UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

Current Report
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **October 24, 2019**

ELI LILLY AND COMPANY
(Exact name of registrant as specified in its charter)

Indiana	001-06351	35-0470950
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

Lilly Corporate Center
Indianapolis, Indiana 46285
(Address of Principal Executive Offices, and Zip Code)

(317) 276-2000
Registrant's Telephone Number, Including Area Code

Not Applicable
Former Name or Former Address, if Changed Since Last Report

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).
Emerging growth company ☐

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

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

Item 8.01 Other Events

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, beginning in our Quarterly Report on Form 10-Q for the first quarter of 2019, we presented Elanco as discontinued operations in our consolidated condensed financial statements for all periods presented. We are issuing this Current Report on Form 8-K to recast Elanco as discontinued operations as of and for each of the periods covered by our 2018 Annual Report on Form 10-K (Form 10-K).

Exhibit 99.1 of this current report on Form 8-K, which is incorporated herein by reference, presents a recast of the following sections of our Form 10-K to present Elanco as discontinued operations: Item 6. Selected Financial Data, Item 7. Management's Discussion and Analysis of Results of Operations and Financial Condition, Item 7A. Quantitative and Qualitative Disclosures About Market Risk, and Item 8. Financial Statements and Supplementary Data. Except as specifically set forth herein, no revisions have been made to the Company's Form 10-K to update for other information, developments, or events that have occurred since our Form 10-K was filed on February 19, 2019.

This Current Report on Form 8-K should be read in conjunction with our Form 10-K and subsequent filings with the Securities and Exchange Commission (SEC), including our Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K. These subsequent SEC filings contain important information regarding events, developments, and updates affecting us and our expectations that have occurred since the filing of the Form 10-K.

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

This Current Report on Form 8-K contains management’s current intentions and expectations for the future, which are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Actual results may differ materially due to various factors, including due to competitive developments affecting current products and the impact of actions of governmental and private payers affecting the pricing of, reimbursement for, and access to pharmaceuticals. For additional information, refer to our latest Form 10-K and 10-Q and any 8-Ks filed with the SEC. You should not place undue reliance on forward-looking statements, which speak only as of the date of 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.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits. The following Exhibits are filed as part of this Report on Form 8-K:

Exhibit Number	Description of Exhibit
23.1	Consent of Independent Registered Public Accounting Firm
99.1	Recast of Eli Lilly and Company's Selected Financial Data, Consolidated Financial Statements and notes thereto as of December 31, 2018 and for each of the years ended December 31, 2018, 2017, and 2016, and the related Management's Discussion and Analysis of Results of Operations and Financial Condition.
101	Interactive Data Files (embedded within the Inline XBRL document)
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

SIGNATURES

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

ELI LILLY AND COMPANY
(Registrant)

By: /s/ Donald A. Zakrowski
Name: Donald A. Zakrowski
Title: Vice President, Finance and
Chief Accounting Officer

Dated: October 24, 2019

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statements (Form S-3 ASR No. 333-229735; and Form S-8 Nos. 333-104057 and 333-172422) of Eli Lilly and Company and in the related Prospectus of our report dated February 19, 2019 (except for the effects of discontinued operations discussed in Note 20, as to which the date is October 24, 2019), with respect to the consolidated financial statements of Eli Lilly and Company and subsidiaries and our report dated February 19, 2019, with respect to the effectiveness of internal control over financial reporting of Eli Lilly and Company and subsidiaries, included in this Current Report on Form 8-K.

/s/ Ernst and Young LLP

Indianapolis, Indiana

October 24, 2019

Exhibit 99.1

The information provided in each Item contained in this Exhibit is presented only in connection with the reporting changes described in the accompanying Current Report on Form 8-K. It does not reflect information, developments, or events occurring after February 19, 2019, the date on which we filed our Form 10-K, and does not update the disclosures therein in any way other than as required to reflect Elanco as discontinued operations. Accordingly, this Current Report on Form 8-K should be read in conjunction with our Form 10-K and subsequent filings with the SEC, including our Quarterly Reports on Form 10-Q.

Item 6. Selected Financial Data (unaudited)

ELI LILLY AND COMPANY AND SUBSIDIARIES (Dollars in millions, except revenue per employee and per-share data)	2018	2017	2016	2015	2014
Operations					
Revenue	**$ 21,493.3**	$ 19,973.8	$ 18,312.8	$ 17,050.5	$ 17,553.2
Cost of sales	**4,681.7**	4,447.7	4,160.5	3,373.1	3,957.0
Research and development	**5,051.2**	5,096.2	5,040.0	4,514.2	4,528.7
Marketing, selling, and administrative	**5,975.1**	5,982.4	5,841.9	5,732.4	6,146.0
Other[1]	**2,105.2**	2,142.7	(5.9)	538.9	288.2
Income before income taxes	**3,680.1**	2,304.8	3,276.3	2,891.9	2,633.3
Income taxes[2]	**529.5**	2,391.2	551.4	379.7	480.9
Net income (loss) from continuing operations	**3,150.6**	(86.4)	2,724.9	2,512.2	2,152.4
Net income (loss) from discontinued operations	**81.4**	(117.7)	12.7	(103.8)	238.1
Net income (loss)	**3,232.0**	(204.1)	2,737.6	2,408.4	2,390.5
Net income (loss) from continuing operations as a percent of revenue	**14.7%**	(0.4)%	14.9%	14.7%	12.3%
Net income (loss) per share from continuing operations—diluted	**$ 3.05**	$ (0.08)	$ 2.57	$ 2.36	$ 2.01
Net income (loss) per share from discontinued operations—diluted	**0.08**	(0.11)	0.01	(0.10)	0.22
Net income (loss) per share—diluted	**3.13**	(0.19)	2.58	2.26	2.23
Dividends declared per share	**2.33**	2.12	2.05	2.01	1.97
Weighted-average number of shares outstanding—diluted (thousands)	**1,033,667**	1,052,023	1,061,825	1,065,720	1,074,286
Financial Position					
Current assets	**$ 20,549.6**	$ 19,202.1	$ 15,101.4	$ 12,573.6	$ 11,928.3
Current liabilities	**11,888.1**	14,535.9	10,986.6	8,229.6	9,741.0
Property and equipment—net	**7,996.1**	7,885.1	7,492.6	7,216.4	7,274.0
Total assets	**43,908.4**	44,981.0	38,805.9	35,568.9	36,307.6
Long-term debt	**9,196.4**	9,940.0	8,367.4	7,971.4	5,330.7
Total equity	**10,909.1**	11,667.9	14,080.5	14,590.3	15,388.1
Supplementary Data					
Return on total equity	**25.7%**	(1.5)%	18.5%	16.1%	13.7%
Return on assets	**7.3%**	(0.5)%	7.5%	6.8%	6.8%
Capital expenditures	**$ 1,210.6**	$ 1,076.8	$ 1,037.0	$ 1,066.2	$ 1,162.6
Depreciation and amortization	**1,609.0**	1,567.3	1,496.6	1,427.7	1,379.0
Effective tax rate[2]	**14.4%**	103.7 %	16.8%	13.1%	18.3%
Revenue per employee	**$ 650,000**	$ 575,000	$ 510,000	$ 490,000	$ 477,000
Number of employees	**33,090**	34,750	35,910	34,790	36,765
Number of shareholders of record	**24,000**	25,300	26,800	28,000	29,300

[1] Other includes acquired in-process research and development, asset impairment, restructuring, and other special charges, and other—net, (income) expense; See Note 3 to the consolidated financial statements for discussion regarding in-process research and development charges; See Note 5 to the consolidated financial statements for discussion regarding asset impairment, restructuring, and other special charges.

[2] See Note 13 to the consolidated financial statements for discussion regarding income taxes.

Item 7. 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 financial statements and accompanying footnotes included herein. Certain statements in this Item 7 constitute forward-looking statements. Various risks and uncertainties, including those discussed in "Forward-Looking Statements" and Item 1A, "Risk Factors" in Part I of our Form 10-K, 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 data are presented on a diluted basis.

Financial Results

The following table summarizes our key operating results:

	Year Ended December 31,		
	2018	**2017**	**Percent Change**
Revenue	**$ 21,493.3**	$ 19,973.8	8
Gross margin	**16,811.6**	15,526.1	8
Gross margin as a percent of revenue	**78.2%**	77.7%	
Operating expense	**$ 11,026.3**	$ 11,078.6	—
Acquired in-process research and development	**1,983.9**	1,112.6	78
Asset impairment, restructuring, and other special charges	**266.9**	1,331.6	(80)
Income before income taxes	**3,680.1**	2,304.8	60
Income taxes	**529.5**	2,391.2	(78)
Net income (loss) from continuing operations	**3,150.6**	(86.4)	NM
Net income (loss) from discontinued operations	**81.4**	(117.7)	NM
Net income	**3,232.0**	(204.1)	NM
Earnings (loss) per share from continuing operations	**3.05**	(0.08)	NM
Earnings (loss) per share from discontinued operations	**0.08**	(0.11)	NM
Earnings (loss) per share	**3.13**	(0.19)	NM

NM - not meaningful

Revenue and gross margin increased in 2018. Income before income taxes increased in 2018 as a higher gross margin, lower asset impairment, restructuring, and other special charges were partially offset by higher acquired in-process research and development (IPR&D) charges. Income taxes decreased in 2018 as we recognized an income tax benefit primarily related to measurement period adjustments to the one-time repatriation transition tax (also known as the 'Toll Tax') and the global intangible low-taxed income (GILTI) provision due to the Tax Cuts and Jobs Act (2017 Tax Act).

The following highlighted items affect comparisons of our 2018 and 2017 financial results:

2018

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

- We recognized acquired IPR&D charges of $1.98 billion primarily related to the acquisition of ARMO Biosciences Inc. (ARMO) and the collaboration with Dicerna Pharmaceuticals (Dicerna).

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

- We recognized charges of $266.9 million primarily associated with asset impairments related to the sale of the Posilac® (rbST) brand and the related sale of the Augusta, Georgia manufacturing site and with expenses related to our efforts to reduce our cost structure.

Income Tax Expense (Note 13 to the consolidated financial statements)

- We recognized $313.3 million of income tax benefit primarily due to measurement period adjustments to the Toll Tax and GILTI.

2017

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

- We recognized acquired IPR&D charges of $1.11 billion primarily related to the acquisition of CoLucid Pharmaceuticals, Inc. (CoLucid).

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

- We recognized charges of $1.33 billion primarily associated with efforts to reduce our cost structure, including the United States (U.S.) voluntary early retirement program.

Income Tax Expense (Note 13 to the consolidated financial statements)

- We recognized a provisional tax expense of $1.91 billion due to the 2017 Tax Act.

Late-Stage Pipeline

Our long-term success depends to a great extent on our ability to continue to discover and develop innovative pharmaceutical products and acquire or collaborate on molecules currently in development by other biotechnology or pharmaceutical companies. We currently have approximately 45 potential new drugs in human testing or under regulatory review and a larger number of projects in preclinical research.

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

Abemaciclib (Verzenio®) (Q3 2017)—a small molecule cell-cycle inhibitor, selective for cyclin-dependent kinases 4 and 6 for the treatment of metastatic breast cancer.

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

Galcanezumab* (Emgality®) (Q3 2018)—a once-monthly subcutaneously injected calcitonin gene-related peptide (CGRP) antibody for the treatment of migraine prevention. Refer to Item 3, "Legal Proceedings - Other Patent Litigation" in Part I of our Form 10-K for discussion of the lawsuit filed by Teva Pharmaceuticals International GMBH.

The following NME had received advanced approval by regulatory authorities in at least one of the major geographies for use in the diseases described, however in January 2019 we announced the phase III trial did not meet the primary endpoint of overall survival. As the trial did not confirm clinical benefit, we are suspending promotion and are working with global regulators to determine the appropriate next steps:

Olaratumab* (Lartruvo®) (Q4 2016)—a lgG1 monoclonal antibody for the treatment of advanced soft tissue sarcoma. See the "Results of Operations - Executive Overview - Other Matters" for more information.

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

Lasmiditan (Q4 2018)—an oral 5-HT_{1F} agonist for the acute treatment of migraine. In the U.S., Lasmiditan is protected by a compound patent (2025).

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), with data protection (3.5 years) expected upon approval. In Europe, nasal glucagon is protected by a delivery device patent (2034), with data protection (6 years) expected upon approval.

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

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

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.

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

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

** Diagnostic agent

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

Compound	Indication	U.S.	Europe	Japan	Developments
Endocrinology					
Nasal glucagon	Severe hypoglycemia	Submitted		Phase III	Submitted to U.S. Food and Drug Administration (FDA) in second quarter of 2018. Submitted to European regulatory authorities in third quarter of 2018.
Tirzepatide	Type 2 diabetes	Phase III			Phase III trials were initiated during the fourth quarter of 2018.
Ultra-rapid Lispro	Type 1 and 2 diabetes	Phase III			In the fourth quarter of 2018, announced Phase III trials met primary efficacy endpoint. Submission to regulatory authorities expected in 2019.
Immunology					
Mirikizumab	Psoriasis	Phase III			Phase III trials were initiated during the second quarter of 2018.
	Ulcerative colitis	Phase III			Phase III trial was initiated during the second quarter of 2018.

Compound	Indication	U.S.	Europe	Japan	Developments
Olumiant	Rheumatoid arthritis	Launched			Granted approval of 2mg dose by FDA and launched in U.S. in second quarter of 2018.
	Atopic dermatitis	Phase III			In the first quarter of 2019, announced Phase III trials met primary endpoint. Additional Phase III trials are ongoing.
	Systemic lupus erythematosus	Phase III			Phase III trials were initiated during the third quarter of 2018. Granted Fast Track designation(1) from the FDA in fourth quarter of 2018.
Neuroscience					
Emgality	Cluster headache	Submitted		Phase III	In the second quarter of 2018, announced Phase III trial met primary endpoint for episodic cluster headache. Received Breakthrough Therapy Designation(2) in the third quarter of 2018. Submitted to FDA in fourth quarter of 2018 and to European regulatory authorities in first quarter of 2019. Granted Priority Review(3) from FDA in first quarter of 2019. A separate Phase III trial did not meet primary endpoint for chronic cluster headache.
	Migraine prevention	Launched		Phase III	Approved and launched in the U.S. in the third and fourth quarters of 2018, respectively. Approved and launched in Europe in the fourth quarter of 2018 and first quarter of 2019, respectively.
Flortaucipir	Alzheimer's disease	Phase III			In the third quarter of 2018, announced Phase III trial met primary endpoints. In discussions with regulatory authorities to determine next steps.
Lanabecestat	Early and mild Alzheimer's disease	Discontinued			Phase III trials discontinued in second quarter of 2018.
Lasmiditan	Migraine	Submitted	Phase III		Submitted to FDA in fourth quarter of 2018. Phase III trials are ongoing.
Solanezumab	Preclinical Alzheimer's disease	Phase III			Phase III trial is ongoing.
Tanezumab	Osteoarthritis pain	Phase III			In the third quarter of 2018 and the first quarter of 2019, announced multiple Phase III trials met primary endpoints. We anticipate additional readouts from the program to be available in 2019.
	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 additional readouts from the program to be available in 2019.
	Cancer pain	Phase III			Phase III trial is ongoing.

Compound	Indication	U.S.	Europe	Japan	Developments
Oncology					
Lartruvo	Soft tissue sarcoma	Launched		Phase III	Granted accelerated approval by the FDA based on Phase II data and launched in the U.S. in 2016. Granted conditional approval and launched in Europe in 2016. In the first quarter of 2019, announced confirmatory phase III trial did not meet primary endpoint. As trial did not confirm clinical benefit, we are suspending promotion and are in discussions with global regulators to determine next steps.
Pegilodecakin	Pancreatic cancer	Phase III			Acquired with ARMO in the second quarter of 2018. Phase III trial is ongoing. See Note 3 to the consolidated financial statements for information on the acquisition.
Verzenio	Adjuvant breast cancer	Phase III			Phase III trial is ongoing.
	Metastatic breast cancer	Launched	Approved		Approved in Europe and Japan in the fourth quarter of 2018.

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

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

(3) 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.

There are many difficulties and uncertainties inherent in human pharmaceutical research and development and the introduction of new products. There is a high rate of failure inherent in new drug discovery and development. To bring a drug from the discovery phase to market can take over a decade and often costs in excess of $2 billion. Failure can occur at any point in the process, including in later stages after substantial investment. As a result, most funds invested in research programs will not generate financial returns. New product candidates that appear promising in development may fail to reach the market or may have only limited commercial success because of efficacy or safety concerns, inability to obtain or maintain necessary regulatory approvals or payer reimbursement or coverage, limited scope of approved uses, changes in the relevant treatment standards or the availability of new or better competitive products, difficulty or excessive costs to manufacture, or infringement of the patents or intellectual property rights of others. Regulatory agencies continue to establish increasingly high hurdles for the efficacy and safety of new products. Delays and uncertainties in drug approval processes can result in delays in product launches and lost market opportunity. In addition, it can be very difficult to predict revenue growth rates of new products.

We manage research and development spending across our portfolio of molecules, and a delay in, or termination of, any one project will not necessarily cause a significant change in our total research and development spending. Due to the risks and uncertainties involved in the research and development process, we cannot reliably estimate the nature, timing, and costs of the efforts necessary to complete the development of our research and development projects, nor can we reliably estimate the future potential revenue that will be generated from a successful research and development project. Each project represents only a portion of the overall pipeline, and none is individually material to our consolidated research and development expense. While we do accumulate certain research and development costs on a project level for internal reporting purposes, we must make significant cost estimations and allocations, some of which rely on data that are neither reproducible nor validated through accepted control mechanisms. Therefore, we do not have sufficiently reliable data to report on total research and development costs by project, by preclinical versus clinical spend, or by therapeutic category.

Other Matters

Elanco Animal Health

On September 24, 2018, Elanco Animal Health Incorporated (Elanco), a subsidiary, completed its IPO of 72.3 million shares of its common stock, which represents 19.8 percent of Elanco's outstanding shares, at $24 per share. In addition, Elanco completed a debt offering and entered into a term loan facility during the third quarter of 2018. See Note 20 to the consolidated financial statements for additional details.

On March 11, 2019, we completed the disposition of our remaining 293.3 million shares of Elanco common stock, which represented 80.2 percent ownership of Elanco's outstanding shares, through a tax-free exchange offer. As a result, in the first quarter of 2019, we presented Elanco as discontinued operations in our consolidated condensed financial statements. Accordingly, all prior periods have been recast to conform to this presentation.

Lartruvo

In January 2019, we announced that we are suspending promotion of Lartruvo because the ANNOUNCE study did not meet the primary endpoint of overall survival. We are working with global regulators to determine the appropriate next steps. We expect to incur a charge in the first quarter of 2019 related to the suspension of promotion for Lartruvo. The exact amount of the charge has not yet been determined, but is estimated to be approximately $80 million (pre-tax), or approximately $0.13 per share (after tax). Revenue related to Lartruvo was $304.7 million in 2018.

Patent Matters

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

We lost patent exclusivity for the bipolar mania indication for Zyprexa® in Japan in April 2016. Generic versions of Zyprexa launched in Japan in June 2016. The loss of exclusivity for Zyprexa in Japan has caused a rapid and severe decline in revenue for the product.

We lost our patent exclusivity for Strattera® in the U.S. in May 2017, and generic versions of Strattera were approved in the same month. Following a settlement related to the compound patent challenge for Effient®, generic products launched in the U.S. in the third quarter of 2017. The entry of generic competition for these products has caused a rapid and severe decline in revenue, which, in the aggregate, has had a material adverse effect on our consolidated results of operations and cash flows.

Our compound patent protection for Cialis® (tadalafil) and Adcirca® (tadalafil) expired in major European markets and the U.S. in November 2017; however, in the U.S., we were granted pediatric exclusivity through May 2018. Pursuant to a settlement agreement related to our unit dose patent in the U.S., generic tadalafil entered the U.S. market in September 2018. We expect that the entry of 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 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.

The Alimta® vitamin regimen patents, which provide us with patent protection for Alimta through June 2021 in Japan and major European countries, and through May 2022 in the U.S., have been challenged in each of these jurisdictions. Our vitamin regimen patents have also been challenged in other smaller European jurisdictions. Our compound patent for Alimta expired in the U.S. in January 2017, and expired in major European countries and Japan in December 2015. We expect that the entry of generic competition for Alimta following the loss of effective patent protection will cause a rapid and severe decline in revenue for the product, which will, in the aggregate, have a material adverse effect on our consolidated results of operations and cash flows. See Note 15 to the consolidated 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 similar version of insulin lispro launched in the U.S. in the second quarter of 2018 and in certain European markets in 2017. While it is difficult to estimate the severity of the impact of similar insulin lispro products entering the market, we do not expect and have not experienced a rapid and severe decline in revenue; however, we expect additional pricing pressure and some loss of market share that would continue over time.

Foreign Currency Exchange Rates

As a global company with substantial operations outside the U.S., we face foreign currency risk exposure from fluctuating currency exchange rates, primarily the U.S. dollar against the euro and Japanese yen. While we manage a portion of these exposures through hedging and other risk management techniques, significant fluctuations in currency rates can have a substantial impact, either positive or negative, on our revenue, cost of sales, and operating expenses. While there is uncertainty in the future movements in foreign exchange rates, fluctuations in these rates could negatively impact our future consolidated results of operations and cash flows.

The impact of the Venezuelan financial crisis, including the significant deterioration of the bolívar, resulted in a charge of $203.9 million in 2016. See Note 17 to the consolidated financial statements for additional information related to the charge. As of December 31, 2018, our Venezuelan subsidiaries represented a *de minimis* portion of our consolidated assets and liabilities. We continue to monitor other deteriorating economies and it is possible that additional charges may be recorded in the future. Any additional charges are not expected to have a material adverse effect on our future consolidated results of operations.

Trends Affecting Pharmaceutical Pricing, Reimbursement, and Access

United States

In the U.S., public concern over access to and affordability of pharmaceuticals continues to drive the regulatory and legislative debate. These policy and political issues increase the risk that taxes, fees, rebates, or other cost control measures may be enacted to manage federal and state budgets. Key health policy proposals affecting biopharmaceuticals include a reduction in biologic data exclusivity, modifications to Medicare Parts B and D, language that would allow the Department of Health and Human Services to negotiate prices for biologics and drugs in Medicare, proposals that would require biopharmaceutical manufacturers to disclose proprietary drug pricing information, and state-level proposals related to prescription drug prices and reducing the cost of pharmaceuticals purchased by government health care programs. California and several other states have enacted legislation related to prescription drug pricing transparency and it is unclear the 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. We expect this increase in the Coverage Gap discounts to negatively impact our results of operations by approximately $200 million in 2019. In May 2018, the White House released "American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs" (Blueprint). The Administration’s corresponding request for information included more than 30 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. We are currently reviewing the proposed rule, the impact of which is uncertain at this time.

