar, a long-acting human insulin analog for the treatment of diabetes, increased 56 percent in the U.S. during the three months ended March 31, 2019, driven primarily by increased demand and, to a lesser extent, higher realized prices and changes in estimates to rebates and discounts. Revenue outside the U.S. increased 35 percent during the three months ended March 31, 2019, primarily driven by increased volume, partially offset by lower realized prices and 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 Basaglar.

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 32 percent in the U.S. during the three months ended March 31, 2019, driven by increased demand. Revenue outside the U.S. increased 40 percent during the three months ended March 31, 2019, primarily 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.

Revenue of Cyramza, a treatment for various cancers, increased 10 percent in the U.S. during the three months ended March 31, 2019, driven primarily by increased demand. Revenue outside the U.S. increased 7 percent during the three months ended March 31, 2019, driven by increased volume, partially offset by the unfavorable impact of foreign exchange rates and lower realized prices.

40

Gross Margin, Costs, and Expenses

Gross margin as a percent of revenue increased 1.1 percentage points to 77.6 percent for the three months ended March 31, 2019. The increase in gross margin percent was primarily due to the favorable effect of foreign exchange rates on international inventories sold, partially offset by the timing of planned manufacturing production schedules, decreased volume for post-patent products, unfavorable product mix, the negative impact of price on revenue, and charges resulting from the suspension of promotion of Lartruvo.

Research and development expenses increased 11 percent to $1.23 billion for the three months ended March 31, 2019 driven by higher development expenses for late-stage assets.

Marketing, selling, and administrative expenses increased 13 percent to $1.52 billion for the three months ended March 31, 2019 primarily due to increased marketing expenses related to recent product launches.

We recognized $136.9 million of acquired IPR&D charges for the three months ended March 31, 2019 related to the collaborations with AC Immune and ImmuNext. There were no acquired IPR&D charges for the three months ended March 31, 2018.

We recognized asset impairment, restructuring, and other special charges of $423.9 million for the three months ended March 31, 2019, compared with charges of $56.8 million for the three months ended March 31, 2018. The charges for the three months ended March 31, 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. The charges for the three months ended March 31, 2018 were primarily associated with asset impairment, exit costs, and severance costs related to the decision to end Posilac (rbST) production at the Augusta, Georgia manufacturing site. See Note 6 to the consolidated condensed financial statements for additional information.

Other–net, (income) expense was income of $86.0 million and $69.5 million for the three months ended March 31, 2019 and 2018, respectively. The increase was primarily driven by mark-to-market adjustments on investment securities, partially offset by higher net interest expense. See Note 13 to the consolidated condensed financial statements for additional information.

The effective tax rate was 23.3 percent and 14.5 percent for the three months ended March 31, 2019 and 2018, respectively, primarily due to the non-deductibility of accelerated vesting of Loxo employee equity awards as a result of the closing of the acquisition of Loxo.

Financial Condition

Cash and cash equivalents decreased to $2.04 billion as of March 31, 2019, compared with $7.32 billion as of December 31, 2018. Refer to the consolidated condensed statements of cash flows for additional details on the significant sources and uses of cash for the three months ended March 31, 2019 and 2018.

In addition to our cash and cash equivalents, we held total investments of $2.21 billion and $2.09 billion as of March 31, 2019 and December 31, 2018, respectively. See Note 7 to the consolidated condensed financial statements for additional details.

Total debt increased to $15.97 billion as of March 31, 2019, compared with $10.30 billion as of December 31, 2018. The increase primarily related to the issuance of $4.45 billion 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 details.

As of March 31, 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.

As of March 31, 2019, we had $3.10 billion remaining under our $8.00 billion share repurchase program authorized in June 2018. Our share repurchases are facilitated through payments to a financial institution that purchases the shares on our behalf. As of March 31, 2019, we had paid $700 million to a financial institution for shares that are expected to be repurchased in the second quarter of 2019.

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 $8.57 to $8.67, reflecting the benefits of the disposition of Elanco. We now expect 2019 revenue of between $22.0 billion and $22.5 billion, reflecting the disposition of Elanco. Revenue growth is expected to be driven by volume from Trulicity, Taltz, Basaglar, Jardiance, Verzenio, Cyramza and Olumiant. Revenue growth is also expected to benefit from the recent launch of Emgality and could benefit from the potential approval and launch of other medicines in 2019. 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, continued low- to mid-single digit realized price declines in the U.S. driven primarily by patient affordability programs, rebates, and legislated increases to Medicare Part D cost sharing, price declines in some international markets, and the impact of the planned Lartruvo withdrawal. Gross margin as a percent of revenue is now expected to be approximately 79.0 percent. Research and development expenses are now expected to be in the range of $5.5 billion to $5.7 billion. Marketing, selling, and administrative expenses are now expected to be in the range of $5.7 billion to $6.0 billion. Other—net, (income) expense is now expected to be expense between $100 million and $250 million.

