United States
Securities and Exchange Commission
Washington, D.C. 20549

Form 10-K

Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
for the fiscal year ended December 31, 2021

Commission file number 001-06351

ELI LILLY AND COMPANY

(Exact name of Registrant as specified in its charter)

Indiana	35-0470950
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

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

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

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

Title of Each Class	Trading Symbol(s)
Common Stock (no par value)	LLY
1.000% Notes due 2022	LLY22
7 1/8% Notes due 2025	LLY25
1.625% Notes due 2026	LLY26
2.125% Notes due 2030	LLY30
0.625% Notes due 2031	LLY31
0.500% Notes due 2033	LLY33
6.77% Notes due 2036	LLY36
1.625% Notes due 2043	LLY43
1.700% Notes due 2049	LLY49A
1.125% Notes due 2051	LLY51
1.375% Notes due 2061	LLY61

Securities registered pursuant to Section 12(g) of the Exchange Act: None

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act. Yes ☐ No ☒

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

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files).
Yes ☒ No ☐

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☒	Accelerated filer ☐
Non-accelerated filer ☐	Smaller reporting company ☐
	Emerging growth company ☐

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

Indicate by check mark whether the Registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

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

Yes ☐ No ☒

Aggregate market value of the common equity held by non-affiliates computed by reference to the price at which the common equity was last sold as of the last business day of the Registrant's most recently completed second fiscal quarter: approximately $193,649,000,000.

Number of shares of common stock outstanding as of February 18, 2022: 952,347,126

Portions of the Registrant's Proxy Statement for the 2022 Annual Meeting of Shareholders have been incorporated by reference into Part III of this report.

Eli Lilly and Company

Form 10-K
For the Year Ended December 31, 2021

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Forward-Looking Statements

This Annual Report on Form 10-K and our other publicly available documents include forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 (Exchange Act), and are subject to the safe harbor created thereby under the Private Securities Litigation Reform Act of 1995. In particular, information appearing under "Business," "Risk Factors," and "Management's Discussion and Analysis of Results of Operations and Financial Condition" includes forward-looking statements. Forward-looking statements include all statements that do not relate solely to historical or current facts, and generally can be identified by the use of words such as "may," "believe," "will," "expect," "project," "estimate," "intend," "anticipate," "plan," "continue," or similar expressions or future or conditional verbs.

Forward-looking statements inherently involve many risks and uncertainties that could cause actual results to differ materially from those expressed in forward-looking statements. Where, in any forward-looking statement, we express an expectation or belief as to future results or events, it is based on management's current plans and expectations, expressed in good faith and believed to have a reasonable basis. However, we can give no assurance that any such expectation or belief will result or will be achieved or accomplished. Investors therefore should not place undue reliance on forward-looking statements. The following include some but not all of the factors that could cause actual results or events to differ materially from those anticipated:

- the impact of the evolving COVID-19 pandemic or any future pandemic, epidemic, or similar public health threat and the global response thereto;
- uncertainties related to our efforts to develop, manufacture, and distribute potential treatments for COVID-19;
- the significant costs and uncertainties in the pharmaceutical research and development process, including with respect to the timing and process of obtaining regulatory approvals;
- the impact and outcome of acquisitions and business development transactions and related integration costs;
- the expiration of intellectual property protection for certain of our products and competition from generic and/or biosimilar products;
- our ability to protect and enforce patents and other intellectual property;
- changes in patent law or regulations related to data package exclusivity;
- competitive developments affecting current products and our pipeline;
- market uptake of recently launched products;
- information technology system inadequacies, breaches, or operating failures;
- unauthorized access, disclosure, misappropriation, or compromise of confidential information or other data stored in our information technology systems, networks, and facilities, or those of third parties with whom we share our data;
- unexpected safety or efficacy concerns associated with our products;
- litigation, investigations, or other similar proceedings involving past, current, or future products or commercial activities as we are largely self-insured;
- issues with product supply and regulatory approvals stemming from manufacturing difficulties, disruptions, or shortages, including as a result of demand, labor shortages, third-party performance, or regulatory actions relating to our facilities;
- reliance on third-party relationships and outsourcing arrangements;
- regulatory changes or other developments;
- regulatory actions regarding currently marketed products;
- continued pricing pressures and the impact of actions of governmental and private payers affecting pricing of, reimbursement for, and access to pharmaceuticals;
- devaluations in foreign currency exchange rates, changes in interest rates, and inflation;
- changes in tax law, tax rates, or events that differ from our assumptions related to tax positions;

- asset impairments and restructuring charges;

- the impact of global macroeconomic conditions, trade disruptions, global disputes, unrest, war, or other costs, uncertainties and risks related to engaging in business in foreign jurisdictions;
- changes in accounting and reporting standards promulgated by the Financial Accounting Standards Board and the Securities and Exchange Commission (SEC); and
- regulatory compliance problems or government investigations.

Investors should also carefully read the factors described under Item 1A, "Risk Factors" in this Annual Report on Form 10-K for a description of certain risks that could, among other things, cause our actual results to differ from those expressed in forward-looking statements. Investors should understand that it is not possible to predict or identify all such factors and should not consider the risks described above and under Item 1A, "Risk Factors" to be a complete statement of all potential risks and uncertainties.

All forward-looking statements speak only as of the date of this Annual Report and are expressly qualified in their entirety by the risk factors and cautionary statements included in this Annual 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 Annual Report.

Part I

Item 1. Business

Eli Lilly and Company (referred to as the company, Lilly, we, or us) was incorporated in 1901 in Indiana to succeed to the drug manufacturing business founded in Indianapolis, Indiana, in 1876 by Colonel Eli Lilly. We discover, develop, manufacture, and market products in a single business segment—human pharmaceutical products.

Our purpose is to unite caring with discovery to create medicines that make life better for people around the world. Most of the products we sell today were discovered or developed by our own scientists, and our long-term success depends on our ability to continually discover or acquire, develop, and commercialize innovative new medicines.

We manufacture and distribute our products through facilities in the United States (U.S.), including Puerto Rico, and 7 other countries. Our products are sold in approximately 120 countries.

Products

Our products include:

Diabetes products, including:

- *Basaglar*®, in collaboration with Boehringer Ingelheim, a long-acting human insulin analog for the treatment of diabetes.
- *Humalog*®, *Humalog Mix 75/25, Humalog U-100, Humalog U-200, Humalog Mix 50/50*, *insulin lispro, insulin lispro protamine*, and *insulin lispro mix 75/25,* human insulin analogs for the treatment of diabetes.
- *Humulin*®, *Humulin 70/30, Humulin N, Humulin R,* and *Humulin U-500*, human insulins of recombinant DNA origin for the treatment of diabetes.
- *Jardiance*®, in collaboration with Boehringer Ingelheim, for the treatment of type 2 diabetes; to reduce the risk of cardiovascular death in adult patients with type 2 diabetes and established cardiovascular disease; and to reduce the risk of cardiovascular death and hospitalizations for heart failure in adults with heart failure and reduced ejection fraction.
- *Trajenta*®, in collaboration with Boehringer Ingelheim, for the treatment of type 2 diabetes.
- *Trulicity*®, for the treatment of type 2 diabetes and to reduce the risk of major adverse cardiovascular events in adult patients with type 2 diabetes and established cardiovascular disease or multiple cardiovascular risk factors.

Oncology products, including:

- *Alimta*®, for the first-line treatment, in combination with two other agents, of advanced non-small cell lung cancer (NSCLC) for patients with non-squamous cell histology and no epidermal growth factor receptor or anaplastic lymphoma kinase genomic tumor aberrations; for the first-line treatment, in combination with another agent, of advanced non-squamous NSCLC; for the second-line treatment of advanced non-squamous NSCLC; as monotherapy for the maintenance treatment of advanced non-squamous NSCLC in patients whose disease has not progressed immediately following chemotherapy treatment; and in combination with another agent for the treatment of malignant pleural mesothelioma.
- *Cyramza*®, for use as monotherapy or in combination with another agent as a second-line treatment of advanced or metastatic gastric cancer or gastro-esophageal junction adenocarcinoma; in combination with another agent as a second-line treatment of metastatic NSCLC; in combination with another agent as a second-line treatment of metastatic colorectal cancer; as a monotherapy as a second-line treatment of hepatocellular carcinoma; and in combination with another agent as a first-line treatment of adult patients with metastatic NSCLC with activating epidermal growth factor receptor mutations.

- *Erbitux*®, indicated both as monotherapy and in combination with another agent for the treatment of certain types of colorectal cancers; and as monotherapy, in combination with chemotherapy, or in combination with radiation therapy for the treatment of certain types of head and neck cancers.

- *Retevmo*®, for the treatment of metastatic NSCLC in adult patients; for the treatment of advanced metastatic medullary thyroid cancer who require systemic therapy in adult and pediatric patients; and for the treatment of advanced metastatic thyroid cancer in adult and pediatric patients who require systemic therapy and are radioactive iodin-refractory.
- *Tyvyt*®, in collaboration with Innovent Biologics, Inc., for the treatment of relapsed or refractory classic Hodgkin's lymphoma and for the first-line treatment of non-squamous NSCLC in combination with Alimta and another agent in China.
- *Verzenio*®, for use as monotherapy or in combination with endocrine therapy for the treatment of HR+, HER2- metastatic breast cancer and in combination with endocrine therapy for treatment of HR+, HER2-, node positive, early breast cancer at high risk of recurrence and a Ki-67 score at least 20%, as determined by a U.S. Food and Drug Administration (FDA) approved test.

Immunology products, including:

- *Olumiant*®, in collaboration with Incyte Corporation, for the treatment of adults with moderately-to-severely active rheumatoid arthritis and for moderate to severe atopic dermatitis.
- *Baricitinib* was granted Emergency Use Authorization (EUA) in 2021 for the treatment of COVID-19 in hospitalized adults and pediatric patients 2 years of age or older requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation.
- *Taltz*®, for the treatment of adults and pediatric patients aged 6 years or older with moderate-to-severe plaque psoriasis, adults with active psoriatic arthritis, adults with ankylosing spondylitis, and adults with active non-radiographic axial spondyloarthritis.

Neuroscience products, including:

- *Cymbalta*®, for the treatment of major depressive disorder, diabetic peripheral neuropathic pain, generalized anxiety disorder, fibromyalgia, and chronic musculoskeletal pain due to chronic low back pain or chronic pain due to osteoarthritis.
- *Emgality*®, for migraine prevention and the treatment of episodic cluster headache in adults.
- *Zyprexa*®, for the treatment of schizophrenia, acute mixed or manic episodes associated with bipolar I disorder, and bipolar maintenance.

Other therapies, including:

- *Bamlanivimab* and *etesevimab*, administered together, for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients from birth to 12 years old with positive results of direct SARS-CoV-2 viral testing and who are at high risk for progression to severe COVID-19, including hospitalization or death (EUA granted in 2021). In January 2022, the FDA revised the EUA for bamlanivimab and etesevimab administered together to limit their use to only when the patient is likely to have been infected with or exposed to a variant that is susceptible to this combination treatment.
- *Bebtelovimab*, for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older and weighing at least 40 kilograms) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options approved or authorized by the FDA are not accessible or clinically appropriate (EUA granted in 2022).
- *Cialis*®, for the treatment of erectile dysfunction and benign prostatic hyperplasia.
- *Forteo*®, for the treatment of osteoporosis in postmenopausal women and men at high risk for fracture and for glucocorticoid-induced osteoporosis in men and postmenopausal women.

Marketing and Distribution

We sell most of our products worldwide. We adapt our marketing methods and product emphasis in various countries to meet local customer needs and comply with local regulations.

U.S.

We promote our major products in the U.S. through sales representatives who engage with physicians and other health care professionals. We also educate healthcare providers about our products in various other ways, including promoting in online health care channels, distributing literature and samples of certain products to physicians, and exhibiting at medical meetings. In addition, we advertise certain products directly to consumers in the U.S., and we maintain websites and other media channels with information about our major products. We supplement our employee sales force with contract sales organizations to leverage our resources and reach additional patients in need.

We maintain special business groups to service wholesalers, pharmacy benefit managers, managed care organizations, group purchasing organizations, government and long-term care institutions, hospitals, and certain retail pharmacies. We enter into arrangements with these organizations providing for discounts or rebates on our products.

In the U.S., most of our products are distributed through wholesalers that serve pharmacies, physicians and other health care professionals, and hospitals. In 2021, 2020, and 2019, three wholesale distributors in the U.S.—McKesson Corporation, AmerisourceBergen Corporation, and Cardinal Health, Inc.—each accounted for between 15 percent and 20 percent of our consolidated revenue. No other customer accounted for more than 10 percent of our consolidated revenue in any of these years.

Outside the U.S.

Outside the U.S., we promote our products to healthcare providers primarily through sales representatives and other health care channels. While the products we market vary from country to country, diabetes products constitute the largest single group of our consolidated revenue. Distribution patterns for our products also vary from country to country. In most countries in which we operate, we maintain our own sales organizations, but in some smaller countries we market our products through third-party distributors, some of which we have engaged through distribution and promotion arrangements.

Marketing Collaborations

Certain of our products are marketed in arrangements with other pharmaceutical companies. For example, we and Boehringer Ingelheim have a global agreement to develop and commercialize a portfolio of diabetes products, including Trajenta, Jentadueto®, Jardiance, Glyxambi®, Synjardy®, Trijardy® XR, and Basaglar.

For additional information, see Item 8, "Financial Statements and Supplementary Data - Note 4, Collaborations and Other Arrangements."

Competition

Our products compete globally with many other pharmaceutical products in highly competitive markets.

Important competitive factors include effectiveness, safety, and ease of use; formulary placement, price, and demonstrated cost-effectiveness; marketing effectiveness; and research and development of new products, processes, modalities, and uses. Most new products that we introduce must compete with other branded, biosimilar, or generic products already on the market or that are later developed by competitors. When competitors introduce new products or delivery systems with therapeutic or cost advantages, including by developing new modalities, our products become subject to decreased sales, progressive price reductions, or both.

We believe our long-term competitive success depends on discovering and developing (either alone or in collaboration with others) or acquiring innovative, cost-effective products that provide improved outcomes for patients and deliver value to payers, and continuously improving the productivity of our operations in a highly competitive environment. There can be no assurance that our efforts will result in commercially successful products, and it is possible that our products will be, or will become, uncompetitive from time to time as a result of products developed by our competitors.

Generic Pharmaceuticals

One of the biggest competitive challenges we face is from generic pharmaceuticals. In the U.S. and Europe, the regulatory approval process for pharmaceuticals (other than biological products (biologics)) exempts generics from costly and time-consuming clinical trials to demonstrate their safety and efficacy, allowing generic manufacturers to rely on the safety and efficacy of the innovator product. As a result, generic manufacturers generally invest far fewer resources than we do in research and development and can price their products significantly lower than our branded products. Accordingly, when a branded non-biologic pharmaceutical loses its market exclusivity, it normally faces intense price competition from generic forms of the product, which can cause us to lose a significant portion of the product's revenue in a very short period of time.

Further, public and private payers typically encourage the use of generics as alternatives to brand-name drugs in their healthcare programs. Laws in the U.S. generally allow, and in many cases require, pharmacists to substitute generic drugs that have been rated under government procedures to be essentially equivalent to a brand-name drug. Where substitution is mandatory, it must be made unless the prescribing physician expressly forbids it. In many countries outside the U.S., intellectual property protection is weak, and we must compete with generic or counterfeit versions of our products relatively shortly after launch.

Biosimilars

A number of our products and potential new medicines in our clinical-stage pipeline are biologics. In the U.S., the FDA regulates biologics under the Federal Food, Drug and Cosmetic Act, the Public Health Service Act, and implementing regulations. Competition for Lilly's biologics may be affected by the approval of follow-on biologics, also known as biosimilars. A biosimilar is a subsequent version of an approved innovator biologic that, due to its analytical and clinical similarity to the innovator biologic, may be approved based on an abbreviated data package that relies in part on the full testing required of the innovator biologic. Approval by the FDA ultimately depends on many factors, including a showing that the biosimilar is "highly similar" to the original product and has no clinically meaningful differences from the original product in terms of safety, purity, and potency.

Globally, most governments have developed abbreviated regulatory pathways to approve biosimilars as follow-ons to innovator-developed biologics, including the Biologics Price Competition and Innovation Act of 2009 (the BPCIA) in the U.S. A number of biosimilars have been licensed under the BPCIA and in Europe. The patent and regulatory exclusivity for the existing innovator biologic generally must expire in a given market before biosimilars may enter that market. However, in the U.S., the product exclusivity period under the BPCIA could be affected by recent government proposals and litigation. See "- Patents, Trademarks, and Other Intellectual Property Rights." In addition, the extent to which a biosimilar, once approved, will be substituted for the innovator biologic in a way that is similar to traditional generic substitution for non-biologic products is not yet entirely clear, and will depend on a number of regulatory and marketplace factors that are still developing. In the U.S., currently only a biosimilar product that is determined to be "interchangeable" by the FDA will be considered substitutable for the original biologic product without the intervention of the health care provider who prescribed the original biologic product. To prove that a biosimilar product is interchangeable, the applicant must demonstrate that the product can be expected to produce the same clinical results as the original biologic product in any given patient, and if the product is administered more than once in a patient, that safety risks and potential for diminished efficacy of alternating or switching between the use of the interchangeable biosimilar biologic product and the original biologic product is no greater than the risk of using the original biologic product without switching. The FDA has begun to issue "interchangeable" designations for biosimilar products.

Biosimilars may present both competitive challenges and opportunities. For example, a competitor company has developed a version of insulin lispro that competes with our product Humalog. On the other hand, in collaboration with Boehringer Ingelheim, we developed Basaglar, an insulin glargine product, which has the same amino acid sequence as a product currently marketed by a competitor and has launched as a follow-on biologic in the U.S., and as a biosimilar in Europe and Japan. However, in March 2020, the FDA began regulating all of our insulin products as "biologics" rather than "drugs." Based on FDA draft guidance, this change may lessen the amount of data required for competitor biosimilar

products to enter the market, some of which could be designated as interchangeable and therefore substituted for our insulin products at U.S. pharmacies. For example, in June 2020, the FDA approved a New Drug Application (NDA) for Semglee, a follow-on insulin glargine product that competes with Basaglar in the U.S., and, in July 2021, Semglee received additional FDA approval as a biosimilar that is interchangeable to its reference insulin glargine product. The FDA's interpretation of important aspects of the laws regulating biosimilars continues to evolve and, therefore, the impact of these laws on our business remains subject to substantial uncertainty.

U.S. Private Sector Dynamics

In the U.S. private sector, consolidation and integration among healthcare providers significantly affects the competitive marketplace for pharmaceuticals. Health plans, managed care organizations, pharmacy benefit managers, wholesalers, and other supply chain stakeholders have been consolidating into fewer, larger entities, thus enhancing their purchasing strength and importance. Private third-party insurers, as well as governments, typically maintain formularies that 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) to control costs by negotiating discounted prices in exchange for formulary inclusion.

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 face increased pressure in pricing and usage negotiation, and compete fiercely for formulary placement, not only on the basis of product attributes such as efficacy, safety profile, or patient ease of use, but also by providing rebates. As payers and pharmaceutical companies continue to negotiate formulary placement and pricing, value-based agreements, where pricing is based on achievement (or not) of specified outcomes, are another tool that may become increasingly prevalent. 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. We expect these downward pricing pressures will continue to negatively affect our consolidated results of operations. In addition to formulary placement, changes in insurance designs continue to drive greater consumer cost-sharing through high deductible plans and higher co-insurance or co-pays. For additional information on pricing and reimbursement for our pharmaceutical products, see "- Regulations and Private Payer Actions Affecting Pharmaceutical Pricing, Reimbursement, and Access - U.S."

Patents, Trademarks, and Other Intellectual Property Rights

Overview

Intellectual property protection is critical to our ability to successfully commercialize our life sciences innovations and invest in the search for new medicines. We own, have applied for, or are licensed under, a large number of patents in the U.S. and many other countries relating to products, product uses, formulations, and manufacturing processes. In addition, as discussed below, for some products we have effective intellectual property protection in the form of data protection under pharmaceutical regulatory laws.

The patent protection anticipated to be of most relevance to pharmaceuticals is provided by national patents claiming the active ingredient (the compound patent), particularly those in major markets such as the U.S., major European countries, and Japan. These patents may be issued based upon the filing of international patent applications, usually filed under the Patent Cooperation Treaty (PCT). Patent applications covering compounds are generally filed during the Discovery Phase of the drug discovery process, which is described in the "Research and Development" section below. In general, national patents in each relevant country are available for a period of 20 years from the filing date of the PCT application, which is often years prior to the launch of a commercial product. Further patent term adjustments and restorations may extend the original patent term:

- Patent term adjustment is a statutory right available to all U.S. patent applicants to provide relief in the event that a patent grant is delayed during examination by the United States Patent and Trademark Office (USPTO).
- Patent term restoration is a statutory right provided to U.S. patent holders that claim inventions subject to review by the FDA. To make up for a portion of the time invested in clinical trials and the FDA review process, a single patent for a pharmaceutical product may be eligible for patent term restoration. Patent term restoration is limited by a formula and cannot be calculated until product approval due to uncertainty about the duration of clinical trials and the time it takes the FDA to review an application. There is a five-year cap on any restoration, and no patent's expiration date may be extended beyond 14 years from FDA approval. Some countries outside the U.S. similarly

offer forms of patent term restoration for patents claiming inventions subject to a local review by a regulatory agency. For example, Supplementary Protection Certificates are available to extend the life of a European patent up to an additional five years (subject to a 15-year cap from European Medicines Agency (EMA) approval). Also, in Japan, South Korea, and Australia, patent terms can be extended up to five years, depending on the length of regulatory review and other factors.

Loss of effective patent protection for pharmaceuticals, especially for non-biologic products, typically results in the loss of effective market exclusivity for the product, which often results in severe and rapid decline in revenues for the product. However, in some cases the innovator company may retain exclusivity despite approval of the generic, biosimilar, or other follow-on versions of a new medicine beyond the expiration of the compound patent through manufacturing trade secrets, later-expiring patents on manufacturing processes, methods of use or formulations, or data protection that may be available under pharmaceutical regulatory laws. Changes to the laws and regulations governing these protections could result in earlier loss of effective market exclusivity. The primary forms of data protection are as follows:

- Regulatory authorities in major markets generally grant data package protection for a period of years following new drug approvals in recognition of the substantial investment required to complete clinical trials. Data package protection prohibits other manufacturers from submitting regulatory applications for marketing approval in reliance on the innovator company's regulatory submission data for the drug. The base period of data package protection depends on the country. For example, the period is generally five years in the U.S. (12 years for new biologics as described below), effectively 10 years in Europe, and eight years in Japan. The period begins on the date of product approval and runs concurrently with the patent term for any relevant patent.
- Under the BPCIA, the FDA has the authority to approve biosimilars. A competitor seeking approval of a biosimilar must file an application to show its molecule is highly similar to an approved innovator biologic and include a certain amount of safety and efficacy data that the FDA will consider on a case-by-case basis. Under the data protection provisions of this law, the FDA cannot approve a biosimilar application until 12 years after initial marketing approval of the innovator biologic, subject to certain conditions.
- In the U.S., the FDA has the authority to grant additional data protection for approved drugs where the sponsor conducts specified testing in pediatric or adolescent populations within a specified time period. If granted, this "pediatric exclusivity" provides an additional six months of exclusivity, which is added to the term of data protection and, for products other than biologics, to the term of any relevant patents, to the extent these protections have not already expired. While the term of the pediatric exclusivity attaches to the term of any relevant patent, pediatric exclusivity is a regulatory exclusivity—i.e., a bar to generic or biosimilar approval, not a patent right.
- Under the U.S. orphan drug law, a specific use of a drug or biologic can receive "orphan" designation if it is intended to treat a disease or condition affecting fewer than 200,000 people in the U.S., or affecting more than 200,000 people but not reasonably expected to recover its development and marketing costs through U.S. sales. Among other benefits, orphan designation entitles the particular use of the drug to seven years of market exclusivity, meaning that the FDA cannot (with limited exceptions) approve another marketing application for the same drug for the same indication until expiration of the seven-year period. Unlike pediatric exclusivity, the orphan exclusivity period is independent of and runs in parallel with any applicable patents.