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

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 the relevant tax laws, regulations, administrative practices, and interpretations could adversely affect our future effective tax rates. The U.S. recently enacted tax reform legislation, including the 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.

Our accounting for the effects of the 2017 Tax Act, signed into law in December 2017, is complete (see Note 13 to the consolidated financial statements for further information related to the 2017 Tax Act); however, we expect that additional guidance will be issued in 2019 which may materially affect our assumptions and estimates used to record our U.S. federal and state income tax expense resulting from the 2017 Tax Act. Refer to “Results of Operations - Financial Condition” for discussion of the impact of the 2017 Tax Act on our liquidity.

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. Since January 1, 2019, we have acquired Loxo Oncology, Inc. (Loxo). for a purchase price of $235 per share, or approximately $8 billion. We also entered into a license and collaboration agreement with AC Immune SA for an upfront fee of CHF80.0 million and $50.0 million in exchange for a note, convertible to equity at a premium. See Note 3 to the consolidated financial statements for further discussion regarding our recent acquisitions of businesses and assets.

Operating Results—2018

Revenue

The following table summarizes our revenue activity by region:

	Year Ended December 31,		
	2018	2017	Percent Change
U.S.[(1)]	**$ 12,391.9**	$ 11,414.4	9
Outside U.S.	**9,101.4**	8,559.4	6
Revenue	**$ 21,493.3**	$ 19,973.8	8

Numbers may not add due to rounding.

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

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

	2018 vs. 2017		
	U.S.	Outside U.S.	Consolidated
Volume	9 %	8 %	9 %
Price	(1)%	(4)%	(2)%
Foreign exchange rates	— %	2 %	1 %
Percent change	9 %	6 %	8 %

Numbers may not add due to rounding.

In the U.S., the revenue increase in 2018 was driven by increased volume for newer products, including Trulicity®, Basaglar®, Taltz®, Verzenio, and Jardiance®. The increase in revenue was partially offset by decreased volume for products that have lost exclusivity, including Cialis, Effient, and Strattera, as well as lower realized prices for several products, including Trulicity, Basaglar, Forteo, and Taltz.

Outside the U.S., the revenue increase in 2018 was due to increased volume for several newer products, primarily driven by Trulicity, Olumiant, and Taltz and, to a lesser extent, the favorable impact of foreign exchange rates. The increase in revenue was partially offset by lower realized prices for several products.

The following table summarizes our revenue activity in 2018 compared with 2017:

	Year Ended December 31,				
	2018			2017	
Product	U.S.[1]	Outside U.S.	Total	Total	Percent Change
Trulicity	**$ 2,515.8**	**$ 683.3**	**$ 3,199.1**	$ 2,029.8	58
Humalog	**1,787.8**	**1,208.7**	**2,996.5**	2,865.2	5
Alimta	**1,131.0**	**1,001.9**	**2,132.9**	2,062.5	3
Cialis	**1,129.2**	**722.7**	**1,851.8**	2,323.1	(20)
Forteo	**757.9**	**817.7**	**1,575.6**	1,749.0	(10)
Humulin®	**910.2**	**421.2**	**1,331.4**	1,335.4	—
Taltz	**738.7**	**198.7**	**937.5**	559.2	68
Cyramza®	**291.5**	**529.9**	**821.4**	758.3	8
Basaglar	**622.8**	**178.5**	**801.2**	432.1	85
Cymbalta®	**54.3**	**653.7**	**708.0**	757.2	(6)
Jardiance[2]	**400.2**	**258.1**	**658.3**	447.5	47
Erbitux®	**531.6**	**103.8**	**635.3**	645.9	(2)
Trajenta®[3]	**224.2**	**350.5**	**574.7**	537.9	7
Zyprexa	**36.2**	**435.1**	**471.3**	581.2	(19)
Strattera	**89.7**	**361.1**	**450.8**	618.2	(27)
Other products	**1,170.8**	**1,176.5**	**2,347.5**	2,271.3	3
Revenue	**$ 12,391.9**	**$ 9,101.4**	**$ 21,493.3**	$ 19,973.8	8

Numbers may not add due to rounding.

[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 56 percent in the U.S., driven by higher demand. Revenue outside the U.S. increased 63 percent primarily driven by increased volume and, to a lesser extent, the favorable impact of foreign exchange rates, partially offset by lower realized prices.

Revenue of Humalog, our injectable human insulin analog for the treatment of diabetes, increased 4 percent in the U.S., primarily driven by increased demand and, to a lesser extent, higher realized prices due to changes in estimates to rebates and discounts. Revenue outside the U.S. increased 5 percent, driven by increased volume and, to a lesser extent, the favorable impact of foreign exchange rates, partially offset by lower realized prices. A similar version of insulin lispro launched in the U.S. in the second quarter of 2018 and in certain European markets in 2017. While it is difficult to estimate the severity of the impact of similar insulin lispro products entering the market, we do not expect and have not experienced a rapid severe decline in revenue; however, we expect additional pricing pressure and some loss of market share that would continue over time.

Revenue of Alimta, a treatment for various cancers, increased 9 percent in the U.S., driven by increased demand and higher realized prices. Revenue outside the U.S. decreased 3 percent, driven by lower volume due to competitive pressure and the loss of exclusivity in certain European countries, including Germany, and lower realized prices, partially offset by the favorable impact of foreign exchange rates. We have faced and remain exposed to generic entry in multiple countries, which has eroded revenue and is likely to continue to erode revenue in those countries from current levels.

Revenue of Cialis, a treatment for erectile dysfunction and benign prostatic hyperplasia, decreased 17 percent in the U.S., driven by decreased demand primarily due to the entry of generic tadalafil, partially offset by higher realized prices. Revenue outside the U.S. decreased 25 percent, driven by the loss of exclusivity in Europe. We lost our compound patent protection for Cialis in major European markets in November 2017 and U.S. exclusivity ended in late September 2018. See "Results of Operations - Executive Overview - Other Matters - Patent Matters" for more information. In addition to competition from generic tadalafil, we also currently face competition from generic sildenafil, which accelerated during 2018. We expect that the entry of generic competition due to the loss of exclusivity will continue to cause a rapid and severe decline in revenue.

Revenue of Forteo, an injectable treatment for osteoporosis in postmenopausal women and men at high risk for fracture and for glucocorticoid-induced osteoporosis in men and postmenopausal women, decreased 21 percent in the U.S., driven by decreased demand, and, to a lesser extent, lower realized prices. Revenue outside the U.S. increased 4 percent, driven by increased volume and the favorable impact of foreign exchange rates, partially offset by lower realized prices. Our formulation patent for Forteo expired in December 2018 in major European markets and the U.S. Our use patent for Forteo expires 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. See "Executive Overview - Other Matters - Patent Matters" for more information.

Revenue of Humulin, an injectable human insulin for the treatment of diabetes, increased 3 percent in the U.S., driven by increased volume, partially offset by lower realized prices primarily due to changes in segment mix and, to a lesser extent, the impact of patient affordability programs. Revenue outside the U.S. decreased 7 percent, primarily driven by decreased volume and, to a lesser extent, lower realized prices.

Revenue of Taltz, a treatment for moderate-to-severe plaque psoriasis and active psoriatic arthritis, increased 52 percent in the U.S., primarily driven by increased demand, partially offset by lower realized prices. Revenue outside the U.S. increased $125.6 million, driven by increased volume from recent launches, partially offset by lower realized prices.

Revenue of Cyramza, a treatment for various cancers, increased 5 percent in the U.S., driven by increased demand and, to a lesser extent, higher realized prices. Revenue outside the U.S. increased 10 percent, primarily due to increased volume and, to a lesser extent, the favorable impact of foreign exchange rates, partially offset by lower realized prices.

Revenue of Basaglar, a long-acting human insulin analog for the treatment of diabetes, increased $311.7 million in the U.S., driven by increased demand, partially offset by lower realized prices due to increased volume in Medicare Part D. Revenue outside the U.S. increased $57.5 million primarily driven by increased volume.

Revenue of Cymbalta, a product for the treatment of major depressive disorder, diabetic peripheral neuropathic pain, generalized anxiety disorder, chronic musculoskeletal pain, and the management of fibromyalgia, decreased 53 percent in the U.S. driven by decreased volume, partially offset by higher realized prices. Revenue outside the U.S. increased 2 percent, driven by increased volume in Japan.

Gross Margin, Costs, and Expenses

Gross margin as a percent of total revenue was 78.2 percent in 2018, an increase of 0.5 percentage points compared with 2017, primarily due to manufacturing efficiencies and lower amortization expenses, offset by the impact of foreign exchange rates on international inventories sold, the timing of manufacturing production, and the negative impact of price on revenue.

Research and development expenses decreased 1 percent to $5.05 billion in 2018 driven by lower development expenses for lanabecestat, partially offset by higher expenses for other late-stage assets.

Marketing, selling, and administrative expenses remained flat in 2018 compared to 2017.

Both research and development expenses and marketing, selling, and administrative expenses benefited during 2018 from actions taken to reduce our cost structure.

We recognized acquired IPR&D charges of $1.98 billion in 2018 primarily related to the acquisition of ARMO and the collaboration with Dicerna. In 2017, we recognized acquired IPR&D charges of $1.11 billion primarily related to the acquisition of CoLucid.

We recognized asset impairment, restructuring, and other special charges of $266.9 million in 2018. The charges are primarily associated with asset impairments related to the sale of the Posilac (rbST) brand and the related sale of the Augusta, Georgia manufacturing site and with expenses associated with efforts to reduce our cost structure. In 2017, we recognized $1.33 billion of asset impairment, restructuring, and other special charges primarily associated with efforts to reduce our cost structure, including the U.S. voluntary early retirement program, and asset impairments related to lower projected revenue for Posilac (rbST).

Other—net, (income) expense was income of $145.6 million in 2018 compared to income of $301.5 million in 2017 driven by lower net gains on sales of investments.

During 2018, we recorded income tax expense of $529.5 million while earning $3.68 billion of income before income taxes. We recognized $313.3 million of income tax benefit primarily due to measurement period adjustments to the Toll Tax and GILTI. During 2017, we recorded income tax expense of $2.40 billion, which included a provisional tax charge of $1.91 billion, despite earning $2.30 billion of income before income taxes. The provisional tax charge was a result of the 2017 Tax Act, including the Toll Tax.

Operating Results—2017

Financial Results

The following table summarizes our key operating results:

	Year Ended December 31,		
	2017	2016	Percent Change
Revenue	$ 19,973.8	$ 18,312.8	9
Gross margin	15,526.1	14,152.3	10
Gross margin as a percent of revenue	77.7%	77.3%	
Operating expense	$ 11,078.6	$ 10,881.9	2
Acquired in-process research and development	1,112.6	30.0	NM
Asset impairment, restructuring, and other special charges	1,331.6	72.9	NM
Income before income taxes	2,304.8	3,276.3	(30)
Income taxes	2,391.2	551.4	NM
Net income (loss) from continuing operations	(86.4)	2,724.9	NM
Net income (loss) from discontinued operations	(117.7)	12.7	NM
Net income (loss)	(204.1)	2,737.6	NM
Earnings (loss) per share from continuing operations	(0.08)	2.57	NM
Earnings (loss) per share from discontinued operations	(0.11)	0.01	NM
Earnings (loss) per share	(0.19)	2.58	NM

NM - not meaningful

Revenue and gross margin increased in 2017. The increase in operating expense in 2017 was primarily due to an increase in marketing, selling, and administrative expense. Income before income taxes decreased in 2017 as higher asset impairment, restructuring, and other special charges, acquired IPR&D charges and, to a lesser extent, higher operating expense were partially offset by a higher gross margin. Tax expense exceeded income before income taxes in 2017 as a result of the 2017 Tax Act, resulting in a net loss for the year.

Certain items affect the comparisons of our 2017 and 2016 results. The 2017 highlighted items are summarized in the "Results of Operations - Executive Overview" section. The 2016 highlighted items are summarized as follows:

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

- We recognized acquired IPR&D charges of $30.0 million related to upfront fees paid in connection with a collaboration agreement with AstraZeneca to co-develop MEDI1814, a potential disease-modifying treatment for Alzheimer's disease.

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

- We recognized charges of $72.9 million primarily related to global severance costs.

Other-Net, (Income) Expense (Note 17 to the consolidated financial statements)

- We recognized charges of $203.9 million related to the impact of the Venezuelan financial crisis, including the significant deterioration of the bolívar.

Revenue

The following table summarizes our revenue activity by region:

	Year Ended December 31,		
	2017	2016	Percent Change
U.S. [1]	$ 11,414.4	$ 10,147.0	12
Outside U.S.	8,559.4	8,165.8	5
Revenue	$ 19,973.8	$ 18,312.8	9

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 to the prior year:

	2017 vs. 2016		
	U.S.	Outside U.S.	Consolidated
Volume	7%	7 %	7%
Price	6%	(1)%	3%
Foreign exchange rates	—%	(1)%	—%
Percent change	12%	5 %	9%

Numbers may not add due to rounding.

In the U.S., the revenue increase in 2017 was driven by increased volume for newer products, including Trulicity, Taltz, Basaglar, Lartruvo, and Jardiance, and higher realized prices for several products, primarily Forteo and Cialis. The increase in revenue was partially offset by decreased volume due to loss of exclusivity for Strattera and Effient, as well as decreased demand for Cialis. Cymbalta revenue declined, as 2016 revenue benefited from reductions to the reserve for expected product returns of approximately $175 million.

Outside the U.S., the revenue increase in 2017 was due to increased volume for several new products, primarily driven by Trulicity and Cyramza. The increase in revenue was partially offset by competitive pressure and the loss of exclusivity for Alimta in several countries and lower volume from the loss of exclusivity for Zyprexa in Japan.

The following table summarizes our revenue activity in 2017 compared with 2016:

	Year Ended December 31,				
	2017			2016	
Product	U.S.[1]	Outside U.S.	Total	Total	Percent Change
Humalog	$ 1,717.8	$ 1,147.4	$ 2,865.2	$ 2,768.8	3
Cialis	1,358.6	964.5	2,323.1	2,471.6	(6)
Alimta	1,034.3	1,028.2	2,062.5	2,283.3	(10)
Trulicity	1,609.8	419.9	2,029.8	925.5	NM
Forteo	965.2	783.8	1,749.0	1,500.0	17
Humulin	884.6	450.7	1,335.4	1,365.9	(2)
Cyramza	278.8	479.6	758.3	614.1	23
Cymbalta	114.9	642.2	757.2	930.5	(19)
Erbitux	541.7	104.2	645.9	687.0	(6)
Strattera	284.9	333.3	618.2	854.7	(28)
Zyprexa	75.5	505.7	581.2	725.3	(20)
Taltz	486.0	73.2	559.2	113.1	NM
Trajenta[2]	213.2	324.7	537.9	436.6	23
Jardiance[3]	290.4	157.0	447.5	201.9	NM
Basaglar	311.1	121.0	432.1	86.1	NM
Effient	340.1	48.8	388.9	535.2	(27)
Other products	907.5	975.2	1,882.4	1,813.2	4
Revenue	$ 11,414.4	$ 8,559.4	$ 19,973.8	$ 18,312.8	9

Numbers may not add due to rounding.

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

[2] Trajenta revenue includes Jentadueto.

[3] Jardiance revenue includes Glyxambi and Synjardy.

NM - not meaningful

Revenue of Humalog increased 2 percent in the U.S., primarily driven by higher realized prices due to changes in estimates for rebates and discounts, which decreased revenue in 2016 and increased revenue in 2017. Revenue outside the U.S. increased 6 percent, driven by increased volume and, to a lesser extent, higher realized prices, partially offset by the unfavorable impact of foreign exchange rates.

Revenue of Cialis decreased 8 percent in the U.S., driven by decreased demand partially offset by higher realized prices. Revenue outside the U.S. decreased 4 percent, driven by decreased volume, partially offset by higher realized prices.

Revenue of Alimta decreased 6 percent in the U.S., driven by decreased demand due to competitive pressure. Revenue outside the U.S. decreased 13 percent, driven by competitive pressure and the loss of exclusivity in several countries.

Revenue of Trulicity increased 118 percent in the U.S., driven by increased share of market for Trulicity and growth in the GLP-1 class. Revenue outside the U.S. increased 123 percent.

Revenue of Forteo increased 25 percent in the U.S., driven by higher realized prices and increased volume, primarily due to wholesaler buying patterns. Revenue outside the U.S. increased 7 percent, driven by increased volume, partially offset by the unfavorable impact of foreign exchange rates and lower realized prices.

Revenue of Humulin increased 3 percent in the U.S., driven by higher realized prices. Revenue outside the U.S. decreased 11 percent, driven primarily by decreased volume and lower realized prices.

Revenue of Cyramza increased 3 percent in the U.S., driven by increased volume. Revenue outside the U.S. increased 39 percent, primarily due to strong volume growth in Japan, partially offset by lower realized prices and, to a lesser extent, the unfavorable impact of foreign exchange rates.

Revenue of Cymbalta decreased 57 percent in the U.S., driven by reductions to the reserve for expected product returns, which increased revenue by approximately $175 million in 2016. Revenue outside the U.S. decreased 3 percent driven by the loss of exclusivity in Canada and Europe, partially offset by increased volume in Japan.

Revenue of Erbitux, a treatment for various cancers, decreased 7 percent in the U.S. in 2017. The decrease was due to increased competition from immuno-oncology products.

Revenue of Strattera, a treatment for attention-deficit hyperactivity disorder, decreased 47 percent in the U.S., driven by the loss of exclusivity in the second quarter of 2017, partially offset by higher realized prices. The entry of generic competition following the loss of effective patent protection has caused a rapid and severe decline in revenue. Revenue outside the U.S. increased 4 percent, driven by increased volume in Japan, partially offset by lower realized prices and the unfavorable impact of foreign exchange rates, primarily the Japanese yen.

Gross Margin, Costs, and Expenses

Gross margin as a percent of total revenue was 77.7 percent in 2017, an increase of 0.4 percentage points compared with 2016.

Research and development expenses increased 1 percent to $5.10 billion in 2017.

Marketing, selling, and administrative expenses increased 2 percent to $5.98 billion in 2017, driven by increased marketing expenses for new products that were partially offset by decreased expenses related to late life-cycle products.

We recognized acquired IPR&D charges of $1.11 billion in 2017 resulting from business development activity, primarily related to the acquisition of CoLucid. In 2016, we recognized acquired IPR&D charges of $30.0 million associated with the agreement with AstraZeneca to co-develop MEDI1814. See Note 3 to the consolidated financial statements for additional information.

We recognized asset impairment, restructuring, and other special charges of $1.33 billion in 2017. The charges are primarily associated with efforts to reduce our cost structure, including the U.S. voluntary early retirement program and asset impairments related to lower projected revenue for Posilac (rbST). In 2016, we recognized $72.9 million of asset impairment, restructuring, and other special charges primarily associated with global severance costs associated with actions taken to reduce cost structure. See Note 5 to the consolidated financial statements for additional information.

Other-net, (income) expense was income of $301.5 million in 2017, compared with income of $108.8 million in 2016. Other-net, (income) expense in 2016 included a $203.9 million charge related to the impact of the Venezuelan financial crisis, including the significant deterioration of the bolívar. See Note 17 to the consolidated financial statements for additional information.

During 2017, we recorded income tax expense of $2.39 billion, which included a provisional tax charge of $1.91 billion, despite earning $2.30 billion of income before income taxes. The provisional tax charge was a result of the 2017 Tax Act. The effective tax rate in 2016 was 16.8 percent.

FINANCIAL CONDITION

As of December 31, 2018, cash and cash equivalents were $7.32 billion, an increase of $1.11 billion, compared with $6.21 billion at December 31, 2017. Refer to the Consolidated Statements of Cash Flows for additional details on the significant sources and uses of cash for the years ended December 31, 2018 and December 31, 2017.

In addition to our cash and cash equivalents, we held total investments of $2.09 billion and $7.16 billion as of December 31, 2018 and December 31, 2017, respectively. See Note 7 to the consolidated financial statements for additional details.

As of December 31, 2018, total debt was $10.30 billion, a decrease of $3.35 billion compared with $13.65 billion at December 31, 2017. The decrease was primarily due to the net decrease in the balance of commercial paper outstanding of $2.20 billion and the repayment of $1.01 billion of long term debt. See Note 10 to the consolidated financial statements for additional details.

As of December 31, 2018, we had a total of $5.42 billion of unused committed bank credit facilities, $5.00 billion of which is available to support our commercial paper program. See Note 10 to the consolidated financial statements for additional details. In January 2019, we entered into a $4.00 billion credit facility to support our commercial paper program. We believe that amounts accessible through existing commercial paper markets should be adequate to fund short-term borrowing needs.

For the 133rd consecutive year, we distributed dividends to our shareholders. Dividends of $2.25 per share and $2.08 per share were paid in 2018 and 2017, respectively. In the fourth quarter of 2018, effective for the dividend to be paid in the first quarter of 2019, the quarterly dividend was increased to $0.645 per share, resulting in an indicated annual rate for 2019 of $2.58 per share.

Capital expenditures of $1.21 billion during 2018 were $133.8 million more than in 2017.

In 2018, we repurchased $4.15 billion of shares. We completed the $5.00 billion share repurchase program announced in October 2013, and the board authorized a new $8.00 billion share repurchase program. There were $2.10 billion of shares repurchased under the $8.00 billion program during 2018. See Note 12 to the consolidated financial statements for additional details. In January 2019, we initiated $3.50 billion of share repurchases that will conclude in the first half of 2019. These purchases are part of the $8.00 billion program previously authorized by the Board.

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.

In February 2019, we completed our acquisition of Loxo for $235 per share or approximately $8 billion, which will be funded through a mixture of cash and debt. See Note 3 to the consolidated financial statements for additional information.

See "Results of Operations - Executive Overview - Other Matters - Patent Matters" for information regarding recent and upcoming losses of patent protection.

Pursuant to the 2017 Tax Act, the U.S. transitioned to a territorial tax system effective January 1, 2018; therefore, repatriations of cash from our foreign subsidiaries to the U.S. provides us with additional liquidity in the U.S. without the requirement to pay U.S. taxes as existed prior to the enactment of the new tax law. We believe cash provided by operating activities, along with available cash and cash equivalents, should be sufficient to fund our normal operating needs, including installment payments of the Toll Tax, dividends paid to shareholders, share repurchases, and capital expenditures.