The 2019 tax rate is expected to be in the range of 15 percent to 16 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 March 31, 2019, and concluded that they were effective.

(b) Changes in Internal Controls. During the first 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 "Notes to Consolidated Condensed Financial Statements - Note 11, Contingencies" for information on various legal proceedings, including but not limited to:

- The patent litigation and administrative proceedings involving Alimta;
- The product liability litigation involving Cymbalta;
- The litigation in Brazil regarding the Cosmopolis facility;
- The proceedings involving Adocia; and
- The insulin and glucagon 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).

Other Product Liability Litigation

We are named as a defendant in approximately 480 Axiron personal injury/product liability lawsuits in the U.S. involving approximately 480 plaintiffs. In about one-third of the cases, other manufacturers of testosterone are named as co-defendants. Nearly all of these lawsuits have been consolidated in a federal 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. There can be no assurances, however, that a final settlement 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 has filed a Notice of Appeal from this dismissal order. 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 Teva Pharmaceuticals International GMBH and Teva Pharmaceuticals USA, Inc. (collectively, Teva) in the U.S. District Court for the District of Massachusetts seeking a ruling that various claims in nine different Teva patents would be infringed by our launch and continued sales of Emgality for the prevention of migraine in adults. We believe this lawsuit is without merit and are defending against it vigorously. Separately, the U.S. Patent and Trademark Office has granted our request to initiate an inter partes review (IPR) to reexamine the validity of the nine Teva patents asserted against us in the litigation. The litigation in the U.S. District Court for the District of Massachusetts has been stayed pending the outcome of the IPR.

Other Matters

We are also a defendant in other litigation and investigations, including product liability, patent, employment, and premises liability litigation, of a character we regard as normal to our business.

Item 1A. Risk Factors

Our material risk factors are disclosed in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 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 March 31, 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)
January 2019	24,196	$ 115.72	24,196	$ 3,100.0
February 2019	—	—	—	3,100.0
March 2019	—	—	—	3,100.0
Total	24,196	115.72	24,196	

During the three months ended March 31, 2019, we repurchased $2.80 billion of shares under the $8.00 billion share repurchase program authorized in June 2018.

Item 6. Exhibits

The following documents are filed as exhibits to this Report:

EXHIBIT 2.1	Loxo Oncology, Inc. Agreement and Plan of Merger
EXHIBIT 3.1	Amended Articles of Incorporation
EXHIBIT 3.2	By-laws, as amended
EXHIBIT 4.1	Indenture with respect to Debt Securities dated as of February 1, 1991, between Eli Lilly and Company and Deutsche Bank Trust Company Americas, as successor trustee to Citibank, N.A., Trustee
EXHIBIT 4.2	Agreement dated September 13, 2007 appointing Deutsche Bank Trust Company Americas as Successor Trustee under the Indenture listed above
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 2.1	Agreement and Plan of Merger, dated January 5, 2019, among Eli Lilly and Company, Bowfin Acquisition Corporation and Loxo Oncology, Inc, is incorporated by reference to Exhibit 2.1 to the Current Report on Form 8-K filed by Loxo Oncology on January 7, 2019
EXHIBIT 3.1	Amended Articles of Incorporation are incorporated by reference to Exhibit 3.1 to the Company's Report on Form 10-K for the year ended December 31, 2013
EXHIBIT 3.2	By-laws, as amended, are incorporated by reference to Exhibit 99.1 to the Company's Report on Form 8-K dated August 29, 2017
EXHIBIT 4.1	Indenture with respect to Debt Securities dated as of February 1, 1991, between Eli Lilly and Company and Deutsche Bank Trust Company Americas, as successor trustee to Citibank, N.A., Trustee, is incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-3, Registration No. 33-186979
EXHIBIT 4.2	Agreement dated September 13, 2007 appointing Deutsche Bank Trust Company Americas as Successor Trustee under the Indenture listed above, is incorporated by reference to Exhibit 4.2 to the Company's Report on Form 10-K for the year ended December 31, 2008
EXHIBIT 31.1	Rule 13a-14(a) Certification of David A. Ricks, Chairman, President, and Chief Executive Officer
EXHIBIT 31.2	Rule 13a-14(a) Certification of Joshua L. Smiley, Senior Vice President and Chief Financial Officer
EXHIBIT 32.	Section 1350 Certification
EXHIBIT 101.	Interactive Data Files

Signatures

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

ELI LILLY AND COMPANY
(Registrant)

Date: May 2, 2019 /s/Bronwen L. Mantlo
Bronwen L. Mantlo
Corporate Secretary

Date: May 2, 2019 /s/Donald A. Zakrowski
Donald A. Zakrowski
Vice President, Finance and Chief Accounting Officer