Outside the major markets, the adequacy and effectiveness of intellectual property protection for pharmaceuticals varies widely, and in a number of these markets we are unable to patent our products or to enforce the patents we receive for our products. Under the Trade-Related Aspects of Intellectual Property Agreement (TRIPs) administered by the World Trade Organization, more than 140 countries have agreed to provide non-discriminatory protection for most pharmaceutical inventions and to assure that adequate and effective rights are available to patent owners. Certain developing countries limit protection for biopharmaceutical products under their interpretation of "flexibilities" allowed under the agreement. Thus, some types of patents, such as those on new uses of compounds or new forms of molecules, are not available in certain developing countries. Further, many developing countries, and some developed countries, do not provide effective data package protection even though it is specified in TRIPs.

Our Intellectual Property Portfolio

We consider intellectual property protection for certain products, processes, uses, and formulations—particularly with respect to those products discussed below—to be important to our operations. In addition to the patents and data protection identified below, we may hold patents on manufacturing processes,

formulations, devices, or uses that extend exclusivity beyond the dates shown below. For approved products, dates include, where applicable, pending or granted patent term extensions.

The most relevant U.S. patent protection or data protection and associated expiry dates for our major or recently launched patent-protected marketed products are as follows:

- Alimta is protected by pediatric exclusivity (2022). See Item 8, "Financial Statements and Supplementary Data - Note 16, Contingencies," for information regarding our settlement agreement with Eagle Pharmaceuticals, Inc. and its impact on our exclusivity for Alimta.
- Baqsimi® is protected by data protection (2022).
- Cyramza is protected by a compound patent and biologics data protection (2026).
- Emgality is protected by a compound patent (2033) and biologics data protection (2030).
- Jardiance, and the related combination product Glyxambi, is protected by a compound patent (2028).
- Olumiant is protected by a compound patent (2032).
- Retevmo is protected by a compound patent (2037) and by data protection (2025).
- Reyvow® is protected by a compound patent (2030).
- Taltz is protected by a compound patent (2030) and by biologics data protection (2028).
- Trulicity is protected by a compound patent (2027) and by biologics data protection (2026).
- Verzenio is protected by a compound patent (2031) and by data protection (2022).

Outside the U.S., important patent protection or data protection includes:

- Baqsimi is protected by data protection in Japan (2026).
- Cyramza is protected by a compound patent (2028) and by data protection (2024) in major European countries, and by a compound patent (2026) and by data protection (2023) in Japan.
- Emgality is protected by a compound patent (2033) and by data protection (2028) in major European countries, and by a compound patent (2035) and by data protection (2029) in Japan.
- Jardiance is protected by a compound patent in major European countries (2029) and Japan (2030).
- Olumiant is protected by a compound patent (2032) and by data protection (2027) in major European countries, and by a compound patent (2033) and by data protection (2025) in Japan.
- Retevmo is protected by a compound patent (2037) and by data protection (2031) in major European countries, and by a compound patent (2038) and by data protection (2029) in Japan.
- Reyvow is protected by a compound patent (2026) and by data protection (2032) in Japan.
- Taltz is protected by a compound patent (2031) and data protection (2027) in major European countries and a compound patent (2030) and data protection (2024) in Japan.
- Trulicity is protected by a compound patent (2029) and by data protection (2024) in major European countries and by a compound patent (2029) and by data protection (2023) in Japan.
- Verzenio is protected by a compound patent (2033) and data protection (2028) in major European countries and by a compound patent (2034) and data protection (2026) in Japan.

The following product candidates are currently under regulatory review. Upon approval, we expect relevant compound patent and data protections to apply:

- We have commenced a rolling submission in the U.S. for donanemab for the treatment of Alzheimer's disease.
- We have commenced a rolling submission in the U.S. for pirtobrutinib (LOXO-305) for the treatment of mantle cell lymphoma.
- Reyvow has been submitted for regulatory review in certain major European countries for the acute treatment of migraine.

- Tirzepatide has been submitted for regulatory review in the U.S., in Japan, and in certain major European countries as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes.

Worldwide, we sell all of our major products under trademarks consisting of our product names, logos, and unique product appearances (e.g., the appearance of our Trulicity autoinjector) which we consider in the aggregate to be important to our operations. Trademark protection varies throughout the world, with protection continuing in some countries as long as the mark is used, and in other countries as long as it is registered. Registrations are normally for fixed but renewable terms. Trademark protection typically extends beyond the patent and data protection for a product.

Patent Licenses and Collaborations

Most of our major products are not subject to significant license and collaboration agreements. For information on our license and collaboration agreements, see Item 8, "Financial Statements and Supplementary Data - Note 4, Collaborations and Other Arrangements."

Patent Challenges

In the U.S., the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, authorizes the FDA to approve generic versions of innovative pharmaceuticals (other than biologics, which are discussed below in more detail) when the generic manufacturer has not conducted safety and efficacy studies but files an Abbreviated New Drug Application (ANDA). In an ANDA, the generic manufacturer must demonstrate only "pharmaceutical equivalence" and "bioequivalence" between the generic version and the NDA-approved drug—not safety and efficacy. Establishing pharmaceutical equivalence and bioequivalence is generally straightforward and inexpensive for the generic company.

Absent a patent challenge, the FDA cannot approve an ANDA until after certain of the innovator's patents expire. However, after the innovator has marketed its product for four years, a generic manufacturer may file an ANDA alleging that one or more or all of the patents listed in the innovator's NDA are invalid or not infringed. This allegation is commonly known as a "Paragraph IV certification." If the innovator responds by filing suit against the generic manufacturer, the FDA is then prohibited from approving the generic company's application for a 30-month period (which can be shortened or extended by the trial court judge hearing the patent challenge). If one or more of the NDA-listed patents are challenged, the first filer(s) of a Paragraph IV certification may be entitled to a 180-day period of market exclusivity over all other generic manufacturers.

Generic manufacturers use Paragraph IV certifications extensively to challenge patents on innovative pharmaceuticals. In addition, generic companies have shown willingness to launch "at risk," i.e., after receiving ANDA approval but before final resolution of their patent challenge.

Under the BPCIA, the FDA cannot approve an application for a biosimilar product until data protection expires, 12 years after initial marketing approval of the innovator biologic, and an application may not be submitted until four years following the date the innovator biologic was first approved. However, the BPCIA does provide a mechanism for a competitor to challenge the validity of an innovator's patents as early as four years after initial marketing approval of the innovator biologic.

The patent litigation scheme under the BPCIA, and the BPCIA itself, is complex and continues to be interpreted and implemented by the FDA as well as courts. Courts have held that biosimilar applicants are not required to engage in the BPCIA patent litigation scheme and patent holders retain the right to bring suit under normal patent law procedures if a biosimilar applicant attempts to commercialize a product prior to patent expiration. Further, in the U.S., the increased likelihood of generic and biosimilar challenges to innovators' intellectual property has increased the risk of loss of innovators' market exclusivity. See also "- Competition - Biosimilars." In addition, there is a procedure in U.S. patent law, known as inter partes review (IPR), which allows any member of the public to file a petition with the USPTO seeking the review of any issued U.S. patent for validity. IPRs are conducted before Administrative Patent Judges in the USPTO using a lower standard of proof than used in federal district court. In addition, the challenged patents are not accorded the presumption of validity as they are in federal district court. Generic drug companies and even some investment firms have engaged in the IPR process in attempts to invalidate our patents. The use of IPR proceedings after the institution of litigation pursuant to the BPCIA or Hatch-Waxman Act is currently a topic of debate among legislators. We expect additional changes to the Patent Trial and Appeal Board (PTAB), including potentially to the policy to discretionarily deny an otherwise

meritorious petition for IPR in light of a concurrent district court proceeding. See "Risk Factors—Risks Related to Our Business—Our long-term success depends on intellectual property protection; if our intellectual property rights are invalidated, circumvented, or weakened, our business will be adversely affected."

Outside the U.S., the legal doctrines and processes by which pharmaceutical patents can be challenged vary widely. In recent years, we have experienced an increase in patent challenges from generic manufacturers in many countries outside the U.S.

For more information on administrative challenges and litigation involving our intellectual property rights, see Item 8, "Financial Statements and Supplementary Data - Note 16, Contingencies."

Government Regulation of Our Operations

Our operations are regulated extensively by numerous national, state, and local agencies.

Regulation of Products

The lengthy process of laboratory and clinical testing, data analysis, manufacturing development, and regulatory review necessary for governmental approvals of our products is extremely costly and can significantly delay product introductions and revenue generation. In addition, our operations are subject to complex federal, state, local, and foreign laws and regulations concerning relationships with healthcare providers and suppliers, the environment, occupational health and safety, data privacy, and other matters. Evolving regulatory priorities have intensified governmental scrutiny of our operations, including with respect to current Good Manufacturing Practices (cGMP), quality assurance, and similar regulations. Compliance with the laws and regulations affecting the manufacture and sale of current products and the discovery, development, and introduction of new products will continue to require substantial effort, expense, and capital investment.

Of particular importance to our business is regulation by the FDA in the U.S. Pursuant to laws and regulations that include the Federal Food, Drug, and Cosmetic Act, the FDA has jurisdiction over all of our products and devices in the U.S. and administers requirements covering the testing, safety, effectiveness, manufacturing, quality control, distribution, labeling, marketing, promotion, advertising, dissemination of information, and post-marketing surveillance of those products.

Following approval, our products remain subject to regulation by various agencies in connection with labeling, import, export, storage, recordkeeping, advertising, promotion, and safety reporting. We conduct extensive post-marketing surveillance of the safety of the products we sell. The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after a product reaches the market. The FDA strictly regulates marketing, labeling, advertising, and promotion of products that are placed on the market. Pharmaceutical products may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

The FDA extensively regulates all aspects of manufacturing quality for pharmaceuticals under its cGMP regulations. Outside the U.S., our products and operations are subject to similar regulatory requirements, notably by the EMA in Europe, the Ministry of Health, Labor and Welfare in Japan, and the National Medical Products Administration in China. Specific regulatory requirements vary from country to country. Regulatory requirements and approval processes outside the U.S. may differ from those in the U.S. and may involve additional costs, uncertainties, and risks.

We make substantial investments of capital and operating expenses to implement comprehensive, company-wide quality systems and controls in our manufacturing, product development, and process development operations in an effort to maintain sustained compliance with cGMP and similar regulations. However, in the event we fail to adhere to these requirements, we become subject to potential government investigations, regulatory and legal actions, product recalls and seizures, fines and penalties, interruption of production leading to product shortages, import bans or denials of import certifications, delays or denials in new product approvals, and reputational harm, any of which would adversely affect our business. Certain of our products are manufactured by third parties, and their failure to comply with these regulations could adversely affect us, including through failure to supply product to us or delays in new product approvals. Any determination by the FDA or other regulatory authorities of manufacturing or other deficiencies could adversely affect our business.

We are also subject to a variety of federal, state, local, and foreign environmental, health and safety, and other laws and regulations that may affect our research, development or production efforts.

Emergency Use Authorizations

The Secretary of Health and Human Services may authorize unapproved medical products to be manufactured, marketed, and sold in the context of an actual or potential emergency that has been designated by the government. After an emergency has been announced, the Secretary of Health and Human Services may authorize EUAs for the use of specific products based on criteria established by statute, including that the product at issue may be effective in diagnosing, treating, or preventing serious or life-threatening diseases when there are no adequate, approved, and available alternatives. An EUA is subject to additional conditions and restrictions, such as the obligation to provide fact sheets for healthcare providers administering the product and those to whom it is administered, adverse event monitoring and reporting, and recordkeeping and reporting requirements by product manufacturers. The FDA may also establish additional discretionary conditions of authorization that the FDA deems necessary or appropriate to protect the public health, including conditions related to product distribution, product administration and data collection and analysis concerning the safety and effectiveness of the product. In issuing an EUA, the FDA considers the totality of available scientific evidence regarding quality, safety and efficacy, including the known and potential risks of such products and the adequacy and availability of approved alternatives, among other factors. An EUA is not a substitute for obtaining FDA approval, licensure, or clearance for use of a product. An EUA terminates when the emergency determination underlying the EUA terminates, and EUAs can be revoked under other circumstances, the timing of which may occur unexpectedly or be difficult to predict.

Outside the U.S., the emergency use of medical products is subject to regulatory processes and requirements that differ from those in the U.S.

The COVID-19 pandemic has been designated as a national emergency in the U.S. On the basis of such determination, the Secretary of Health and Human Services declared that circumstances exist justifying the authorization of emergency use of drugs and biologics during the COVID-19 pandemic. The FDA has granted EUAs for bamlanivimab and etesevimab administered together, baricitinib, and bebtelovimab, and similar actions have been taken by other regulators in certain jurisdictions outside the U.S. However, the FDA has revised, and may in the future revise, any EUA for our COVID-19 antibodies in response to the prevalence of variants against which our antibodies have varying degrees of efficacy. For example, in January 2022, the FDA revised the EUA for bamlanivimab and etesevimab administered together to limit their use to only when the patient is likely to have been infected with or exposed to a variant that is susceptible to this combination treatment.

Other Laws and Regulations

The marketing, promotional, and pricing practices of pharmaceutical manufacturers, as well as the manner in which manufacturers interact with purchasers, prescribers, and patients, are subject to various other U.S. federal and state laws, as well as analogous foreign laws and regulations, including the federal anti-kickback statute, the False Claims Act, and state laws governing kickbacks, false claims, unfair trade practices, and consumer protection. These laws are administered by, among others, the Department of Justice, the Office of Inspector General of the Department of Health and Human Services, the Federal Trade Commission, the Office of Personnel Management, and state attorneys general. Over the past several years, state, federal, and foreign governments, agencies, and other regulatory bodies have increased their oversight, enforcement activities, and coordination with respect to pharmaceutical companies, which has resulted in intensified scrutiny, corporate criminal sanctions, and substantial civil settlements in the pharmaceutical industry.

In December 2020, the Office of Inspector General of the U.S. Department of Health and Human Services and the Centers for Medicare & Medicaid Services (CMS) issued final rules expanding and modifying existing, and adding new, regulatory "safe harbors" and exceptions, respectively, under the anti-kickback statute and the Ethics in Patient Referrals Act. We are currently evaluating the impact, if any, these regulatory amendments will have upon becoming effective on our consolidated results of operations, liquidity, and financial position, which is uncertain at this time.

The U.S. Foreign Corrupt Practices Act of 1977 (FCPA) prohibits certain individuals and entities, including U.S. publicly traded companies, from promising, offering, or giving anything of value to foreign officials with the corrupt intent of influencing the foreign official for the purpose of helping the company obtain or

retain business or gain any improper advantage. The FCPA also imposes specific recordkeeping and internal controls requirements on U.S. publicly traded companies. As noted above, outside the U.S., our business is heavily regulated and therefore involves significant interaction with foreign officials. Additionally, in many countries outside the U.S., healthcare providers who prescribe pharmaceuticals are employed by the government and purchasers of pharmaceuticals are government entities; therefore, our interactions with these prescribers and purchasers are subject to regulation under the FCPA.

In addition to the U.S. application and enforcement of the FCPA, the various jurisdictions in which we operate and supply our products have laws and regulations aimed at preventing and penalizing corrupt and anticompetitive behavior. In recent years, several jurisdictions have enhanced their laws and regulations in this area, increased their enforcement activities, and/or increased the level of cross-border coordination and information sharing.

We are and could in the future become subject to administrative and legal proceedings and actions, which could include claims for civil penalties (including treble damages under the False Claims Act), criminal sanctions, and administrative remedies, including exclusion from U.S. federal and other health care programs. It is possible that an adverse outcome in future actions could have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

We are also subject to a variety of federal, state, local, and foreign environmental, health and safety, and other laws and regulations that may affect our research, development or production efforts.

Regulations and Private Payer Actions Affecting Pharmaceutical Pricing, Reimbursement, and Access

U.S.

There continues to be considerable public and government scrutiny of pharmaceutical pricing, and measures to address the perceived high cost of pharmaceuticals are being considered at various levels of state and federal government. In addition, U.S. government action to reduce federal spending on entitlement programs, including Medicare and Medicaid, may affect payment for our products or services associated with the provision of our products. Additionally, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drug products. Restrictive or unfavorable pricing, coverage, or reimbursement determinations for our medicines or product candidates by governments, regulatory agencies, or private payers could also adversely impact our business and financial results. For example, in January 2022, the CMS proposed a national coverage determination (NCD) decision memorandum stating that the proposed NCD would cover FDA approved monoclonal antibodies that target amyloid for the treatment of Alzheimer's disease for people with Medicare only if they are enrolled in qualifying clinical trials (the Alzheimer’s Monoclonal Antibody NCD). If finalized in its current form, the proposed Alzheimer’s Monoclonal Antibody NCD would result in reduced coverage for, and negatively impact, our product candidate donanemab, and may negatively impact our business and financial results. The regulatory priorities of the current U.S. presidential administration could further intensify these efforts, which could have a material adverse impact on our business.

In the U.S., we are required to provide rebates to the federal government and respective state governments on their purchases of our pharmaceuticals under various federal and state healthcare programs, including state Medicaid and Medicaid Managed Care programs (minimum of 23.1 percent plus adjustments for price increases over time) and discounts to private entities who treat patients in certain types of health care facilities intended to serve low-income and uninsured patients (known as 340B facilities). No rebates are required at this time in the Medicare Part B (physician and hospital outpatient) program where reimbursement is set on an "average sales price plus 4.3 percent" formula. Additionally, an annual fee is imposed on pharmaceutical manufacturers and importers that sell branded prescription drugs to specified government programs. Since 2019, the Bipartisan Budget Act has required manufacturers of brand-name drugs, biologics, and biosimilars to provide a discount of 70 percent of the cost of branded prescription drugs for Medicare Part D participants who are in the "doughnut hole" (the coverage gap in Medicare prescription drug coverage).

Rebates are also negotiated in the private sector. We pay rebates to private payers that provide prescription drug benefits to seniors covered by Medicare and to private payers that provide prescription drug benefits to their customers. These rebates are affected by the introduction of competitive products and generics in the same class. Our approach to the rebates we offer to private payers that provide prescription drug benefits to seniors covered by Medicare may be impacted by the 2020 regulatory

amendments to the anti-kickback statute's discount safe harbor, which have currently been stayed until at least January 1, 2026. Pending legislation could repeal the amendments to the discount safe harbor. Accordingly, their impact on our business is uncertain at this time.

Outside the U.S.

Globally, public and private payers are increasingly restricting access to pharmaceuticals based on assessments of comparative effectiveness and value, including through the establishment of formal health technology assessment processes. In addition, third-party organizations, including professional associations, academic institutions, and non-profit entities associated with payers, are conducting and publishing comparative effectiveness and cost/benefit analyses on medicines, the impact of which are uncertain at this time.

In most international markets, we operate in an environment of government-mandated cost-containment programs, which may include price controls, international reference pricing (to other countries' prices), discounts and rebates, therapeutic reference pricing (to other, often generic, pharmaceutical choices), restrictions on physician prescription levels, and mandatory generic substitution. We may experience additional pricing pressures resulting from the financial strain of the COVID-19 pandemic on government-funded healthcare systems around the world.

We cannot predict the extent to which our business may be affected by these or other potential future legislative, regulatory, or payer developments. However, in general we expect to see continued focus on regulating pricing resulting in additional state, federal, and international legislative and regulatory developments that could have further negative effects on pricing and reimbursement for our products.

See Item 7, "Management's Discussion and Analysis - Results of Operations - Executive Overview - Other Matters - Trends Affecting Pharmaceutical Pricing, Reimbursement, and Access" for additional information regarding recent legislative, administrative, and other pricing initiatives and their impact on our results.

Research and Development

Our commitment to research and development dates back more than 140 years. We invest heavily in research and development because we believe it is critical to our long-term competitiveness. At the end of 2021, we employed approximately 8,100 people in pharmaceutical research and development activities, including a substantial number of physicians, scientists holding graduate or postgraduate degrees, and highly skilled technical personnel.

Our internal pharmaceutical research focuses primarily on the areas of diabetes, immunology, neuroscience, and oncology. During the past two years, we have also focused on researching and developing potential treatments for COVID-19. In addition to discovering and developing new medicines, we seek to expand the value of existing products through new uses, formulations, and therapeutic approaches that provide additional value to patients.

To supplement our internal efforts, we collaborate with others, including academic institutions and research-based pharmaceutical and biotechnology companies. We use the services of physicians, hospitals, medical schools, and other research organizations worldwide to conduct clinical trials to establish the safety and effectiveness of our medicines. We also invest in external research and technologies that we believe complement and strengthen our own efforts. These investments can take many forms, including, among others, licensing arrangements, co-development agreements, co-promotion arrangements, joint ventures, acquisitions, and equity investments.

Pharmaceutical development is time-consuming, expensive, and risky. Very few of the candidates discovered by researchers ultimately become approved medicines. The process from discovery to regulatory approval can take over a decade. Candidates can fail at any stage of the process, and even late-stage candidates sometimes fail to receive regulatory approval or achieve commercial success. The following describes in more detail the research and development process for pharmaceutical products:

Phases of New Drug Development

- **Discovery Phase**

  In the discovery phase, scientists identify, design, and synthesize promising candidates by analyzing their effect on biological targets thought to play a role in disease. Targets are often unproven and only candidates that have the desired effect on the target and meet other design criteria move to the next phase of development, which includes the initiation of studies in animals to support regulatory and

safety requirements for clinical research in humans. The discovery phase can take years and the probability of any one candidate becoming a medicine is extremely low.

- **Early Development Phase**

  Early development includes initial testing for safety and efficacy and early analyses of manufacturing requirements. Safety testing is initially performed in laboratory tests and animals, as necessary. In general, the first human tests (often referred to as Phase I) are conducted in small groups of subjects to assess safety and evaluate the potential dosing range. Subsequently, larger populations of patients are studied (Phase II) to identify initial signs of efficacy while continuing to assess safety. In parallel, scientists work to identify safe, effective, and economical manufacturing processes. Long-term animal studies continue to test for potential safety issues. Of the candidates that enter the early development phase, approximately 10 percent move to the late development phase. The early development phase varies but can take several years to complete.

- **Late Development Phase**

  Late phase development projects (typically Phase III) have met initial safety requirements and shown initial evidence of efficacy in earlier studies. As a result, these candidates generally have a higher likelihood of success and trials include larger patient populations to demonstrate safety and efficacy in the disease. These studies are designed to demonstrate the benefit and risk of the potential new medicine and may be compared to competitive therapies, placebo, or both. Phase III studies are generally conducted globally and are designed to support regulatory filings for marketing approval. The duration of Phase III testing varies by disease and may take two to four years.

- **Submission Phase**

  Once a potential new medicine is submitted to regulatory agencies, the time to final marketing approval can vary from several months to several years, depending on the disease state, the strength and complexity of available data, the degree of unmet need, and the time required for the regulatory agency(ies) to evaluate the submission, which can depend on prioritization by regulators and other factors. There is no guarantee that a potential medicine will receive marketing approval, or that decisions on marketing approvals or indications will be consistent across geographic areas.

We believe our investments in research, both internally and in collaboration with others, have resulted in a robust pipeline of potential new medicines and new treatment indications in all stages of development. We currently have approximately 45 new medicine candidates in clinical development or under regulatory review, and a larger number of projects in the discovery phase. See Item 7, "Management's Discussion and Analysis - Results of Operations - Executive Overview - Late-Stage Pipeline," for more information on certain of our product candidates.