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; and various international government funding levels.

In the normal course of business, our operations are exposed to fluctuations in interest rates and currency values. These fluctuations 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 on earnings of fluctuations in interest and currency exchange rates. All derivative activities are for purposes other than trading.

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 positions and may enter into interest rate derivatives to help maintain that balance. Based on our overall interest rate exposure at December 31, 2018 and 2017, including derivatives and other interest rate risk-sensitive instruments, a hypothetical 10 percent change in interest rates applied to the fair value of the instruments as of December 31, 2018 and 2017, respectively, would not have a material impact on earnings, cash flows, or fair values of interest rate risk-sensitive instruments over a one-year period.

Our foreign currency risk exposure results from fluctuating currency exchange rates, primarily the U.S. dollar against the euro and Japanese yen. We face foreign currency exchange exposures when we enter into transactions arising from subsidiary trade and loan payables and receivables denominated in foreign currencies. We also face currency exposure that arises from translating the results of our global operations to the U.S. dollar at exchange rates that have fluctuated from the beginning of the period. We may enter into foreign currency forward or option derivative contracts to reduce the effect of fluctuating currency exchange rates (principally the euro and the Japanese yen). Our corporate risk-management policy outlines the minimum and maximum hedge coverage of such exposures. Gains and losses on these derivative contracts offset, in part, the impact of currency fluctuations on the existing assets and liabilities. We periodically analyze the fair values of the outstanding foreign currency derivative contracts to determine their sensitivity to changes in foreign exchange rates. A hypothetical 10 percent change in exchange rates (primarily against the U.S. dollar) applied to the fair values of our outstanding foreign currency derivative contracts as of December 31, 2018 and 2017, would not have a material impact on earnings, cash flows, or financial position over a one-year period. This sensitivity analysis does not consider the impact that hypothetical changes in exchange rates would have on the underlying foreign currency denominated transactions.

Off-Balance Sheet Arrangements and Contractual Obligations

We have no off-balance sheet arrangements that have a material current effect or that are reasonably likely to have a material future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures, or capital resources. We acquire and collaborate on potential products still in development and enter into research and development arrangements with third parties that often require milestone and royalty payments to the third party contingent upon the occurrence of certain future events linked to the success of the asset in development. Milestone payments may be required contingent upon the successful achievement of an important point in the development life cycle of the pharmaceutical product (e.g., approval for marketing by the appropriate regulatory agency or upon the achievement of certain sales levels). If required by the arrangement, we may make royalty payments based upon a percentage of the sales of the pharmaceutical product in the event that regulatory approval for marketing is obtained. Because of the contingent nature of these payments, they are not included in the table of contractual obligations below.

Individually, these arrangements are generally not material in any one annual reporting period. However, if milestones for multiple products covered by these arrangements were reached in the same reporting period, the aggregate charge to expense or aggregate milestone payments made could be material to the results of operations or cash flows, respectively, in that period. See Note 4 to the consolidated financial statements for additional details. These arrangements often give us the discretion to unilaterally terminate development of the product, which would allow us to avoid making the contingent payments; however, we are unlikely to cease development if the compound successfully achieves milestone objectives. We also note that, from a business perspective, we view these payments as positive because they signify that the product is successfully moving through development and is now generating or is more likely to generate cash flows from sales of products.

Our current noncancelable contractual obligations that will require future cash payments are as follows:

	Payments Due by Period				
(Dollars in millions)	Total	Less Than 1 Year	1-3 Years	3-5 Years	More Than 5 Years
Long-term debt, including interest payments[1]	$ 13,647.3	$ 847.8	$ 552.6	$ 1,970.5	$ 10,276.4
Capital lease obligations	11.8	4.5	5.9	1.4	—
Operating leases	709.6	130.6	183.4	114.6	281.0
Purchase obligations[2]	15,930.7	15,716.6	204.5	9.6	—
2017 Tax Act one-time Toll Tax[3]	2,836.5	159.8	509.8	732.9	1,434.0
Other long-term liabilities reflected on our balance sheet[4]	1,559.8	—	401.6	190.8	967.4
Total	$ 34,695.7	$ 16,859.3	$ 1,857.8	$ 3,019.8	$ 12,958.8

[1] Our long-term debt obligations include both our expected principal and interest obligations and our interest rate swaps. We used the interest rate forward curve at December 31, 2018, to compute the amount of the contractual obligation for interest on the variable rate debt instruments and swaps.

[2] We have included the following:

- Purchase obligations consisting primarily of all open purchase orders as of December 31, 2018. Some of these purchase orders may be cancelable; however, for purposes of this disclosure, we have not distinguished between cancelable and noncancelable purchase obligations.
- Contractual payment obligations with each of our significant vendors, which are noncancelable and are not contingent.

[3] The 2017 Tax Act provided an election to taxpayers subject to the Toll Tax to make payments over an eight-year period. We made this election; therefore, we have included future Toll Tax payments accordingly.

[4] We have included long-term liabilities consisting primarily of our nonqualified supplemental pension funding requirements and other post-employment benefit liabilities. We excluded long-term income taxes payable of $1.02 billion, because we cannot reasonably estimate the timing of future cash outflows associated with those liabilities.

The contractual obligations table is current as of December 31, 2018. We expect the amount of these obligations to change materially over time as new contracts are initiated and existing contracts are completed, terminated, or modified.

APPLICATION OF CRITICAL ACCOUNTING ESTIMATES

In preparing our financial statements in accordance with accounting principles generally accepted in the U.S. (GAAP), we must often make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses, and related disclosures. Some of those judgments can be subjective and complex, and consequently actual results could differ from those estimates. For any given individual estimate or assumption we make, it is possible that other people applying reasonable judgment to the same facts and circumstances could develop different estimates. We believe that, given current facts and circumstances, it is unlikely that applying any such other reasonable judgment would cause a material adverse effect on our consolidated results of operations, financial position, or liquidity for the periods presented in this report. Our most critical accounting estimates have been discussed with our audit committee and are described below.

Revenue Recognition and Sales Return, Rebate, and Discount Accruals

We recognize revenue primarily from two different types of contracts, product sales to customers (net product revenue) and collaborations and other arrangements. Revenue recognized from collaborations and other arrangements will include our share of profits from the collaboration, as well as royalties, upfront and milestone payments we receive under these types of contracts. Refer to Note 1 to the consolidated financial statements for further information on revenue recognition and sales return, rebate, and discount accruals.

Financial Statement Impact

We believe that our accruals for sales returns, rebates, and discounts are reasonable and appropriate based on current facts and circumstances. Our global rebate and discount liabilities are included in sales rebates and discounts on our consolidated balance sheet. Our global sales return liability is included in other current liabilities and other noncurrent liabilities on our consolidated balance sheet. As of December 31, 2018, a 5 percent change in our global sales return, rebate, and discount liability would have led to an approximate $265 million effect on our income before income taxes.

The portion of our global sales return, rebate, and discount liability resulting from sales of our products in the U.S. was approximately 90 percent as of December 31, 2018 and December 31, 2017.

The following represents a roll-forward of our most significant U.S. sales return, rebate, and discount liability balances, including managed care, Medicare, and Medicaid:

(Dollars in millions)	2018	2017
Sales return, rebate, and discount liabilities, beginning of year	**$ 4,172.0**	$ 3,601.8
Reduction of net sales due to sales returns, discounts, and rebates[1]	**12,529.6**	10,603.4
Cash payments of discounts and rebates	**(12,023.4)**	(10,033.2)
Sales return, rebate, and discount liabilities, end of year	**$ 4,678.2**	$ 4,172.0

[1] Adjustments of the estimates for these returns, rebates, and discounts to actual results were approximately 1 percent of consolidated net sales for each of the years presented.

Product Litigation Liabilities and Other Contingencies

Background and Uncertainties

Product litigation liabilities and other contingencies are, by their nature, uncertain and based upon complex judgments and probabilities. The factors we consider in developing our product litigation liability reserves and other contingent liability amounts include the merits and jurisdiction of the litigation, the nature and the number of other similar current and past matters, the nature of the product and the current assessment of the science subject to the litigation, and the likelihood of settlement and current state of settlement discussions, if any. In addition, we accrue for certain product liability claims incurred, but not filed, to the extent we can formulate a reasonable estimate of their costs based primarily on historical claims experience and data regarding product usage. We accrue legal defense costs expected to be incurred in connection with significant product liability contingencies when both probable and reasonably estimable.

We also consider the insurance coverage we have to diminish the exposure for periods covered by insurance. In assessing our insurance coverage, we consider the policy coverage limits and exclusions, the potential for denial of coverage by the insurance company, the financial condition of the insurers, and the possibility of and length of time for collection. Due to a very restrictive market for product liability insurance, we are self-insured for product liability losses for all our currently marketed products. In addition to insurance coverage, we also consider any third-party indemnification to which we are entitled or under which we are obligated. With respect to our third-party indemnification rights, these considerations include the nature of the indemnification, the financial condition of the indemnifying party, and the possibility of and length of time for collection.

The litigation accruals and environmental liabilities and the related estimated insurance recoverables have been reflected on a gross basis as liabilities and assets, respectively, on our consolidated balance sheets.

Impairment of Indefinite-Lived and Long-Lived Assets

Background and Uncertainties

We review the carrying value of long-lived assets (both intangible and tangible) for potential impairment on a periodic basis and whenever events or changes in circumstances indicate the carrying value of an asset (or asset group) may not be recoverable. We identify impairment by comparing the projected undiscounted cash flows to be generated by the asset (or asset group) to its carrying value. If an impairment is identified, a loss is recorded equal to the excess of the asset's net book value over its fair value, and the cost basis is adjusted.

Goodwill and indefinite-lived intangible assets are reviewed for impairment at least annually and when certain impairment indicators are present. When required, a comparison of fair value to the carrying amount of assets is performed to determine the amount of any impairment.

Several methods may be used to determine the estimated fair value of acquired IPR&D, all of which require multiple assumptions. We utilize the "income method," as described in Note 8 to the consolidated financial statements.

For acquired IPR&D assets, the risk of failure has been factored into the fair value measure and there can be no certainty that these assets ultimately will yield a successful product, as discussed previously in "Results of Operations - Executive Overview - Late-Stage Pipeline." The nature of the pharmaceutical business is high-risk and requires that we invest in a large number of projects to maintain a successful portfolio of approved products. As such, it is likely that some acquired IPR&D assets will become impaired in the future.

Estimates of future cash flows, based on what we believe to be reasonable and supportable assumptions and projections, require management's judgment. Actual results could vary materially from these estimates.

Retirement Benefits Assumptions

Background and Uncertainties

Defined benefit pension plan and retiree health benefit plan costs include assumptions for the discount rate, expected return on plan assets, and retirement age. These assumptions have a significant effect on the amounts reported. In addition to the analysis below, see Note 14 to the consolidated financial statements for additional information regarding our retirement benefits.

Annually, we evaluate the discount rate and the expected return on plan assets in our defined benefit pension and retiree health benefit plans. We use an actuarially determined, plan-specific yield curve of high quality, fixed income debt instruments to determine the discount rates. In evaluating the expected return on plan assets, we consider many factors, with a primary analysis of current and projected market conditions, asset returns and asset allocations (approximately 70 percent of which are growth investments); and the views of leading financial advisers and economists. We may also review our historical assumptions compared with actual results, as well as the discount rates and expected return on plan assets of other companies, where applicable. In evaluating our expected retirement age assumption, we consider the retirement ages of our past employees eligible for pension and medical benefits together with our expectations of future retirement ages.

Financial Statement Impact

If the 2018 discount rate for the U.S. defined benefit pension and retiree health benefit plans (U.S. plans) were to change by a quarter percentage point, income before income taxes would change by $33.7 million. If the 2018 expected return on plan assets for U.S. plans were to change by a quarter percentage point, income before income taxes would change by $25.6 million. If our assumption regarding the 2018 expected age of future retirees for U.S. plans were adjusted by one year, our income before income taxes would be affected by $49.1 million. The U.S. plans, including Puerto Rico, represent approximately 75 percent and 80 percent of the total projected benefit obligation and total plan assets, respectively, at December 31, 2018.

Income Taxes

Background and Uncertainties

We prepare and file tax returns based upon our interpretation of tax laws and regulations and record estimates based on these judgments and interpretations. In the normal course of business, our tax returns are subject to examination by various taxing authorities, which may result in future tax, interest, and penalty assessments by these authorities. Inherent uncertainties exist in estimates of many tax positions due to changes in tax law resulting from legislation and regulation as concluded through the various jurisdictions' tax court systems. We recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The tax benefits recognized in the financial statements from such a position are measured based on the largest benefit that has a greater than 50 percent likelihood of being realized upon ultimate resolution. The amount of unrecognized tax benefits is adjusted for changes in facts and circumstances. For example, adjustments could result from significant amendments to existing tax law, the issuance of regulations or interpretations by the taxing authorities, new information obtained during a tax examination, or resolution of a tax examination. We believe our estimates for uncertain tax positions are appropriate and sufficient to pay assessments that may result from examinations of our tax returns. We recognize both accrued interest and penalties related to unrecognized tax benefits in income tax expense.

We have recorded valuation allowances against certain of our deferred tax assets, primarily those that have been generated from net operating losses and tax credit carryforwards in certain taxing jurisdictions. In evaluating whether we would more likely than not recover these deferred tax assets, we have not assumed any future taxable income or tax planning strategies in the jurisdictions associated with these carryforwards where history does not support such an assumption. Implementation of tax planning strategies to recover these deferred tax assets or future income generation in these jurisdictions could lead to the reversal of these valuation allowances and a reduction of income tax expense.

The 2017 Tax Act was enacted in December 2017 and introduced significant changes to the U.S. corporate income tax system. In accordance with GAAP, our accounting for the effects of the 2017 Tax Act is complete

(refer to "Results of Operations - Executive Overview - Other Matters - Tax Matters" and Note 13 to the consolidated financial statements for further discussion on the 2017 Tax Act). Subsequent to the enactment of the 2017 Tax Act, numerous items of additional guidance were issued, including Notices, Proposed Regulations, and Final Regulations. We expect that further guidance will be issued in 2019 which may change our interpretations of the new tax laws and could materially affect the estimates used to record U.S. federal and state income tax expense.

Financial Statement Impact

As of December 31, 2018, a 5 percent change in the amount of uncertain tax positions and the valuation allowance would result in a change in net income of $74.0 million and $28.7 million, respectively.

Acquisitions

Background and Uncertainties

To determine whether acquisitions or licensing transactions should be accounted for as a business combination or as an asset acquisition, we make certain judgments, which include assessing whether the acquired set of activities and assets would meet the definition of a business under the relevant accounting rules.

If the acquired set of activities and assets meets the definition of a business, assets acquired and liabilities assumed are required to be recorded at their respective fair values as of the acquisition date. The excess of the purchase price over the fair value of the acquired net assets, where applicable, is recorded as goodwill. If the acquired set of activities and assets does not meet the definition of a business, the transaction is recorded as an acquisition of assets and, therefore, any acquired IPR&D that does not have an alternative future use is charged to expense at the acquisition date, and goodwill is not recorded. Refer to Note 3 to the consolidated financial statements for additional information.

The judgments made in determining estimated fair values assigned to assets acquired and liabilities assumed in a business combination, as well as estimated asset lives, can materially affect our consolidated results of operations. The fair values of intangible assets, including acquired IPR&D, are determined using information available near the acquisition date based on expectations and assumptions that are deemed reasonable by management. Depending on the facts and circumstances, we may deem it necessary to engage an independent valuation expert to assist in valuing significant assets and liabilities.

The fair values of identifiable intangible assets are primarily determined using an "income method," as described in Note 8 to the consolidated financial statements.

LEGAL AND REGULATORY MATTERS

Information relating to certain legal proceedings can be found in Note 15 to the consolidated financial statements and is incorporated here by reference.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

You can find quantitative and qualitative disclosures about market risk (*e.g.,* interest rate risk) at Item 7, “Management’s Discussion and Analysis - Financial Condition.” That information is incorporated in this report by reference.

Item 8. Financial Statements and Supplementary Data

Consolidated Statements of Operations

ELI LILLY AND COMPANY AND SUBSIDIARIES
(Dollars in millions and shares in thousands, except per-share data)

Year Ended December 31	2018	2017	2016
Revenue	**$ 21,493.3**	$ 19,973.8	$ 18,312.8
Costs, expenses, and other:			
Cost of sales	**4,681.7**	4,447.7	4,160.5
Research and development	**5,051.2**	5,096.2	5,040.0
Marketing, selling, and administrative	**5,975.1**	5,982.4	5,841.9
Acquired in-process research and development (Note 3)	**1,983.9**	1,112.6	30.0
Asset impairment, restructuring, and other special charges (Note 5)	**266.9**	1,331.6	72.9
Other—net, (income) expense (Note 17)	**(145.6)**	(301.5)	(108.8)
	17,813.2	17,669.0	15,036.5
Income before income taxes	**3,680.1**	2,304.8	3,276.3
Income taxes (Note 13)	**529.5**	2,391.2	551.4
Net income (loss) from continuing operations	**3,150.6**	(86.4)	2,724.9
Net Income (loss) from discontinued operations (Note 20)	**81.4**	(117.7)	12.7
Net income (loss)	**$ 3,232.0**	$ (204.1)	$ 2,737.6
Earnings (loss) per share:			
Earnings (loss) from continuing operations - basic	**3.07**	(0.08)	2.57
Earnings (loss) from discontinued operations - basic	**0.07**	(0.11)	0.02
Earnings (loss) per share - basic	**$ 3.14**	$ (0.19)	$ 2.59
Earnings (loss) from continuing operations - diluted	**3.05**	(0.08)	2.57
Earnings (loss) from discontinued operations - diluted	**0.08**	(0.11)	0.01
Earnings (loss) per share - diluted	**$ 3.13**	$ (0.19)	$ 2.58
Shares used in calculation of earnings (loss) per share:			
Basic	**1,027,721**	1,052,023	1,058,324
Diluted	**1,033,667**	1,052,023	1,061,825

See notes to consolidated financial statements.

Consolidated Statements of Comprehensive Income (Loss)

ELI LILLY AND COMPANY AND SUBSIDIARIES (Dollars in millions) Year Ended December 31	2018	2017	2016
Net income (loss)	**$ 3,232.0**	$ (204.1)	$ 2,737.6
Other comprehensive income (loss) from continuing operations:			
Change in foreign currency translation gains (losses)	**(429.6)**	362.9	(300.0)
Change in net unrealized gains (losses) on securities	**(8.8)**	(181.3)	303.0
Change in defined benefit pension and retiree health benefit plans (Note 14)	**544.0**	(566.8)	(508.5)
Change in effective portion of cash flow hedges	**(6.0)**	27.8	11.7
Other comprehensive income (loss) from continuing operations before income taxes	**99.6**	(357.4)	(493.8)
Benefit (provision) for income taxes related to other comprehensive income (loss) from continuing operations	**(30.3)**	402.7	(10.6)
Other comprehensive income (loss) from continuing operations, net of tax (Note 16)	**69.3**	45.3	(504.4)
Other comprehensive income (loss) from discontinuing operations, net of tax (Note 16)	**14.3**	129.2	(140.7)
Other comprehensive income (loss), net of tax (Note 16)[(1)]	**83.6**	174.5	(645.1)
Comprehensive income (loss)	**$ 3,315.6**	$ (29.6)	$ 2,092.5

[(1)] Other comprehensive income in 2018 consists of $72.6 million of other comprehensive income attributable to controlling interest and $11.0 million of other comprehensive income attributable to noncontrolling interest. Other comprehensive income in 2017 consists of $199.0 million of other comprehensive income attributable to controlling interest and $24.5 million of other comprehensive loss attributable to noncontrolling interest. Other comprehensive loss in 2016 consists of $693.3 million of other comprehensive loss attributable to controlling interest and $48.2 million of other comprehensive income attributable to noncontrolling interest.

See notes to consolidated financial statements.

Consolidated Balance Sheets

ELI LILLY AND COMPANY AND SUBSIDIARIES (Dollars in millions, shares in thousands)	December 31	2018	2017
Assets			
Current Assets			
Cash and cash equivalents (Note 7)		**$ 7,320.7**	$ 6,211.8
Short-term investments (Note 7)		**88.2**	1,497.9
Accounts receivable, net of allowances of **$24.1 (2018)** and $28.9 (2017)		**4,593.9**	3,977.0
Other receivables		**1,182.9**	689.5
Inventories (Note 6)		**3,098.1**	3,396.0
Prepaid expenses and other		**2,036.7**	1,319.9
Current assets of discontinued operations (Note 20)		**2,229.1**	2,110.0
Total current assets		**20,549.6**	19,202.1
Investments (Note 7)		**2,005.4**	5,666.5
Goodwill (Note 8)		**1,366.6**	1,378.0
Other intangibles, net (Note 8)		**1,068.0**	1,354.4
Deferred tax assets (Note 13)		**2,613.7**	1,216.9
Sundry		**1,824.9**	1,609.3
Property and equipment, net (Note 9)		**7,996.1**	7,885.1
Noncurrent assets of discontinued operations (Note 20)		**6,484.1**	6,668.7
Total assets		**$ 43,908.4**	$ 44,981.0
Liabilities and Equity			
Current Liabilities			
Short-term borrowings and current maturities of long-term debt (Note 10)		**$ 1,102.2**	$ 3,706.5
Accounts payable		**1,207.1**	1,206.9
Employee compensation		**955.6**	911.8
Sales rebates and discounts		**4,849.5**	4,310.1
Dividends payable		**650.8**	590.6
Income taxes payable (Note 13)		**393.4**	522.5
Other current liabilities		**2,036.7**	2,650.0
Current liabilities of discontinued operations (Note 20)		**692.8**	637.5
Total current liabilities		**11,888.1**	14,535.9
Other Liabilities			
Long-term debt (Note 10)		**9,196.4**	9,940.0
Accrued retirement benefits (Note 14)		**2,802.2**	3,376.0
Long-term income taxes payable (Note 13)		**3,700.0**	3,747.0
Other noncurrent liabilities		**2,670.3**	1,362.6
Noncurrent liabilities of discontinued operations (Note 20)		**2,742.3**	351.6
Total other liabilities		**21,111.2**	18,777.2
Commitments and Contingencies (Note 15)			
Eli Lilly and Company Shareholders' Equity (Notes 11 and 12)			
Common stock—no par value Authorized shares: 3,200,000 Issued shares: **1,057,639 (2018)** and 1,100,672 (2017)		**661.0**	687.9
Additional paid-in capital		**6,583.6**	5,817.8
Retained earnings		**11,395.9**	13,894.1
Employee benefit trust		**(3,013.2)**	(3,013.2)
Accumulated other comprehensive loss (Note 16)		**(5,729.2)**	(5,718.6)
Cost of common stock in treasury		**(69.4)**	(75.8)
Total Eli Lilly and Company shareholders' equity		**9,828.7**	11,592.2
Noncontrolling interests		**1,080.4**	75.7
Total equity		**10,909.1**	11,667.9
Total liabilities and equity		**$ 43,908.4**	$ 44,981.0

See notes to consolidated financial statements.