Raw Materials and Product Supply

Most of the principal materials we use in our manufacturing operations are available from more than one source. However, we obtain certain raw or intermediate materials primarily from only one source. We generally seek to maintain sufficient inventory to supply the market until an alternative source of supply could be implemented, in the event one of these suppliers was unable to provide the materials or product. However, various developments from time to time lead to interruption or shortages in supply until we establish new sources or, in some cases, implement alternative processes.

The majority of our revenue comes from products produced in our own facilities. Our principal active ingredient manufacturing occurs at sites we own in the U.S., including Puerto Rico, and Ireland. Finishing operations, including formulation, filling, assembling, delivery device manufacturing, and packaging, take place at a number of sites throughout the world. We utilize third parties for certain active ingredient manufacturing and finishing operations.

We manage our supply chain (including our own facilities, contracted arrangements, and inventory) in a way that is intended to allow us to meet substantially all expected product demand while maintaining flexibility to reallocate manufacturing capacity to improve efficiency and respond to changes in supply and demand. To maintain a stable supply of our products, we use a variety of techniques including comprehensive quality systems, inventory management, and back-up sites.

However, pharmaceutical production processes are complex, highly regulated, and vary widely from product to product. Shifting or adding manufacturing capacity can be a very lengthy process requiring significant capital expenditures, process modifications, and regulatory approvals. Accordingly, developments such as unplanned plant shutdowns, manufacturing or quality assurance difficulties at one of our facilities or contracted facilities, failure or refusal of a supplier or contract manufacturer to supply contracted quantities, increases in demand on a supplier, or difficulties in predicting or variability in demand for our products, from time to time lead to interruption or higher costs in the supply of certain products or product shortages. Further, global transportation and logistics challenges, as well as tight labor markets, have caused, and in the future may cause, delays in, and/or increase costs related to, distribution of our medicines, the construction or acquisition of manufacturing capacity, procurement activity, and supplier or contract manufacturer arrangements. For more information on the additional risks we face in connection with any difficulties, disruptions, and shortages in the manufacturing, distribution, and sale of our products, see "Risk Factors - Risks Related to Our Business - Manufacturing and supply chain difficulties, disruptions, or shortages could lead to product supply problems."

In addition, the strain on global transportation, logistics, and labor markets caused by the COVID-19 pandemic and an increase in overall demand in our industry for certain materials have had, and may continue to have, a number of impacts on our business, including increased costs to provide a consistent supply of our medicines where they are needed and disruptions in the supply of our medicines. For more information, see Item 1A, "Risk Factors - Risks Related to Our Business - The COVID-19 pandemic has adversely impacted and may continue to adversely impact our business and operations. We are currently unable to predict the full extent to which the COVID-19 pandemic or any future pandemic, epidemic, or similar public health threat will adversely impact our business and operations in the future." and Item 7, "Management's Discussion and Analysis - Results of Operations - Executive Overview - COVID-19 Pandemic."

Quality Assurance

Our success depends in great measure on customer confidence in the quality of our products and in the integrity of the data that support their safety and effectiveness. Product quality arises from a total commitment to quality in all parts of our operations, including research and development, purchasing, facilities planning, manufacturing, distribution, and dissemination of information about our medicines.

Quality of production processes involves strict control of ingredients, equipment, facilities, manufacturing methods, packaging materials, and labeling. We perform tests at various stages of production processes and on the final product in an effort to ensure that the product meets all applicable regulatory requirements and our internal standards. These tests may involve chemical and physical chemical analyses, microbiological testing, testing in animals, or a combination thereof. Additional assurance of quality is provided by quality assurance groups that audit and monitor all aspects of quality related to pharmaceutical manufacturing procedures and systems in company operations and at third-party suppliers.

Executive Officers of the Company

The following table sets forth certain information regarding our current executive officers.

The term of office for each executive officer expires on the date of the annual meeting of the board of directors, to be held on May 2, 2022 in connection with the company's annual meeting of shareholders, or on the date his or her successor is chosen and qualified. No director or executive officer has a "family relationship" with any other director or executive officer of the company, as that term is defined for purposes of this disclosure requirement. There is no understanding between any executive officer or director and any other person pursuant to which the executive officer was selected.

Name	Age	Titles and Business Experience
David A. Ricks	54	Chair, President, and Chief Executive Officer (CEO) (since 2017). Previously, Mr. Ricks held various leadership roles with Lilly, including senior vice president and president, Lilly Bio-Medicines. Mr. Ricks has 25 years of service with Lilly.
Anat Ashkenazi	49	Senior Vice President and Chief Financial Officer (since 2021). Previously, Ms. Ashkenazi held various leadership roles with Lilly, including senior vice president, controller and chief financial officer, Lilly Research Laboratories, and vice president, finance and chief financial officer, Lilly Diabetes and Lilly global manufacturing and quality. Ms. Ashkenazi has 20 years of service with Lilly.
Stephen F. Fry	56	Senior Vice President, Human Resources and Diversity (since 2011). Previously, Mr. Fry held various leadership roles with Lilly, including vice president, human resources. Mr. Fry has 34 years of service with Lilly.
Anat Hakim	52	Senior Vice President, General Counsel and Secretary (since 2020). Prior to joining Lilly, Ms. Hakim was senior vice president, general counsel and secretary of WellCare Health Plans, Inc. (WellCare) from 2016 to 2018, and executive vice president, general counsel and secretary of WellCare from 2018 to 2020. Prior to joining WellCare, she served as divisional vice president and associate general counsel of intellectual property litigation at Abbott Laboratories from 2010 to 2013 and divisional vice president and associate general counsel of litigation from 2013 to 2016. Ms. Hakim has two years of service with Lilly.
Edgardo Hernandez	47	Senior Vice President and President, Manufacturing Operations (since 2021). Previously, Mr. Hernandez held various leadership roles with Lilly, including senior vice president, global parenteral drug product, delivery devices and regional manufacturing, and vice president, Fegersheim operations. Mr. Hernandez has 17 years of service with Lilly.
Patrik Jonsson	55	Senior Vice President and President, Lilly Immunology, Lilly USA, and Chief Customer Officer (since 2021). Previously, Mr. Jonsson held various leadership roles with Lilly, including senior vice president and president, Lilly USA, and chief customer officer, senior vice president and president, Lilly Bio-Medicines and president and general manager, Lilly Japan. Mr. Jonsson has 31 years of service with Lilly.
Michael B. Mason	55	Senior Vice President and President, Lilly Diabetes (since 2020). Previously, Mr. Mason held various leadership roles with Lilly, including senior vice president, connected care and insulins and vice president of U.S. Diabetes. Mr. Mason has 32 years of service with Lilly.
Johna L. Norton	55	Senior Vice President, Global Quality (since 2017). Previously, Ms. Norton held various leadership roles with Lilly, including vice president, global quality assurance API manufacturing and product research and development. Ms. Norton has 31 years of service with Lilly.
Leigh Ann Pusey	59	Senior Vice President, Corporate Affairs and Communications (since 2017). Prior to joining Lilly, Ms. Pusey was president and chief executive officer of the American Insurance Association from 2009 to 2017. Ms. Pusey has four years of service with Lilly.
Diogo Rau	47	Senior Vice President and Chief Information and Digital Officer (since 2021). Prior to joining Lilly, Mr. Rau was senior director of information systems and technology for retail and online stores of Apple Inc. from 2011 to 2021. Prior to his tenure at Apple, he served as a partner at McKinsey & Company.
Daniel M. Skovronsky, M.D., Ph.D.	48	Senior Vice President, Chief Scientific and Medical Officer, and President, Lilly Research Laboratories (since 2021). Previously, Dr. Skovronsky held various leadership roles with Lilly, including senior vice president, chief scientific officer, and president, Lilly Research Laboratories, and senior vice president, clinical and product development. Dr. Skovronsky has 11 years of service with Lilly.
Jacob Van Naarden	37	Senior Vice President, CEO Loxo Oncology at Lilly, and President, Lilly Oncology (since 2021). Previously, Mr. Van Naarden served as Chief Executive Officer-Loxo Oncology at Lilly, and Chief Operating Officer-Loxo Oncology at Lilly. Mr. Van Naarden joined Lilly in 2019 when the company acquired Loxo Oncology, Inc., where he was the chief operating officer. In previous roles, Mr. Van Naarden worked in various biotechnology investing, operating, and advisory capacities, including positions with HealthCor Management, Aisling Capital, and Goldman Sachs. Mr. Van Naarden has three years of service with Lilly.
Alonzo Weems	51	Senior Vice President, Enterprise Risk Management, and Chief Ethics and Compliance Officer (since 2021). Previously, Mr. Weems held various leadership roles with Lilly, including vice president and deputy general counsel for corporate legal functions, general counsel for Lilly USA, and general counsel for biomedicines and diabetes. Mr. Weems has 24 years of service with Lilly.
Anne E. White	53	Senior Vice President and President, Lilly Neuroscience (since 2021). Previously, Ms. White held various leadership roles with Lilly, including senior vice president and president, Lilly Oncology, vice president of Portfolio Management, Chorus, and Next Generation Research and Development. Ms. White has 26 years of service with Lilly.
Ilya Yuffa	47	Senior Vice President and President, Lilly International (since 2021). Previously, Mr. Yuffa held various leadership roles with Lilly, including senior vice president and president, Lilly Bio-Medicines, vice president of U.S. Diabetes, general manager of Italy Hub, and vice president, global ethics and compliance officer since 2014. Mr. Yuffa has 25 years of service with Lilly.

Human Capital Management

Our core values—integrity, excellence, and respect for people—shape our approach to attracting, retaining, engaging, and developing a highly skilled and ethical workforce, which is critical to executing our strategy. We believe the strength of our workforce significantly contributes to our financial performance and enables us to make life better for people around the world. For instance, most of the products we sell today were discovered or developed by our own scientists, and our long-term success depends on our ability to continually discover or acquire, develop, and commercialize innovative new medicines. We believe that fostering a positive culture that values the contributions of our talented colleagues helps drive our success.

We are committed to creating a safe, supportive, ethical, and rewarding work environment through strategic focus on our human capital management process, fairness and nondiscrimination in our employment practices, robust training and development opportunities, and competitive pay and benefits. We believe our dedication to promoting diversity, equity, and inclusion (DEI) within our company reflects our values and is a key driver of business success and growth.

We regularly conduct anonymous employee surveys to seek feedback from our workforce on a variety of topics. These results are reviewed and analyzed by our leaders in order to implement changes to our policies and benefits designed to improve our employees' well-being. As a result of our efforts, we believe that we have a highly performing, cohesive workforce and that our employee relations are good.

At the end of 2021, we employed approximately 35,000 people, including approximately 19,600 employees outside the U.S. Our employees include approximately 8,100 people engaged in research and development activities.

Strategy and Oversight

In order to build diverse and inclusive teams, our CEO and executive committee set expectations for inclusive leadership and hold leaders accountable for achieving results. Because dedication to human capital management is also a core component of our corporate governance, our board of directors regularly engages with management and facilitates a system of reporting designed to monitor human capital management initiatives and progress as part of the overarching framework that guides how we attract, retain, engage, and develop a workforce that aligns with our values and mission.

Diversity, Equity, and Inclusion

We are committed to fairness and nondiscrimination in our employment practices, and we deeply value diverse backgrounds, skills, and global perspectives. To fulfill our purpose, we believe we must look at challenges from multiple viewpoints and understand the diverse experiences of the patients who depend on us.

We believe that fostering DEI begins with understanding. For example, our *Employee Journeys* research has yielded important insights about the experiences of women, Black/African American, Latinx, Asian, and LGBTQ+ employees at Lilly. The results of this research are reviewed by our senior leadership, and we deploy actions and activities in response to these insights to improve our workplace and corporate culture.

In 2020, as part of our DEI and community initiatives, Lilly and the Lilly Foundation launched the Racial Justice Commitment and pledged $25 million and 25,000 volunteer hours over five years to help decrease the burden of racial injustice and its effects on communities of color. The Racial Justice Commitment aims to drive change across five areas: internal people development, health equity, social impact, diversity partners, and family sustaining jobs, through the use of financial and people resources. In 2021, we made progress in these efforts, including through the development of two apprenticeship programs at Lilly for individuals without college degrees.

Since 2017, we have committed to increasing the number of women, Black/African American, Latinx, and Asian populations in leadership roles, and we actively monitor our progress. From the end of 2017 through the end of 2021, we increased the percentage of women in management globally from 41 percent to 48 percent. For minority group members (MGM) in the U.S. over the same period, we increased management representation from 16 percent to 24 percent. Across all levels of our workforce, from the end of 2017

through the end of 2021, we have seen increased representation for MGMs in the U.S. and women globally. Our focus on DEI is also evident at our executive committee and board of directors. Five of 15 current members (approximately 33 percent) of our executive committee (which includes our CEO) are women and two are MGM. In addition, as of the filing of this report, the company's 13-member board of directors includes four women and six members who are MGMs.

Our efforts in DEI and workplace benefits have garnered numerous recognitions, including, in 2021, Top 50 Companies for Diversity by DiversityInc., America's Best Employers for Diversity by Forbes, America's Most JUST Companies and Forbes JUST 100 by Forbes and JUST Capital, Perfect Score on the Human Rights Campaign Foundation Corporate Equality Index, World's Most Ethical Companies by Ethisphere, Leading Disability Employer by the National Organization on Disability, Top Employers by Science Magazine, and 100 Best Companies, Top Companies for Executive Women, Best Companies for Dads, and Best Companies for Multicultural Women by Working Mother Magazine.

Employee Development

We believe talent begins with the hiring process. We therefore require hiring managers to consider a diverse pool of candidates and we strive to provide a diverse panel of interviewers for open positions. We believe that hiring in this way helps ensure that people from all backgrounds have equal opportunity to advance their careers.

We offer training to enable our employees to perform their duties in our highly regulated industry. We also strive to cultivate a culture that promotes ongoing learning by encouraging employees to seek further education and growth experiences, helping them build rewarding careers. We have introduced online programming to facilitate access to our learning and development offerings. Many training courses are designed to improve accessibility for people with disabilities and other unique needs. Across Lilly, we are working to design learning experiences to be more inclusive and effective. In addition, we have implemented tools and resources and improved our talent programs and processes to provide broad access to information and transparency regarding career development and advancement at Lilly.

In early 2022, we launched *Discover*, a 12-month new employee onboarding program with multiple touchpoints designed to foster integration into the Lilly culture, to accelerate learning in their new roles and to create connections to further a sense of belonging at Lilly. *Discover* was shaped in part by external benchmarking, feedback from employees, and learnings from onboarding remotely during the COVID-19 pandemic.

Employee resource groups (ERGs) are another important component of developing talent at Lilly. We currently have 11 ERGs representing groups including women, MGMs, LGBTQ+ individuals, veterans, and people with disabilities. ERGs offer our diverse workforce opportunities to build relationships, engage with senior leaders, advance our caring community, and offer unique insights and perspectives to improve our business.

We have continued our efforts to create an inclusive workplace with the goal of ensuring that all employees feel safe to speak up and share their ideas at work. Our *Make it Safe to Thrive* education and awareness program is designed to help employees and leaders understand how individual psychological safety can be created and enhanced and includes live and online training and a monthly video series.

Lilly is committed to fostering a culture of diversity and respect in the workplace—an environment free of discrimination, harassment, or retaliation of any kind. In 2022, as part of our annual review of The Red Book (Lilly's comprehensive code of business conduct applicable to our board and all employees worldwide) and related policies and procedures, we revised the Global Conduct in the Workplace procedure to continue to help ensure that we maintain a respectful, safe, inclusive, and professional workplace.

Employee Health and Safety

We strive to foster a healthy, vibrant work environment, which includes keeping our employees safe. We seek to create a companywide culture where best-in-class safety practices are consistently followed. To do this, we assess and continuously attempt to improve our companywide safety performance to promote the well-being of employees and to help safeguard communities where we operate. As the COVID-19 pandemic has evolved, we have taken various measures to protect and support the health and safety of our employees globally, including instituting travel restrictions and work-from-home arrangements, offering onsite testing and vaccination options where possible, and instituting safety precautions such as masking, social distancing, and enhanced cleaning practices. To support employee well-being in the U.S., we also enhanced local benefits related to health care, childcare, and time off. We believe this holistic approach

and dedication to safety helps us be our best as we deliver on our company purpose to improve lives around the world.

Information Available on Our Website

Our company website is **www.lilly.com**. None of the information accessible on or through our website is incorporated into this Annual Report on Form 10-K. We make available through the website, free of charge, our company filings with the SEC as soon as reasonably practicable after we electronically file them with, or furnish them to, the SEC. These include our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, proxy statements, registration statements, and any amendments to those documents. The link to our SEC filings is **investor.lilly.com/financial-information/sec-filings**.

Paper copies of the company's Annual Report on Form 10-K and Quarterly Reports on Form 10-Q that are filed with the SEC are available without charge upon written request to:

ELI LILLY AND COMPANY
c/o General Counsel and Secretary
Lilly Corporate Center
Indianapolis, Indiana 46285

In addition, the Governance portion of our website includes our corporate governance guidelines, board of directors and committee information (including committee charters), and our articles of incorporation and bylaws. The link to our corporate governance information is **lilly.com/leadership/governance**.

Item 1A. Risk Factors

In addition to the other information contained in this Annual Report on Form 10-K, the following risk factors should be considered carefully in evaluating our company. It is possible that our business, financial condition, liquidity, cash flows, or results of operations could be materially adversely affected by any of these risks. Certain of these risks could also adversely affect the company's reputation. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial could also adversely affect our business and reputation.

Risks Related to Our Business

- **The COVID-19 pandemic has adversely impacted and may continue to adversely impact our business and operations. We are currently unable to predict the full extent to which the COVID-19 pandemic or any future pandemic, epidemic, or similar public health threat will adversely impact our business and operations in the future.**

  The COVID-19 pandemic continues to burden healthcare systems worldwide. The focus of resources on COVID-19, widespread protective measures implemented to control the spread of COVID-19, and the resulting strain on global transportation, manufacturing, and labor markets have negatively impacted development, manufacturing, supply, distribution, and sales of our medicines.

  Although in-person interactions with healthcare professionals have largely resumed, we continue to see a lack of "normal" access and fewer in-person interactions by patients and our employees with healthcare professionals. As the COVID-19 pandemic continues to develop, we may decide to halt such in-person interactions in the future and, in those cases, expect to resume such interactions as it is safe to do so and in compliance with applicable guidance and requirements.

  The strain on global transportation, logistics, and labor markets caused by the COVID-19 pandemic and an increase in overall demand in our industry for certain materials resulting in changed buying patterns and constrained supply have had, and may continue to have, a number of impacts on our business, including increased costs to provide a consistent supply of our medicines where they are needed and disruptions and shortages in the supply of our medicines. These factors may negatively affect our results of operations.

  We also face risks and uncertainties related to our COVID-19 therapies, including heightened regulatory scrutiny of our manufacturing practices, quality assurance, and similar regulations, restrictions on administration that limit widespread and timely access to our therapies, and risks related to handling, return, and/or refund of product after delivery by us. In addition, expedited authorization processes have allowed restricted distribution of products with less than typical safety and efficacy data, and additional data that become available may call into question the safety or effectiveness of our COVID-19 therapies. The availability of superior or competitive therapies, including therapies that can be administered more easily, or preventative measures such as vaccines, coupled with the unpredictable nature of pandemics, have and could further negatively impact or eliminate demand for our COVID-19 therapies. We also expect that additional revenue from the sale of bamlanivimab and etesevimab after the first quarter of 2022 will be limited. Mutations or the spread of other variants of the coronavirus have in some cases impacted the effectiveness of our COVID-19 therapies, and may further render our therapies more or less effective or ineffective. Furthermore, the FDA has revised, and may in the future revise, any EUA for our COVID-19 therapies in response to the prevalence of variants against which our therapies have varying degrees of efficacy. These and other risks related to COVID-19 could affect other aspects of our business or intensify other risks inherent in our business, including potentially resulting in delays or denials in the approval or launch of other products or indications.

  It remains difficult to reasonably assess or predict the full extent of the ongoing impact of the COVID-19 pandemic on us. The degree to which the COVID-19 pandemic continues to affect us will depend on developments that are highly uncertain and beyond our knowledge or control, including, but not limited to, the duration and severity of the pandemic, the actions taken to reduce its transmission, including widespread availability and efficacy of vaccines, the introduction and spread of new variants of the coronavirus that may be resistant to currently approved vaccines, the continuation

of existing or implementation of new government restrictions and the speed with which, and extent to which, more stable economic and operating conditions resume. Should the COVID-19 pandemic, or any future pandemic, epidemic, or similar public health threat, and any associated supply chain disruption, labor

market impact, recession, or depression continue for a prolonged period, these risks could be exacerbated, causing further impact on our business and operations in the future.

- **Pharmaceutical research and development is very costly and highly uncertain; we may not succeed in developing, licensing, or acquiring commercially successful products sufficient in number or value to replace revenues of products that have lost or will soon lose intellectual property protection or are displaced by competing products or therapies.**

  There are many difficulties and uncertainties inherent in pharmaceutical research and development, the introduction of new products, and business development activities to enhance our product pipeline.

  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, label changes, 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 establish high hurdles for the efficacy and safety of new products and indications. 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 and indications.

  We cannot state with certainty when or whether our products now under development will be approved or launched; whether, if initially granted, such approval will be maintained; whether we will be able to develop, license, or otherwise acquire additional product candidates or products; or whether our products, once launched, will be commercially successful.

  We must maintain a continuous flow of successful new products and successful new indications or brand extensions for existing products, both through our internal efforts and our business development activities, sufficient both to cover our substantial research and development costs and to replace revenues that are lost as profitable products lose intellectual property exclusivity or are displaced by competing products or therapies. Failure to do so in the short-term or long-term would have a material adverse effect on our business, results of operations, cash flows, and financial position.

  We engage in various forms of business development activities to enhance our product pipeline, including licensing arrangements, co-development agreements, co-promotion arrangements, joint ventures, acquisitions, and equity investments. There are substantial risks associated with identifying successful business development targets and consummating related transactions. Increased focus on business combinations in our industry, including by the Federal Trade Commission, and heightened competition for attractive targets has and could continue to delay, jeopardize or increase the costs of our business development activities. In addition, failures or difficulties in integrating or retaining new personnel or the operations of the businesses, products, or assets we acquire (including related technology, commercial operations, compliance programs, manufacturing, distribution, and general business operations and procedures) may affect our ability to realize the expected benefits of business development transactions and may result in our incurrence of substantial asset impairment or restructuring charges. We also may fail to generate the expected revenue and pipeline enhancement from business development activities due to developments outside our control, including unsuccessful clinical trials, issues related to the quality, integrity, or broad applicability of data, regulatory impediments, and commercialization challenges. Accordingly, business development transactions may not be completed in a timely manner (if at all), may not result in successful commercialization of any product, and may give rise to legal proceedings or regulatory scrutiny.

  See Item 1, "Business - Research and Development - Phases of New Drug Development" and Item 7, "Management's Discussion and Analysis - Results of Operations - Executive Overview - Late-Stage Pipeline," for more details about our current product pipeline.

- **We depend on products with intellectual property protection for most of our revenues, cash flows, and earnings; we have lost or soon will lose effective intellectual property protection for a number of our products, which has resulted and is likely to continue to result in rapid and severe declines in revenues.**

  A number of our products, including Alimta and Forteo, have recently lost, or soon will lose, significant patent protection and/or data protection in the U.S. as well as in key jurisdictions outside the U.S. We have faced, and remain exposed to, generic competition following the loss of such intellectual property protection. In particular, we expect that the entry of generic competition for Alimta in the U.S. following the loss of patent exclusivity will cause a rapid and severe decline in revenue for the product and have a material adverse effect on our consolidated results of operations and cash flows.

  Certain other significant products no longer have effective exclusivity through patent protection or data protection. For non-biologic products, loss of exclusivity (whether by expiration of legal rights or by termination thereof as a consequence of litigation) typically results in the entry of one or more generic competitors, leading to a rapid and severe decline in revenues, especially in the U.S. For biologics (such as Humalog, Humulin, Erbitux, Cyramza, Trulicity, Taltz, and Emgality), loss of exclusivity may or may not result in the near-term entry of competitor versions (i.e., biosimilars) due to many factors, including development timelines, manufacturing challenges, and/or uncertainties regarding the regulatory pathways for approval of the competitor versions. Generic pharmaceutical companies could also introduce a generic product before resolution of any related patent litigation.

  There is no assurance that the patents we are seeking will be granted or that the patents we hold will be found valid and enforceable if challenged. Moreover, patents relating to particular products, uses, formulations, or processes do not preclude other manufacturers from employing alternative processes or marketing alternative products or formulations that compete with our patented products. In addition, competitors or other third parties may assert claims that our activities infringe patents or other intellectual property rights held by them, or allege a third-party right of ownership in our existing intellectual property. See Item 7, "Management's Discussion and Analysis - Results of Operations - Executive Overview - Other Matters - Patent Matters," and Item 1, "Business - Patents, Trademarks, and Other Intellectual Property Rights," for more details.

- **Our long-term success depends on intellectual property protection; if our intellectual property rights are invalidated, circumvented, or weakened, our business will be adversely affected.**

  Our long-term success depends on our ability to continually discover or acquire, develop, and commercialize innovative new medicines. Without strong intellectual property protection, we would be unable to generate the returns necessary to support our significant investments in research and development, as well as the other expenditures required to bring new drugs to the market. Intellectual property protection varies throughout the world and is subject to change over time, depending on local laws and regulations. Changes to such laws and regulations could reduce protections for our innovative products. In the U.S., in addition to the process for challenging patents set forth in the BPCIA, which applies to biologic products, the Hatch-Waxman Act provides generic companies substantial incentives to seek to invalidate our patents covering pharmaceutical products. As a result, we expect that our U.S. patents on major pharmaceutical products, including biologics, will continue to be routinely challenged in litigation and may not be upheld. In addition, a separate IPR process currently allows competitors to seek invalidation of patents at the USPTO without the protections of the BPCIA or Hatch-Waxman Act. The use of IPR proceedings after the institution of litigation pursuant to the BPCIA or Hatch-Waxman Act is currently a topic of debate among legislators and the future ability of our competitors to use IPR proceedings as an alternative to Hatch-Waxman Act or BPCIA litigation procedures to challenge our patents remains uncertain. However, if our patents are challenged through this expedited review process, even if we prevail in demonstrating the validity of our patent, our win provides limited precedential value at the PTAB and no precedential value in federal district court, meaning the same patent can be challenged by other competitors. We face many generic manufacturer challenges to our patents outside the U.S. as well. The entry of generic competitors typically results in rapid and severe declines in revenues. In addition, competitors or other third parties may claim that our activities infringe patents or other intellectual property rights held by them. If successful, such claims could result in our being unable to market a product in a particular

territory or being required to pay significant damages for past infringement or royalties on future sales. In addition, intellectual property protection in certain jurisdictions outside the U.S. is weak and we face additional risks to our intellectual property rights, including competition with generic or counterfeit versions of our products relatively shortly after launch. See Item 1, "Business -

Patents, Trademarks, and Other Intellectual Property Rights," and Item 8, "Financial Statements and Supplementary Data - Note 16: Contingencies," for more details.

- **We and our products face intense competition from multinational pharmaceutical companies, biotechnology companies, and lower-cost generic and biosimilar manufacturers, and such competition could have a material adverse effect on our business.**

  We compete with a large number of multinational pharmaceutical companies, biotechnology companies, and generic pharmaceutical companies and, in many cases, our products compete against the leading products of one or more of our competitors. To compete successfully, we must continue to deliver to the market innovative, cost-effective products that meet important medical needs. Our product revenues can be adversely affected by the introduction by competitors of branded products that are perceived as superior by the marketplace, by generic or biosimilar versions of our branded products, and by generic or biosimilar versions of other products in the same therapeutic class as our branded products. Our revenues can also be adversely affected by treatment innovations that eliminate or minimize the need for treatment with our drugs.

  Regulation of generic and biosimilar products varies around the world and such regulation is complex and subject to ongoing interpretation and implementation by regulatory agencies and courts. Particularly for biosimilars, recent health authority guidelines and legislative proposals could make it less burdensome for competitor products to enter the market and further incentivize uptake of biosimilars. In the U.S., the FDA has begun issuing "interchangeability" designations for biosimilar products, which could – subject to state law requirements – enable pharmacies to substitute biosimilars for innovator biological products. Given the importance of biologic products to our clinical-stage pipeline, such regulation could have a material adverse effect on our business. See Item 1, "Business - Competition" and "Business - Research and Development," for more details.

  In addition, we rely on our ability to attract, engage, and retain highly qualified and skilled personnel in order to compete effectively. To continue to commercialize our products, and advance the research, development, and commercialization of additional modalities and product candidates, we may need to expand our workforce, including in the areas of manufacturing, clinical trials management, regulatory affairs, and sales and marketing, both in and outside the U.S. We continue to face intense competition for qualified individuals from numerous multinational pharmaceutical companies, biotechnology companies, academic and other research institutions, as well as employers near our manufacturing and other facilities, which has and may continue to increase our labor costs. Our ability to attract and retain talent in our increasingly competitive environment may be further complicated by evolving employment trends arising from the COVID-19 pandemic, including vaccination mandates, increased preferences for remote, alternative, or flexible work arrangements, and other factors. Our failure to compete effectively for talent could negatively affect sales of our current and any future approved products, and could result in material financial, legal, commercial, or reputational harm to our business.

- **Failure, inadequacy, breach of, or unauthorized access to, our IT systems or those of our third-party service providers, unauthorized access to our confidential information, or violations of data protection laws, could each result in material harm to our business and reputation.**

  A great deal of confidential information owned by us or our business partners or other third parties is stored in our information systems, networks, and facilities or those of third parties. This includes valuable trade secrets and intellectual property, clinical trial information, corporate strategic plans, marketing plans, customer information, and personally identifiable information, such as employee and patient information (collectively, confidential information). We also rely, to a large extent, on the efficient and uninterrupted operation of complex information technology systems, infrastructure, and hardware (together, IT systems), some of which are within our control and some of which are within the control of third parties, to accumulate, process, store, and transmit large amounts of confidential information and other data. We are subject to a variety of continuously evolving and developing laws and regulations around the world related to privacy, data protection, and data security. Maintaining the security, confidentiality, integrity and availability of our IT systems and confidential information is vital to our business. Our failure, or the failure of our third party service providers, to protect and maintain

the security, confidentiality, integrity, and availability of our (or their) IT systems and our confidential information and other data could significantly harm our reputation as well as result in significant costs, including those related to fines, litigation, and obligations to comply with applicable data breach laws.

IT systems are vulnerable to system inadequacies, operating failures, service interruptions or failures, security breaches, malicious intrusions, or cyber-attacks from a variety of sources. Cyber-attacks are growing in their frequency, sophistication, and intensity, and are becoming increasingly difficult to detect, mitigate, or prevent. Cyber-attacks come in many forms, including the deployment of harmful malware, exploitation of vulnerabilities (including those of third-party software or systems), denial-of-service attacks, the use of social engineering, and other means to compromise the confidentiality, integrity and availability of our IT systems, confidential information, and other data. Breaches resulting in the compromise, disruption, degradation, manipulation, loss, theft, destruction, or unauthorized disclosure or use of confidential information, or the unauthorized access to, disruption of, or interference with our IT systems, products and services, can occur in a variety of ways, including but not limited to, negligent or wrongful conduct by employees or others with permitted access to our systems and information, or wrongful conduct by hackers, competitors, certain governments or nation-states, or other current or former company personnel. Our third-party partners, including third-party providers of data hosting or cloud services, as well as suppliers, distributors, alliances, and other third parties with whom we may share data, face similar risks, which could affect us directly or indirectly. The healthcare industry has been and continues to be a target for cyber-attacks, and the number of threats has only increased over time. Numerous federal agencies that monitor and regulate internet and cyber-crime have issued guidance, alerts and directives warning of software vulnerabilities that require immediate patching, malicious actors targeting healthcare related systems and nation-state sponsored hacking designed to steal valuable information.

The failure, inadequacy, or breach of our IT systems or business processes, the compromise, disruption, degradation, manipulation, loss, theft, destruction, or unauthorized access to, disclosure or use of, confidential information, or the unauthorized access to, disruption of, or interference with our products and services that rely on IT systems or business processes, could impair our ability to secure and maintain intellectual property rights; result in a product manufacturing interruption or failure, or in the interruption or failure of products or services that rely on IT systems or business processes; damage our operations, customer relationships, or reputation; result in unfavorable clinical trial results by virtue of incorrect or unreliable data; and/or cause us to lose trade secrets or other competitive advantages. Unauthorized disclosure of personally identifiable information could expose us to significant sanctions for violations of data privacy laws and regulations around the world and could damage public trust in our company. In addition, IT system security in jurisdictions outside the U.S. is weaker and may result in additional costs, uncertainties, and risks.

To date, system inadequacies, operating failures, unauthorized access, service interruptions or failures, security breaches, malicious intrusions, cyber-attacks, and the compromise, disruption, degradation, manipulation, loss, theft, destruction, or unauthorized disclosure or use of confidential information have not had a material impact on our consolidated results of operations. We maintain cyber liability insurance; however, this insurance may not be sufficient to cover the financial, legal, business, or reputational losses that may result from an interruption or breach of our IT systems. We continue to implement measures in an effort to protect, detect, respond to, and minimize or prevent these risks and to enhance the resiliency of our IT systems; however, these measures may not be successful and we may fail to detect or remediate security breaches, malicious intrusions, cyber-attacks, or other compromises of our systems. Any of these events could result in material financial, legal, commercial, or reputational harm to our business.

- **Significant economic downturns or international trade and other global disruptions or disputes could adversely affect our business and operating results.**

  While pharmaceuticals have generally been less sensitive to overall economic cycles, prolonged economic slowdowns could lead to decreased utilization of our products, affecting our sales volume. Declining tax revenues attributable to economic downturns increase the pressure on governments to reduce health care spending, leading to increasing government efforts to control drug prices and utilization. Additionally, some customers, including governments or other entities reliant upon government funding, may be unable to pay for our products in a timely manner. Also, if our customers, suppliers, or collaboration partners experience financial difficulties, we could experience slower customer collections, greater bad debt expense, and performance defaults by suppliers or

collaboration partners. Similarly, in the event of a significant economic downturn, we could have difficulty accessing credit markets.

Significant portions of our business are conducted in Europe, including the United Kingdom, in Asia, including China, and in other international geographies. Trade and other global disputes and interruptions in international relationships, including related to tariffs, trade protection measures, import or export licensing requirements, the imposition of trade sanctions or similar restrictions by the U.S. or other governments, unrest or war, as well as pandemic diseases, such as COVID-19, affect our ability to do business. For example, tensions between the U.S. and China have led to a series of tariffs and sanctions being imposed by the U.S. on imports from China mainland, as well as other business restrictions. These and similar events could adversely affect us, or our business partners or customers.

- **Pharmaceutical products can develop unexpected safety or efficacy concerns, which could have a material adverse effect on our revenues, income, and reputation.**

  Pharmaceutical products receive regulatory approval based on data obtained in controlled clinical trials of limited duration. After approval, the products are used for longer periods of time by much larger numbers of patients. Accordingly, we and others (including regulatory agencies and private payers) collect extensive information on the efficacy and safety of our marketed products by continuously monitoring the use of our products in the marketplace. In addition, we or others may conduct post-marketing clinical studies on efficacy and safety of our marketed products. New safety or efficacy data from both market surveillance and post-marketing clinical studies may result in product label changes or other measures that could reduce the product's market acceptance and result in declining sales. Serious safety or efficacy issues that arise after product approval have, and could in the future, result in voluntary or mandatory product recalls or withdrawals from the market. Safety issues have, and could in the future, result in costly product liability claims. See also " - The COVID-19 pandemic has adversely impacted and may continue to adversely impact our business and operations. We are currently unable to predict the full extent to which the COVID-19 pandemic or any future pandemic, epidemic, or similar public health threat will adversely impact our business and operations in the future."

- **We face litigation and investigations related to our products, how we price our products, and how we commercialize our products; we could face large numbers of claims in the future, which could adversely affect our business, and we are self-insured for such matters.**

  We are subject to a substantial number of product liability claims involving various current and historical products, litigation and investigations related to how we commercialize and/or how we price our products, including relating to our 340B drug pricing program, as well as contractual disputes. See Item 8, "Financial Statements and Supplementary Data - Note 16, Contingencies" for more information on our current product liability litigation, as well as pricing litigation, investigations, and inquiries. Because of the nature of pharmaceutical products, we are and could in the future become subject to large numbers of product liability claims for our previous, current, or future products, or to further litigation or investigations, including related to pricing or other commercial practices. Such matters could affect our results of operations or require us to recognize substantial charges to resolve and, if involving marketed products, could adversely affect sales of the product. Due to a very restrictive market for liability insurance, we are self-insured for litigation liability losses for all our currently marketed products, as well as for litigation or investigations related to our pricing practices or other similar matters.

- **Manufacturing and supply chain difficulties, disruptions, or shortages could lead to product supply problems.**

  Pharmaceutical manufacturing is complex and highly regulated. Manufacturing or quality assurance difficulties at our facilities or contracted facilities, the failure or refusal of a supplier or contract manufacturer to supply contracted quantities, or increases in demand on a supplier could result in delays and disruptions in the manufacturing, distribution, and sale of our products and/or product shortages, leading to lost revenue. Further, global transportation and logistics challenges, as well as tight labor markets, have caused, and in the future may cause, delays in, and/or increase costs related to, distribution of our medicines, the construction or other acquisition of manufacturing capacity, procurement activity, and supplier or contract manufacturer arrangements. Such difficulties, disruptions, or challenges could result from quality, oversight, or regulatory compliance problems;

natural disasters or pandemic disease; equipment, mechanical, data, or information technology system vulnerabilities, such as system inadequacies, inadequate controls or procedures, operating failures, service interruptions or failures, security breaches, malicious intrusions, or cyber-attacks from a variety of sources; labor shortages; contractual disputes with our suppliers and contract manufacturers; or inability to obtain single-source or other raw or intermediate materials. In addition, difficulties in predicting or variability in demand for our

products and indications and the very long lead times necessary for the expansion and regulatory qualification of pharmaceutical manufacturing capacity from time to time result in difficulty meeting demand for, or disruptions, shortages, and higher costs in the supply of, our products. See Item 1, "Business - Raw Materials and Product Supply," for more details.

- **Reliance on third-party relationships and outsourcing arrangements could adversely affect our business.**

  We rely on third parties, including suppliers, distributors, alliances, and collaborations with other pharmaceutical and biotechnology companies, and third-party service providers, for selected aspects of product and clinical development, manufacturing, commercialization, hosting of, and support for, information technology systems, product distribution, and certain financial transactional processes. As examples, we outsource the day-to-day management and oversight of some of our clinical trials to contract research organizations and the distribution of our products through logistics providers. Outsourcing these functions involves the risk that the third parties may not perform to our standards or legal requirements; may not produce reliable results; may not perform in a timely manner; may not maintain the confidentiality, integrity, and availability of confidential and proprietary information relating to us, our clinical trial subjects, or patients; may experience disruption or fail to perform due to information technology system vulnerabilities, breaches, cyber-attacks, or inadequate controls or procedures; may be unable to satisfy their commitments to us in which case we may not be able to achieve acceptable alternative sourcing; or may fail to perform at all. The foregoing risks may be heightened in jurisdictions outside the U.S., where we may face additional costs, uncertainties, and risks. Failure of these third parties to meet their contractual, regulatory, confidentiality, privacy, security, or other obligations to us, our clinical trial subjects, and our patients could have a material adverse effect on our business.

Risks Related to Government Regulation

- **Our business is subject to increasing government price controls and other public and private restrictions on pricing, reimbursement, and access for our drugs, which could have a material adverse effect on our reputation or business.**

  Public and private payers continue to take aggressive steps to control their expenditures for pharmaceuticals by placing restrictions on pricing and reimbursement for, and patient access to, our medicines. These pressures could continue to negatively affect our future revenues and net income. Governments and private payers worldwide have intensified their scrutiny of, and actions intended to address, pricing, reimbursement, and access to pharmaceutical products. Additional policies, regulations, legislation, or enforcement, including as a result of the regulatory priorities of the current U.S. presidential administration and other regulatory authorities worldwide, could adversely impact our business and revenue. For example, pending legislation in the U.S. could result in government negotiation of the price of some of our medicines, including insulin. Furthermore, restrictive or unfavorable pricing, coverage, or reimbursement determinations for our medicines or product candidates by governments, regulatory agencies, or private payers, such as the recently proposed Alzheimer’s Monoclonal Antibody NCD, may adversely impact our business and financial results. However, we cannot predict the likelihood, nature, or extent of current and future health care reform efforts. We also may continue to experience potential additional pricing pressures resulting from the financial strain of the COVID-19 pandemic on government-funded healthcare systems around the world.

  For more details, see Item 1, "Business - Regulations and Private Payer Actions Affecting Pharmaceutical Pricing, Reimbursement, and Access," Item 7, "Management's Discussion and Analysis - Results of Operations - Executive Overview - Other Matters - Trends Affecting Pharmaceutical Pricing, Reimbursement, and Access," and Item 8, "Financial Statements and Supplementary Data - Note 16: Contingencies."

- **Changes in foreign currency rates, interest rate risks, or inflation could materially affect our results of operations.**

As a global company, we face foreign currency risk exposure from fluctuating currency exchange rates, interest rate risk from our exposure to floating and variable interest rates, and inflation risk from existing and expected rates of inflation in the U.S. and other jurisdictions. While we seek to manage a portion of these exposures through hedging and other risk management techniques, significant fluctuations in currency rates, interest rates, and inflation can have a material impact, either positive or negative, on our

results of operations. Further, in the event of an extreme devaluation of local currency, the price of our products could become unsustainable in the relevant market. In addition, the discontinuation, modification, or other reform of the London Interbank Offered Rate (LIBOR), or the replacement of LIBOR with a different reference rate, could increase our interest expense, decrease our cash flows, and/or require us to amend certain of our existing agreements. See Item 7, "Management's Discussion and Analysis - Financial Condition and Liquidity" and Item 8, "Financial Statements and Supplementary Data - Note 1: Summary of Significant Accounting Policies and Implementation of New Financial Accounting Standard" for more details.

- **Changes in tax laws or exposure to additional tax liabilities could increase our income taxes and decrease our net income.**

  We are subject to income taxes in the U.S. and numerous foreign jurisdictions, and in the course of our business, we make judgments about the expected tax treatment of various transactions and events. Changes in tax laws, regulations, administrative practices, principles, and interpretations, as well as events that differ from our expectations, have affected and may adversely affect our effective tax rates, cash flows, and/or and results of operations. For example, in December 2017, the U.S. enacted tax reform legislation significantly revising U.S. tax laws, and a number of other countries are also actively considering or enacting tax changes. Significant uncertainty currently exists regarding proposed tax policies of the current U.S. presidential administration and Congress, including modifications to certain aspects of the 2017 tax law. In addition, tax authorities in the U.S. and other jurisdictions in which we do business routinely examine our tax returns and are intensifying their scrutiny and examinations of profit allocations among jurisdictions, which could unfavorably impact our results of operations. Further, actions taken with respect to tax-related matters by associations such as the Organisation for Economic Cooperation and Development and the European Commission could influence tax laws in countries in which we operate. Modifications to key elements of the current U.S. or international tax framework could have a significant impact on our effective tax rate, results of operations, and cash flows. See Item 7, "Management's Discussion and Analysis - Results of Operations - Executive Overview - Other Matters - Tax Matters" and Item 8, "Financial Statements and Supplementary Data - Note 14: Income Taxes," for more details.

- **Regulatory compliance problems could be damaging to the company.**

  The marketing, promotional, and pricing practices of pharmaceutical manufacturers, as well as the manner in which manufacturers interact with purchasers, prescribers, and patients, are subject to extensive regulation. Many companies, including us, have been subject to claims related to these practices asserted by federal, state, and foreign governmental authorities, private payers, and consumers. These claims have resulted in substantial expense and other significant consequences to us. We are and could in the future become subject to such investigations, the outcomes of which could include criminal charges and fines, penalties, or other monetary or non-monetary remedies, including exclusion from U.S. federal and other health care programs. Such investigations have intensified and may continue to intensify as a result of the regulatory priorities of the current U.S. presidential administration and other regulatory authorities worldwide. In addition, regulatory issues concerning compliance with cGMP, quality assurance, and similar regulations (and comparable foreign regulations) for our products can lead to regulatory and legal actions, product recalls and seizures, fines and penalties, interruption of production leading to product shortages, import bans or denials of import certifications, delays or denials in the approvals of new products or supplemental approvals of current products pending resolution of the issues, and reputational harm, any of which would adversely affect our business. Regulatory compliance and processes in jurisdictions outside the U.S. may also be less predictable and result in additional costs, uncertainties, and risks. See Item 1, "Business - Government Regulation of Our Operations," for more details.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our principal domestic and international executive offices are located in Indianapolis. At December 31, 2021, we owned 9 production and distribution sites in the United States (U.S.), including Puerto Rico. Together with the corporate administrative offices, these facilities contain an aggregate of approximately 8.1 million square feet of floor area dedicated to production, distribution, and administration. Major production sites include Indianapolis, Indiana; Carolina, Puerto Rico; and Branchburg, New Jersey.

We own production and distribution sites in 7 countries outside the U.S., containing an aggregate of approximately 4.7 million square feet of floor area. Major production sites include facilities in Ireland, France, Spain, Italy, and China.

In the U.S., our research and development facilities contain an aggregate of approximately 4.4 million square feet of floor area, primarily consisting of owned facilities located in Indianapolis and smaller leased sites primarily in San Diego, California; San Francisco, California; and New York, New York. Outside the U.S., we own a small research and development facility in Spain and lease a small site in Singapore.

We believe that none of our properties is subject to any encumbrance, easement, or other restriction that would detract materially from its value or impair its use in the operation of the business. The buildings we own are of varying ages and in good condition.

Item 3. Legal Proceedings

We are a party to various currently pending legal actions, government investigations, and environmental proceedings. Information pertaining to legal proceedings is described in Item 8, "Financial Statements and Supplementary Data - Note 16: Contingencies," and incorporated by reference herein.

Item 4. Mine Safety Disclosures

Not applicable.

Part II

Item 5. Market for the Registrant's Common Equity, Related Stockholder Matters, and Issuer Purchases of Equity Securities

Information relating to the principal market for our common stock and related stockholder matters is described in Item 7, "Management's Discussion and Analysis of Results of Operations and Financial Condition" and Item 12, "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters." This information is incorporated herein by reference.

As of February 18, 2022, there were approximately 20,641 holders of record of our common stock based on information provided by EQ Shareowner Services, our transfer agent. Our common stock is listed under the ticker symbol LLY on the New York Stock Exchange (NYSE).