Consolidated Statements of Shareholders' Equity

ELI LILLY AND COMPANY AND SUBSIDIARIES (Dollars in millions, shares in thousands)	Equity of Eli Lilly and Company Shareholders								Noncontrolling Interest
	Common Stock		Additional Paid-in Capital	Retained Earnings	Employee Benefit Trust	Accumulated Other Comprehensive Loss	Common Stock in Treasury		
	Shares	Amount					Shares	Amount	
Balance at January 1, 2016	1,106,063	$ 691.3	$ 5,552.1	$ 16,011.8	$ (3,013.2)	$ (4,580.7)	796	$ (90.0)	$ 19.0
Net income				2,737.6					16.3
Other comprehensive income (loss), net of tax						(693.3)			48.2
Cash dividends declared per share: $2.05				(2,167.6)					
Retirement of treasury shares	(7,306)	(4.6)		(535.5)			(7,306)	540.1	
Purchase of treasury shares			(60.0)				7,306	(540.1)	
Issuance of stock under employee stock plans, net	2,829	1.8	(106.8)				(85)	9.5	
Stock-based compensation			255.3						
Other									(10.7)
Balance at December 31, 2016	1,101,586	688.5	5,640.6	16,046.3	(3,013.2)	(5,274.0)	711	(80.5)	72.8
Net income (loss)				(204.1)					30.5
Other comprehensive income (loss), net of tax						199.0			(24.5)
Cash dividends declared per share: $2.12				(2,234.6)					
Retirement of treasury shares	(4,390)	(2.7)		(357.1)			(4,390)	359.8	
Purchase of treasury shares			60.0				4,390	(359.8)	
Issuance of stock under employee stock plans, net	3,476	2.1	(164.1)				(47)	4.7	
Stock-based compensation			281.3						
Reclassification of stranded tax effects (Note 2)				643.6		(643.6)			
Other									(3.1)
Balance at December 31, 2017	1,100,672	687.9	5,817.8	13,894.1	(3,013.2)	(5,718.6)	664	(75.8)	75.7
Net income				**3,232.0**					**3.7**
Other comprehensive income (loss), net of tax						**85.6**			**(2.0)**
Cash dividends declared per share: $2.33				**(2,372.0)**					
Retirement of treasury shares	**(45,882)**	**(28.7)**		**(4,122.0)**			**(45,882)**	**4,150.7**	
Purchase of treasury shares							**45,882**	**(4,150.7)**	
Issuance of stock under employee stock plans, net	**2,849**	**1.8**	**(139.0)**				**(60)**	**6.4**	
Stock-based compensation			**279.5**						
Adoption of new accounting standards (Note 2)				**763.8**		**(105.2)**			
Sale of Elanco Stock (Note 20)			**629.2**			**9.0**			**1,017.2**
Other			**(3.9)**						**(14.2)**
Balance at December 31, 2018	**1,057,639**	**$ 661.0**	**$ 6,583.6**	**$ 11,395.9**	**$ (3,013.2)**	**$ (5,729.2)**	**604**	**$ (69.4)**	**$ 1,080.4**

See notes to consolidated financial statements.

Consolidated Statements of Cash Flows

ELI LILLY AND COMPANY AND SUBSIDIARIES (Dollars in millions) Year Ended December 31	2018	2017	2016
Cash Flows from Operating Activities			
Net income (loss)	**$ 3,232.0**	$ (204.1)	$ 2,737.6
Adjustments to Reconcile Net Income (Loss) to Cash Flows from Operating Activities:			
Depreciation and amortization	**1,609.0**	1,567.3	1,496.6
Change in deferred income taxes	**326.8**	(787.9)	439.5
Stock-based compensation expense	**279.5**	281.3	255.3
Acquired in-process research and development	**1,983.9**	1,112.6	30.0
Other non-cash operating activities, net	**472.0**	441.5	376.1
Other changes in operating assets and liabilities, net of acquisitions and divestitures:			
Receivables—(increase) decrease	**(996.7)**	(357.0)	(709.4)
Inventories—(increase) decrease	**7.8**	(253.9)	(328.2)
Other assets—(increase) decrease	**(980.0)**	(590.1)	(265.5)
Income taxes payable—increase (decrease)	**(125.3)**	3,489.6	(304.8)
Accounts payable and other liabilities—increase (decrease)	**(284.5)**	916.3	1,123.8
Net Cash Provided by Operating Activities	**5,524.5**	5,615.6	4,851.0
Cash Flows from Investing Activities			
Purchases of property and equipment	**(1,210.6)**	(1,076.8)	(1,037.0)
Proceeds from disposals of property and equipment	**3.6**	40.7	73.4
Proceeds from sales and maturities of short-term investments	**2,552.5**	4,852.5	1,642.0
Purchases of short-term investments	**(112.2)**	(3,389.7)	(1,327.4)
Proceeds from sales of noncurrent investments	**3,509.5**	2,586.0	2,086.0
Purchases of noncurrent investments	**(837.9)**	(4,611.6)	(4,346.0)
Purchases of in-process research and development	**(1,807.6)**	(1,086.8)	(55.0)
Cash paid for acquisitions, net of cash acquired (Note 3 and 20)	**—**	(882.1)	(45.0)
Other investing activities, net	**(191.3)**	(215.8)	(130.1)
Net Cash Provided by (Used for) Investing Activities	**1,906.0**	(3,783.6)	(3,139.1)
Cash Flows from Financing Activities			
Dividends paid	**(2,311.8)**	(2,192.1)	(2,158.5)
Net change in short-term borrowings	**(2,197.9)**	1,397.5	1,293.2
Proceeds from issuance of long-term debt	**2,477.7**	2,232.0	1,206.6
Repayments of long-term debt	**(1,009.1)**	(630.6)	(0.2)
Purchases of common stock	**(4,150.7)**	(299.8)	(600.1)
Net proceeds from Elanco initial public offering (Note 20)	**1,659.7**	—	—
Other financing activities, net	**(372.8)**	(364.4)	(300.8)
Net Cash Provided by (Used for) Financing Activities	**(5,904.9)**	142.6	(559.8)
Effect of exchange rate changes on cash and cash equivalents	**(63.6)**	(20.5)	(236.4)
Net increase in cash and cash equivalents	**1,462.0**	1,954.1	915.7
Cash and cash equivalents at beginning of year (includes $324.4 (2018), $258.8 (2017), and $460.6 (2016) of discontinued operations)	**6,536.2**	4,582.1	3,666.4
Cash and Cash Equivalents at End of Year (includes $677.5 (2018), $324.4 (2017), and $258.8 (2016) of discontinued operations)	**$ 7,998.2**	$ 6,536.2	$ 4,582.1

See notes to consolidated financial statements.

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

Note 1: Summary of Significant Accounting Policies

Basis of presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (GAAP). The accounts of all wholly-owned and majority-owned subsidiaries are included in the consolidated financial statements. Where our ownership of consolidated subsidiaries is less than 100 percent, the noncontrolling shareholders' interests are reflected as a separate component of equity. All intercompany balances and transactions have been eliminated.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses, and related disclosures at the date of the financial statements and during the reporting period. Actual results could differ from those estimates. We issued our financial statements by filing with the Securities and Exchange Commission (SEC) and have evaluated subsequent events up to the time of the filing of our Form 10-K.

On September 24, 2018, Elanco Animal Health Incorporated (Elanco), one of our subsidiaries, completed its initial public offering (IPO) of 72.3 million shares of its common stock, which represents 19.8 percent of Elanco's outstanding shares, at $24 per share. 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, in the first quarter of 2019, we presented Elanco as discontinued operations in our consolidated condensed financial statements for all periods presented. Accordingly, all prior periods have been recast to conform to this presentation.

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

All per-share amounts, unless otherwise noted in the footnotes, are presented on a diluted basis.

Adoption of Revenue Accounting Standard

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

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

	2018	2017	2016
Net product revenue	**$ 19,866.4**	$ 18,776.5	$ 17,480.0
Collaboration and other revenue[(1)]	**1,626.9**	1,197.3	832.8
Revenue	**$ 21,493.3**	$ 19,973.8	$ 18,312.8

[(1)] Collaboration and other revenue associated with prior year transfers of intellectual property was $303.2 million, $144.9 million, and $145.3 million during the years ended 2018, 2017, and 2016, respectively.

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

Boehringer Ingelheim discussed in Note 4. Substantially all of the remainder of collaboration and other revenue is related to contracts accounted for as contracts with customers.

Net Product Revenue

Revenue from sales of products is recognized at the point where the customer obtains control of the goods and we satisfy our performance obligation, which generally is at the time we ship the product to the customer. Payment terms differ by jurisdiction and customer, but payment terms in most of our major jurisdictions typically range from 30 to 70 days from date of shipment. Revenue for our product sales has not been adjusted for the effects of a financing component as we expect, at contract inception, that the period between when we transfer control of the product and when we receive payment will be one year or less. Any exceptions are either not material or we collect interest for payments made after the due date. Provisions for rebates and discounts, and returns are established in the same period the related sales are recognized. We generally ship product shortly after orders are received; therefore, we generally only have a few days of orders received but not yet shipped at the end of any reporting period. Shipping and handling activities are considered to be fulfillment activities and are not considered to be a separate performance obligation. We exclude from the measurement of the transaction price all taxes assessed by a governmental authority that are imposed on our sales of product and collected from a customer.

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

Sales Rebates and Discounts - Background and Uncertainties

- Most of our products are sold to wholesalers that serve pharmacies, physicians and other health care professionals, and hospitals. We initially invoice our customers at contractual list prices. Contracts with direct and indirect customers may provide for various rebates and discounts that may differ in each contract. As a consequence, to determine the appropriate transaction price for our product sales at the time we recognize a sale to a direct customer, we must estimate any rebates or discounts that ultimately will be due to the direct customer and other customers in the distribution chain under the terms of our contracts. Significant judgments are required in making these estimates.
- The rebate and discount amounts are recorded as a deduction to arrive at our net product revenue. Sales rebates and discounts that require the use of judgment in the establishment of the accrual include managed care, Medicare, Medicaid, chargebacks, long-term care, hospital, patient assistance programs, and various other programs. We estimate these accruals using an expected value approach.
- The largest of our sales rebate and discount amounts are rebates associated with sales covered by managed care, Medicare, Medicaid, and chargeback contracts in the United States (U.S.) In determining the appropriate accrual amount, we consider our historical rebate payments for these programs by product as a percentage of our historical sales as well as any significant changes in sales trends (e.g., patent expiries and product launches), an evaluation of the current contracts for these programs, the percentage of our products that are sold via these programs, and our product pricing. Although we accrue a liability for rebates related to these programs at the time we record the sale, the rebate related to that sale is typically paid up to six months later. Because of this time lag, in any particular period our rebate adjustments may incorporate revisions of accruals for several periods.
- Most of our rebates outside the U.S. are contractual or legislatively mandated and are estimated and recognized in the same period as the related sales. In some large European countries, government rebates are based on the anticipated budget for pharmaceutical payments in the country. An estimate of these rebates, updated as governmental authorities revise budgeted deficits, is recognized in the same period as the related sale.

Sales Returns - Background and Uncertainties

- When product sales occur, to determine the appropriate transaction price for our sales, we estimate a reserve for future product returns related to those sales using an expected value approach. This estimate is based on several factors, including: historical return rates, expiration date by product (on average, approximately 24 months after the initial sale of a product to our customer), and estimated levels of inventory in the wholesale and retail channels, as well as any other specifically-identified anticipated returns due to known factors such as the loss of patent exclusivity, product recalls and

discontinuances, or a changing competitive environment. We maintain a returns policy that allows U.S. customers to return product for dating issues within a specified period prior to and subsequent to the product's expiration date. Following the loss of exclusivity for a patent-dependent product, we expect to experience an elevated level of product returns as product inventory remaining in the wholesale and retail channels expires. Adjustments to the returns reserve have been and may in the future be required based on revised estimates to our assumptions. We record the return amounts as a deduction to arrive at our net product revenue. Once the product is returned, it is destroyed; we do not record a right of return asset. Our returns policies outside the U.S. are generally more restrictive than in the U.S. as returns are not allowed for reasons other than failure to meet product specifications in many countries. Our reserve for future product returns for product sales outside the U.S. is not material.

- As a part of our process to estimate a reserve for product returns, we regularly review the supply levels of our significant products sold to major wholesalers in the U.S. and in major markets outside the U.S., primarily by reviewing periodic inventory reports supplied by our major wholesalers and available prescription volume information for our products, or alternative approaches. We attempt to maintain U.S. wholesaler inventory levels at an average of approximately one month or less on a consistent basis across our product portfolio. Causes of unusual wholesaler buying patterns include actual or anticipated product-supply issues, weather patterns, anticipated changes in the transportation network, redundant holiday stocking, and changes in wholesaler business operations. In the U.S., the current structure of our arrangements provides us with data on inventory levels at our wholesalers; however, our data on inventory levels in the retail channel is more limited. Wholesaler stocking and destocking activity historically has not caused any material changes in the rate of actual product returns.
- Actual product returns have been less than 2 percent of our net revenue over each of the past three years and have not fluctuated significantly as a percentage of revenue, although fluctuations are more likely in periods following loss of patent exclusivity for major products in the U.S. market.

Adjustments to Revenue

Adjustments to revenue recognized as a result of changes in estimates for the judgments described above during 2018 for product shipped in previous years were approximately 1 percent of revenue.

Disaggregation of Revenue

Our disaggregated revenue is disclosed in Note 18.

Collaborations and Other Arrangements

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

- Revenue related to products we sell pursuant to these arrangements is included in net product revenue, while other sources of revenue (e.g., royalties and profit sharing from our partner) are included in collaboration and other revenue.
- Initial fees and developmental milestones we receive in collaborative and other similar arrangements from the partnering of our compounds under development are generally deferred and amortized into income through the expected product approval date.
- Profit-sharing due from our collaboration partners, which is based upon gross margins reported to us by our partners, is recognized as collaboration and other revenue as earned.
- Royalty revenue from licensees, which is based on sales to third-parties of licensed products and technology, is recorded when the third-party sale occurs and the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). This royalty revenue is included in collaboration and other revenue.
- For arrangements involving multiple goods or services (e.g., research and development, marketing and selling, manufacturing, and distribution), each required good or service is evaluated to determine whether it is distinct. If a good or service does not qualify as distinct, it is combined with the other non-distinct goods or services within the arrangement and these combined goods or services are

treated as a single performance obligation for accounting purposes. The arrangement's transaction price is then allocated to each performance obligation based on the relative standalone selling price of each performance obligation. For arrangements that involve variable consideration where we have sold intellectual property, we recognize revenue based on estimates of the amount of consideration we believe we will be entitled to receive from the other party, subject to a constraint. These estimates are adjusted to reflect the actual amounts to be collected when those facts and circumstances become known.

- Significant judgments must be made in determining the transaction price for our sales of intellectual property. Because of the risk that products in development will not receive regulatory approval, we generally do not recognize any contingent payments that would be due to us upon or after regulatory approval.
- We have entered into arrangements whereby we transferred rights to products and committed to supply for a period of time. For those arrangements for which we concluded that the obligations were not distinct, any amounts received upfront are being amortized to revenue as net product revenue over the period of the supply arrangement as the performance obligation is satisfied.

Contract Liabilities

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

We have the following amounts recorded for contract liabilities:

	2018	2017
Contract liabilities	**$ 294.9**	$ 330.9

The contract liabilities amount disclosed above as of December 31, 2018 and 2017, are primarily related to:

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

Revenue recognized from contract liabilities as of January 1, 2018, during the year ended December 31, 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.

Research and development expenses and acquired in-process research and development

Research and development expenses include the following:

- Research and development costs, which are expensed as incurred.
- Milestone payment obligations incurred prior to regulatory approval of the product, which are accrued when the event requiring payment of the milestone occurs.

Acquired in-process research and development (IPR&D) expense includes the initial costs of IPR&D projects, acquired directly in a transaction other than a business combination, that do not have an alternative future use.

Earnings per share

We calculate basic earnings per share (EPS) based on the weighted-average number of common shares outstanding and incremental shares from potential participating securities. We calculate diluted EPS based on the weighted-average number of common shares outstanding, including incremental shares from our stock-based compensation programs.

Foreign Currency Translation

Operations in our subsidiaries outside the U.S. are recorded in the functional currency of each subsidiary which is determined by a review of the environment where each subsidiary primarily generates and expends cash. The results of operations for our subsidiaries outside the U.S. are translated from functional currencies into U.S. dollars using the weighted average currency rate for the period. Assets and liabilities are translated

using the period end exchange rates. The U.S. dollar effects that arise from translating the net assets of these subsidiaries are recorded in other comprehensive income (loss).

Other significant accounting policies

Our other significant accounting policies are described in the remaining appropriate notes to the consolidated financial statements.

Note 2: Implementation of New Financial Accounting Pronouncements

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

Standard	Description	Effect on the financial statements or other significant matters
Accounting Standards Update 2014-09 and various other related updates, *Revenue from Contracts with Customers*	This standard replaced existing revenue recognition standards and requires entities to recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. An entity can apply the new revenue standard retrospectively to each prior reporting period presented or with the cumulative effect of initially applying the standard recognized at the date of initial application in retained earnings. We applied the latter approach.	Application of the new standard to applicable contracts resulted in an increase of approximately $5 million to retained earnings as of January 1, 2018. Disclosures required by the new standard are included in Note 1, Note 4, and Note 18.
Accounting Standards Update 2016-01, *Financial Instruments - Overall: Recognition and Measurement of Financial Assets and Financial Liabilities*	This standard requires entities to recognize changes in the fair value of equity investments with readily determinable fair values in net income (except for investments accounted for under the equity method of accounting or those that result in consolidation of the investee). An entity should apply the new standard through a cumulative effect adjustment to retained earnings as of the beginning of the fiscal year of adoption.	Upon adoption, we reclassified from accumulated other comprehensive loss the after-tax amount of net unrealized gains resulting in an increase to retained earnings of approximately $105 million. Adoption of this standard did not result in a material change in net income in 2018.
Accounting Standards Update 2016-16, *Income Taxes: Intra-Entity Transfers of Assets Other Than Inventory*	This standard requires entities to recognize the income tax consequences of intra-entity transfers of assets other than inventory at the time of transfer. This standard requires a modified retrospective approach to adoption.	Upon adoption, the cumulative effect of applying the standard resulted in an increase of approximately $700 million to retained earnings, $2.5 billion to deferred tax assets, and $1.8 billion to deferred tax liabilities. Adoption of this standard did not result in a material change in net income in 2018.

Accounting Standards Update 2017-07, *Compensation-Retirement Benefits: Improving the Presentation of Net Periodic Pension Cost and Net Periodic Postretirement Benefit Cost*	This standard was issued to improve the transparency and comparability among organizations by requiring entities to separate their net periodic pension cost and net periodic postretirement benefit cost into a service cost component and other components. Previously, the costs of the other components along with the service cost component were classified based upon the function of the employee. This standard requires entities to classify the service cost component in the same financial statement line item or items as other compensation costs arising from services rendered by pertinent employees. The other components of net benefit cost are now presented separately from the line items that include the service cost component. When applicable, the service cost component is now the only component eligible for capitalization. An entity should apply the new standard retrospectively for the classification of the service cost and other components and prospectively for the capitalization of the service cost component.	Upon adoption of this standard, pension and postretirement benefit cost components other than service costs are presented in other–net, (income) expense. The application of the new standard resulted in reclassification to other income of $249.0 million for the year ended December 31, 2017, while increasing cost of sales by $80.8 million, research and development expenses by $75.8 million, and marketing, selling, and administrative expenses by $92.4 million for the same period. The application of the new standard resulted in reclassification to other income of $197.1 million for the year ended December 31, 2016, while increasing cost of sales by $54.2 million, research and development expenses by $66.4 million, and marketing, selling, and administrative expenses by $76.5 million for the same period. We do not expect application of the new standard to have a material impact on an ongoing basis.

We elected to early adopt Accounting Standards Update 2018-02, *Income Statement-Reporting Comprehensive Income: Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income* as of December 31, 2017, which allowed a reclassification from accumulated other comprehensive loss to retained earnings for stranded tax effects resulting from the Tax Cuts and Jobs Act (2017 Tax Act - see Note 13). This standard allowed us to reclassify the effect of remeasuring deferred tax liabilities and assets related to items within accumulated other comprehensive loss using the then newly enacted 21 percent federal corporate income tax rate. The provisional effect of this early adoption was a reclassification from accumulated other comprehensive loss, which resulted in an increase to retained earnings of $643.6 million as of December 31, 2017.

The following table provides a brief description of the accounting standard that had not yet been adopted as of December 31, 2018:

Standard	Description	Effective Date	Effect on the financial statements or other significant matters
Accounting Standards Update 2016-02, *Leases*	This standard was issued to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities, including leases classified as operating leases under current GAAP, on the balance sheet and requiring additional disclosures about leasing arrangements. An entity can apply the new leases standard retrospectively to each prior reporting period presented or with the cumulative effect of initially applying the standard recognized at the date of initial application in retained earnings. We plan to use the latter approach.	This standard was effective January 1, 2019, and we adopted on that date.	We expect to record a right-of-use asset and lease liability for operating leases of approximately $575 million on our consolidated balance sheet as of January 1, 2019. Our accounting for capital leases will remain substantially unchanged. This standard will not have a material impact on our consolidated statement of operations.

Note 3: Acquisitions

We acquired assets in development in 2018, 2017, and 2016 which are further discussed in this note below in Asset Acquisitions. Upon acquisition, the acquired IPR&D charges related to these products were immediately expensed because the products had no alternative future use. For the years ended December 31, 2018, 2017, and 2016, we recorded acquired IPR&D charges of $1.98 billion, $1.11 billion, and $30.0 million, respectively. The acquired IPR&D charges in 2018 were primarily related to the acquisition of ARMO Biosciences, Inc. (ARMO). Substantially all of the value of ARMO was related to pegilodecakin, its only significant asset.