The following table summarizes the activity related to repurchases of our equity securities during the fourth quarter ended December 31, 2021:

Period	Total Number of Shares Purchased (in thousands)	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs (in thousands)	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs (dollars in millions)
October 2021	2,398	$ 254.70	2,398	$ 4,889.1
November 2021	—	—	—	4,889.1
December 2021	546	254.70	546	4,750.0
Total	2,944	254.70	2,944	

During the three months ended December 31, 2021, we repurchased the remaining $500.0 million of shares available under the $8.00 billion share repurchase program authorized in June 2018 and $250.0 million of shares available under the $5.00 billion share repurchase program authorized in May 2021.

PERFORMANCE GRAPH

The following graph compares the return on Lilly stock with that of the Standard & Poor's (S&P) 500 Stock Index and our peer group for the years 2017 through 2021. The graph assumes that, on the last business day of 2016, a person invested $100 each in Lilly stock, the S&P 500 Stock Index, and the peer group's collective common stock. The graph measures total shareholder return, which takes into account both stock price and dividends. It assumes that dividends paid by a company are immediately reinvested in that company's stock.

Value of $100 Invested on Last Business Day of 2016 Comparison of Five-Year Cumulative Total Shareholder Return Among Lilly, S&P 500 Stock Index, and Peer Group[(1)]

	Lilly	Peer Group	S&P 500
Dec-16	$ 100.00	$ 100.00	$ 100.00
Dec-17	117.83	117.86	121.83
Dec-18	165.50	123.85	116.49
Dec-19	192.23	146.23	153.17
Dec-20	251.93	149.47	181.35
Dec-21	418.40	179.16	233.41

(1) We constructed the peer group as the industry index for this graph. It is comprised of the following companies in the pharmaceutical and biotechnology industries: AbbVie Inc.; Amgen Inc.; AstraZeneca PLC; Biogen Inc.; Bristol-Myers Squibb Company; Gilead Sciences Inc.; GlaxoSmithKline plc; Johnson & Johnson; Merck & Co., Inc.; Novartis AG.; Novo Nordisk A/S; Pfizer Inc.; Roche Holding AG; Sanofi S.A.; and Takeda Pharmaceutical Company Limited. The peer group used for performance benchmarking aligns with the peer group used for executive compensation purposes for 2021 other than our peer group for performance benchmarking excludes Allergan plc, Celgene Corporation, and Shire plc as they were acquired in 2020, 2019 and 2019, respectively.

Item 6. [Reserved]

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 Item 8, "Financial Statements and Supplementary Data." 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," may cause our actual results, financial position, and cash generated from operations to differ materially from these forward-looking statements.

Executive Overview

This section provides an overview of our financial results, recent product and late-stage pipeline developments, and other matters affecting our company and the pharmaceutical industry. Earnings per share (EPS) data are presented on a diluted basis.

COVID-19 Pandemic

In response to the COVID-19 pandemic, we have focused on maintaining a supply of our medicines; reducing the strain on the medical system; developing treatments for COVID-19; protecting the health, safety, and well-being of our employees; supporting our communities; and ensuring affordability of and access to our medicines, particularly insulin. As part of our response to the COVID-19 pandemic, and at the request of the United States (U.S.) and international governments, we invested in large-scale manufacturing of COVID-19 antibodies at risk, in order to ensure rapid access to patients around the world.

The U.S. Food and Drug Administration (FDA) granted Emergency Use Authorizations (EUA) for bamlanivimab and etesevimab administered together for higher-risk patients who have been recently diagnosed with mild-to-moderate COVID-19 and for baricitinib for treatment with or without remdesivir in hospitalized COVID-19 patients. In the third quarter of 2021, the FDA expanded the EUA for bamlanivimab and etesevimab administered together to include post-exposure prophylaxis in certain individuals for the prevention of SARS-CoV-2 infection. We expect that additional revenue from the sale of bamlanivimab and etesevimab after the first quarter of 2022 will be limited. In February 2022, the FDA granted an EUA for bebtelovimab for certain high-risk patients who have been recently diagnosed with mild-to-moderate COVID-19. We have agreed with the U.S. government to supply up to 600,000 doses of bebtelovimab no later than March 31, 2022 for at least $720 million with an option of 500,000 additional doses no later than July 31, 2022. The FDA has revised, and may in the future revise, any EUA for our COVID-19 therapies in response to the prevalence of variants against which our therapies have varying degrees of efficacy.

The COVID-19 pandemic has, and may continue to, adversely impact our business and operations. The focus of resources on COVID-19, widespread protective measures implemented to control the spread of COVID-19, and the resulting strain on global transportation, manufacturing, and labor markets have negatively impacted development, manufacturing, supply, distribution, and sales of our medicines. In addition to decreases in new prescriptions, changes in payer segment mix, and the increased use of patient affordability programs in the U.S., we have experienced, and may continue to experience if the COVID-19 pandemic undergoes resurgent or more severe waves, decreased demand as a result of lack

of "normal" access and fewer in-person interactions by patients and our employees with healthcare professionals.

We also face risks and uncertainties related to our COVID-19 therapies, including heightened regulatory scrutiny of our manufacturing practices, quality assurance, and similar regulations, restrictions on administration that limit widespread and timely access to our therapies, and risks related to handling, return, and/or refund of product after delivery by us. The availability of superior or competitive therapies, including therapies that can be administered more easily, or preventative measures such as vaccines, coupled with the unpredictable nature of pandemics, have and could further negatively impact or eliminate demand for our COVID-19 therapies. Mutations or the spread of other variants of the coronavirus have in some cases impacted the effectiveness of our COVID-19 therapies, and may further render our therapies more or less effective or ineffective.

The strain on global transportation, logistics, and labor markets caused by the COVID-19 pandemic and an increase in overall demand in our industry for certain materials resulting in changed buying patterns and constrained supply have had, and may continue to have, a number of impacts on our business, including increased costs to provide a consistent supply of our medicines where they are needed and potential disruptions in the supply of our medications. These factors may negatively affect our results of operations.

It remains difficult to reasonably assess or predict the full extent of the ongoing impact of the COVID-19 pandemic on us. The degree to which the COVID-19 pandemic continues to affect us will depend on developments that are highly uncertain and beyond our knowledge or control. We are currently unable to predict the full extent to which the COVID-19 pandemic or any future pandemic, epidemic or similar public health threat will adversely impact our business and operations in the future.

See Item 1A, "Risk Factors" for additional information on risk factors that could impact our business and operations.

Financial Results

The following table summarizes our key operating results:

	Year Ended December 31		Percent Change
	2021	**2020**	
Revenue	**$ 28,318.4**	$ 24,539.8	15
Gross margin	**21,005.6**	19,056.5	10
Gross margin as a percent of revenue	**74.2 %**	77.7 %	
Operating expenses	**$ 13,457.5**	$ 12,206.9	10
Acquired in-process research and development	**874.9**	660.4	32
Asset impairment, restructuring, and other special charges	**316.1**	131.2	NM
Other—net, (income) expense	**201.6**	(1,171.9)	NM
Income before income taxes	**6,155.5**	7,229.9	(15)
Income taxes	**573.8**	1,036.2	(45)
Net income	**5,581.7**	6,193.7	(10)
EPS	**6.12**	6.79	(10)

NM - not meaningful

Revenue increased in 2021 driven by increased volume and, to a lesser extent, the favorable impact of foreign exchange rates, partially offset by lower realized prices. Operating expenses, defined as the sum of research and development and marketing, selling, and administrative expenses, increased in 2021, driven primarily by higher development expenses for late-stage assets. The decreases in net income and EPS in 2021 were driven primarily by reduction in other-net, (income) expense and higher operating expenses, partially offset by higher gross margin.

The following highlighted items affect comparisons of our 2021 and 2020 financial results:

2021

Cost of Sales (See Note 6 to the consolidated financial statements)

- We recognized a net inventory impairment charge related to our COVID-19 antibodies of $339.7 million. As part of our response to the COVID-19 pandemic, and at the request of the U.S. and international governments, we invested in large-scale manufacturing of COVID-19 antibodies at risk, in order to ensure rapid access to patients around the world. As the COVID-19 pandemic evolved during 2021, we incurred a net inventory impairment charge primarily due to the combination of changes to current and forecasted demand from U.S. and international governments, including changes to our agreement with the U.S. government, and near-term expiry dates of COVID-19 antibodies.

Acquired In-Process Research and Development (IPR&D) (Note 3 to the consolidated financial statements)

- We recognized acquired IPR&D charges of $874.9 million related to business development transactions.

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

- We recognized charges of $316.1 million primarily related to an impairment of a contract-based intangible asset from our acquisition of Loxo Oncology, Inc. (Loxo), an intangible asset impairment resulting from the sale of the rights to Qbrexza®, as well as acquisition and integration costs associated with the acquisition of Prevail Therapeutics Inc. (Prevail).

Other-Net, (Income) Expense (Note 18 to the consolidated financial statements)

- We recognized a debt extinguishment loss of $405.2 million related to the repurchase of debt.
- We recognized $176.9 million of net investment gains on equity securities.

2020

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

- We recognized acquired IPR&D charges of $660.4 million related to business development transactions.

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

- We recognized charges of $131.2 million primarily related to severance costs incurred as a result of actions taken worldwide to reduce our cost structure.

Other-Net, (Income) Expense (Note 18 to the consolidated financial statements)

- We recognized $1.44 billion of net investment gains on equity securities.

Late-Stage Pipeline

Our long-term success depends on our ability to continually discover or acquire, develop, and commercialize innovative new medicines. We currently have approximately 45 new medicine candidates in clinical development or under regulatory review, and a larger number of projects in the discovery phase.

The following certain new molecular entities (NMEs) are currently in Phase II or Phase III clinical trials or have been submitted for regulatory review in the U.S., Europe, or Japan. The following table reflects the status of certain NMEs, including certain other developments since our Quarterly Report on Form 10-Q for the quarter ended September 30, 2021.

Compound	Indication	Status	Developments
COVID-19 Antibodies			
Bebtelovimab (LY-CoV1404)	COVID-19	Emergency Use Authorization	The FDA granted EUA for certain high-risk patients recently diagnosed with mild-to-moderate COVID-19 in February 2022.
Diabetes			
Tirzepatide	Type 2 diabetes	Submitted	Submitted in the U.S. using a priority review voucher and in Europe and Japan in 2021.
	Heart failure with preserved ejection fraction	Phase III	Phase III trials are ongoing.
	Obesity		
	Nonalcoholic steatohepatitis	Phase II	Phase II trial is ongoing.
Basal Insulin-Fc	Type 1 and 2 diabetes	Phase II	Phase II trials are ongoing.
GGG Tri-Agonist	Obesity	Phase II	Phase II trials are ongoing.
	Type 2 diabetes		
GLP-1R NPA	Obesity	Phase II	Phase II trials are ongoing.
	Type 2 diabetes		
Immunology			
Lebrikizumab[1]	Atopic dermatitis	Phase III	Granted FDA Fast Track designation[2]. Announced in 2021 that Phase III trials met primary and all key secondary endpoints. Phase III trials are ongoing.
Mirikizumab	Crohn's Disease	Phase III	Phase III trials are ongoing.
	Ulcerative colitis		Announced in 2021 that Phase III trials met primary and all key secondary endpoints.
CXCR1/2 Ligands Monoclonal Antibody	Hidradenitis suppurativa	Phase II	Phase II trial is ongoing.
IL-2 Conjugate	Systemic lupus erythematosus	Phase II	Phase II trials are ongoing.
	Ulcerative colitis		
PD-1 MAB Agonist	Rheumatoid arthritis	Phase II	Phase II trial is ongoing.

Compound	Indication	Status	Developments
Neuroscience			
Donanemab	Early Alzheimer's disease	Submission initiated	Granted FDA Breakthrough Therapy designation[3]. Initiated a rolling submission in the U.S. for accelerated approval in 2021. Phase III trials are ongoing.
	Preclinical Alzheimer's disease	Phase III	Phase III trial is ongoing.
Solanezumab	Preclinical Alzheimer's disease	Phase III	Phase III trial is ongoing.
Epiregulin/TGFα MAB	Chronic pain	Phase II	Phase II trials are ongoing.
GBA1 Gene Therapy (PR001)	Parkinson's disease	Phase II	Acquired in the Prevail acquisition in 2021. Granted FDA Fast Track designation[2]. Phase II trials are ongoing.
GRN Gene Therapy (PR006)	Frontotemporal dementia	Phase II	
O-glc-NAcase	Alzheimer's disease	Phase II	Phase II trial initiated in the fourth quarter of 2021.
PACAP38 Antibody	Chronic pain	Phase II	Phase II trial is ongoing.
SSTR4 Agonist	Chronic pain	Phase II	Phase II trials are ongoing.
TRPA1 Antagonist	Pain	Phase II	Phase II trials are ongoing.
Oncology			
Selpercatinib (Retevmo®)	Lung cancer	Approved[4]	Phase III trials are ongoing.
	Thyroid cancer		
Sintilimab injection[5]	Lung cancer	Submitted	In February 2022, the Oncologic Drugs Advisory Committee recommended that the FDA require additional clinical trials prior to a final regulatory decision.
Pirtobrutinib (LOXO-305)	Mantle cell lymphoma	Submission initiated	Initiated a rolling submission in the U.S. for accelerated approval in the fourth quarter of 2021. Phase II and Phase III trials are ongoing.
	Chronic lymphocytic leukemia	Phase III	Phase III trials are ongoing.
	B-cell malignancies	Phase II	Phase II trial is ongoing.
Imlunestrant	ER+HER2- metastatic breast cancer	Phase III	Phase III trial is ongoing.

[1] In collaboration with Almirall, S.A. in Europe.

(2) Fast Track designation is designed to expedite the development and review of new therapies to treat serious conditions and address unmet medical needs.

(3) 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.

(4) Continued approval may be contingent on verification and description of clinical benefit in confirmatory Phase III trials.

(5) In collaboration with Innovent Biologics, Inc.

Our pipeline also contains several new indication line extension (NILEX) products. The following certain NILEX products for use in the indication described are currently in Phase II or Phase III clinical trials or have been submitted for regulatory review in the U.S., Europe, or Japan. The following table reflects the status of certain NILEX products, including certain other developments since our Quarterly Report on Form 10-Q for the quarter ended September 30, 2021:

Compound	Indication	Status	Developments
Diabetes			
Empagliflozin (Jardiance®)[1]	Heart failure with preserved ejection fraction	Submitted	Granted FDA Breakthrough Therapy designation[2] and FDA Fast Track designation[3]. Submitted in the U.S. and Europe in 2021 and in Japan in January 2022. The FDA granted priority review for adults with heart failure independent of left ventricular ejection fraction.
	Chronic kidney disease	Phase III	Granted FDA Fast Track designation[3]. Phase III trials are ongoing.
Immunology			
Baricitinib (Olumiant®)	COVID-19	Emergency Use Authorization[4]	Submitted in the U.S. and the FDA granted priority review in January 2022.
	Alopecia areata	Submitted	Granted FDA Breakthrough Therapy designation[2]. Submitted in U.S., Europe and Japan in 2021.
	Systemic lupus erythematosus	Discontinued	Announced in January 2022 that, based on top-line efficacy results from Phase III trials, we discontinued development.
Oncology			
Abemaciclib (Verzenio®)	HR+, HER2- Adjuvant breast cancer	Approved	Approved in the U.S. and Japan in the fourth quarter of 2021.
	Prostate cancer	Phase III	Phase III trial is ongoing.
	HR+, HER2+ Adjuvant breast cancer	Discontinued	Announced in January 2022 that we will discontinue the Phase III trial in response to the changing treatment landscape and global enrollment challenges.

[1] In collaboration with Boehringer Ingelheim.

[2] 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] Fast Track designation is designed to expedite the development and review of new therapies to treat serious conditions and address unmet medical needs.

[4] The FDA granted EUA for treatment with or without remdesivir in hospitalized COVID-19 patients.

There are many difficulties and uncertainties inherent in pharmaceutical research and development and the introduction of new products, as well as 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, label changes, 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 establish high hurdles for the efficacy and safety of new products and indications. 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 and indications.

We manage research and development spending across our portfolio of potential new medicines. 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 any 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

Patent Matters

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

In 2021, our vitamin regimen patents for Alimta® expired worldwide. Following the loss of patent exclusivity in major European countries and Japan, we faced, and remain exposed to, generic competition which has eroded revenue and is likely to continue to rapidly and severely erode revenue from current levels. In the U.S., we expect pediatric data exclusivity to provide us with protection through May 2022. However, we and Eagle Pharmaceuticals, Inc. (Eagle) reached an agreement in December 2019 to settle all pending U.S. patent litigation, allowing Eagle a limited initial entry into the market with its product starting February 2022 (up to an approximate three-week supply) and subsequent unlimited entry starting April 2022. We expect that the entry of generic competition in the U.S. following the loss of exclusivity will cause a rapid and severe decline in revenue and will have a material adverse effect on our consolidated results of operations and cash flows. See Note 16 to the consolidated financial statements for a more detailed account of the legal proceedings currently pending regarding, among others, our Alimta patents.

Our compound patent for Humalog® (insulin lispro) has expired in major markets. Global regulators have different legal pathways to approve similar versions of insulin lispro. A competitor has similar version of insulin lispro in the U.S. and in certain European markets. While it is difficult to estimate the severity of the impact of insulin lispro products entering the market, we do not expect and have not experienced a rapid and severe decline in revenue; however, we expect additional pricing pressure and some loss of market share that may continue over time.

Our formulation and use patents for Forteo® have expired in major markets. We expect further decline in revenue as a result of the entry of generic and biosimilar competition due to the loss of patent exclusivity in major markets.

Our regulatory data and patent exclusivity for Cymbalta® expired in Japan. Beginning in mid-2021, we have faced, and remain exposed to, generic competition which has eroded revenue and is likely to continue to rapidly and severely erode revenue from current levels.

Foreign Currency Exchange Rates

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

Trends Affecting Pharmaceutical Pricing, Reimbursement, and Access

Global concern over access to and affordability of pharmaceutical products continues to drive regulatory and legislative debate, as well as worldwide cost containment efforts by governmental authorities. Such measures may include the use of mandated discounts, price reporting requirements, mandated reference prices, restrictive formularies, changes to available intellectual property protections, as well as other efforts. In addition, consolidation of private payors in the U.S. has significantly impacted the market for pharmaceuticals by increasing payor leverage in negotiating manufacturer price concessions and pharmacy reimbursement rates. Furthermore, restrictive or unfavorable pricing, coverage, or reimbursement determinations for our medicines or product candidates by governments, regulatory agencies, or private payers, such as the recently proposed Alzheimer's Monoclonal Antibody national coverage determination, may adversely impact our business and financial results. We expect that these actions may intensify and could particularly affect certain products, such as insulin, as governments manage and emerge from the COVID-19 pandemic, which could adversely affect our business. In addition, we are engaged in litigation and investigations related to our 340B program that, if resolved adversely to us, could negatively impact our business and consolidated results of operations. It is not currently possible to predict the overall potential adverse impact to us or the general pharmaceutical industry of continued cost containment efforts worldwide.

In addition, evolving regulatory priorities have intensified governmental scrutiny of our operations and our industry, including with respect to current Good Manufacturing Practices, quality assurance, and similar regulations, and increased focus on business combinations in our industry. Any regulatory issues concerning these matters could lead to regulatory and legal actions, product recalls and seizures, fines and penalties, interruption of production leading to product shortages, import bans or denials of import certifications, delays or denials in the approvals of new products or supplemental approvals of current products pending resolution of the issues, impediments to the completion of business combinations, and reputational harm, any of which would adversely affect our business.

See Item 1, "Business - Regulations and Private Payer Actions Affecting Pharmaceutical Pricing, Reimbursement, and Access" and Note 16 to the consolidated financial statements for additional information.

Tax Matters

We are subject to income taxes and various other taxes in the U.S. and in many foreign jurisdictions; therefore, changes in both domestic and international tax laws or regulations have affected and may affect our effective tax rate, results of operations, and cash flows. In 2017, the U.S. enacted the Tax Cuts and Jobs Act (the 2017 Tax Act), which contains a provision that requires capitalization and amortization of research and development expenses for tax purposes starting in 2022. Previously, these expenses could be deducted in the year incurred. While this provision of the 2017 Tax Act is expected to have an immaterial impact on our consolidated results of operations, if it is not deferred or repealed by Congress, we expect that the implementation of this provision will increase our cash payments of income taxes by up to $1.50 billion in 2022 and subsequently decrease our cash payments of income taxes moderately over the five-year amortization period.

The U.S. and countries around the world are actively considering and enacting tax law changes. Tax proposals introduced by Congress and the U.S. presidential administration contain significant changes, including increases to the tax rates at which both domestic and foreign income of U.S. companies would be taxed. In addition, tax authorities in the U.S. and other jurisdictions in which we do business routinely examine our tax returns and are intensifying their scrutiny and examinations of profit allocations among jurisdictions, which could adversely impact our future consolidated results of operations and cash flows. Further, actions taken with respect to tax-related matters by associations such as the Organisation for Economic Co-operation and Development and the European Commission could influence tax laws in countries in which we operate.

Acquisitions

We opportunistically invest in external research and technologies that we believe complement and strengthen our own efforts. These investments can take many forms, including acquisitions, collaborations, investments, and licensing arrangements. We view our business development activity as a way to enhance our pipeline and strengthen our business.

In January 2021, we acquired all shares of Prevail for a purchase price that included $22.50 per share in cash (or an aggregate of $747.4 million, net of cash acquired) plus one non-tradable contingent value right (CVR) per share. The CVR entitles Prevail stockholders up to an additional $4.00 per share in cash (or an aggregate of approximately $160 million) payable, subject to certain terms and conditions, upon the first regulatory approval of a Prevail product in one of the following countries: U.S., Japan, United Kingdom, Germany, France, Italy, or Spain. Under the terms of the agreement, we acquired potentially disease-modifying AAV9-based gene therapies for patients with neurodegenerative diseases. The acquisition establishes a new modality for drug discovery and development, extending our research efforts through the creation of a gene therapy program that is being anchored by Prevail's portfolio of assets.

In February 2020, we acquired all shares of Dermira, Inc. for a purchase price of $849.3 million, net of cash acquired. Under the terms of the agreement, we acquired lebrikizumab, a novel, investigational, monoclonal antibody being evaluated for the treatment of moderate-to-severe atopic dermatitis. Lebrikizumab was granted Fast Track designation from the FDA. We also acquired Qbrexza cloth, a medicated cloth for the topical treatment of primary axillary hyperhidrosis (uncontrolled excessive underarm sweating). In 2021, we sold the rights to Qbrexza. See Note 5 to the consolidated financial statements for additional information regarding the sale of the rights to Qbrexza.

In February 2019, we acquired all shares of Loxo for a purchase price of $6.92 billion, net of cash acquired. Under the terms of the agreement, we acquired a pipeline of investigational medicines, including selpercatinib, an oral RET inhibitor, and LOXO-305 (pirtobrutinib), an oral BTK inhibitor. In the second quarter of 2020, the FDA approved selpercatinib (Retevmo) under its Accelerated Approval regulations and continued approval may be contingent upon verification and description of clinical benefit in confirmatory trials.

See Note 3 to the consolidated financial statements for additional information regarding our recent acquisitions.

Operating Results—2021

Revenue

The following table summarizes our revenue activity by region:

	Year Ended December 31,		
	2021	2020	Percent Change
U.S.	**$ 16,811.0**	$ 14,229.3	18
Outside U.S.	**11,507.4**	10,310.5	12
Revenue	**$ 28,318.4**	$ 24,539.8	15

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

	2021 vs. 2020		
	U.S.	Outside U.S.	Consolidated
Volume	19 %	13 %	16 %
Price	(1)%	(4)%	(2)%
Foreign exchange rates	— %	3 %	1 %
Percent change	18 %	12 %	15 %

Numbers may not add due to rounding.

In the U.S the increase in volume in 2021 was primarily driven by COVID-19 antibodies, Trulicity®, and Taltz®.

Outside the U.S. the increase in volume in 2021 was primarily driven by Trulicity, Olumiant, COVID-19 antibodies, Verzenio, and Taltz. The decrease in realized prices outside the U.S. was primarily driven by the price impact of the updated National Reimbursement Drug List formulary for certain products, largely Tyvyt®, in China.

The following table summarizes our revenue activity in 2021 compared with 2020:

	Year Ended December 31,				
	2021			2020	
Product	U.S.	Outside U.S.	Total	Total	Percent Change
Trulicity	**$ 4,914.4**	**$ 1,557.6**	**$ 6,471.9**	$ 5,068.1	28
Humalog[(1)]	**1,320.7**	**1,132.3**	**2,453.0**	2,625.9	(7)
COVID-19 antibodies[(2)]	**1,978.0**	**261.4**	**2,239.3**	871.2	NM
Taltz	**1,542.4**	**670.4**	**2,212.8**	1,788.5	24
Alimta	**1,233.9**	**827.5**	**2,061.4**	2,329.9	(12)
Jardiance[(3)]	**807.3**	**683.5**	**1,490.8**	1,153.8	29
Verzenio	**834.9**	**515.0**	**1,349.9**	912.7	48
Humulin®	**832.9**	**389.6**	**1,222.6**	1,259.6	(3)
Olumiant[(4)]	**324.1**	**791.0**	**1,115.1**	638.9	75
Cyramza®	**358.1**	**674.8**	**1,033.0**	1,032.6	—
Basaglar®	**588.3**	**304.2**	**892.5**	1,124.4	(21)
Forteo	**441.6**	**360.3**	**801.9**	1,046.3	(23)
Cialis®	**10.6**	**707.9**	**718.4**	607.1	18
Cymbalta	**38.7**	**542.8**	**581.5**	767.7	(24)
Emgality®	**434.5**	**142.7**	**577.2**	362.9	59
Erbitux®	**481.8**	**66.4**	**548.3**	536.4	2
Zyprexa®	**39.6**	**390.7**	**430.3**	406.5	6
Tyvyt	**—**	**418.1**	**418.1**	308.7	35
Trajenta®[(5)]	**82.1**	**290.4**	**372.5**	358.5	4
Other products	**547.1**	**780.8**	**1,327.9**	1,340.1	(1)
Revenue	**$ 16,811.0**	**$ 11,507.4**	**$ 28,318.4**	$ 24,539.8	15

Numbers may not add due to rounding.

NM - Not meaningful

(1) Humalog revenue includes insulin lispro.

(2) COVID-19 antibodies include sales for bamlanivimab administered alone as well as sales for bamlanivimab and etesevimab administered together and were made pursuant to EUAs or similar regulatory authorizations.

(3) Jardiance revenue includes Glyxambi®, Synjardy®, and Trijardy® XR.

(4) Olumiant revenue includes sales for baricitinib, for treatment in hospitalized COVID-19 patients, that were made pursuant to EUA or similar regulatory authorizations.

(5) Trajenta revenue includes Jentadueto®.

Revenue of Trulicity, a treatment for type 2 diabetes and to reduce the risk of major adverse cardiovascular events in adult patients with type 2 diabetes and established cardiovascular disease or multiple cardiovascular risk factors, increased 28 percent in the U.S., driven by increased demand. Revenue outside the U.S. increased 26 percent, 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, an injectable human insulin analog for the treatment of diabetes, decreased 11 percent in the U.S., primarily driven by lower realized prices. Humalog's lower realized prices in the U.S. in 2021 were driven by higher contracted rebates and discounts and increased utilization in more highly-rebated government segments, partially offset by lower utilization in the 340B segment. Revenue outside the U.S. decreased 1 percent, driven by decreased volume and, to a lesser extent, lower realized prices, largely offset by the favorable impact of foreign exchange rates. Included in the revenue of Humalog in the U.S. are our own insulin lispro authorized generics. While it is difficult to estimate the severity of the impact of similar insulin lispro products entering the market, we do not expect and have not experienced a rapid and severe decline in revenue. However, due to the impact of competition and due to pricing pressure in

the U.S. and some international markets, we expect some price decline and loss of market share to continue over time.

Revenue of COVID-19 antibodies, treatments for mild to moderate COVID-19 for higher-risk patients and for post-exposure prophylaxis in certain individuals for the prevention of SARS-CoV-2 infection, was $1.98 billion in the U.S. during the year ended December 31, 2021. Revenue outside the U.S. was $261.4 million during the year ended December 31, 2021. The availability of superior or competitive therapies, including therapies that can be administered more easily, or preventative measures, such as vaccines, coupled with the unpredictable nature of pandemics, have and could further negatively impact or eliminate demand for these COVID-19 antibodies. The FDA has revised, and may in the future revise, any EUA for our COVID-19 antibodies in response to the prevalence of variants against which our antibodies have varying degrees of efficacy. We expect that additional revenue from the sale of bamlanivimab and etesevimab after the first quarter of 2022 will be limited.

Revenue of Taltz, a treatment for moderate-to-severe plaque psoriasis, active psoriatic arthritis, ankylosing spondylitis, and active non-radiographic axial spondyloarthritis, increased 20 percent in the U.S., driven by increased demand, partially offset by lower realized prices due to increased rebates to gain commercial access. Revenue outside the U.S. increased 34 percent, primarily driven by increased volume.

Revenue of Alimta, a treatment for various cancers, decreased 2 percent in the U.S., driven by decreased volume, partially offset by higher realized prices. Revenue outside the U.S. decreased 22 percent, primarily driven by decreased volume due to the entry of generic competition in certain markets and, to a lesser extent, lower realized prices, partially offset by the favorable impact of foreign exchange rates. Following the loss of exclusivity in major European countries and Japan in June 2021, we faced, and remain exposed to, generic competition which has eroded revenue and is likely to continue to rapidly and severely erode revenue from current levels. In the U.S., we expect the limited entry of generic competition starting February 2022 and subsequent unlimited entry starting April 2022. We expect that the entry of generic competition following the loss of exclusivity in the U.S. will cause a rapid and severe decline in revenue. See "Executive Overview - Other Matters- Patent Matters" for additional information.

Revenue of Jardiance, a treatment for type 2 diabetes, to reduce the risk of cardiovascular death in adult patients with type 2 diabetes and established cardiovascular disease, and to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure and reduced ejection fraction, increased 30 percent in the U.S., primarily driven by increased demand. Revenue outside the U.S. increased 28 percent, primarily driven by increased volume. See Note 4 to the consolidated financial statements for information regarding our collaboration with Boehringer Ingelheim involving Jardiance.

Revenue of Verzenio, a treatment for HR+, HER2- metastatic breast cancer and high risk early breast cancer, increased 35 percent in the U.S., driven by increased demand. Revenue outside the U.S. increased 75 percent, driven by increased volume.

Revenue of Humulin, an injectable human insulin for the treatment of diabetes, decreased 4 percent in the U.S., driven by decreased demand and, to a lesser extent, lower realized prices. Revenue outside the U.S. decreased 1 percent, driven by decreased volume, largely offset by higher realized prices and the favorable impact of foreign exchange rates.

Revenue of Olumiant, a treatment for adults with moderately-to-severely active rheumatoid arthritis, moderate to severe atopic dermatitis, and of baricitinib, a treatment, with or without remdesivir, of hospitalized patients with COVID-19, increased $260.3 million in the U.S., driven by increased volume and, to a lesser extent, higher realized prices. Revenue outside the U.S. increased 38 percent, driven by increased volume and, to a lesser extent, the favorable impact of foreign exchange rates, partially offset by lower realized prices. Increased volume worldwide was partially driven by utilization of Olumiant for the treatment of hospitalized patients with COVID-19.

Revenue of Cyramza, a treatment for various cancers, decreased 6 percent in the U.S., driven by decreased demand, partially offset by higher realized prices. Revenue outside the U.S. increased 4 percent, driven by increased volume, partially offset by lower realized prices.

Gross Margin, Costs, and Expenses

Gross margin as a percent of revenue was 74.2 percent in 2021, a decrease of 3.5 percentage points compared with 2020, driven by higher sales of COVID-19 antibodies.

Research and development expenses increased 15 percent to $7.03 billion in 2021, primarily driven by higher development expenses for late-stage assets.

Marketing, selling, and administrative expenses increased 5 percent to $6.43 billion in 2021, primarily due to increased marketing costs to continue to drive growth for certain products, investment in preparation for new launches, and lower marketing activities in 2020 as a result of pandemic-related spending reductions.

We recognized acquired IPR&D charges of $874.9 million and $660.4 million in 2021 and 2020, respectively, related to business development transactions. See Note 3 to the consolidated financial statements for additional information.

We recognized asset impairment, restructuring, and other special charges of $316.1 million in 2021. The charges were primarily related to an impairment of a contract-based intangible asset from our acquisition of Loxo, an intangible asset impairment resulting from the sale of the rights to Qbrexza, as well as acquisition and integration costs associated with the acquisition of Prevail. In 2020, we recognized $131.2 million of asset impairment, restructuring, and other special charges primarily related to severance costs incurred as a result of actions taken worldwide to reduce our cost structure.

Other—net, (income) expense was expense of $201.6 million in 2021 compared to income of $1.17 billion in 2020, primarily driven by lower net investment gains on equity securities and a debt extinguishment loss of $405.2 million related to the repurchase of debt.

Our effective tax rate was 9.3 percent in 2021, compared with an effective tax rate of 14.3 percent in 2020, primarily driven by the tax impacts of acquired IPR&D charges, lower net investment gains on equity securities, as well as a net discrete tax benefit.

Operating Results—2020

For a discussion of our results of operations pertaining to 2020 and 2019 see Item 7, "Management's Discussion and Analysis of Results of Operations and Financial Condition" in our Annual Report on Form 10-K for the year ended December 31, 2020.

FINANCIAL CONDITION AND LIQUIDITY

We believe our available cash and cash equivalents, together with our ability to generate operating cash flow and our access to short-term and long-term borrowings, are sufficient to fund our existing and planned capital requirements, which include:

- working capital requirements, including related to employee payroll, clinical trials, manufacturing materials, and taxes;
- capital expenditures;
- share repurchases and dividends;
- repayment of outstanding short-term and long-term borrowings;
- contributions to our defined benefit pension and retiree health benefit plans;
- milestone and royalty payments; and
- potential business development activities, including acquisitions, collaborations, investments, and licensing arrangements.

Our management continuously evaluates our liquidity and capital resources, including our access to external capital, to ensure we can adequately and efficiently finance our capital requirements. As of December 31, 2021, our material cash requirements primarily related to purchases of goods and services to produce our products and conduct our operations, capital equipment expenditures, dividends, repayment of outstanding borrowings, milestone and royalty payments, the remaining obligations for the one-time repatriation transition tax (also known as the 'Toll Tax') from the 2017 Tax Act, leases, unfunded commitments to invest in venture capital funds, and retirement benefits (see Notes 11, 4, 14, 10, 7, and 15 to the consolidated financial statements). We anticipate our cash requirements related to ordinary course purchases of goods and services and capital equipment expenditures will be consistent with our past levels relative to revenues.

Beginning in 2022, the 2017 Tax Act contains a provision that requires us to capitalize and amortize research and development expenses for tax purposes, whereas previously we could fully deduct these expenses in the year incurred. While this provision of the 2017 Tax Act is expected to have an immaterial impact on our consolidated results of operations, if it is not deferred or repealed by Congress, we expect that the implementation of this provision will increase our cash payments of income taxes by up to $1.50 billion in 2022 and subsequently decrease our cash payments of income taxes moderately over the five-year amortization period. See "Results of Operations - Executive Overview - Other Matters -Tax Matters" for additional information.

We plan to invest more than $1 billion over several years in a new facility in Concord, North Carolina to manufacture parenteral (injectable) products and devices. We plan to invest more than 400 million euros over several years in a new facility in Limerick, Ireland to expand our manufacturing network for biologic active ingredients.

Cash and cash equivalents increased to $3.82 billion as of December 31, 2021, compared with $3.66 billion at December 31, 2020. Net cash provided by operating activities was $7.26 billion in 2021, compared with $6.50 billion in 2020. Refer to the consolidated statements of cash flows for additional information on the significant sources and uses of cash for the years ended December 31, 2021 and 2020.

In addition to our cash and cash equivalents, we held total investments of $3.30 billion and $2.99 billion as of December 31, 2021 and 2020, respectively. See Note 7 to the consolidated financial statements for additional information.

In January 2021, we acquired all shares of Prevail for a purchase price that included $22.50 per share in cash (or an aggregate of $747.4 million, net of cash acquired) plus one non-tradable CVR per share. The CVR entitles Prevail stockholders up to an additional $4.00 per share in cash (or an aggregate of approximately $160 million) payable, subject to certain terms and conditions. This acquisition was funded primarily through cash on hand. See Note 3 to the consolidated financial statements for additional information.

As of December 31, 2021, total debt was $16.88 billion, an increase of $289.4 million compared with $16.60 billion at December 31, 2020. In September 2021, we issued euro-denominated notes consisting of €500.0 million of 1.125 percent fixed-rate notes due in September 2051 and €700.0 million of 1.375 percent fixed-rate notes due in September 2061, with interest to be paid annually, and British pound-denominated notes consisting of £250.0 million of 1.625 percent fixed-rate notes due in September 2043, with interest to be paid annually. We paid $1.91 billion of the net cash proceeds from the offering to purchase and redeem certain higher interest rate U.S. dollar-denominated notes with an aggregate principal amount of $1.50 billion. We used the remaining net proceeds from the offering to prefund certain 2022 debt maturities and for general corporate purposes. In addition, in September 2021, we issued euro-denominated notes consisting of €600.0 million of 0.50 percent fixed-rate notes due in September 2033, with interest to be paid annually. The net proceeds from the offering will be used to fund, in whole or in part, eligible projects designed to advance one or more of our environmental, social, and governance objectives. See Note 11 to the consolidated financial statements for additional information.

As of December 31, 2021, we had a total of $5.26 billion of unused committed bank credit facilities, $5.00 billion of which is available to support our commercial paper program. See Note 11 to the consolidated financial statements for additional information. We believe that amounts accessible through existing commercial paper markets should be adequate to fund any short-term borrowing needs.

For the 136th consecutive year, we distributed dividends to our shareholders. Dividends of $3.40 per share and $2.96 per share were paid in 2021 and 2020, respectively. In the fourth quarter of 2021, effective for the dividend to be paid in the first quarter of 2022, the quarterly dividend was increased to $0.98 per share, resulting in an indicated annual rate for 2022 of $3.92 per share.

Capital expenditures of $1.31 billion during 2021, compared to $1.39 billion in 2020.

In 2021, we repurchased $1.00 billion of shares, which completed our $8.00 billion share repurchase program authorized in June 2018. Additionally, our board authorized a $5.00 billion share repurchase program in May 2021. In 2021, we repurchased $250.0 million of shares under the $5.00 billion share repurchase program. As of December 31, 2021, we had $4.75 billion remaining under the $5.00 billion share repurchase program. See Note 13 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.

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, currency values, and fair values of equity securities. 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 this risk management program 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. As of December 31, 2021, substantially all of our total long-term debt carries interest at a fixed rate. We have converted approximately 13 percent of our long-term fixed-rate notes to floating rates through the use of interest rate swaps. Based on our overall interest rate exposure at December 31, 2021 and 2020, 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, 2021 and 2020, 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, Japanese yen, and Chinese yuan. 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 (primarily the euro, the Japanese yen, and Chinese yuan). 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, 2021 and 2020, 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.

Our fair value risk exposure relates primarily to our public equity investments and to equity investments that do not have readily determinable fair values. As of December 31, 2021 and 2020, our carrying values of these investments were $1.83 billion and $2.04 billion, respectively. A hypothetical 20 percent change in fair value of the equity instruments would have impacted other-net, (income) expense by $365.6 million and $407.6 million as of December 31, 2021 and 2020, respectively.

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 product in the event that regulatory approval for marketing is obtained.

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 expense or aggregate milestone payments made could be material to our results of operations or cash flows, respectively, in that period. See Note 4 to the consolidated financial statements for additional information. 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.

APPLICATION OF CRITICAL ACCOUNTING ESTIMATES

In preparing our financial statements in accordance with accounting principles generally accepted in the U.S., 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. For product sales to customers, provisions for returns, rebates and discounts are established in the same period the related product sales are recognized. To determine the appropriate transaction price for our product sales at the time we recognize a sale to a direct customer, we 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 largest of our sales rebate and discount amounts are rebates associated with sales covered by managed care, Medicare, Medicaid, chargeback, and patient assistance programs in the U.S. In determining the appropriate accrual amount, we consider our historical rebate payments for these programs by product as a percentage of our historical sales as well as any significant changes in sales trends (e.g., patent expiries and product launches), an evaluation of the current contracts for these programs, the percentage of our products that are sold via these programs, and our product pricing.

Refer to Note 2 to the consolidated financial statements for further information on revenue recognition and sales return, rebate, and discount accruals.

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.

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 rebate and discount liabilities are included in sales rebates and discounts on our consolidated balance sheet. Our sales return liability is included in other current liabilities and other noncurrent liabilities on our consolidated balance sheet. As of December 31, 2021, a 5 percent change in our consolidated sales return, rebate, and discount liability would have led to an approximate $366 million effect on our income before income taxes.

The portion of our consolidated sales return, rebate, and discount liability resulting from sales of our products in the U.S. was approximately 90 percent as of December 31, 2021 and 2020.

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

(Dollars in millions)	2021	2020
Sales return, rebate, and discount liabilities, beginning of year	**$ 5,400.0**	$ 4,635.5
Reduction of net sales[(1)]	**20,106.3**	18,668.4
Cash payments	**(19,344.7)**	(17,903.9)
Sales return, rebate, and discount liabilities, end of year	**$ 6,161.6**	$ 5,400.0

[(1)] Adjustments of the estimates for these returns, rebates, and discounts to actual results were less than 1 percent of consolidated revenue for each of the years presented.

Litigation Liabilities and Other Contingencies

Background and Uncertainties

Litigation liabilities and other contingencies are, by their nature, uncertain and based upon complex judgments and probabilities. The factors we consider in developing our 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, as applicable, and the likelihood of settlement and current state of settlement discussions, if any. In addition, we accrue for certain 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 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 litigation liability insurance, we are self-insured for litigation liability losses for all our currently marketed products. In addition to insurance coverage, we 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.

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. See 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 estimates and assumptions that are deemed reasonable by management. Significant estimates and assumptions include, but are not limited to, probability of technical success, revenue growth and discount rate. 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.

The fair value of any contingent consideration liability that results from a business combination is primarily determined using a discounted cash flow analysis, as described in Note 7 to the consolidated financial statements. Estimating the fair value of contingent consideration requires the use of significant estimates and judgments, including, but not limited to, probability of technical success and the discount rate.

Financial Statement Impact

As of December 31, 2021, a 5 percent change in the contingent consideration liability would result in a change in income before income taxes of $3.5 million.

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, or more frequently if impairment indicators are present, by first assessing qualitative factors to determine whether it is more likely than not that the fair value of the intangible asset is less than its carrying amount. If we conclude it is more likely than not that the fair value is less than the carrying amount, a quantitative test that compares the fair value of the intangible asset to its carrying value 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 15 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 75 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.

Annually, we determine the fair value of the plan assets in our defined benefit pension and retiree health benefit plans. Approximately 38 percent of our plan assets are in hedge funds and private equity-like investment funds (collectively, alternative assets). We value these alternative investments using significant unobservable inputs or using the net asset value reported by the counterparty, adjusted as necessary. Inputs include underlying net asset values, discounted cash flows valuations, comparable market valuations, and adjustments for currency, credit, liquidity and other risks.

Financial Statement Impact

If the 2021 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 $21.6 million. If the 2021 expected return on plan assets for U.S. plans were to change by a quarter percentage point, income before income taxes would change by $31.5 million. If our assumption regarding the 2021 expected age of future retirees for U.S. plans were adjusted by one year, our income before income taxes would be affected by $51.1 million. The U.S. plans, including Puerto Rico, represent approximately 80 percent of each of the total projected benefit obligation and total plan assets at December 31, 2021.

Adjustments to the fair value of plan assets are not recognized in pension and retiree health benefit expense in the year that the adjustments occur. Such changes are deferred, along with other actuarial gains and losses, and are amortized into expense over the expected remaining service life of employees.

Income Taxes

Background and Uncertainties

We prepare and file tax returns based upon our interpretation of tax laws and regulations, and we record estimates based upon these interpretations. Our tax returns are routinely subject to examination by taxing authorities, which could result in future tax, interest, and penalty assessments. 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 upon 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 changes to existing tax law, the issuance of regulations by 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, tax credits, and other tax carryforwards and carrybacks in certain taxing jurisdictions. In evaluating whether we would more likely than not recover these deferred tax assets, we have not assumed future taxable income 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 to generate future taxable income in these jurisdictions could lead to the reversal of all or a portion of these valuation allowances and a reduction of income tax expense.

Financial Statement Impact

As of December 31, 2021, a 5 percent change in the amount of uncertain tax positions and the valuation allowance would result in a change in net income of $84.9 million and $43.8 million, respectively.

LEGAL AND REGULATORY MATTERS

Information relating to certain legal proceedings can be found in Note 16 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 and Liquidity." That information is incorporated by reference herein.

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	2021	2020	2019
Revenue (Note 2)	**$ 28,318.4**	$ 24,539.8	$ 22,319.5
Costs, expenses, and other:			
Cost of sales	**7,312.8**	5,483.3	4,721.2
Research and development	**7,025.9**	6,085.7	5,595.0
Marketing, selling, and administrative	**6,431.6**	6,121.2	6,213.8
Acquired in-process research and development (Note 3)	**874.9**	660.4	239.6
Asset impairment, restructuring, and other special charges (Note 5)	**316.1**	131.2	575.6
Other—net, (income) expense (Note 18)	**201.6**	(1,171.9)	(291.6)
	22,162.9	17,309.9	17,053.6
Income before income taxes	**6,155.5**	7,229.9	5,265.9
Income taxes (Note 14)	**573.8**	1,036.2	628.0
Net income from continuing operations	**5,581.7**	6,193.7	4,637.9
Net income from discontinued operations (Note 19)	**—**	—	3,680.5
Net income	**$ 5,581.7**	$ 6,193.7	$ 8,318.4
Earnings per share:			
Earnings from continuing operations - basic	**$ 6.15**	$ 6.82	$ 4.98
Earnings from discontinued operations - basic	**—**	—	3.95
Earnings per share - basic	**$ 6.15**	$ 6.82	$ 8.93
Earnings from continuing operations - diluted	**$ 6.12**	$ 6.79	$ 4.96
Earnings from discontinued operations - diluted	**—**	—	3.93
Earnings per share - diluted	**$ 6.12**	$ 6.79	$ 8.89
Shares used in calculation of earnings per share:			
Basic	**906,963**	907,634	931,059
Diluted	**911,681**	912,505	935,684

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	2021	2020	2019
Net income	**$ 5,581.7**	$ 6,193.7	$ 8,318.4
Other comprehensive income (loss) from continuing operations:			
Change in foreign currency translation gains (losses)	**13.5**	122.1	(89.9)
Change in net unrealized gains (losses) on securities	**(15.9)**	14.2	34.4
Change in defined benefit pension and retiree health benefit plans (Note 15)	**2,699.4**	(157.1)	(970.0)
Change in effective portion of cash flow hedges	**151.6**	(152.9)	34.3
Other comprehensive income (loss) from continuing operations before income taxes	**2,848.6**	(173.7)	(991.2)
Benefit (provision) for income taxes related to other comprehensive income (loss) from continuing operations	**(695.3)**	200.9	151.0
Other comprehensive income (loss) from continuing operations, net of tax (Note 17)	**2,153.3**	27.2	(840.2)
Other comprehensive income from discontinued operations, net of tax (Note 17)	**—**	—	56.8
Other comprehensive income (loss), net of tax (Note 17)	**2,153.3**	27.2	(783.4)
Comprehensive income	**$ 7,735.0**	$ 6,220.9	$ 7,535.0

See notes to consolidated financial statements.