Acquisition of a Business

Subsequent Event - Loxo Oncology, Inc. (Loxo) Acquisition

Overview of transaction

On February 15, 2019, we acquired Loxo for a purchase price of $235 per share, or approximately $8 billion. Under the terms of the agreement, we acquired a pipeline of highly selective potential medicines for patients with genomically defined cancers. Loxo's pipeline includes LOXO-292, an oral RET inhibitor being studied across multiple tumor types, which recently was granted Breakthrough Therapy designation by the U.S. Food and Drug Administration. The accounting impact of this acquisition and the results of the operations for Loxo will be included in our consolidated financial statements beginning in the first quarter of 2019.

Assets Acquired and Liabilities Assumed

The initial accounting for this acquisition is incomplete. Significant, relevant information needed to complete the initial accounting is not available because the valuation of assets acquired and liabilities assumed is not complete. As a result, determining these values is not practicable and we are unable to disclose these values or provide other related disclosures at this time.

Asset Acquisitions

The following table and narrative summarize our asset acquisitions during 2018, 2017, and 2016.

Counterparty	Compound(s),Therapy, or Asset	Acquisition Month	Phase of Development[1]	Acquired IPR&D Expense
Sigilon Therapeutics	Encapsulated cell therapies for the potential treatment of type 1 diabetes	April 2018	Pre-clinical	$ 66.9
AurKa Pharma, Inc.	AK-01, an Aurora kinase A inhibitor	June 2018	Phase I	81.8
ARMO	Cancer therapy - pegilodecakin	June 2018	Phase III	1,475.8
Anima Biotech	Translation inhibitors for selected neuroscience targets	July 2018	Pre-clinical	30.0
SIGA Technologies, Inc.	Priority Review Voucher	October 2018	Not applicable	80.0
Chugai Pharmaceutical Company	OWL833, an oral non-peptidic GLP-1 receptor agonist	October 2018	Pre-clinical	50.0
NextCure, Inc.	Immuno-oncology cancer therapies	November 2018	Pre-clinical	28.1
Dicerna Pharmaceuticals	Cardio-metabolic disease, neurodegeneration, and pain	December 2018	Pre-clinical	148.7
Hydra Biosciences	TRPA1 antagonists program for the potential treatment of chronic pain syndromes	December 2018	Pre-clinical	22.6
CoLucid Pharmaceuticals, Inc. (CoLucid)	Oral therapy for the acute treatment of migraine - lasmiditan	March 2017	Phase III	857.6
KeyBioscience AG	Multiple molecules for treatment of metabolic disorders	July 2017	Phase II	55.0
Nektar Therapeutics	Immunological therapy - NKTR-358	August 2017	Phase I	150.0
CureVac AG	Cancer vaccines	November 2017	Pre-clinical	50.0
AstraZeneca	Antibody selective for amyloid-beta 42 (Aβ42) - MEDI1814	December 2016	Phase I	30.0

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

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 Event - AC Immune SA

In January 2019, we entered into a license and collaboration agreement with AC Immune SA for the discovery and development of tau aggregation inhibitor small molecules for the potential treatment of Alzheimer's disease and other neurodegenerative diseases. Under terms of the agreement, we paid an upfront fee of CHF80.0 million and we will pay $50.0 million in exchange for a note, convertible to equity at a premium. As a result of this transaction, we will record an acquired IPR&D expense of $96.9 million in the first quarter of 2019.

Note 4: Collaborations and Other Arrangements

We often enter into collaborative and other similar arrangements to develop and commercialize drug candidates. Collaborative activities may include research and development, marketing and selling (including promotional activities and physician detailing), manufacturing, and distribution. These arrangements often require milestone and royalty or profit-share payments, contingent upon the occurrence of certain future events linked to the success of the asset in development, as well as expense reimbursements or payments to the collaboration partner. See Note 1 for amounts of collaboration and other revenue recognized from these types of arrangements.

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

Boehringer Ingelheim Diabetes Collaboration

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

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

	Milestones (Deferred) Capitalized[1]		
Product Family	Year		Amount
Trajenta[2]	Cumulative[4]	$	446.4
Jardiance[3]	Cumulative[4]		289.0
Basaglar	2018		—
	2017		—
	2016		(187.5)
	Cumulative[4]		(250.0)

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

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

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

[4] The cumulative amount represents the total amounts that have been (deferred) or capitalized from the start of this collaboration through the end of the reporting period.

In the most significant markets, we and Boehringer Ingelheim share equally the ongoing development costs, commercialization costs, and agreed upon gross margin for any product resulting from the collaboration. We record our portion of the gross margin associated with Boehringer Ingelheim's 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 their portion of the gross margin recorded as cost of sales. For all compounds under this collaboration, we record our portion of the development and commercialization costs as research and development expense and marketing, selling, and administrative expense, respectively. Each company is entitled to potential performance payments depending on the sales of the molecules it contributes to the collaboration. These performance payments result in the owner of the molecule retaining a greater share of the agreed upon gross margin of that product. Subject to achieving these thresholds, in a given period, our reported revenue for Trajenta and Jardiance may be reduced by any performance payments we make related to these products. Similarly, performance payments we may receive related to Basaglar effectively reduce Boehringer Ingelheim's share of the gross margin, which reduces our cost of sales.

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

	2018	2017	2016
Basaglar	**$ 801.2**	$ 432.1	$ 86.1
Jardiance	**658.3**	447.5	201.9
Trajenta	**574.7**	537.9	436.6

Erbitux®

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

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

	2018	2017	2016
Net product revenue	**$ 536.1**	$ 548.2	$ 587.0
Collaboration and other revenue	**99.2**	97.7	100.0
Revenue	**$ 635.3**	$ 645.9	$ 687.0

Bristol-Myers Squibb Company

Pursuant to commercial agreements with Bristol-Myers Squibb Company and E.R. Squibb (collectively, BMS), we had been co-developing Erbitux in North America exclusively with BMS. On October 1, 2015, BMS transferred their commercialization rights to us with respect to Erbitux in North America pursuant to a modification of our existing arrangement, and we began selling Erbitux at that time. This modification did not affect our rights with respect to Erbitux in other jurisdictions. In connection with the modification of terms, we provided consideration to BMS based upon a tiered percentage of net sales of Erbitux in North America estimated to average 38 percent through September 2018. The transfer of the commercialization rights was accounted for as an acquisition of a business. The consideration to be paid to BMS was accounted for as contingent consideration liability.

Merck KGaA

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

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

Olumiant®

We have a worldwide license and collaboration agreement with Incyte Corporation (Incyte) which provides us the development and commercialization rights to its Janus tyrosine kinase (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 if the product is successfully commercialized. The agreement provides Incyte with options to co-develop these compounds on an indication-by-indication basis by funding 30 percent of the associated development costs from the initiation of a Phase IIb trial through regulatory approval in exchange for increased tiered royalties ranging up to percentages in the high twenties. Incyte exercised its option to co-develop Olumiant in rheumatoid arthritis in 2010 and psoriatic arthritis, atopic dermatitis, alopecia areata, and systemic lupus erythematosus (SLE) in 2017. The agreement calls for payments by us to Incyte associated with certain development, success-based regulatory, and sales-based milestones. The following table summarizes our milestones achieved:

Year	Event	Classification	Amount
2018	Regulatory approval in the U.S.	Intangible asset	**$ 100.0**
	Began Phase III testing for 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 December 31, 2018, Incyte is eligible to receive up to $130.0 million of additional payments from us contingent upon certain development and success-based regulatory milestones. Incyte is also eligible to receive up to $150.0 million of potential sales-based milestones.

Effient®

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

Territory	Marketing Rights	Selling Party
U.S.	Co-promotion	Lilly
Major European markets	Co-promotion	Daiichi Sankyo
Japan	Exclusive	Daiichi Sankyo

The parties share approximately 50/50 in the profits, as well as in the costs of development and marketing in the co-promotion territories. A third party manufactures bulk product, and we produce the finished product for our exclusive and co-promotion territories, including the major European markets.

We record net product revenue in our exclusive and co-promotion territories where we are the selling party. Profit-share payments due to Daiichi Sankyo for co-promotion countries where we are the selling party are recorded as marketing, selling, and administrative expenses. Any profit-share payments due to us from Daiichi Sankyo for the major European markets are recorded as collaboration and other revenue. We also record our share of the expenses in these co-promotion territories as marketing, selling, and administrative expenses. In our exclusive territories, we pay Daiichi Sankyo a royalty specific to these territories. All royalties due to Daiichi Sankyo and the third-party manufacturer are recorded in cost of sales. Generic versions of Effient launched in the U.S. in the third quarter of 2017.

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

	2018	2017	2016
Revenue	**$ 122.2**	$ 388.9	$ 535.2

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 December 31, 2018, Pfizer is eligible to receive up to $350.0 million in success-based regulatory milestones and up to $1.23 billion in a series of sales-based milestones, contingent upon the commercial success of tanezumab.

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

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

	2018	2017	2016
Severance	**$ 127.8**	$ 601.0	$ 85.9
Pension and post-retirement medical charges associated with U.S. voluntary early retirement program (see Note 14)	**—**	446.7	—
Asset impairment (gains from facility sales) and other special charges	**139.1**	283.9	(13.0)
Total asset impairment, restructuring, and other special charges	**$ 266.9**	$ 1,331.6	$ 72.9

Severance costs recognized during the years ended December 31, 2018, 2017 and 2016 were incurred as a result of actions taken to reduce our cost structure. Severance costs recognized in 2017 were associated with the U.S. voluntary early retirement program. During 2017, severance costs recognized in the U.S. and outside the U.S. were $368.3 million and $232.7 million, respectively. Substantially all of the severance costs incurred in 2016 and 2017 have been paid. Of the severance costs incurred during the year ended December 31, 2018, approximately half will be paid in 2019 and half will be paid in 2020.

Asset impairment and other special charges recognized during the year ended December 31, 2018 resulted primarily from asset impairment and other special charges related to the sale of the Posilac® (rbST) brand and the associated Augusta, Georgia manufacturing site.

Asset impairment and other special charges recognized during the year ended December 31, 2017 resulted primarily from asset impairments related to lower projected revenue for Posilac (rbST). The assets associated with Posilac (rbST) were written down to their fair values, which were determined based upon a discounted cash flow valuation. Impairment charges were recorded for the associated fixed assets and intangible asset of $151.5 million and $50.0 million, respectively (refer to Note 8 for further detail relating to intangible asset impairments). In addition, we incurred approximately $43.4 million of costs associated with the temporary shut down of our Puerto Rico facility following Hurricane Maria.

Note 6: Inventories

We use the last-in, first-out (LIFO) method for the majority of our inventories located in the continental U.S. Other inventories are valued by the first-in, first-out (FIFO) method. FIFO cost approximates current replacement cost. Inventories measured using LIFO must be valued at the lower of cost or market. Inventories measured using FIFO must be valued at the lower of cost or net realizable value.

Inventories at December 31 consisted of the following:

	2018	2017
Finished products	**$ 577.8**	$ 759.4
Work in process	**2,057.8**	2,117.7
Raw materials and supplies	**426.1**	418.4
Total (approximates replacement cost)	**3,061.7**	3,295.5
Increase (reduction) to LIFO cost	**36.4**	100.5
Inventories	**$ 3,098.1**	$ 3,396.0

Inventories valued under the LIFO method comprised $1.37 billion and $1.33 billion of total inventories at December 31, 2018 and 2017, respectively.

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 December 31, 2018, we had outstanding foreign currency forward commitments to purchase 785.5 million U.S. dollars and sell 685.3 million euro; commitments to purchase 2.05 billion euro and sell 2.35 billion U.S. dollars; commitments to purchase 435.1 million U.S. dollars and sell 48.85 billion Japanese yen, commitments to purchase 255.6 million Swiss francs and sell 259.7 million U.S. dollars, commitments to purchase 388.3 million U.S. dollars and sell 306.7 million

British pounds, and commitments to purchase 354.0 million British pounds and sell 448.1 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 $3.40 billion and $3.70 billion as of December 31, 2018 and 2017, respectively, of which $2.65 billion and $3.70 billion have been designated as, and are effective as, economic hedges of net investments in certain of our euro-denominated and Swiss franc-denominated foreign operations as of December 31, 2018 and 2017, respectively. 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. At December 31, 2018, we had outstanding cross currency swaps with notional amounts of $2.46 billion swapping U.S. dollars to euro, $754.0 million 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.

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 statements of cash flows. At December 31, 2018, substantially all of our total long-term debt is at a fixed rate. We have converted approximately 25 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.

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

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

	2018	2017	2016
Fair value hedges:			
Effect from hedged fixed-rate debt	**$ (40.9)**	$ (14.1)	$ (30.8)
Effect from interest rate contracts	**40.9**	14.1	30.8
Cash flow hedges:			
Effective portion of losses on interest rate contracts reclassified from accumulated other comprehensive loss	**14.8**	14.8	15.0
Net losses on foreign currency exchange contracts not designated as hedging instruments	**100.0**	97.9	78.8
Total	**$ 114.8**	$ 112.7	$ 93.8

During the years ended December 31, 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.

During the years ended December 31, 2017, and 2016, net losses related to ineffectiveness, as well as net losses related to the portion of our risk-management hedging instruments, fair value hedges, and cash flow hedges that were excluded from the assessment of effectiveness, were not material.

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

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

	2018	2017	2016
Net investment hedges:			
Foreign currency-denominated notes	**$ 110.4**	$ (361.5)	$ 137.5
Cross-currency interest rate swaps	**96.8**	(126.6)	32.5
Foreign currency exchange contracts	**5.7**	—	31.9
Cash flow hedges:			
Forward-starting interest rate swaps	—	13.0	(3.4)

During the next 12 months, we expect to reclassify $15.0 million of pretax net losses on cash flow hedges from accumulated other comprehensive loss to other–net, (income) expense. During the year ended December 31, 2018, 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 December 31 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:

Description	Carrying Amount	Cost [1]	Fair Value Measurements Using			Fair Value
			Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
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**					
December 31, 2017						
Cash equivalents	$ 4,763.9	$ 4,763.9	$ 4,712.4	$ 51.5	$ —	$ 4,763.9
Short-term investments:						
U.S. government and agency securities	$ 217.8	$ 218.2	$ 217.8	$ —	$ —	$ 217.8
Corporate debt securities	1,182.3	1,183.2	—	1,182.3	—	1,182.3
Asset-backed securities	94.2	94.3	—	94.2	—	94.2
Other securities	3.6	3.6	—	3.6	—	3.6
Short-term investments	$ 1,497.9					
Noncurrent investments:						
U.S. government and agency securities	$ 360.0	$ 365.0	$ 360.0	$ —	$ —	$ 360.0
Corporate debt securities	3,464.3	3,473.5	—	3,464.3	—	3,464.3
Mortgage-backed securities	202.4	204.2	—	202.4	—	202.4
Asset-backed securities	653.9	656.0	—	653.9	—	653.9
Other securities	132.1	66.4	—	—	132.1	132.1
Marketable equity securities	281.3	131.0	281.3	—	—	281.3
Cost and equity method investments[2]	572.5					
Noncurrent investments	$ 5,666.5					

[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.

Description	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					
December 31, 2018	**$ (498.9)**	**$ —**	**$ (497.6)**	**$ —**	**$ (497.6)**
December 31, 2017	(2,696.8)	—	(2,690.6)	—	(2,690.6)
Long-term debt, including current portion					
December 31, 2018	**$ (9,799.7)**	**$ —**	**$ (9,989.4)**	**$ —**	**$ (9,989.4)**
December 31, 2017	(10,950.3)	—	(11,529.9)	—	(11,529.9)

Description	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
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)**
December 31, 2017					
Risk-management instruments					
Interest rate contracts designated as fair value hedges:					
Other receivables	$ 0.8	$ —	$ 0.8	$ —	$ 0.8
Sundry	35.1	—	35.1	—	35.1
Other current liabilities	(0.2)	—	(0.2)	—	(0.2)
Other noncurrent liabilities	(10.5)	—	(10.5)	—	(10.5)
Cross-currency interest rate contracts designated as net investment hedges:					
Other current liabilities	(33.4)	—	(33.4)	—	(33.4)
Other noncurrent liabilities	(26.0)	—	(26.0)	—	(26.0)
Foreign exchange contracts not designated as hedging instruments:					
Other receivables	26.8	—	26.8	—	26.8
Other current liabilities	(36.0)	—	(36.0)	—	(36.0)
Contingent consideration liabilities					
Other current liabilities	(206.7)	—	—	(206.7)	(206.7)

Risk-management instruments above are disclosed on a gross basis. There are various rights of setoff associated with certain of the risk-management instruments above that are subject to an enforceable master netting arrangement or similar agreements. Although various rights of setoff and master netting arrangements or similar agreements may exist with the individual counterparties to the risk-management instruments above, individually, these financial rights are not material.

We determine our Level 1 and Level 2 fair value measurements based on a market approach using quoted market values, significant other observable inputs for identical or comparable assets or liabilities, or discounted cash flow analyses. Level 3 fair value measurements for other investment securities are determined using unobservable inputs, including the investments' cost adjusted for impairments and price changes from orderly transactions. The fair values of equity method investments and investments measured under the measurement alternative for equity investments that do not have readily determinable fair values are not readily available.

Contingent consideration liabilities were recorded at fair value and were estimated using a discounted cash flow analysis and Level 3 inputs, including projections representative of a market participant view for net sales and an estimated discount rate. The decrease in the fair value of the contingent consideration liabilities during the years ended December 31, 2018 and 2017 was due primarily to cash payments of $199.7 million and $203.1 million, which related to Erbitux (see Note 4). The change in the fair value of the contingent consideration liabilities recognized in earnings during the years ended December 31, 2018, 2017, and 2016 due to changes in time value of money was not material.

The table below summarizes the contractual maturities of our investments in debt securities measured at fair value as of December 31, 2018:

	Maturities by Period				
	Total	Less Than 1 Year	1-5 Years	6-10 Years	More Than 10 Years
Fair value of debt securities	$ 943.0	$ 86.8	$ 604.8	$ 97.0	$ 154.4

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:

	2018	2017
Unrealized gross gains	**$ 0.8**	$ 184.7
Unrealized gross losses	**29.0**	47.5
Fair value of securities in an unrealized gain position	**84.3**	1,434.2
Fair value of securities in an unrealized loss position	**858.6**	4,692.8

The unrealized losses (pretax) recognized in our consolidated statement of operations for equity securities held as of December 31, 2018 was $20.1 million.

We periodically assess our investment in available-for-sale securities for other-than-temporary impairment losses. There were no other-than-temporary impairment losses recognized in 2018 or 2017. Other-than-temporary impairment losses recognized during the year ended December 31, 2016 totaled $53.0 million. Other-than-temporary impairment losses recognized during 2016 related primarily to our cost and equity method investments.

We periodically assess our investments in equity securities other than public equity securities for impairment losses. Impairment losses recognized on these equity securities in 2018 were immaterial.

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

For equity securities, factors considered in assessing impairment losses include the financial condition and near term prospects of the issuer and general market conditions and industry specific factors.

As of December 31, 2018, the available-for-sale securities in an unrealized loss position include primarily fixed-rate debt securities of varying maturities, which are sensitive to changes in the yield curve and other market conditions. Approximately 55 percent of the fixed-rate debt securities in a loss position are investment-grade debt securities. As of December 31, 2018, we do not intend to sell, and it is not more likely than not that we will be required to sell, the securities in a loss position before the market values recover or the underlying cash flows have been received, and there is no indication of default on interest or principal payments for any of our debt securities.

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

	2018	2017	2016
Proceeds from sales	**$ 5,668.0**	$ 5,769.3	$ 3,240.5
Realized gross gains on sales	**11.8**	176.0	30.7
Realized gross losses on sales	**51.3**	5.8	14.6

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.

Adjustments recorded to our equity investments without readily determinable fair values are based upon changes in the equity instrument's value resulting from observable price changes in orderly transactions for an identical or similar investment of the same issuer. Downward adjustments resulting from an impairment are recorded based upon the impairment considerations mentioned above. Adjustments recorded during 2018 were not material.

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 $696.2 million and $723.2 million of accounts receivable as of December 31, 2018 and 2017, respectively, under these factoring arrangements. The costs of factoring such accounts receivable on our consolidated results of operations for the years ended December 31, 2018, 2017, and 2016 were not material.

Note 8: Goodwill and Other Intangibles

Goodwill

Goodwill results from excess consideration in a business combination over the fair value of identifiable net assets acquired. Goodwill is not amortized but is reviewed for impairment at least annually and when impairment indicators are present. When required, a comparison of the fair value of the reporting unit to its carrying amount including goodwill is used to determine the amount of any impairment.

No impairments occurred with respect to the carrying value of goodwill for the years ended December 31, 2018, 2017, and 2016.

Other Intangibles

The components of intangible assets other than goodwill at December 31 were as follows:

	2018			2017		
Description	Carrying Amount, Gross	Accumulated Amortization	Carrying Amount, Net	Carrying Amount, Gross	Accumulated Amortization	Carrying Amount, Net
Finite-lived intangible assets:						
Marketed products	**$ 2,077.2**	**$ (1,069.0)**	**$ 1,008.2**	$ 4,528.8	$ (3,251.3)	$ 1,277.5
Other	**89.5**	**(29.7)**	**59.8**	117.1	(40.2)	76.9
Other intangibles	**$ 2,166.7**	**$ (1,098.7)**	**$ 1,068.0**	$ 4,645.9	$ (3,291.5)	$ 1,354.4

Marketed products consist of the amortized cost of the rights to assets acquired in business combinations and approved for marketing in a significant global jurisdiction (U.S., Europe, and Japan) and capitalized milestone payments. For transactions other than a business combination, we capitalize milestone payments incurred at or after the product has obtained regulatory approval for marketing.

Other finite-lived intangibles consist primarily of the amortized cost of licensed platform technologies that have alternative future uses in research and development, manufacturing technologies, and customer relationships from business combinations.

Acquired IPR&D consists of the related costs capitalized, adjusted for subsequent impairments, if any. The costs of acquired IPR&D projects acquired directly in a transaction other than a business combination are capitalized if the projects have an alternative future use; otherwise, they are expensed immediately. The fair values of acquired IPR&D projects acquired in business combinations, if any, are capitalized as other intangible assets. As of December 31, 2018 and 2017, we had no acquired IPR&D indefinite-lived intangible assets.

Several methods may be used to determine the estimated fair value of other intangibles acquired in a business combination. We utilize the “income method,” which is a Level 3 fair value measurement and applies a probability weighting that considers the risk of development and commercialization to the estimated future net cash flows that are derived from projected revenues and estimated costs. These projections are based on factors such as relevant market size, patent protection, historical pricing of similar products, and expected industry trends. The estimated future net cash flows are then discounted to the present value using an appropriate discount rate. This analysis is performed for each asset independently. The acquired IPR&D assets are treated as indefinite-lived intangible assets until completion or abandonment of the projects, at which time the assets are tested for impairment and amortized over the remaining useful life or written off, as appropriate.

See Note 4 for additional discussion of recent capitalized milestone payments.

Other indefinite-lived intangible assets are reviewed for impairment at least annually and when impairment indicators are present. Finite-lived intangible assets are reviewed for impairment when an indicator of impairment is present. When required, a comparison of fair value to the carrying amount of assets is performed to determine the amount of any impairment. When determining the fair value of indefinite-lived acquired IPR&D as well as the fair value of finite-lived intangible assets for impairment testing purposes, we utilize the "income method" discussed above. During 2018, we had finite-lived intangible impairment charges of $46.9 million which were recorded in asset impairment, restructuring and other special charges on the consolidated statements of operations. These impairments were primarily related to the sale of the Posilac (rbST) brand. During 2017, we had finite-lived intangible impairment charges of $50.0 million which were recorded in asset impairment, restructuring and other special charges on the consolidated statements of operations. These impairments were related to lower projected revenue for Posilac (rbST). No material impairments occurred with respect to the carrying value of other intangible assets for the year ended December 31, 2016.

Intangible assets with finite lives are capitalized and are amortized over their estimated useful lives, ranging from three to 20 years. As of December 31, 2018, the remaining weighted-average amortization period for finite-lived intangible assets was approximately 10 years.

Amortization expense related to finite-lived intangible assets was as follows:

	2018	2017	2016
Amortization expense	**$ 361.3**	$ 462.2	$ 517.2

The estimated amortization expense for each of the next five years associated with our finite-lived intangible assets as of December 31, 2018 is as follows:

	2019	2020	2021	2022	2023
Estimated amortization expense	$ 145.4	$ 144.0	$ 141.6	$ 133.8	$ 122.6

Amortization expense is included in either cost of sales, marketing, selling, and administrative or research and development depending on the nature of the intangible asset being amortized.

Note 9: Property and Equipment

Property and equipment is stated on the basis of cost. Provisions for depreciation of buildings and equipment are computed generally by the straight-line method at rates based on their estimated useful lives (12 to 50 years for buildings and three to 25 years for equipment). We review the carrying value of long-lived assets for potential impairment on a periodic basis and whenever events or changes in circumstances indicate the carrying value of an asset may not be recoverable. Impairment is determined by comparing projected undiscounted cash flows to be generated by the asset to its carrying value. If an impairment is identified, a loss is recorded equal to the excess of the asset's net book value over its fair value, and the cost basis is adjusted.

At December 31, property and equipment consisted of the following:

	2018	2017
Land	**$ 165.5**	$ 167.7
Buildings	**7,116.6**	6,826.9
Equipment	**7,792.3**	7,684.1
Construction in progress	**1,588.6**	1,600.6
	16,663.0	16,279.3
Less accumulated depreciation	**(8,666.9)**	(8,394.2)
Property and equipment, net	**$ 7,996.1**	$ 7,885.1

Depreciation expense related to property and equipment and rental expense for all leases, including contingent rentals (not material), was as follows:

	2018	2017	2016
Depreciation expense	**$ 797.1**	$ 681.7	$ 638.8
Rental expense	**175.7**	177.4	179.2

The future minimum rental commitments under non-cancelable operating leases are as follows:

	2019	2020	2021	2022	2023	After 2023
Lease commitments	$ 130.6	$ 107.9	$ 75.5	$ 64.7	$ 49.9	$ 281.0

Capitalized interest costs were not material for the years ended December 31, 2018, 2017, and 2016.

Assets under capital leases included in property and equipment, net on the consolidated balance sheets, capital lease obligations entered into, and future minimum rental commitments are not material.

Note 10: Borrowings

Debt at December 31 consisted of the following:

	2018	2017
Short-term commercial paper borrowings	**$ 498.9**	$ 2,696.8
0.15 to 7.13 percent long-term notes (due 2019-2047)	**9,640.8**	10,756.7
Other long-term debt	**10.1**	13.0
Unamortized debt issuance costs	**(28.4)**	(49.0)
Fair value adjustment on hedged long-term notes	**177.2**	229.0
Total debt	**10,298.6**	13,646.5
Less current portion	**(1,102.2)**	(3,706.5)
Long-term debt	**$ 9,196.4**	$ 9,940.0

The weighted-average effective borrowing rate on outstanding commercial paper at December 31, 2018 was 2.36 percent.

At December 31, 2018, we had a total of $5.42 billion of unused committed bank credit facilities, which consisted primarily of a $3.00 billion credit facility that expires in December 2023 and a $2.00 billion 364-day facility that expires in December 2019, both of which are available to support our commercial paper program. We have not drawn against the $3.00 billion and $2.00 billion facilities. Of the remaining facilities, there was $25.9 million outstanding under the revolving credit facilities as of December 31, 2018, and $6.0 million was outstanding under these facilities as of December 31, 2017. Compensating balances and commitment fees are not material, and there are no conditions that are probable of occurring under which the lines may be withdrawn.

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

The aggregate amounts of maturities on long-term debt for the next five years are as follows:

	2019	2020	2021	2022	2023
Maturities on long-term debt	$ 604.5	$ 3.5	$ 2.3	$ 1,439.0	$ 0.3

We have converted approximately 25 percent of our long-term fixed-rate notes to floating rates through the use of interest rate swaps. The weighted-average effective borrowing rates based on long-term debt obligations and interest rates at December 31, 2018 and 2017, including the effects of interest rate swaps for hedged debt obligations, were 3.13 percent and 2.65 percent, respectively.

The aggregate amount of cash payments for interest on borrowings, net of capitalized interest, are as follows:

	2018	2017	2016
Cash payments for interest on borrowings	**$ 223.8**	$ 192.7	$ 146.4

In accordance with the requirements of derivatives and hedging guidance, the portion of our fixed-rate debt obligations that is hedged as a fair value hedge is reflected in the consolidated balance sheets as an amount equal to the sum of the debt's carrying value plus the fair value adjustment representing changes in fair value of the hedged debt attributable to movements in market interest rates subsequent to the inception of the hedge.

Note 11: Stock-Based Compensation

Our stock-based compensation expense consists of performance awards (PAs), shareholder value awards (SVAs), and restricted stock units (RSUs). We recognize the fair value of stock-based compensation as expense over the requisite service period of the individual grantees, which generally equals the vesting period. We provide newly issued shares of our common stock and treasury stock to satisfy the issuance of PA, SVA, and RSU shares.

Stock-based compensation expense and the related tax benefits were as follows:

	2018	2017	2016
Stock-based compensation expense	**$ 253.5**	$ 256.3	$ 234.9
Tax benefit	**53.2**	64.1	82.2

At December 31, 2018, stock-based compensation awards may be granted under the 2002 Lilly Stock Plan for not more than 53.3 million additional shares.

Performance Award Program

PAs are granted to officers and management and are payable in shares of our common stock. The number of PA shares actually issued, if any, varies depending on the achievement of certain pre-established earnings-per-share targets over a two-year period. PA shares are accounted for at fair value based upon the closing stock price on the date of grant and fully vest at the end of the measurement period. The fair values of PAs granted for the years ended December 31, 2018, 2017, and 2016 were $71.63, $73.54, and $72.00, respectively. The number of shares ultimately issued for the PA program is dependent upon the EPS achieved during the vesting period. Pursuant to this program, approximately 0.9 million shares, 1.3 million shares, and 0.5 million shares were issued during the years ended December 31, 2018, 2017, and 2016, respectively. Approximately 1.2 million shares are expected to be issued in 2019. As of December 31, 2018, the total remaining unrecognized compensation cost related to nonvested PAs was $57.9 million, which will be amortized over the weighted-average remaining requisite service period of 12 months.

Shareholder Value Award Program

SVAs are granted to officers and management and are payable in shares of our common stock. The number of shares actually issued, if any, varies depending on our stock price at the end of the three-year vesting period compared to pre-established target stock prices. We measure the fair value of the SVA unit on the grant date using a Monte Carlo simulation model. The model utilizes multiple input variables that determine the probability of satisfying the market condition stipulated in the award grant and calculates the fair value of the award. Expected volatilities utilized in the model are based on implied volatilities from traded options on our stock, historical volatility of our stock price, and other factors. Similarly, the dividend yield is based on historical experience and our estimate of future dividend yields. The risk-free interest rate is derived from the U.S. Treasury yield curve in effect at the time of grant. The weighted-average fair values of the SVA units granted during the years ended December 31, 2018, 2017, and 2016 were $48.51, $66.25, and $48.68, respectively, determined using the following assumptions:

(Percents)	2018	2017	2016
Expected dividend yield	**2.50%**	2.50%	2.00%
Risk-free interest rate	**2.31**	1.38	0.92
Volatility	**22.26**	22.91	21.68

Pursuant to this program, approximately 0.7 million shares, 1.1 million shares, and 1.0 million shares were issued during the years ended December 31, 2018, 2017, and 2016, respectively. Approximately 1.0 million shares are expected to be issued in 2019. As of December 31, 2018, the total remaining unrecognized compensation cost related to nonvested SVAs was $52.2 million, which will be amortized over the weighted-average remaining requisite service period of 20 months.

Restricted Stock Units

RSUs are granted to certain employees and are payable in shares of our common stock. RSU shares are accounted for at fair value based upon the closing stock price on the date of grant. The corresponding expense is amortized over the vesting period, typically three years. The fair values of RSU awards granted during the years ended December 31, 2018, 2017, and 2016 were $70.95, $72.47, and $71.46, respectively. The number of shares ultimately issued for the RSU program remains constant with the exception of forfeitures. Pursuant to this program, 1.3 million, 1.4 million, and 1.3 million shares were granted and approximately 1.0 million, 0.9 million, and 0.6 million shares were issued during the years ended December 31, 2018, 2017, and 2016, respectively. Approximately 0.8 million shares are expected to be issued in 2019. As of December 31, 2018, the total remaining unrecognized compensation cost related to nonvested RSUs was $99.7 million, which will be amortized over the weighted-average remaining requisite service period of 21 months.

Note 12: Shareholders' Equity

During 2018, 2017, and 2016, we repurchased $4.15 billion, $359.8 million and $540.1 million, respectively, of shares associated with our share repurchase programs. A payment of $60.0 million was made in 2016 for shares repurchased in 2017.

During 2018, we repurchased $2.05 billion of shares, which completed the $5.00 billion share repurchase program announced in October 2013 and our board authorized an $8.00 billion share repurchase program.

There were $2.10 billion repurchased under the $8.00 billion program in 2018. As of December 31, 2018, there were $5.90 billion of shares remaining under the 2018 program.

We have 5.0 million authorized shares of preferred stock. As of December 31, 2018 and 2017, no preferred stock was issued.

We have an employee benefit trust that held 50.0 million shares of our common stock at both December 31, 2018 and 2017, to provide a source of funds to assist us in meeting our obligations under various employee benefit plans. The cost basis of the shares held in the trust was $3.01 billion at both December 31, 2018 and 2017, and is shown as a reduction of shareholders' equity. Any dividend transactions between us and the trust are eliminated. Stock held by the trust is not considered outstanding in the computation of EPS. The assets of the trust were not used to fund any of our obligations under these employee benefit plans during the years ended December 31, 2018, 2017, and 2016.

Note 13: Income Taxes

2017 Tax Act
In December 2017, the President of the U.S. signed into law the 2017 Tax Act. The 2017 Tax Act included significant changes to the U.S. corporate income tax system, such as the reduction in the corporate income tax rate from 35 percent to 21 percent, transition to a territorial tax system, changes to business related exclusions, deductions and credits, and modifications to international tax provisions, including a one-time repatriation transition tax (also known as the 'Toll Tax') on unremitted foreign earnings.

GAAP requires that the income tax accounting effects from a change in tax laws or tax rates be recognized in continuing operations in the reporting period that includes the enactment date of the change. These effects include, among other things, re-measuring deferred tax assets and liabilities, evaluating deferred tax assets for valuation allowances, and assessing the impact of the Toll Tax and certain other provisions of the 2017 Tax Act. Our accounting for the tax effects of the enactment of the 2017 Tax Act was not complete as of December 31, 2017; however, in certain cases we made a reasonable estimate. In other cases, we were not able to make a reasonable estimate and continued to account for those items based on our existing accounting model under ASC 740, *Income Taxes*, and the provisions of the tax laws that were in effect immediately prior to enactment. For the items for which we were able to determine a reasonable estimate, we recognized a provisional amount of $1.91 billion, which was included as a component of income tax expense from continuing operations. Our accounting for the effects of the 2017 Tax Act was completed in the current period, and we recorded $313.3 million of income tax benefit in 2018, mainly attributable to measurement period adjustments to the Toll Tax and the global intangible low-taxed income (GILTI) provision, the new U.S. minimum tax on the earnings of our foreign subsidiaries. Related to GILTI, we elected to establish deferred taxes in the amount of $1.74 billion for the reversal of temporary items in future years.

Subsequent to the enactment of the 2017 Tax Act, additional guidance was issued, including Notices, Proposed Regulations, and Final Regulations. We expect that further guidance will continue to be issued in 2019 which may impact our interpretations of the 2017 Tax Act and could materially affect the estimates used.

Deferred taxes are recognized for the future tax effects of temporary differences between financial and income tax reporting based on enacted tax laws and rates.

We recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The tax benefits recognized in the financial statements from such a position are measured based on the largest benefit that has a greater than 50 percent likelihood of being realized upon ultimate resolution.

Following is the composition of income tax expense:

	2018	2017	2016
Current:			
Federal	**$ (31.9)**	$ (66.5)	$ 20.0
Foreign	**106.8**	47.5	397.0
State	**4.7**	(5.4)	(134.4)
2017 Tax Act	**201.5**	3,247.5	—
Total current tax expense	**281.1**	3,223.1	282.6
Deferred:			
Federal	**22.5**	732.3	410.0
Foreign	**248.7**	(230.9)	(136.3)
State	**3.4**	0.2	(4.9)
2017 Tax Act	**(26.2)**	(1,333.5)	—
Total deferred tax (benefit) expense	**248.4**	(831.9)	268.8
Income taxes	**$ 529.5**	$ 2,391.2	$ 551.4

Significant components of our deferred tax assets and liabilities as of December 31 are as follows:

	2018	2017
Deferred tax assets:		
Purchases of intangible assets	**$ 2,627.7**	$ 441.9
Compensation and benefits	**781.6**	995.3
Tax credit carryforwards and carrybacks	**359.4**	467.5
Tax loss carryforwards and carrybacks	**248.2**	471.3
Product return reserves	**95.3**	83.4
Other comprehensive loss on hedging transactions	**68.9**	68.9
Debt	**40.3**	53.5
Contingent consideration	**11.7**	32.1
Other	**680.1**	524.3
Total gross deferred tax assets	**4,913.2**	3,138.2
Valuation allowances	**(574.8)**	(681.8)
Total deferred tax assets	**4,338.4**	2,456.4
Deferred tax liabilities:		
Earnings of foreign subsidiaries	**(1,745.3)**	(16.6)
Inventories	**(681.3)**	(649.5)
Property and equipment	**(260.9)**	(247.5)
Prepaid employee benefits	**(240.1)**	(231.5)
Intangibles	**(86.9)**	(120.7)
Financial instruments	**(22.8)**	(41.6)
Total deferred tax liabilities	**(3,037.3)**	(1,307.4)
Deferred tax assets - net	**$ 1,301.1**	$ 1,149.0

Our accounting for the effects of the 2017 Tax Act was completed in the current period; therefore, deferred tax assets and liabilities reflect re-measurement resulting from the 2017 Tax Act.

The deferred tax asset and related valuation allowance amounts for U.S. federal and state net operating losses and tax credits shown above have been reduced for differences between financial reporting and tax return filings.

At December 31, 2018, based on filed tax returns we have tax credit carryforwards and carrybacks of $729.5 million available to reduce future income taxes; $150.5 million, if unused, will expire by 2027. The remaining portion of the tax credit carryforwards is related to federal tax credits of $122.9 million, international tax credits of $119.3 million, and state tax credits of $336.9 million, all of which are substantially reserved.

At December 31, 2018, based on filed tax returns we had net operating losses and other carryforwards for international and U.S. federal income tax purposes of $773.2 million: $12.1 million will expire by 2023; $462.2 million will expire between 2024 and 2038; and $298.9 million of the carryforwards will never expire. Net operating losses and other carryforwards for international and U.S. federal income tax purposes are partially reserved. Deferred tax assets related to state net operating losses of $99.7 million and other state carryforwards of $2.6 million are fully reserved.

Domestic and Puerto Rican companies contributed approximately 15 percent, 16 percent, and 63 percent for the years ended December 31, 2018, 2017, and 2016, respectively, to consolidated income before income taxes. We have a subsidiary operating in Puerto Rico under a tax incentive grant effective through the end of 2031.

The 2017 Tax Act introduced international tax provisions that fundamentally change the U.S. taxation of foreign earnings. As a result, substantially all of the unremitted earnings of our foreign subsidiaries are considered to not be indefinitely reinvested for continued use in our foreign operations. At December 31, 2018, we have accrued an immaterial amount of foreign withholding taxes and state income taxes that would be owed upon future distributions of unremitted earnings of our foreign subsidiaries that are not indefinitely reinvested. For the amount considered to be indefinitely reinvested, it is not practicable to determine the amount of the related deferred income tax liability due to the complexities in the tax laws and assumptions we would have to make.

Cash payments of income taxes were as follows:

	2018	2017	2016
Cash payments of income taxes	**$ 1,076.7**	$ 221.5	$ 686.4

The 2017 Tax Act provided an election to taxpayers subject to the Toll Tax to make payments over an eight-year period. We made this election; therefore, we have included Toll Tax payments accordingly.

Following is a reconciliation of the income tax expense applying the U.S. federal statutory rate to income before income taxes to reported income tax expense:

	2018	2017	2016
Income tax at the U.S. federal statutory tax rate	**$ 772.8**	$ 806.7	$ 1,146.7
Add (deduct):			
International operations, including Puerto Rico	**(627.1)**	(480.8)	(357.2)
General business credits	**(87.4)**	(66.8)	(57.0)
Non-deductible acquired IPR&D[(1)]	**309.9**	300.1	—
2017 Tax Act	**175.3**	1,914.0	—
Other	**(14.0)**	(82.0)	(181.1)
Income taxes	**$ 529.5**	$ 2,391.2	$ 551.4

[(1)] Non-deductible acquired IPR&D was related to ARMO in 2018 and CoLucid in 2017. See Note 3 for additional information related to acquisitions.

A reconciliation of the beginning and ending amount of gross unrecognized tax benefits is as follows:

	2018	2017	2016
Beginning balance at January 1	**$ 1,000.8**	$ 843.3	$ 1,057.2
Additions based on tax positions related to the current year	**798.2**	133.8	73.4
Additions for tax positions of prior years	**410.9**	93.8	11.0
Reductions for tax positions of prior years	**(115.4)**	(59.3)	(12.1)
Settlements	**(33.2)**	(2.4)	(171.9)
Lapses of statutes of limitation	**(20.5)**	(19.3)	(110.0)
Changes related to the impact of foreign currency translation	**(6.2)**	10.9	(4.3)
Ending balance at December 31	**$ 2,034.6**	$ 1,000.8	$ 843.3

The total amount of unrecognized tax benefits that, if recognized, would affect our effective tax rate was $1.48 billion and $657.1 million at December 31, 2018 and 2017, respectively.

We file income tax returns in the U.S. federal jurisdiction and various state, local, and non-U.S. jurisdictions. We are no longer subject to U.S. federal, state and local, or non-U.S. income tax examinations in most major taxing jurisdictions for years before 2010.

The U.S. examination of tax years 2010-2012 commenced during the fourth quarter of 2013. In December 2015, we executed a closing agreement with the Internal Revenue Service which effectively settled certain matters for tax years 2010-2012. Accordingly, we reduced our gross uncertain tax positions by approximately $320 million in 2015. During 2016, we effectively settled the remaining matters related to tax years

2010-2012. As a result of this resolution, our gross uncertain tax positions were further reduced by approximately $140 million, and our consolidated results of operations benefited from an immaterial reduction in income tax expense. During 2016, we made cash payments of approximately $150 million related to tax years 2010-2012 after application of available tax credit carryforwards and carrybacks. The U.S. examination of tax years 2013-2015 began in 2016, and we believe it is reasonably possible that this examination could reach resolution within the next 12 months for tax years 2013-2014 and certain matters under examination for tax year 2015, for which the audit 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.

We recognize both accrued interest and penalties related to unrecognized tax benefits in income tax expense. We recognized income tax (benefit) expense related to interest and penalties as follows:

	2018	2017	2016
Income tax expense (benefit)	**$ 25.1**	$ 22.8	$ (63.8)

At December 31, 2018 and 2017, our accruals for the payment of interest and penalties totaled $183.9 million and $155.0 million, respectively.