Consolidated Balance Sheets

ELI LILLY AND COMPANY AND SUBSIDIARIES

(Dollars in millions, shares in thousands) December 31	2021	2020
Assets		
Current Assets		
Cash and cash equivalents (Note 7)	**$ 3,818.5**	$ 3,657.1
Short-term investments (Note 7)	**90.1**	24.2
Accounts receivable, net of allowances of **$22.5 (2021)** and $25.9 (2020)	**6,672.8**	5,875.3
Other receivables	**1,454.4**	1,053.7
Inventories (Note 6)	**3,886.0**	3,980.3
Prepaid expenses and other	**2,530.6**	2,871.5
Total current assets	**18,452.4**	17,462.1
Investments (Note 7)	**3,212.6**	2,966.8
Goodwill (Note 8)	**3,892.0**	3,766.5
Other intangibles, net (Note 8)	**7,691.9**	7,450.0
Deferred tax assets (Note 14)	**2,489.3**	2,830.4
Property and equipment, net (Note 9)	**8,985.1**	8,681.9
Other noncurrent assets	**4,082.7**	3,475.4
Total assets	**$ 48,806.0**	$ 46,633.1
Liabilities and Equity		
Current Liabilities		
Short-term borrowings and current maturities of long-term debt (Note 11)	**$ 1,538.3**	$ 8.7
Accounts payable	**1,670.6**	1,606.7
Employee compensation	**958.1**	997.2
Sales rebates and discounts	**6,845.8**	5,853.0
Dividends payable	**885.5**	770.6
Income taxes payable (Note 14)	**126.9**	495.1
Other current liabilities	**3,027.5**	2,750.3
Total current liabilities	**15,052.7**	12,481.6
Other Liabilities		
Long-term debt (Note 11)	**15,346.4**	16,586.6
Accrued retirement benefits (Note 15)	**1,954.1**	4,094.5
Long-term income taxes payable (Note 14)	**3,920.0**	3,837.8
Deferred tax liabilities (Note 14)	**1,733.7**	2,099.9
Other noncurrent liabilities	**1,644.3**	1,707.5
Total other liabilities	**24,598.5**	28,326.3
Commitments and Contingencies (Note 16)		
Eli Lilly and Company Shareholders' Equity (Notes 12 and 13)		
Common stock—no par value Authorized shares: 3,200,000 Issued shares: **954,116 (2021)** and 957,077 (2020)	**596.3**	598.2
Additional paid-in capital	**6,833.4**	6,778.5
Retained earnings	**8,958.5**	7,830.2
Employee benefit trust	**(3,013.2)**	(3,013.2)
Accumulated other comprehensive loss (Note 17)	**(4,343.1)**	(6,496.4)
Cost of common stock in treasury	**(52.7)**	(55.7)
Total Eli Lilly and Company shareholders' equity	**8,979.2**	5,641.6
Noncontrolling interests	**175.6**	183.6
Total equity	**9,154.8**	5,825.2
Total liabilities and equity	**$ 48,806.0**	$ 46,633.1

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								
	Common Stock						Common Stock in Treasury		
	Shares	Amount	Additional Paid-in Capital	Retained Earnings	Employee Benefit Trust	Accumulated Other Comprehensive Loss	Shares	Amount	Noncontrolling Interest
Balance at January 1, 2019	1,057,639	$ 661.0	$ 6,583.6	$ 11,395.9	$ (3,013.2)	$ (5,729.2)	604	$ (69.4)	$ 1,080.4
Net income				8,318.4					37.7
Other comprehensive income (loss), net of tax						(794.4)			11.0
Cash dividends declared per share: $2.68				(2,430.5)					
Retirement of treasury shares	(102,640)	(64.1)		(12,363.4)			(102,640)	12,427.5	
Purchase of treasury shares							37,639	(4,400.0)	
Issuance of stock under employee stock plans, net	3,057	1.9	(210.7)				(74)	8.6	
Stock-based compensation			312.4						
Acquisition of common stock in exchange offer							65,001	(8,027.5)	
Deconsolidation of Elanco									(1,028.9)
Other									(8.0)
Balance at December 31, 2019	958,056	598.8	6,685.3	4,920.4	(3,013.2)	(6,523.6)	530	(60.8)	92.2
Net income				6,193.7					126.6
Other comprehensive income, net of tax						27.2			
Cash dividends declared per share: $3.07				(2,786.2)					
Retirement of treasury shares	(3,627)	(2.3)		(497.7)			(3,627)	500.0	
Purchase of treasury shares							3,627	(500.0)	
Issuance of stock under employee stock plans, net	2,648	1.7	(212.7)				(43)	5.1	
Stock-based compensation			308.1						
Other			(2.2)						(35.2)
Balance at December 31, 2020	957,077	598.2	6,778.5	7,830.2	(3,013.2)	(6,496.4)	487	(55.7)	183.6
Net income				**5,581.7**					**3.4**
Other comprehensive income, net of tax						**2,153.3**			
Cash dividends declared per share: $3.53				**(3,201.7)**					
Retirement of treasury shares	**(5,412)**	**(3.4)**		**(1,246.6)**			**(5,412)**	**1,250.0**	
Purchase of treasury shares							**5,412**	**(1,250.0)**	
Issuance of stock under employee stock plans, net	**2,451**	**1.5**	**(287.9)**				**(24)**	**3.0**	
Stock-based compensation			**342.8**						
Other				**(5.1)**					**(11.4)**
Balance at December 31, 2021	**954,116**	**$ 596.3**	**$ 6,833.4**	**$ 8,958.5**	**$ (3,013.2)**	**$ (4,343.1)**	**463**	**$ (52.7)**	**$ 175.6**

See notes to consolidated financial statements.

Consolidated Statements of Cash Flows

ELI LILLY AND COMPANY AND SUBSIDIARIES (Dollars in millions)	Year Ended December 31 2021	2020	2019
Cash Flows from Operating Activities			
Net income	**$ 5,581.7**	$ 6,193.7	$ 8,318.4
Adjustments to Reconcile Net Income to Cash Flows from Operating Activities:			
Gain related to disposition of Elanco (Note 19)	**—**	—	(3,680.5)
Gain on sale of antibiotic business in China (Note 3)	**—**	—	(309.8)
Depreciation and amortization	**1,547.6**	1,323.9	1,232.6
Debt extinguishment loss (Note 11)	**405.2**	—	252.5
Change in deferred income taxes	**(802.3)**	(134.5)	62.4
Stock-based compensation expense	**342.8**	308.1	312.4
Net investment gains	**(178.0)**	(1,438.5)	(403.1)
Acquired in-process research and development (Note 3)	**874.9**	660.4	239.6
Other non-cash operating activities, net	**511.4**	333.9	499.3
Other changes in operating assets and liabilities, net of acquisitions and divestitures:			
Receivables—(increase) decrease	**(1,278.3)**	(1,350.2)	(127.2)
Inventories—(increase) decrease	**(235.9)**	(533.4)	(258.7)
Other assets—(increase) decrease	**1,515.4**	(457.1)	(602.3)
Income taxes payable—increase (decrease)	**(359.7)**	322.0	(221.3)
Accounts payable and other liabilities—increase (decrease)	**(664.1)**	1,271.3	(477.7)
Net Cash Provided by Operating Activities	**7,260.7**	6,499.6	4,836.6
Cash Flows from Investing Activities			
Purchases of property and equipment	**(1,309.8)**	(1,387.9)	(1,033.9)
Proceeds from sales and maturities of short-term investments	**47.4**	129.7	136.6
Purchases of short-term investments	**(83.5)**	(11.4)	(42.7)
Proceeds from sales of noncurrent investments	**800.0**	757.1	609.8
Purchases of noncurrent investments	**(929.9)**	(358.7)	(247.5)
Purchases of in-process research and development	**(563.4)**	(641.2)	(319.6)
Cash paid for acquisitions, net of cash acquired (Note 3)	**(747.4)**	(849.3)	(6,917.7)
Cash distributed to Elanco upon disposition	**—**	—	(374.0)
Cash received for sale of antibiotic business in China	**—**	—	354.8
Other investing activities, net	**24.3**	102.8	(248.7)
Net Cash Used for Investing Activities	**(2,762.3)**	(2,258.9)	(8,082.9)
Cash Flows from Financing Activities			
Dividends paid	**(3,086.8)**	(2,687.1)	(2,409.8)
Net change in short-term borrowings	**(4.0)**	(1,494.2)	995.4
Proceeds from issuance of long-term debt	**2,410.8**	2,062.3	6,556.4
Repayments of long-term debt	**(1,905.4)**	(276.5)	(2,866.4)
Purchases of common stock	**(1,250.0)**	(500.0)	(4,400.0)
Other financing activities, net	**(295.9)**	(241.6)	(200.1)
Net Cash Used for Financing Activities	**(4,131.3)**	(3,137.1)	(2,324.5)
Effect of exchange rate changes on cash and cash equivalents	**(205.7)**	216.0	(89.9)
Net increase (decrease) in cash and cash equivalents	**161.4**	1,319.6	(5,660.7)
Cash and cash equivalents at beginning of year (2019 includes $677.5 of discontinued operations)	**3,657.1**	2,337.5	7,998.2
Cash and Cash Equivalents at End of Year	**$ 3,818.5**	$ 3,657.1	$ 2,337.5

See notes to consolidated financial statements.

Notes to Consolidated Financial Statements

ELI LILLY AND COMPANY AND SUBSIDIARIES
(Tables present dollars in millions, except per-share data)

Note 1: Summary of Significant Accounting Policies and Implementation of New Financial Accounting Standard

Basis of Presentation

The accompanying consolidated financial statements include Eli Lilly and Company and all subsidiaries and have been prepared in accordance with accounting principles generally accepted in the United States (GAAP). We consider majority voting interests, as well as effective economic or other control over an entity when deciding whether or not to consolidate an entity. We generally do not have control by means other than voting interests. 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 this Annual Report on Form 10-K.

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.

On March 11, 2019, we completed the disposition of our remaining 80.2 percent ownership of Elanco Animal Health Incorporated (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.

We 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.

Research and Development Expenses and Acquired In-Process Research and Development (IPR&D)

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 IPR&D expense includes the initial costs of externally developed IPR&D projects, acquired directly in a transaction other than a business combination, that do not have an alternative future use.

Earnings Per Share (EPS)

We calculate basic EPS based on the weighted-average number of common shares outstanding plus the effect of incremental shares from potential participating securities. We calculate diluted EPS based on the

weighted-average number of common shares outstanding plus the effect of incremental shares from our stock-based compensation programs.

Foreign Currency Translation

Operations in our subsidiaries outside the United States (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).

Advertising Expenses

Costs associated with advertising are expensed as incurred and are included in marketing, selling, and administrative expenses. Advertising expenses, comprised primarily of television, radio, print media, and Internet advertising, totaled approximately $1.2 billion, $1.1 billion, and $1.1 billion in 2021, 2020, and 2019, respectively, which was less than 5 percent of revenue each year.

Other Significant Accounting Policies

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

Implementation of New Financial Accounting Standard

Accounting Standards Update 2021-01, *Reference Rate Reform,* provides for temporary optional expedients and exceptions in applying current GAAP to contracts, hedging relationships, and other transactions affected by the transition from the use of the London Interbank Offered Rate (LIBOR) to an alternative reference rate. The standard can be adopted immediately and is applicable to contracts entered into before January 1, 2023. We do not expect the transition from the use of LIBOR to an alternative reference rate to have a material impact to our consolidated statements of operations or balance sheets at the initial transition.

Note 2: Revenue

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

	2021	2020	2019
Net product revenue	**$ 25,957.9**	$ 22,694.8	$ 20,377.3
Collaboration and other revenue[(1)]	**2,360.5**	1,845.0	1,942.2
Revenue	**$ 28,318.4**	$ 24,539.8	$ 22,319.5

(1) Collaboration and other revenue associated with prior period transfers of intellectual property was $175.0 million, $135.6 million, and $301.5 million during the years ended December 31, 2021, 2020, and 2019, 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 Jardiance® and Trajenta® 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, 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.

Most of our products are sold to wholesalers that serve pharmacies, physicians and other health care professionals, and hospitals. For the years ended December 31, 2021, 2020, and 2019, our three largest wholesalers each accounted for between 15 percent and 20 percent of consolidated revenue. Further, they each accounted for between 18 percent and 28 percent of accounts receivable as of December 31, 2021 and 2020.

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

Sales Rebates and Discounts - Background and Uncertainties

- 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, chargeback, and patient assistance programs in the U.S. In determining the appropriate accrual amount, we consider our historical rebate payments for these programs by product as a percentage of our historical sales as well as any significant changes in sales trends (e.g., patent expiries and product launches), an evaluation of the current contracts for these programs, the percentage of our products that are sold via these programs, and our product pricing. Although we accrue a liability for rebates related to these programs at the time we record the sale, the rebate related to that sale is typically paid up to six months later. Because of this time lag, in any particular period our rebate adjustments may incorporate revisions of accruals for several periods.
- Most of our rebates outside the U.S. are contractual or legislatively mandated and are estimated and recognized in the same period as the related sales. In some large European countries, government rebates are based on the anticipated budget for pharmaceutical payments in the country. An estimate of these rebates, updated as governmental authorities revise budgeted deficits, is recognized in the same period as the related sale.

Sales Returns - Background and Uncertainties

- When product sales occur, to determine the appropriate transaction price for our sales, we estimate a reserve for future product returns related to those sales using an expected value approach. This estimate is based on several factors, including: historical return rates, expiration date by product (on average, approximately 24 months after the initial sale of a product to our customer), and estimated levels of inventory in the wholesale and retail channels, as well as any other specifically-identified anticipated returns due to known factors such as the loss of patent exclusivity, product recalls and discontinuances, or a changing competitive environment. We maintain a returns policy that allows most 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 at the 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 U.S. product returns have been less than 2 percent of our U.S. revenue during 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

We record adjustments to revenue as a result of changes in estimates, for the judgments described above, for our most significant U.S. sales returns, rebates and discounts liability balances. Such adjustments for products shipped in previous periods resulted in approximately 2 percent or less increase to U.S revenue during each of the years ended December 31, 2021, 2020, and 2019.

Collaboration 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 and certain of our collaboration partners, 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.

Contract Liabilities

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

The following table summarizes contract liability balances:

	2021	2020
Contract liabilities	**$ 262.6**	$ 276.8

The contract liabilities balances disclosed above as of December 31, 2021 and 2020 were primarily related to the remaining license period of symbolic intellectual property and obligations to perform research and development activities or supply product for a defined period of time.

During the years ended December 31, 2021, 2020, and 2019, revenue recognized from contract liabilities as of the beginning of the respective year 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.

Disaggregation of Revenue

The following table summarizes revenue by product:

	U.S.			Outside U.S.		
	2021	2020	2019	2021	2020	2019
Revenue—to unaffiliated customers:						
Diabetes:						
Trulicity®	**$ 4,914.4**	$ 3,835.9	$ 3,155.2	**$ 1,557.6**	$ 1,232.2	$ 972.7
Humalog® (1)	**1,320.7**	1,485.6	1,669.7	**1,132.3**	1,140.3	1,151.0
Jardiance (2)	**807.3**	620.8	565.9	**683.5**	533.0	378.3
Humulin®	**832.9**	866.4	879.7	**389.6**	393.2	410.4
Basaglar®	**588.3**	842.3	876.2	**304.2**	282.1	236.3
Trajenta (3)	**82.1**	95.6	224.8	**290.4**	263.0	365.8
Other Diabetes	**173.6**	162.5	158.0	**111.2**	81.5	88.1
Total Diabetes	**8,719.3**	7,909.1	7,529.5	**4,468.8**	3,925.3	3,602.6
Oncology:						
Alimta®	**1,233.9**	1,265.3	1,219.5	**827.5**	1,064.7	896.4
Verzenio®	**834.9**	618.2	454.8	**515.0**	294.4	124.9
Cyramza®	**358.1**	381.9	335.3	**674.8**	650.8	589.9
Erbitux®	**481.8**	480.1	487.9	**66.4**	56.3	55.4
Tyvyt®	**—**	—	—	**418.1**	308.7	134.0
Other Oncology	**120.1**	46.6	111.0	**210.7**	152.3	205.3
Total Oncology	**3,028.8**	2,792.1	2,608.5	**2,712.5**	2,527.2	2,005.9
Immunology:						
Taltz®	**1,542.4**	1,288.5	1,016.8	**670.4**	500.0	349.6
Olumiant® (4)	**324.1**	63.8	42.2	**791.0**	575.0	384.7
Other Immunology	**15.3**	20.0	—	**17.6**	14.6	—
Total Immunology	**1,881.8**	1,372.3	1,059.0	**1,479.0**	1,089.6	734.3
Neuroscience:						
Cymbalta®	**38.7**	42.1	49.6	**542.8**	725.6	675.8
Emgality®	**434.5**	325.9	154.9	**142.7**	37.0	7.7
Zyprexa®	**39.6**	46.1	41.0	**390.7**	360.5	377.6
Other Neuroscience	**102.0**	73.2	111.0	**207.5**	220.9	305.3
Total Neuroscience	**614.8**	487.3	356.5	**1,283.7**	1,344.0	1,366.4
Other:						
COVID-19 Antibodies (5)	**1,978.0**	850.0	—	**261.4**	21.2	—
Forteo®	**441.6**	510.3	645.5	**360.3**	536.0	759.1
Cialis®	**10.6**	61.8	231.7	**707.9**	545.4	658.8
Other	**136.1**	246.4	291.9	**233.9**	321.8	469.7
Total Other	**2,566.4**	1,668.4	1,169.1	**1,563.5**	1,424.4	1,887.7
Revenue	**$ 16,811.0**	$ 14,229.3	$ 12,722.6	**$ 11,507.4**	$ 10,310.5	$ 9,596.8

Numbers may not add due to rounding.

(1) Humalog revenue includes insulin lispro.

(2) Jardiance revenue includes Glyxambi®, Synjardy®, and Trijardy® XR.

(3) Trajenta revenue includes Jentadueto®.

(4) Olumiant revenue includes sales for baricitinib, for treatment in hospitalized COVID-19 patients, that were made pursuant to Emergency Use Authorization (EUA) or similar regulatory authorizations.

(5) COVID-19 antibodies include sales for bamlanivimab administered alone as well as sales for bamlanivimab and etesevimab administered together and were made pursuant to EUAs or similar regulatory authorizations.

The following table summarizes revenue by geographical area:

	2021	2020	2019
Revenue—to unaffiliated customers[(1)]:			
U.S.	**$ 16,811.0**	$ 14,229.3	$ 12,722.6
Europe	**4,776.8**	4,187.7	3,765.0
Japan	**2,367.0**	2,583.1	2,547.6
China	**1,661.4**	1,116.9	939.4
Other foreign countries	**2,702.2**	2,422.7	2,344.9
Revenue	**$ 28,318.4**	$ 24,539.8	$ 22,319.5

Numbers may not add due to rounding.
(1) Revenue is attributed to the countries based on the location of the customer.

Note 3: Acquisitions and Divestiture

In January 2021, February 2020 and 2019, we completed the acquisitions of Prevail Therapeutics Inc. (Prevail), Dermira, Inc. (Dermira) and Loxo Oncology, Inc. (Loxo), respectively. These transactions, as further discussed in this note below in Acquisitions of Businesses, were accounted for as business combinations under the acquisition method of accounting. Under this method, the assets acquired and liabilities assumed were recorded at their respective fair values as of the acquisition date in our consolidated financial statements. The determination of estimated fair value required management to make significant estimates and assumptions. The excess of the purchase price over the fair value of the acquired net assets, where applicable, has been recorded as goodwill. The results of operations of these acquisitions have been included in our consolidated financial statements from the date of acquisition.

We also acquired assets in development in 2021, 2020, and 2019, which are further discussed in this note below in Asset Acquisitions. Upon each acquisition, the cost allocated to acquired IPR&D was immediately expensed because the compound acquired had no alternative future use. For the years ended December 31, 2021, 2020, and 2019, we recorded acquired IPR&D charges of $874.9 million, $660.4 million, and $239.6 million, respectively.

Acquisitions of Businesses

Prevail Acquisition

Overview of Transaction

In January 2021, we acquired all shares of Prevail for a purchase price that included $22.50 per share in cash (or an aggregate of $747.4 million, net of cash acquired) plus one non-tradable contingent value right (CVR) per share. The CVR entitles Prevail stockholders up to an additional $4.00 per share in cash (or an aggregate of approximately $160 million) payable, subject to certain terms and conditions, upon the first regulatory approval of a Prevail product in one of the following countries: U.S., Japan, United Kingdom, Germany, France, Italy or Spain. To achieve the full value of the CVR, such regulatory approval must occur by December 31, 2024. If such regulatory approval occurs after December 31, 2024, the value of the CVR will be reduced by approximately 8.3 cents per month until December 1, 2028, at which point the CVR will expire without payment.

Under the terms of the agreement, we acquired potentially disease-modifying AAV9-based gene therapies for patients with neurodegenerative diseases. The acquisition establishes a new modality for drug discovery and development, extending our research efforts through the creation of a gene therapy program that is being anchored by Prevail's portfolio of assets. The lead gene therapies in clinical development that we acquired were PR001 for patients with Parkinson's disease with GBA1 mutations and neuronopathic Gaucher disease and PR006 for patients with frontotemporal dementia with GRN mutations. Both PR001 and PR006 were granted Fast Track designation from the U.S. Food and Drug Administration (FDA).

Assets Acquired and Liabilities Assumed

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

Estimated Fair Value at January 22, 2021		
Cash	$	90.5
Acquired IPR&D[(1)]		824.0
Goodwill[(2)]		126.8
Deferred tax liabilities		(106.0)
Other assets and liabilities, net		(31.5)
Acquisition date fair value of consideration transferred		903.8
Less:		
Cash acquired		(90.5)
Fair value of CVR liability[(3)]		(65.9)
Cash paid, net of cash acquired	$	747.4

[(1)] Acquired IPR&D intangibles primarily relate to PR001.

[(2)] The goodwill recognized from this acquisition is not deductible for tax purposes.

[(3)] See Note 7 for a discussion on the estimation of the CVR liability.

We are unable to provide the results of operations for the year ended December 31, 2021 attributable to Prevail as those operations were substantially integrated into our legacy business.

Pro forma information has not been included as this acquisition did not have a material impact on our consolidated statements of operations for the years ended December 31, 2021 and 2020.

Dermira Acquisition

Overview of Transaction

In February 2020, we acquired all shares of Dermira for a purchase price of approximately $849.3 million, net of cash acquired. Under terms of the agreement, we acquired lebrikizumab, a novel, investigational, monoclonal antibody being evaluated for the treatment of moderate-to-severe atopic dermatitis. Lebrikizumab was granted Fast Track designation from the FDA. We also acquired Qbrexza® (glycopyrronium) cloth, a medicated cloth approved by the FDA for the topical treatment of primary axillary hyperhidrosis (uncontrolled excessive underarm sweating). During the year ended December 31, 2021, we sold the rights to Qbrexza. See Note 5 for additional information.

Assets Acquired and Liabilities Assumed

The fair values recognized related to the assets acquired and liabilities assumed in this acquisition included goodwill of $86.8 million, other intangibles of $1.20 billion primarily related to lebrikizumab, deferred income tax liabilities of $49.5 million, and long-term debt of $375.5 million. After the acquisition, we repaid $276.2 million of long-term debt assumed as part of our acquisition of Dermira.