Note 14: Retirement Benefits

We use a measurement date of December 31 to develop the change in benefit obligation, change in plan assets, funded status, and amounts recognized in the consolidated balance sheets at December 31 for our defined benefit pension and retiree health benefit plans, which were as follows:

	Defined Benefit Pension Plans		Retiree Health Benefit Plans	
	2018	2017	2018	2017
Change in benefit obligation:				
Benefit obligation at beginning of year	**$ 14,839.7**	$ 12,230.9	**$ 1,718.7**	$ 1,494.6
Service cost	**292.7**	320.8	**41.5**	46.4
Interest cost	**458.5**	411.6	**57.3**	52.9
Actuarial (gain) loss	**(1,386.5)**	1,556.0	**(176.9)**	30.2
Benefits paid	**(579.4)**	(467.8)	**(82.8)**	(60.1)
Plan amendments	**17.6**	—	**(14.1)**	—
Curtailment (gain) loss	**(43.9)**	90.4	**2.5**	105.2
Special termination benefit	**—**	317.2	**—**	37.5
Foreign currency exchange rate changes and other adjustments	**(171.6)**	380.6	**(6.2)**	12.0
Benefit obligation at end of year	**13,427.1**	14,839.7	**1,540.0**	1,718.7
Change in plan assets:				
Fair value of plan assets at beginning of year	**11,713.0**	10,056.0	**2,372.4**	1,961.2
Actual return on plan assets	**(360.1)**	1,434.3	**32.6**	462.0
Employer contribution	**319.0**	410.4	**75.9**	9.1
Benefits paid	**(579.4)**	(467.8)	**(82.8)**	(60.1)
Foreign currency exchange rate changes and other adjustments	**(159.9)**	280.1	**—**	0.2
Fair value of plan assets at end of year	**10,932.6**	11,713.0	**2,398.1**	2,372.4
Funded status	**(2,494.5)**	(3,126.7)	**858.1**	653.7
Unrecognized net actuarial loss	**5,011.3**	5,616.4	**140.6**	182.0
Unrecognized prior service (benefit) cost	**25.0**	14.5	**(299.9)**	(395.0)
Net amount recognized	**$ 2,541.8**	$ 2,504.2	**$ 698.8**	$ 440.7
Amounts recognized in the consolidated balance sheet consisted of:				
Sundry	**$ 193.7**	$ 104.5	**$ 1,043.6**	$ 870.1
Other current liabilities	**(64.2)**	(64.5)	**(7.3)**	(7.1)
Accrued retirement benefits	**(2,624.0)**	(3,166.7)	**(178.2)**	(209.3)
Accumulated other comprehensive (income) loss before income taxes	**5,036.3**	5,630.9	**(159.3)**	(213.0)
Net amount recognized	**$ 2,541.8**	$ 2,504.2	**$ 698.8**	$ 440.7

The unrecognized net actuarial loss and unrecognized prior service cost (benefit) have not yet been recognized in net periodic pension costs and are included in accumulated other comprehensive loss at December 31, 2018.

In July 2018, we announced that we would amend our defined benefit pension and retiree health benefit plans to freeze or reduce benefits for certain employees effective January 1, 2019. We remeasured the impacted pension and retiree health plans' benefit obligations as of July 31, 2018, which resulted in a net curtailment gain of $28.0 million, which was recorded in asset impairment, restructuring, and other special charges. Market variables associated with this remeasurement, specifically an increase in the discount rate, were the primary driver for the $1.59 billion decrease in the benefit obligations in 2018.

The workforce reduction plan initiated in 2017 included a curtailment loss of $159.0 million and a special termination benefit of $354.7 million, which $446.7 million was recorded in asset impairment, restructuring, and other special charges and $67.0 million was recorded in discontinued operations, as a result of a remeasurement as of October 31, 2017. The special termination benefits related to early retirement incentives

offered as part of a voluntary early retirement program for the U.S. plan in the fourth quarter of 2017. This program allowed certain employees the opportunity to voluntarily leave the Company. Market variables associated with this remeasurement, specifically a decrease in the discount rate, were the primary driver for the $2.83 billion increase in the benefit obligations in 2017.

The following represents our weighted-average assumptions as of December 31:

	Defined Benefit Pension Plans			Retiree Health Benefit Plans		
(Percents)	2018	2017	2016	2018	2017	2016
Discount rate for benefit obligation	**4.0%**	3.4%	3.9%	**4.4%**	3.7%	4.3%
Discount rate for net benefit costs	**3.4**	3.9	4.3	**3.7**	4.3	4.5
Rate of compensation increase for benefit obligation	**3.4**	3.4	3.4			
Rate of compensation increase for net benefit costs	**3.4**	3.4	3.4			
Expected return on plan assets for net benefit costs	**7.4**	7.4	7.4	**8.0**	8.0	8.0

We annually evaluate the expected return on plan assets in our defined benefit pension and retiree health benefit plans. In evaluating the expected rate of return, we consider many factors, with a primary analysis of current and projected market conditions; asset returns and asset allocations; and the views of leading financial advisers and economists. We may also review our historical assumptions compared with actual results, as well as the assumptions and trend rates utilized by similar plans, where applicable.

Given the design of our retiree health benefit plans, healthcare-cost trend rates do not have a material impact on our financial condition or results of operations.

The following benefit payments, which reflect expected future service, as appropriate, are expected to be paid as follows:

	2019	2020	2021	2022	2023	2024-2028
Defined benefit pension plans	$ 604.1	$ 607.2	$ 616.5	$ 632.1	$ 641.6	$ 3,524.7
Retiree health benefit plans	98.0	99.1	100.7	99.9	98.5	505.3

Amounts relating to defined benefit pension plans with projected benefit obligations in excess of plan assets were as follows at December 31:

	2018	2017
Projected benefit obligation	**$ 11,584.2**	$ 12,773.4
Fair value of plan assets	**8,895.6**	9,542.5

Amounts relating to defined benefit pension plans and retiree health benefit plans with accumulated benefit obligations in excess of plan assets were as follows at December 31:

	Defined Benefit Pension Plans		Retiree Health Benefit Plans	
	2018	2017	2018	2017
Accumulated benefit obligation	**$ 10,837.8**	$ 11,733.6	**$ 189.4**	$ 225.1
Fair value of plan assets	**8,895.6**	9,517.6	**—**	—

The total accumulated benefit obligation for our defined benefit pension plans was $12.57 billion and $13.67 billion at December 31, 2018 and 2017, respectively.

Net pension and retiree health benefit expense included the following components:

	Defined Benefit Pension Plans			Retiree Health Benefit Plans		
	2018	2017	2016	2018	2017	2016
Components of net periodic (benefit) cost:						
Service cost	**$ 292.7**	$ 320.8	$ 268.4	**$ 41.5**	$ 46.4	$ 39.1
Interest cost	**458.5**	411.6	419.0	**57.3**	52.9	53.2
Expected return on plan assets	**(842.1)**	(773.6)	(748.7)	**(177.9)**	(160.7)	(150.2)
Amortization of prior service (benefit) cost	**4.6**	5.6	11.7	**(79.5)**	(90.0)	(85.8)
Recognized actuarial loss	**332.5**	286.8	284.6	**6.1**	18.4	19.1
Curtailment (gain) loss	**1.3**	93.5	—	**(29.3)**	65.5	—
Special termination benefit	**—**	317.2	—	**—**	37.5	—
Net periodic (benefit) cost	**$ 247.5**	$ 661.9	$ 235.0	**$ (181.8)**	$ (30.0)	$ (124.6)

The following represents the amounts recognized in other comprehensive income (loss) for the years ended December 31, 2018, 2017, and 2016:

	Defined Benefit Pension Plans			Retiree Health Benefit Plans		
	2018	2017	2016	2018	2017	2016
Actuarial gain (loss) arising during period	**$ 182.8**	$ (898.1)	$ (719.1)	**$ 37.5**	$ 261.3	$ (132.2)
Plan amendments during period	**(17.6)**	—	—	**14.1**	—	35.8
Curtailment gain (loss)	**45.2**	3.2	—	**(31.8)**	(39.7)	—
Amortization of prior service (benefit) cost included in net income	**4.6**	5.6	11.7	**(79.5)**	(90.0)	(85.8)
Amortization of net actuarial loss included in net income	**332.5**	286.8	284.6	**6.1**	18.4	19.1
Foreign currency exchange rate changes and other	**47.1**	(108.8)	72.6	**(0.1)**	(3.3)	2.5
Total other comprehensive income (loss) during period	**$ 594.6**	$ (711.3)	$ (350.2)	**$ (53.7)**	$ 146.7	$ (160.6)

We have defined contribution savings plans that cover our eligible employees worldwide. The purpose of these plans is generally to provide additional financial security during retirement by providing employees with an incentive to save. Our contributions to the plans are based on employee contributions and the level of our match. Expenses under the plans totaled $132.6 million, $147.0 million, and $155.4 million for the years ended December 31, 2018, 2017, and 2016, respectively.

We provide certain other postemployment benefits primarily related to disability benefits and accrue for the related cost over the service lives of employees. Expenses associated with these benefit plans for the years ended December 31, 2018, 2017, and 2016 were not material.

Benefit Plan Investments

Our benefit plan investment policies are set with specific consideration of return and risk requirements in relationship to the respective liabilities. U.S. and Puerto Rico plans represent approximately 80 percent of our global investments. Given the long-term nature of our liabilities, these plans have the flexibility to manage an above-average degree of risk in the asset portfolios. At the investment-policy level, there are no specifically prohibited investments. However, within individual investment manager mandates, restrictions and limitations are contractually set to align with our investment objectives, ensure risk control, and limit concentrations.

We manage our portfolio to minimize concentration of risk by allocating funds within asset categories. In addition, within a category we use different managers with various management objectives to eliminate any significant concentration of risk.

Our global benefit plans may enter into contractual arrangements (derivatives) to implement the local investment policy or manage particular portfolio risks. Derivatives are principally used to increase or decrease exposure to a particular public equity, fixed income, commodity, or currency market more rapidly or less expensively than could be accomplished through the use of the cash markets. The plans utilize both exchange-traded and over-the-counter instruments. The maximum exposure to either a market or counterparty credit loss is limited to the carrying value of the receivable, and is managed within contractual limits. We expect all of our counterparties to meet their obligations. The gross values of these derivative receivables and payables are not material to the global asset portfolio, and their values are reflected within the tables below.

The defined benefit pension and retiree health benefit plan allocation for the U.S. and Puerto Rico currently comprises approximately 70 percent growth investments and 30 percent fixed-income investments. The growth investment allocation encompasses U.S. and international public equity securities, hedge funds, private equity-like investments, and real estate. These portfolio allocations are intended to reduce overall risk by providing diversification, while seeking moderate to high returns over the long term.

Public equity securities are well diversified and invested in U.S. and international small-to-large companies across various asset managers and styles. The remaining portion of the growth portfolio is invested in private alternative investments.

Fixed-income investments primarily consist of fixed-income securities in U.S. treasuries and agencies, emerging market debt obligations, corporate bonds, mortgage-backed securities, commercial mortgage-backed obligations, and any related repurchase agreements.

Hedge funds are privately owned institutional investment funds that generally have moderate liquidity. Hedge funds seek specified levels of absolute return regardless of overall market conditions, and generally have low correlations to public equity and debt markets. Hedge funds often invest substantially in financial market instruments (stocks, bonds, commodities, currencies, derivatives, etc.) using a very broad range of trading activities to manage portfolio risks. Hedge fund strategies focus primarily on security selection and seek to be neutral with respect to market moves. Common groupings of hedge fund strategies include relative value, tactical, and event driven. Relative value strategies include arbitrage, when the same asset can simultaneously be bought and sold at different prices, achieving an immediate profit. Tactical strategies often take long and short positions to reduce or eliminate overall market risks while seeking a particular investment opportunity. Event strategy opportunities can evolve from specific company announcements such as mergers and acquisitions, and typically have little correlation to overall market directional movements. Our hedge fund investments are made through limited partnership interests primarily in fund-of-funds structures to ensure diversification across many strategies and many individual managers. Plan holdings in hedge funds are valued based on net asset values (NAVs) calculated by each fund or general partner, as applicable, and we have the ability to redeem these investments at NAV.

Private equity-like investment funds typically have low liquidity and are made through long-term partnerships or joint ventures that invest in pools of capital invested in primarily non-publicly traded entities. Underlying investments include venture capital (early stage investing), buyout, and special situation investing. Private equity management firms typically acquire and then reorganize private companies to create increased long term value. Private equity-like funds usually have a limited life of approximately 10-15 years, and require a minimum investment commitment from their limited partners. Our private investments are made both directly into funds and through fund-of-funds structures to ensure broad diversification of management styles and assets across the portfolio. Plan holdings in private equity-like investments are valued using the value reported by the partnership, adjusted for known cash flows and significant events through our reporting date. Values provided by the partnerships are primarily based on analysis of and judgments about the underlying investments. Inputs to these valuations include underlying NAVs, discounted cash flow valuations, comparable market valuations, and may also include adjustments for currency, credit, liquidity and other risks as applicable. The vast majority of these private partnerships provide us with annual audited financial statements including their compliance with fair valuation procedures consistent with applicable accounting standards.

Real estate is composed of both public and private holdings. Real estate investments in registered investment companies that trade on an exchange are classified as Level 1 on the fair value hierarchy. Real estate investments in funds measured at fair value on the basis of NAV provided by the fund manager are classified as such. These NAVs are developed with inputs including discounted cash flow, independent appraisal, and market comparable analyses.

Other assets include cash and cash equivalents and mark-to-market value of derivatives.

The cash value of the trust-owned insurance contract is primarily invested in investment-grade publicly traded equity and fixed-income securities.

Other than hedge funds, private equity-like investments, and real estate, which are discussed above, we determine fair values 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.

The fair values of our defined benefit pension plan and retiree health plan assets as of December 31, 2018 by asset category were as follows:

		Fair Value Measurements Using			
Asset Class	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Investments Valued at Net Asset Value[1]
Defined Benefit Pension Plans					
Public equity securities:					
U.S.	$ 617.7	$ 409.1	$ —	$ —	$ 208.6
International	2,117.8	828.8	—	1.8	1,287.2
Fixed income:					
Developed markets	2,933.4	17.2	2,173.3	—	742.9
Developed markets - repurchase agreements	(1,225.5)	—	(1,225.5)	—	—
Emerging markets	565.2	3.4	255.8	6.1	299.9
Private alternative investments:					
Hedge funds	2,795.3	—	—	—	2,795.3
Equity-like funds	1,893.5	—	—	16.8	1,876.7
Real estate	505.7	147.1	—	—	358.6
Other	729.5	213.0	83.7	—	432.8
Total	$ 10,932.6	$ 1,618.6	$ 1,287.3	$ 24.7	$ 8,002.0
Retiree Health Benefit Plans					
Public equity securities:					
U.S.	$ 59.9	$ 41.0	$ —	$ —	$ 18.9
International	127.0	50.5	—	0.2	76.3
Fixed income:					
Developed markets	69.1	—	61.5	—	7.6
Emerging markets	53.5	—	25.5	0.6	27.4
Private alternative investments:					
Hedge funds	245.8	—	—	—	245.8
Equity-like funds	169.2	—	—	1.7	167.5
Cash value of trust owned insurance contract	1,574.7	—	1,574.7	—	—
Real estate	27.7	14.7	—	—	13.0
Other	71.2	38.1	(3.8)	—	36.9
Total	$ 2,398.1	$ 144.3	$ 1,657.9	$ 2.5	$ 593.4

[1] Certain investments that are measured at fair value using the NAV per share (or its equivalent) as a practical expedient have not been classified in the fair value hierarchy.

No material transfers between Level 1, Level 2, or Level 3 occurred during the year ended December 31, 2018. The activity in the Level 3 investments during the year ended December 31, 2018 was not material.

The fair values of our defined benefit pension plan and retiree health plan assets as of December 31, 2017 by asset category were as follows:

Asset Class	Total	Fair Value Measurements Using: Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Investments Valued at Net Asset Value[1]
Defined Benefit Pension Plans					
Public equity securities:					
U.S.	$ 465.4	$ 199.0	$ —	$ —	$ 266.4
International	2,934.2	955.1	—	—	1,979.1
Fixed income:					
Developed markets	3,153.0	20.5	2,468.1	—	664.4
Developed markets - repurchase agreements	(1,372.9)	—	(1,372.9)	—	—
Emerging markets	577.5	3.6	251.7	3.1	319.1
Private alternative investments:					
Hedge funds	2,977.8	—	—	—	2,977.8
Equity-like funds	1,586.9	—	—	16.8	1,570.1
Real estate	543.7	338.6	—	—	205.1
Other	847.4	119.1	602.7	2.2	123.4
Total	$ 11,713.0	$ 1,635.9	$ 1,949.6	$ 22.1	$ 8,105.4
Retiree Health Benefit Plans					
Public equity securities:					
U.S.	$ 43.0	$ 19.4	$ —	$ —	$ 23.6
International	182.5	61.3	—	—	121.2
Fixed income:					
Developed markets	71.2	—	63.5	—	7.7
Emerging markets	53.1	—	24.4	0.3	28.4
Private alternative investments:					
Hedge funds	256.0	—	—	—	256.0
Equity-like funds	137.0	—	—	1.6	135.4
Cash value of trust owned insurance contract	1,524.6	—	1,524.6	—	—
Real estate	33.0	33.0	—	—	—
Other	72.0	15.0	50.5	0.2	6.3
Total	$ 2,372.4	$ 128.7	$ 1,663.0	$ 2.1	$ 578.6

[1] Certain investments that are measured at fair value using the NAV per share (or its equivalent) as a practical expedient have not been classified in the fair value hierarchy.

No material transfers between Level 1, Level 2, or Level 3 occurred during the year ended December 31, 2017. The activity in the Level 3 investments during the year ended December 31, 2017 was not material.

In 2019, we expect to contribute approximately $45 million to our defined benefit pension plans to satisfy minimum funding requirements for the year. Additional discretionary contributions are not expected to be significant.

Note 15: 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.

Litigation accruals, environmental liabilities, and the related estimated insurance recoverables are reflected on a gross basis as liabilities and assets, respectively, on our consolidated balance sheets. With respect to the product liability claims currently asserted against us, we have accrued for our estimated exposures to the extent they are both probable and reasonably estimable based on the information available to us. We accrue for certain product liability claims incurred but not filed to the extent we can formulate a reasonable estimate of their costs. We estimate these expenses based primarily on historical claims experience and data regarding product usage. Legal defense costs expected to be incurred in connection with significant product liability loss contingencies are accrued when both probable and reasonably estimable.

Alimta Patent Litigation and Administrative Proceedings

A number of generic manufacturers are seeking approvals in the U.S., Japan, and a number of countries in Europe to market generic forms of Alimta prior to the expiration of our vitamin regimen patents, alleging that those patents are invalid, not infringed, or both. We believe our Alimta vitamin regimen patents are valid and enforceable against these generic manufacturers. However, it is not possible to determine the ultimate outcome of the proceedings, and accordingly, we can provide no assurance that we will prevail. An unfavorable outcome could have a material adverse impact on our future consolidated results of operations, liquidity, and financial position. We expect that a loss of exclusivity for Alimta in one or more 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 issued written decisions in our favor following IPR of our vitamin regimen patent, finding that the generic company petitioners failed to show that the claims in our patent are unpatentable. A number of these challengers have appealed. A hearing on the appeal was held in the first quarter of 2019, and we expect a decision in the second quarter of 2019.

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.

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 vitamin regimen patent before the German Federal Patent Court. At a hearing in July 2018, the German Federal Patent Court held that our vitamin regimen patent is invalid. We have appealed this decision. Under German law, the patent remains in force pending appeal. A number of generic competitors have received approval to market generic versions of pemetrexed in Germany. Injunctions are in place against four of these companies, but in two cases the injunctions have been temporarily suspended pending the validity appeal at the German Supreme Court. Stada has recently launched at risk in Germany and we are seeking an injunction. We are pursuing injunctions against others who have launched or are preparing to launch at

risk. 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, makes the timing of further generic entry and market erosion in Germany unpredictable.

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

Japanese Administrative Proceedings

Three separate sets of demands for invalidation of our two vitamin regimen patents, involving several companies, have been filed with the Japanese Patent Office (JPO). 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 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 Com*pany) involving Cymbalta. The plaintiffs, purporting to represent a class of all persons within the U.S. who purchased and/or paid for Cymbalta, asserted claims under the consumer protection statutes of four states, California, Massachusetts, Missouri, and New York, and sought declaratory, injunctive, and monetary relief for various alleged economic injuries arising from discontinuing treatment with Cymbalta. The district court denied the plaintiffs' motions for class certification. The district court dismissed the suits and plaintiffs appealed to the U.S. Court of Appeals for the Ninth Circuit. In November 2017, the U.S. Court of Appeals for the Ninth Circuit dismissed the suit. In July 2018, the U.S. District Court for the District of California denied plaintiffs' motion to reopen the case. Plaintiffs' appeal of this denial is currently pending before the U.S. Court of Appeals for the Ninth Circuit.

Brazil–Employee Litigation

Our subsidiary in Brazil, Eli Lilly do Brasil Limitada (Lilly Brasil), is named in a lawsuit brought by the Labor Attorney for the 15th Region in the Labor Court of Paulinia, State of Sao Paulo, Brazil, alleging possible harm to employees and former employees caused by exposure to heavy metals at a former Lilly Brasil manufacturing facility in Cosmopolis, Brazil, operated by the company between 1977 and 2003. 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 December 31, 2018). 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 first 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 also been named in two similar lawsuits in the same labor court involving approximately 410 individual plaintiffs. As part of the disposition of Elanco, we agreed to indemnify Elanco Quimica Ltda. in this litigation. The plaintiffs' claims in these 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 are appealing.

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 $188.0 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 arbitrations described above, Adocia has made statements alleging that Adocia employees should be listed as inventors on two of our patents related to our ultra-rapid insulin product currently in development. We strongly contest this allegation. While inventorship of these two patents is not at issue in the arbitrations, in October 2018 we filed a declaratory judgment action against Adocia in the U.S. District Court for the Southern District of Indiana to confirm our inventorship.

Insulin and Glucagon Pricing Litigation and Proceedings

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. 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. Finally, the Minnesota Attorney General's Office filed a complaint against us, Sanofi, and Novo Nordisk, *State of Minnesota v. Sanofi-Aventis U.S. LLC et al.,* in the U.S. District Court of New Jersey, alleging unjust enrichment, and violations of various Minnesota state consumer protection laws and the Federal RICO Act. We believe these claims are without merit and 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 a request from the Senate 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, are named as defendants in a lawsuit seeking class action status in the U.S. District Court of New Jersey relating to glucagon pricing. The plaintiffs are seeking damages under various state consumer protection laws, the Federal RICO Act, the Sherman Act, and other state and federal laws. We believe this lawsuit is without merit and are defending against it vigorously.

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 16: Other Comprehensive Income (Loss)

The following table summarizes the activity related to each component of other comprehensive income (loss):

	Continuing Operations					
(Amounts presented net of taxes)	Foreign Currency Translation Gains (Losses)	Unrealized Net Gains (Losses) on Securities	Defined Benefit Pension and Retiree Health Benefit Plans	Effective Portion of Cash Flow Hedges	Discontinued Operations	Accumulated Other Comprehensive Loss
Beginning balance at January 1, 2016	$ (1,315.9)	$ 10.1	$ (2,996.8)	$ (218.5)	$ (59.6)	$ (4,580.7)
Other comprehensive income (loss) before reclassifications	(445.2)	206.7	(514.3)	(2.2)	(140.8)	(895.8)
Net amount reclassified from accumulated other comprehensive loss	74.5	7.2	159.1	9.8	0.1	250.7
Net other comprehensive income (loss)	(370.7)	213.9	(355.2)	7.6	(140.7)	(645.1)
Balance at December 31, 2016[1]	(1,686.6)	224.0	(3,352.0)	(210.9)	(200.3)	(5,225.8)
Other comprehensive income (loss) before reclassifications	525.6	(15.7)	(532.1)	8.5	127.7	114.0
Net amount reclassified from accumulated other comprehensive loss	8.1	(110.6)	151.9	9.6	1.5	60.5
Net other comprehensive income (loss)	533.7	(126.3)	(380.2)	18.1	129.2	174.5
Reclassifications of stranded tax effects (Note 2)	(38.8)	15.8	(579.1)	(41.5)	—	(643.6)
Balance at December 31, 2017[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	**(378.0)**	**24.5**	**250.7**	**(16.3)**	**12.2**	**(106.9)**
Net amount reclassified from accumulated other comprehensive loss	**—**	**(31.2)**	**207.9**	**11.7**	**2.1**	**190.5**
Net other comprehensive income (loss)	**(378.0)**	**(6.7)**	**458.6**	**(4.6)**	**14.3**	**83.6**
Ending balance at December 31, 2018[4]	**$ (1,569.7)**	**$ (22.1)**	**$ (3,852.7)**	**$ (238.9)**	**$ (56.8)**	**$ (5,740.2)**

[1] Accumulated other comprehensive loss as of December 31, 2016 consists of $5.27 billion of accumulated other comprehensive loss attributable to controlling interest and $48.2 million of accumulated other comprehensive income attributable to noncontrolling interest.

[2] Accumulated other comprehensive loss as of December 31, 2017 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. Refer to Note 2 for further details regarding the reclassification due to the adoption of Accounting Standards Update 2016-01, *Financial Instruments - Overall: Recognition and Measurement of Financial Assets and Financial Liabilities.*

[4] Accumulated other comprehensive loss as of December 31, 2018 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.

The tax effects on the net activity related to each component of other comprehensive income (loss) for the years ended December 31, were as follows:

Tax benefit (expense)	2018	2017	2016
Foreign currency translation gains/losses	**$ 51.6**	$ 170.8	$ (70.6)
Unrealized net gains/losses on securities	**2.1**	55.0	(89.2)
Defined benefit pension and retiree health benefit plans	**(85.3)**	186.6	153.3
Effective portion of cash flow hedges	**1.3**	(9.7)	(4.1)
Benefit/(provision) for income taxes allocated to other comprehensive income (loss) items	**$ (30.3)**	$ 402.7	$ (10.6)

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 statements of operations.

Reclassifications out of accumulated other comprehensive loss were as follows:

Details about Accumulated Other Comprehensive Loss Components	Year Ended December 31, 2018	2017	2016	Affected Line Item in the Consolidated Statements of Operations
Amortization of retirement benefit items:				
Prior service benefits, net	**$ (74.9)**	$ (84.4)	$ (74.1)	Other—net, (income) expense
Actuarial losses	**338.6**	305.2	304.7	Other—net, (income) expense
Total before tax	**263.7**	220.8	230.6	
Tax benefit	**(55.8)**	(68.9)	(71.5)	Income taxes
Net of tax	**207.9**	151.9	159.1	
Unrealized gains/losses on available-for-sale securities:				
Realized gains, net	**(39.5)**	(170.2)	(16.1)	Other—net, (income) expense
Impairment losses	**—**	—	27.3	Other—net, (income) expense
Total before tax	**(39.5)**	(170.2)	11.2	
Tax (benefit) expense	**8.3**	59.6	(4.0)	Income taxes
Net of tax	**(31.2)**	(110.6)	7.2	
Other, net of tax[(1)]	**13.8**	19.2	84.4	Other—net, (income) expense
Total reclassifications for the period (net of tax)	**$ 190.5**	$ 60.5	$ 250.7	

[(1)] Amount for year ended December 31, 2016 included primarily $74.5 million of foreign currency translation losses.

Note 17: Other–Net, (Income) Expense

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

	2018	2017	2016
Interest expense	**$ 242.5**	$ 225.0	$ 185.2
Interest income	**(159.3)**	(166.4)	(107.9)
Venezuela charge	**—**	—	203.9
Retirement benefit	**(240.5)**	(249.0)	(197.1)
Other (income) expense	**11.7**	(111.1)	(192.9)
Other–net, (income) expense	**$ (145.6)**	$ (301.5)	$ (108.8)

Due to the financial crisis in Venezuela and the significant deterioration of the bolívar, we changed the exchange rate used to translate the assets and liabilities of our subsidiaries in Venezuela in 2016, which resulted in a charge of $203.9 million for the year ended December 31, 2016. Prior to this change, we used the Supplementary Foreign Currency Administration System (SICAD) rate; however, this official rate was discontinued in the first quarter of 2016. After considering several factors, including the future uncertainty of the Venezuelan economy, published exchange rates, and the limited amount of foreign currency exchanged, we changed to the Divisa Complementaria (DICOM) rate.

As discussed in Note 2, upon adoption of Accounting Standards Update 2017-07, *Compensation-Retirement Benefits: Improving the Presentation of Net Periodic Pension Cost and Net Periodic Postretirement Benefit Cost,* pension and postretirement benefit cost components other than service costs are presented in other–net, (income) expense. Results for the years ended December 31, 2017 and 2016 have been reclassified to reflect the adoption of this standard.

For the years ended December 31, 2017, and 2016, other income is primarily related to net gains on investments (Note 7).

Note 18: Segment Information

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, Elanco has been presented as discontinued operations in our consolidated financial statements for all periods presented. 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.

We lost our compound patent protection for Cialis® (tadalafil) and Adcirca® (tadalafil) in major European markets in November 2017, and in the U.S., pediatric exclusivity expired in 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. Entry of generic competition into these markets following the loss of exclusivity will continue to cause a rapid and severe decline in revenue. Our formulation patents for Forteo® expired in December 2018 and 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.

Most of our products are distributed through wholesalers that serve pharmacies, physicians and other health care professionals, and hospitals. For the years ended December 31, 2018, 2017, and 2016, our three largest wholesalers each accounted for between 13 percent and 21 percent of consolidated total revenue. Further, they each accounted for between 16 percent and 25 percent of accounts receivable as of December 31, 2018 and 2017.

We are exposed to the risk of changes in social, political, and economic conditions inherent in foreign operations, and our results of operations and the value of our foreign assets are affected by fluctuations in foreign currency exchange rates.

The following table summarizes our revenue activity:

	U.S.[1]			Outside U.S.		
	2018	2017	2016	2018	2017	2016
Revenue—to unaffiliated customers:						
Endocrinology:						
Trulicity®	**$ 2,515.8**	$ 1,609.8	$ 737.6	**$ 683.3**	$ 419.9	$ 187.9
Humalog®	**1,787.8**	1,717.8	1,685.2	**1,208.7**	1,147.4	1,083.6
Humulin®	**910.2**	884.6	861.8	**421.2**	450.7	504.1
Forteo	**757.9**	965.2	770.5	**817.7**	783.8	729.4
Basaglar	**622.8**	311.1	15.8	**178.5**	121.0	70.3
Jardiance	**400.2**	290.4	144.5	**258.1**	157.0	57.4
Trajenta	**224.2**	213.2	165.9	**350.5**	324.7	270.7
Other Endocrinology	**292.7**	380.9	450.6	**272.5**	307.7	347.5
Total Endocrinology	**7,511.6**	6,373.0	4,831.9	**4,190.5**	3,712.2	3,250.9
Oncology:						
Alimta	**1,131.0**	1,034.3	1,101.0	**1,001.9**	1,028.2	1,182.3
Erbitux	**531.6**	541.7	581.1	**103.8**	104.2	105.9
Cyramza®	**291.5**	278.8	270.1	**529.9**	479.6	344.0
Other Oncology	**449.1**	195.6	22.9	**221.7**	149.6	114.6
Total Oncology	**2,403.2**	2,050.4	1,975.1	**1,857.3**	1,761.6	1,746.8
Cardiovascular:						
Cialis	**1,129.2**	1,358.6	1,469.5	**722.7**	964.5	1,002.1
Effient	**68.1**	340.1	465.6	**54.1**	48.8	69.6
Other Cardiovascular	**158.4**	24.0	56.3	**121.8**	135.2	162.3
Total Cardiovascular	**1,355.7**	1,722.7	1,991.4	**898.6**	1,148.5	1,234.0
Neuroscience:						
Strattera®	**89.7**	284.9	534.9	**361.1**	333.3	319.8
Cymbalta[2]	**54.3**	114.9	269.3	**653.7**	642.2	661.2
Zyprexa®	**36.2**	75.5	69.8	**435.1**	505.7	655.5
Other Neuroscience	**97.2**	115.7	115.9	**93.4**	98.9	93.9
Total Neuroscience	**277.4**	591.0	989.9	**1,543.3**	1,580.1	1,730.4
Immunology:						
Taltz®	**738.7**	486.0	110.8	**198.7**	73.2	2.3
Other Immunology	**6.7**	—	—	**195.9**	45.8	—
Total Immunology	**745.4**	486.0	110.8	**394.6**	119.0	2.3
Other	**98.5**	191.3	247.9	**217.0**	238.0	201.3
Revenue	**$ 12,391.9**	$ 11,414.4	$ 10,147.0	**$ 9,101.4**	$ 8,559.4	$ 8,165.8

Numbers may not add due to rounding.

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

[2] Cymbalta revenues benefited from reductions to the reserve for expected product returns of approximately $175 million during the year ended December 31, 2016.

	2018	2017	2016
Geographic Information			
Revenue—to unaffiliated customers[1]:			
United States	**$ 12,391.9**	$ 11,414.4	$ 10,147.0
Europe	**3,663.1**	3,390.6	3,214.4
Japan	**2,407.4**	2,339.5	2,253.0
Other foreign countries	**3,030.9**	2,829.3	2,698.3
Revenue	**$ 21,493.3**	$ 19,973.8	$ 18,312.8
Long-lived assets[2]:			
United States	**$ 4,344.0**	$ 4,408.7	$ 4,520.8
Europe	**2,413.5**	2,246.4	1,864.8
Japan	**180.2**	153.4	91.0
Other foreign countries	**1,608.5**	1,672.5	1,690.4
Long-lived assets	**$ 8,546.2**	$ 8,481.0	$ 8,167.0

Numbers may not add due to rounding.

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

[2] Long-lived assets consist of property and equipment, net, and certain sundry assets.

Note 19: Selected Quarterly Data (unaudited)

2018	Fourth	Third	Second	First
Revenue	$ 5,637.6	$ 5,306.9	$ 5,585.0	$ 4,963.8
Cost of sales	1,129.9	1,152.9	1,234.3	1,164.6
Operating expenses[1]	3,085.5	2,738.1	2,756.6	2,446.2
Acquired in-process research and development[2]	329.4	30.0	1,624.5	—
Asset impairment, restructuring, and other special charges	192.7	42.9	(25.5)	56.8
Income before income taxes	931.6	1,341.1	41.7	1,365.7
Income taxes[3]	(189.8)	247.5	273.3	198.5
Net income (loss) from continuing operations	1,121.4	1,093.6	(231.6)	1,167.2
Net income (loss) from discontinued operations	3.7	55.9	(28.3)	50.2
Net income (loss)	1,125.1	1,149.5	(259.9)	1,217.4
Earnings (loss) from continuing operations - basic	1.11	1.07	(0.22)	1.11
Earnings (loss) from discontinued operations - basic	—	0.06	(0.03)	0.05
Earnings (loss) per share—basic	1.11	1.13	(0.25)	1.16
Earnings (loss) from continuing operations - diluted	1.10	1.07	(0.22)	1.11
Earnings (loss) from discontinued operations - diluted	—	0.05	(0.03)	0.05
Earnings (loss) per share—diluted	1.10	1.12	(0.25)	1.16
Dividends paid per share	0.5625	0.5625	0.5625	0.5625

2017	Fourth	Third	Second	First
Revenue	$ 5,406.4	$ 4,961.0	$ 5,091.6	$ 4,514.9
Cost of sales[4]	1,186.4	1,163.5	1,140.1	957.7
Operating expenses[1][4]	3,054.0	2,678.2	2,763.8	2,582.5
Acquired in-process research and development[2]	50.0	205.0	—	857.6
Asset impairment, restructuring, and other special charges[5]	830.7	389.2	0.3	111.4
Income before income taxes	397.0	573.1	1,249.4	85.2
Income taxes[3]	1,947.5	29.0	244.3	170.3
Net income (loss) from continuing operations	(1,550.5)	544.1	1,005.1	(85.1)
Net income (loss) from discontinued operations	(106.4)	11.5	2.9	(25.7)
Net income (loss)	(1,656.9)	555.6	1,008.0	(110.8)
Earnings (loss) from continuing operations - basic	(1.48)	0.52	0.96	(0.08)
Earnings (loss) from discontinued operations - basic	(0.10)	0.01	—	(0.02)
Earnings (loss) per share—basic	(1.58)	0.53	0.96	(0.10)
Earnings (loss) from continuing operations - diluted	(1.48)	0.52	0.95	(0.08)
Earnings (loss) from discontinued operations - diluted	(0.10)	0.01	—	(0.02)
Earnings (loss) per share—diluted	(1.58)	0.53	0.95	(0.10)
Dividends paid per share	0.52	0.52	0.52	0.52

[1] Includes research and development and marketing, selling, and administrative expenses.

[2] Acquired IPR&D charges in the second quarter of 2018 were primarily due to the ARMO acquisition. Acquired IPR&D charges in the first quarter of 2017 were due to the CoLucid acquisition. See Note 3 for further discussion.

[3] Income taxes in the fourth quarter of 2018 were a tax benefit primarily due to adjustments associated with U.S. tax reform. Income taxes in the fourth quarter of 2017 were due to the provisional charge resulting from the 2017 Tax Act. See Note 13 for further discussion.

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

[5] Asset impairment, restructuring, and other special charges in the third quarter 2017 were primarily from asset impairments related to lower projected revenue for Posilac (rbST). In the fourth quarter of 2017, restructuring charges were primarily due to severance costs resulting from the U.S. voluntary early retirement program. See Note 5 for further discussion.

Our common stock is listed under the ticker symbol LLY on the New York Stock Exchange (NYSE) and the NYSE Euronext.

Note 20: Discontinued Operations

On September 24, 2018, Elanco completed its IPO resulting in the issuance of 72.3 million shares of its common stock, which represented 19.8 percent of Elanco's outstanding shares, at $24 per share. Elanco shares began trading on the New York Stock Exchange under the symbol "ELAN" in September 2018.

In connection with the completion of the IPO, through a series of equity and other transactions, we transferred to Elanco the animal health businesses that formed its business. In exchange, Elanco transferred to us consideration of approximately $4.2 billion, which consisted primarily of the net proceeds from the IPO and the net proceeds from a $2.00 billion debt offering and a $500.0 million three-year term loan facility entered into by Elanco in August 2018. The consideration that we received was used for debt repayment, dividends, and/or share repurchases. The excess of the net proceeds from the IPO over the net book value of our divested interest was $629.2 million and was recorded in additional paid-in capital.

Through March 11, 2019, we continued to consolidate Elanco, as we retained control over Elanco. The earnings attributable to the divested, noncontrolling interest for the period from the IPO until December 31, 2018 were not material. As of December 31, 2018, the noncontrolling interest of $1.02 billion associated with Elanco was reflected in noncontrolling interests in the consolidated balance sheet.

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, in the first quarter of 2019, we recognized a gain related to the disposition of approximately $3.7 billion, and we presented Elanco, including the gain related to the disposition, as discontinued operations in our consolidated condensed financial statements for all periods presented.

The following table sets forth details of revenue and net income (loss) from discontinued operations:

	2018	2017	2016
Revenue from discontinued operations	**$ 3,062.4**	$ 2,897.5	$ 2,909.3
Net income (loss) from discontinued operations	**81.4**	(117.7)	12.7

The following table presents the major classes of assets and liabilities from discontinued operations at December 31:

	2018	2017
Inventories	**$ 1,013.7**	$ 1,062.3
Other current assets	**1,215.4**	1,047.7
Current assets of discontinued operations	**$ 2,229.1**	$ 2,110.0
Goodwill	**$ 2,980.9**	$ 2,992.1
Other intangibles, net	**2,453.0**	2,674.8
Property and equipment, net	**923.4**	941.4
Other assets	**126.8**	60.4
Noncurrent assets of discontinued operations	**$ 6,484.1**	$ 6,668.7
Current liabilities of discontinued operations	**$ 692.8**	$ 637.5
Long-term debt	**$ 2,443.3**	$ 0.5
Other liabilities	**299.0**	351.1
Noncurrent liabilities of discontinued operations	**$ 2,742.3**	$ 351.6

Net cash provided by operating activities related to our discontinued operations was approximately $500 million, $300 million, and $300 million for the years ended December 31, 2018, 2017, and 2016, respectively. Net cash used by investing activities related to our discontinued operations was approximately $130 million, $960 million, and $180 million for the years ended December 31, 2018, 2017, and 2016, respectively.

We entered into a transitional services agreement (TSA) with Elanco that is designed to facilitate the orderly transfer of various services to Elanco. The TSA relates primarily to administrative services, which are

generally to be provided over 24 months from March 11, 2019, the disposition date. This agreement is not material and does not confer upon us the ability to influence the operating and/or financial policies of Elanco subsequent to the disposition date.

Management's Reports

Management's Report for Financial Statements—Eli Lilly and Company and Subsidiaries

Management of Eli Lilly and Company and subsidiaries is responsible for the accuracy, integrity, and fair presentation of the financial statements. The statements have been prepared in accordance with generally accepted accounting principles in the United States and include amounts based on judgments and estimates by management. In management's opinion, the consolidated financial statements present fairly our financial position, results of operations, and cash flows.

In addition to the system of internal accounting controls, we maintain a code of conduct (known as "*The Red Book*") that applies to all employees worldwide, requiring proper overall business conduct, avoidance of conflicts of interest, compliance with laws, and confidentiality of proprietary information. All employees must take training annually on *The Red Book* and are required to report suspected violations. A hotline number is published in *The Red Book* to enable employees to report suspected violations anonymously. Employees who report suspected violations are protected from discrimination or retaliation by the company. In addition to *The Red Book*, the chief executive officer and all financial management must sign a financial code of ethics, which further reinforces their ethical and fiduciary responsibilities.

The consolidated financial statements have been audited by Ernst & Young LLP, an independent registered public accounting firm. Their responsibility is to examine our consolidated financial statements in accordance with generally accepted auditing standards of the Public Company Accounting Oversight Board (United States). Ernst & Young's opinion with respect to the fairness of the presentation of the statements is included in Item 8 of this Form 8-K. Ernst & Young reports directly to the audit committee of the board of directors.

Our audit committee includes six nonemployee members of the board of directors, all of whom are independent from our company. The committee charter, which is available on our website, outlines the members' roles and responsibilities and is consistent with enacted corporate reform laws and regulations. It is the audit committee's responsibility to appoint an independent registered public accounting firm subject to shareholder ratification, approve both audit and non-audit services performed by the independent registered public accounting firm, and review the reports submitted by the firm. The audit committee meets several times during the year with management, the internal auditors, and the independent public accounting firm to discuss audit activities, internal controls, and financial reporting matters, including reviews of our externally published financial results. The internal auditors and the independent registered public accounting firm have full and free access to the committee.

We are dedicated to ensuring that we maintain the high standards of financial accounting and reporting that we have established. We are committed to providing financial information that is transparent, timely, complete, relevant, and accurate. Our culture demands integrity and an unyielding commitment to strong internal practices and policies. Finally, we have the highest confidence in our financial reporting, our underlying system of internal controls, and our people, who are objective in their responsibilities and operate under a code of conduct and the highest level of ethical standards.

Management's Report on Internal Control Over Financial Reporting—Eli Lilly and Company and Subsidiaries

Management of Eli Lilly and Company and subsidiaries is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934. We have global financial policies that govern critical areas, including internal controls, financial accounting and reporting, fiduciary accountability, and safeguarding of corporate assets. Our internal accounting control systems are designed to provide reasonable assurance that assets are safeguarded, that transactions are executed in accordance with management's authorization and are properly recorded, and that accounting records are adequate for preparation of financial statements and other financial information. A staff of internal auditors regularly monitors, on a worldwide basis, the adequacy and effectiveness of internal accounting controls. The general auditor reports directly to the audit committee of the board of directors.

We conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in "2013 *Internal Control—Integrated Framework*" issued by the Committee of Sponsoring Organizations of the Treadway Commission.

Based on our evaluation under this framework, we concluded that our internal control over financial reporting was effective as of December 31, 2018. However, because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

The internal control over financial reporting has been assessed by Ernst & Young LLP as of December 31, 2018. Their responsibility is to evaluate whether internal control over financial reporting was designed and operating effectively.

David A. Ricks	Joshua L. Smiley
Chairman, President and Chief Executive Officer	*Senior Vice President and Chief Financial Officer*

February 19, 2019

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of Eli Lilly and Company

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Eli Lilly and Company and subsidiaries (the Company) as of December 31, 2018 and 2017, the related consolidated statements of operations, comprehensive income (loss), shareholders' equity and cash flows for each of the three years in the period ended December 31, 2018, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), and our report dated February 19, 2019 expressed an unqualified opinion thereon.

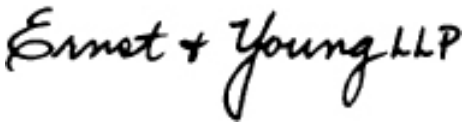
Adoption of Accounting Standards Update ("ASU") No. 2016-16

As discussed in Note 2 to the consolidated financial statements, the Company changed its method of accounting for the recognition of income tax consequences of intra-entity transfers of assets other than inventory in 2018 due to the adoption of ASU No. 2016-16, *Intra-Entity Transfers of Assets Other Than Inventory (Topic 740)*, using the modified retrospective adoption method.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.



We have served as the Company's auditor since 1940.

Indianapolis, Indiana

February 19, 2019, except for the effects of discontinued operations discussed in Note 20, as to which the date is October 24, 2019

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of Eli Lilly and Company

Opinion on Internal Control Over Financial Reporting

We have audited Eli Lilly and Company and subsidiaries' internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Eli Lilly and Company and subsidiaries (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2018 and 2017, the related consolidated statements of operations, comprehensive income (loss), shareholders' equity and cash flows for each of the three years in the period ended December 31, 2018, and the related notes and our report dated February 19, 2019 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

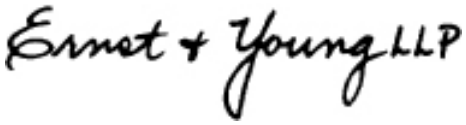
We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.



Indianapolis, Indiana

February 19, 2019