Revenue attributable to assets acquired in the Dermira acquisition did not have a material impact on our consolidated statement of operations for the year ended December 31, 2020. We are unable to provide the results of operations for the year ended December 31, 2020 attributable to Dermira as those operations were substantially integrated into our legacy business.

Pro forma information has not been included because this acquisition did not have a material impact on our consolidated statements of operations for the years ended December 31, 2020 and 2019.

Loxo Acquisition

Overview of Transaction

In February 2019, we acquired all shares of Loxo for a purchase price of $6.92 billion, net of cash acquired. The accelerated vesting of Loxo employee equity awards was recognized as transaction expense included in asset impairment, restructuring, and other special charges during the year ended December 31, 2019 (see Note 5).

Under the terms of the agreement, we acquired a pipeline of investigational medicines, including selpercatinib (LOXO-292), an oral RET inhibitor, and LOXO-305, an oral BTK inhibitor. In the second quarter of 2020, the FDA approved selpercatinib (Retevmo®) under its Accelerated Approval regulations and continued approval may be contingent upon verification and description of clinical benefit in confirmatory trials. At the time of approval, we reclassified our $4.60 billion intangible asset for selpercatinib (Retevmo) from indefinite-lived intangible assets to finite-lived intangible assets and began amortizing straight line over its estimated useful life.

Assets Acquired and Liabilities Assumed

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

Estimated Fair Value at February 15, 2019		
Acquired IPR&D[(1)]	$	4,670.0
Finite-lived intangibles[(2)]		980.0
Deferred income taxes		(1,032.8)
Other assets and liabilities - net		(26.4)
Total identifiable net assets		4,590.8
Goodwill[(3)]		2,326.9
Total consideration transferred - net of cash acquired	$	6,917.7

(1) $4.60 billion of the acquired IPR&D relates to selpercatinib (LOXO-292).

(2) Contract-based intangibles for Vitrakvi and a Phase I molecule which were amortized to cost of sales on a straight-line basis over their estimated useful lives and were expected to have a weighted average useful life of approximately 12 years from the acquisition date. In the fourth quarter of 2021 we impaired the intangible for the Phase I molecule. See Note 5 for additional information.

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

Asset Acquisitions

The following table and narrative summarize our asset acquisitions during 2021, 2020, and 2019.

Counterparty	Compound(s),Therapy, or Asset	Acquisition Month	Phase of Development[1]	Acquired IPR&D Expense
Precision Biosciences, Inc.	Potential in vivo therapies for genetic disorders	January 2021	Pre-clinical	**$ 107.8**
Merus N.V.	CD3-engaging T-cell re-directing bispecific antibodies for the potential treatment of cancer	January 2021	Pre-clinical	**46.5**
Asahi Kasei Pharma Corporation	AK1780, an orally bioavailable P2X7 receptor antagonist for the potential treatment of chronic pain conditions	January 2021	Phase I	**20.0**
Rigel Pharmaceuticals, Inc.	R552, a receptor-interacting serine/threonine-protein kinase 1 (RIPK1) inhibitor, for the potential treatment of autoimmune and inflammatory diseases	March 2021	Phase I	**125.0**
MiNA Therapeutics Limited	Pre-clinical targets that could lead to potential new medicines	May 2021	Pre-clinical	**25.0**
Protomer Technologies Inc.	Glucose-sensing insulin program	July 2021	Pre-clinical	**57.3**

Counterparty	Compound(s),Therapy, or Asset	Acquisition Month	Phase of Development[1]	Acquired IPR&D Expense
Kumquat Biosciences Inc.	Pre-clinical small molecules that stimulate tumor-specific immune responses	July 2021	Pre-clinical	**55.0**
Lycia Therapeutics, Inc.	Several potential modalities across a spectrum of therapeutic areas and diseases	August 2021	Pre-clinical	**35.0**
ProQR Therapeutics N.V.	Pre-clinical targets that could lead to potential new medicines for genetic disorders in the liver and nervous system	September 2021	Pre-clinical	**26.7**
QILU Regor Therapeutics Inc.	Pre-clinical targets that could lead to potential new medicines for metabolic disorders	December 2021	Pre-clinical	**30.0**
Foghorn Therapeutics Inc.	Pre-clinical targets that could lead to potential new oncology medicines	December 2021	Pre-clinical	**316.6**
Entos Pharmaceuticals Inc.	Pre-clinical targets that could lead to potential new nucleic acid-based therapies targeting the central and peripheral nervous system	December 2021	Pre-clinical	**30.0**
Sitryx Therapeutics Limited	Pre-clinical targets that could lead to potential new medicines for autoimmune diseases	March 2020	Pre-clinical	52.3
AbCellera Biologics Inc. (AbCellera)	Neutralizing antibodies for the treatment and prevention of COVID-19	March 2020[2]	Pre-clinical	25.0
Shanghai Junshi Biosciences Co., Ltd. (Junshi Biosciences)	Neutralizing antibodies for the treatment and prevention of COVID-19	May 2020	Pre-clinical	20.0
Petra Pharma Corporation (Petra)	Mutant-selective PI3Kα inhibitor that could lead to potential new medicine	May 2020	Pre-clinical	174.8
Evox Therapeutics Limited	Pre-clinical targets for the potential treatment of neurological disorders	June 2020	Pre-clinical	22.0
Innovent Biologics, Inc. (Innovent)	Sintilimab injection, an anti-PD-1 monoclonal antibody immuno-oncology medicine, for geographies outside of China	October 2020	Phase III	200.0
Disarm Therapeutics, Inc.	Disease-modifying therapeutics program for patients with axonal degeneration	October 2020	Pre-clinical	126.3
Fochon Pharmaceuticals, Ltd.	Pre-clinical molecule targeting hematological malignancies	November 2020	Pre-clinical	40.0

Counterparty	Compound(s),Therapy, or Asset	Acquisition Month	Phase of Development[1]	Acquired IPR&D Expense
AC Immune SA	Tau aggregation inhibitor small molecules for the potential treatment of Alzheimer's disease and other neurodegenerative diseases	January 2019 & September 2019[3]	Pre-clinical	127.1
ImmuNext, Inc.	Novel immunometabolism target	March 2019	Pre-clinical	40.0
Avidity Biosciences, Inc.	Potential new medicines in immunology and other select indications	April 2019	Pre-clinical	25.0
Centrexion Therapeutics Corporation	CNTX-0290, a novel, small molecule somatostatin receptor type 4 agonist	July 2019	Phase I	47.5

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

[2] We recognized acquired IPR&D expense of $25.0 million in May 2020 upon closing of the transaction.

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

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

Divestiture

In October 2019, we completed a transaction in which we sold the rights in China for two legacy antibiotic medicines, as well as a manufacturing facility in Suzhou, China to Eddingpharm, a China-based specialty pharmaceutical company. In connection with the sale, we received net cash proceeds of $354.8 million and $40.3 million from Eddingpharm in 2019 and 2020, respectively. We accounted for the transaction as the sale of a business. We recognized a gain of $309.8 million in other—net, (income) expense in our consolidated statement of operations during the year ended December 31, 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 as well as 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 from or payments to the collaboration partner. See Note 2 for amounts of collaboration and other revenue recognized from these types of arrangements.

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

Boehringer Ingelheim Diabetes Collaboration

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

In connection with the regulatory approvals of Jardiance, Trajenta and Basaglar in the U.S, Europe and Japan, milestone payments made for Jardiance and Trajenta were capitalized as intangible assets and are being amortized to cost of sales, and milestone payments received for Basaglar were recorded as contract liabilities and are being amortized to collaboration and other revenue. These milestones are being amortized through their respective term under the collaboration which, depending on country or region, is determined based on the latest to occur of (a) a defined number of years following launch date, (b) the expiration of the compound patent, or (c) any supplementary protection certificates or extensions thereto. The table below summarizes the net milestones capitalized (deferred) at December 31 for the compounds included in this collaboration:

	Net Milestones Capitalized (Deferred)[1]	
	2021	2020
Jardiance	**$ 136.1**	$ 156.2
Trajenta	**88.5**	114.6
Basaglar	**(149.3)**	(168.0)

[1] This represents the amounts that have been capitalized (deferred) from the start of this collaboration through the end of the reporting period, net of amount amortized.

Through December 31, 2019, in the most significant markets, we and Boehringer Ingelheim shared equally the ongoing development costs, commercialization costs, and agreed upon gross margin for any product resulting from the collaboration. We recorded our portion of the gross margin associated with Boehringer Ingelheim's products as collaboration and other revenue. We recorded 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 recorded our portion of the development and commercialization costs as research and development expense and marketing, selling, and administrative expense, respectively. Each company was entitled to potential performance payments depending on the sales of the molecules it contributes to the collaboration. These performance payments may have resulted 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 have been reduced by any performance payments we made related to these products. Similarly, performance payments we may have received related to Basaglar effectively reduced Boehringer Ingelheim's share of the gross margin, which reduced our cost of sales.

Effective January 1, 2020, we and Boehringer Ingelheim modernized the alliance. For the Jardiance product family, we and Boehringer Ingelheim share equally the ongoing development and commercialization costs in the most significant markets, and we record our portion of the development and commercialization costs as research and development expense and marketing, selling, and administrative expense, respectively. We receive a royalty on net sales of Boehringer Ingelheim's products in the most significant markets and recognize the royalty as collaboration and other revenue. Boehringer Ingelheim is entitled to potential performance payments depending on the net sales of the Jardiance product family; therefore, our reported revenue for Jardiance may be reduced by any potential performance payments we make related to this product family. Beginning January 1, 2021, the royalty received by us related to the Jardiance product family may also be increased or decreased depending on whether net sales for this product family exceed or fall below certain thresholds. We pay to Boehringer Ingelheim a royalty on net sales for Basaglar in the U.S. We record our sales of Basaglar to third parties as net product revenue with the royalty payments made to Boehringer Ingelheim recorded as cost of sales.

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

	2021	2020	2019
Jardiance	**$ 1,490.8**	$ 1,153.8	$ 944.2
Basaglar	**892.5**	1,124.4	1,112.6
Trajenta	**372.5**	358.5	590.6

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 (baricitinib), 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 worldwide net sales with rates ranging up to 20 percent. The agreement calls for payments by us to Incyte associated with certain development, success-based regulatory, and sales-based milestones. In 2020, the agreement was amended to include the treatment of COVID-19, with Incyte obtaining the right to receive an additional royalty ranging up to the low teens on worldwide net sales for the treatment of COVID-19 that exceed a specified aggregate worldwide net sales threshold.

In connection with the regulatory approvals of Olumiant in the U.S., Europe, and Japan, as well as achievement of a sales-based milestone, milestone payments of $260.0 million and $210.0 million were capitalized as intangible assets as of December 31, 2021 and 2020, respectively, and are being amortized to cost of sales through the term of the collaboration. This represents the cumulative amounts that have been capitalized from the start of this collaboration through the end of each reporting period.

As of December 31, 2021, Incyte is eligible to receive up to $100.0 million of additional payments from us contingent upon certain success-based regulatory milestones. Incyte is also eligible to receive up to $100.0 million of potential sales-based milestones.

We record our sales of Olumiant, including sales of baricitinib that were made pursuant to an EUA or similar regulatory authorizations, to third parties as net product revenue with the royalty payments made to Incyte recorded as cost of sales. The following table summarizes our net product revenue recognized with respect to Olumiant:

	2021	2020	2019
Olumiant	**$ 1,115.1**	$ 638.9	$ 426.9

COVID-19 antibodies

In 2020, we entered into a worldwide license and collaboration agreement with AbCellera to co-develop therapeutic antibodies for the potential prevention and treatment of COVID-19, including bamlanivimab and bebtelovimab, for which we hold development and commercialization rights. AbCellera has the right to receive tiered royalty payments on worldwide net sales of bamlanivimab and bebtelovimab with percentages ranging in the mid-teens to mid-twenties. Royalty payments made to AbCellera are recorded as cost of sales.

In 2020, we entered into a license and collaboration agreement with Junshi Biosciences to co-develop therapeutic antibodies for the potential prevention and treatment of COVID-19, including etesevimab, for which we hold development and commercialization rights outside of mainland China and the Special Administrative Regions of Hong Kong and Macau, and for which Junshi Biosciences currently maintains all rights in mainland China and the Special Administrative Regions of Hong Kong and Macau. Junshi Biosciences has the right to receive royalty payments in the mid-teens on our net sales of etesevimab. Junshi Biosciences also had the right to receive certain development, success-based regulatory and sales-based milestones. In connection with the regulatory authorizations of etesevimab (for administration with bamlanivimab) as well as achievement of sales-based milestones in 2021, milestone payments of $195.0 million were capitalized as intangible assets and are being amortized to cost of sales over the estimated useful life of etesevimab. During the year ended December 31, 2020, we recognized $50.0 million of research and development expenses related to development milestones.

Pursuant to EUAs or similar regulatory authorizations, we recognized $2.24 billion and $871.2 million of net product revenue associated with our sales of our COVID-19 antibodies during the years ended December 31, 2021 and 2020, respectively.

Sintilimab Injection

We have a collaboration agreement with Innovent to jointly develop and commercialize sintilimab injection in China, where it is branded and trademarked as Tyvyt. In 2019, we and Innovent began co-commercializing Tyvyt in China. In 2020, we obtained an exclusive license for sintilimab injection from Innovent for geographies outside of China. Innovent, with collaboration from us, has filed the initial registration of sintilimab injection in the U.S., and we plan to pursue initial registration of sintilimab injection in other markets and all other subsequent registrations of sintilimab injection. We have exclusive commercialization rights outside of China.

In connection with a regulatory approval for Tyvyt in China in 2021, we capitalized a milestone payment of $40.0 million as an intangible asset which is being amortized to cost of sales through the term of the collaboration.

As of December 31, 2021, Innovent is eligible to receive up to $825.0 million for geographies outside of China and up to $195.0 million in China in success-based regulatory and sales-based milestones. Innovent is also eligible to receive tiered double digit royalties on net sales for geographies outside of China.

We record our sales of Tyvyt to third parties as net product revenue, with payments made to Innovent for its portion of the gross margin reported as cost of sales. We report as collaboration and other revenue our portion of the gross margin for Tyvyt sales made by Innovent to third parties. The following table summarizes our revenue recognized in China with respect to Tyvyt:

	2021	2020	2019
Tyvyt	**$ 418.1**	$ 308.7	$ 134.0

Lebrikizumab

As a result of our acquisition of Dermira, we have a worldwide license agreement with F. Hoffmann-La Roche Ltd and Genentech, Inc. (collectively Roche), which provides us the worldwide development and commercialization rights to lebrikizumab. Roche has the right to receive tiered royalty payments on future worldwide net sales ranging in percentages from high single digits to high teens if the product is successfully commercialized. As of December 31, 2021, Roche is eligible to receive up to $180.0 million of payments from us contingent upon the achievement of success-based regulatory milestones, and up to $1.03 billion in a series of sales-based milestones, contingent upon the commercial success of lebrikizumab.

As a result of our acquisition of Dermira, we have a license agreement with Almirall, S.A. (Almirall), under which Almirall licensed the rights to develop and commercialize lebrikizumab for the treatment or prevention of dermatology indications, including, but not limited to, atopic dermatitis in Europe. We have the right to receive tiered royalty payments on future net sales in Europe ranging in percentages from low double digits to low twenties if the product is successfully commercialized. As of December 31, 2021, we are eligible to receive additional payments of $85.0 million from Almirall contingent upon the achievement of success-based regulatory milestones and up to $1.25 billion in a series of sales-based milestones, contingent upon the commercial success of lebrikizumab. As of December 31, 2021 and 2020, contract liabilities were not material. During the twelve months ended December 31, 2021 and 2020, milestones received and collaboration and other revenue recognized were not material.

Petra

As a result of our acquisition of Petra, we are required to make milestone payments to Petra shareholders contingent upon the occurrence of certain future events linked to the success of the mutant-selective PI3Kα inhibitor. Our more significant, near term milestones include a development milestone of approximately $205 million in 2022 contingent upon initiation of its Phase I trial and a further development milestone of approximately $164 million in 2023 contingent upon achieving clinical proof of concept.

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:

	2021	2020	2019
Severance	**$ 13.0**	$ 151.2	$ 77.8
Asset impairment (gain) and other special charges	**303.1**	(20.0)	497.8
Total asset impairment, restructuring, and other special charges	**$ 316.1**	$ 131.2	$ 575.6

Severance costs recognized during the years ended December 31, 2020 and 2019 were incurred as a result of actions taken worldwide to reduce our cost structure.

During the year ended December 31, 2021, we recognized $128.0 million of intangible asset impairment as a result of the decision by Bayer AG to discontinue the development of a Phase I molecule related to a contract-based intangible asset from our acquisition of Loxo. Additionally, we recognized $108.1 million of intangible asset impairment from the sale of the rights to Qbrexza, as well as acquisition and integration costs associated with the acquisition of Prevail.

Asset impairment and other special charges recognized during the year ended December 31, 2019 resulted primarily from $400.7 million of other special charges related to the acquisition of Loxo, substantially all of which is associated with the accelerated vesting of Loxo employee equity awards.

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:

	2021	2020
Finished products	**$ 761.9**	$ 758.9
Work in process	**2,372.7**	2,535.4
Raw materials and supplies	**717.2**	651.2
Total (approximates replacement cost)	**3,851.8**	3,945.5
Increase to LIFO cost	**34.2**	34.8
Inventories	**$ 3,886.0**	$ 3,980.3

Inventories valued under the LIFO method comprised $1.36 billion and $1.21 billion of total inventories at December 31, 2021 and 2020, respectively.

We recognized a net inventory impairment charge related to our COVID-19 antibodies of $339.7 million during the year ended December 31, 2021 in cost of sales in our consolidated statements of operations. As part of our response to the COVID-19 pandemic, and at the request of the U.S. and international governments, we invested in large-scale manufacturing of COVID-19 antibodies at risk, in order to ensure rapid access to patients around the world. As the COVID-19 pandemic evolved during 2021, we incurred a net inventory impairment charge primarily due to the combination of changes to current and forecasted demand from U.S. and international governments, including changes to our agreement with the U.S. government, and near-term expiry dates of COVID-19 antibodies.

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. In accordance with documented corporate risk-management policies, we monitor the amount of credit exposure to any one financial institution or corporate issuer. We are exposed to credit-related losses in the event of nonperformance by counterparties to risk-management instruments but do not expect any counterparties to fail to meet their obligations given their high credit ratings.

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

Our equity investments are accounted for using three different methods depending on the type of equity investment:

- Investments in companies over which we have significant influence but not a controlling interest are accounted for using the equity method, with our share of earnings or losses reported in other-net, (income) expense.
- For equity investments that do not have readily determinable fair values, we measure these investments at cost, less any impairment, plus or minus changes resulting from observable price changes in orderly transactions for the identical or similar investment of the same issuer. Any change in recorded value is recorded in other-net, (income) expense.
- Our public equity investments are measured and carried at fair value. Any change in fair value is recognized in other-net, (income) expense.

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

Our derivative activities are initiated within the guidelines of documented corporate risk-management policies and are intended to offset losses and gains on the assets, liabilities, and transactions being hedged. Management reviews the correlation and effectiveness of our derivatives on a quarterly basis.

For derivative instruments that are designated and qualify as fair value hedges, the derivative instrument is marked to market with gains and losses recognized currently in income to offset the respective losses and gains recognized on the underlying exposure. For derivative instruments that are designated and qualify as cash flow hedges, gains and losses are reported as a component of accumulated other comprehensive loss and reclassified into earnings in the same period the hedged transaction affects earnings. For derivative and non-derivative instruments that are designated and qualify as net investment hedges, the foreign currency translation gains or losses due to spot rate fluctuations are reported as a component of accumulated other comprehensive loss. Derivative contracts that are not designated as hedging instruments are recorded at fair value with the gain or loss recognized in earnings during the period of change.

We may enter into foreign currency forward or option contracts to reduce the effect of fluctuating currency exchange rates (principally the euro, British pound, and 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, 2021, we had outstanding foreign currency forward commitments to purchase 4.43 billion U.S. dollars and sell 3.92 billion euro; commitments to purchase 3.84 billion euro and sell 4.37 billion U.S. dollars; commitments to purchase

159.2 million U.S. dollars and sell 18.26 billion Japanese yen, and commitments to purchase 223.0 million British pounds and sell 296.0 million U.S. dollars, which all have settlement dates within 180 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 $7.90 billion and $6.02 billion as of December 31, 2021 and 2020, respectively, of which $5.79 billion and $4.50 billion have been designated as, and are effective as, economic hedges of net investments in certain of our foreign operations as of December 31, 2021 and 2020, respectively. At December 31, 2021, we had outstanding cross currency swaps with notional amounts of $1.02 billion swapping U.S. dollars to euro and $1.00 billion swapping Swiss francs to U.S. dollars which have settlement dates ranging through 2028. Our cross-currency interest rate swaps, for which a majority convert a portion of our U.S. dollar-denominated fixed rate debt to foreign-denominated fixed rate debt, have also been designated as, and are effective as, economic hedges of net investments.

In the normal course of business, our operations are exposed to fluctuations in interest rates which can vary the costs of financing, investing, and operating. We seek to address a portion of these risks through a controlled program of risk management that includes the use of derivative financial instruments. The objective of controlling these risks is to limit the impact of fluctuations in interest rates on earnings. Our primary interest-rate risk exposure results from changes in short-term U.S. dollar interest rates. In an effort to manage interest-rate exposures, we strive to achieve an acceptable balance between fixed- and floating-rate debt and investment positions and may enter into interest rate swaps or collars to help maintain that balance.

Interest rate swaps or collars that convert our fixed-rate debt to a floating rate are designated as fair value hedges of the underlying instruments. Interest rate swaps or collars that convert floating-rate debt to a fixed rate are designated as cash flow hedges. Interest expense on the debt is adjusted to include the payments made or received under the swap agreements. Cash proceeds from or payments to counterparties resulting from the termination of interest rate swaps are classified as operating activities in our consolidated statements of cash flows. At December 31, 2021, substantially all of our total long-term debt is at a fixed rate. We have converted approximately 13 percent of our long-term fixed-rate notes to floating rates through the use of interest rate swaps.

We also may enter into forward-starting interest rate swaps, which we designate as cash flow hedges, as part of any anticipated future debt issuances in order to reduce the risk of cash flow volatility from future changes in interest rates. The change in fair value of these instruments is recorded as part of other comprehensive income (loss) and, upon completion of a debt issuance and termination of the swap, is amortized to interest expense over the life of the underlying debt. As of December 31, 2021, the total notional amounts of forward-starting interest rate contracts in designated cash flow hedging instruments were $1.75 billion, which have settlement dates ranging between 2023 and 2025.

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:

	2021	2020	2019
Fair value hedges:			
Effect from hedged fixed-rate debt	**$ (78.5)**	$ 86.9	$ 112.1
Effect from interest rate contracts	**78.5**	(86.9)	(112.1)
Cash flow hedges:			
Effective portion of losses on interest rate contracts reclassified from accumulated other comprehensive loss	**16.6**	16.4	15.9
Cross-currency interest rate swaps	**41.8**	(102.4)	(17.1)
Net (gains) losses on foreign currency exchange contracts not designated as hedging instruments	**204.6**	(123.7)	61.9
Total	**$ 263.0**	$ (209.7)	$ 60.7

During the years ended December 31, 2021, 2020, and 2019, the amortization of losses related to the portion of our risk management hedging instruments, fair value hedges, and cash flow hedges that was excluded from the assessment of effectiveness was not material.

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

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

	2021	2020	2019
Net investment hedges:			
Foreign currency-denominated notes	**$ 435.0**	$ (404.0)	$ 40.1
Cross-currency interest rate swaps	**213.7**	(207.9)	47.4
Cash flow hedges:			
Forward-starting interest rate swaps	**97.6**	(110.9)	31.6
Cross-currency interest rate swaps	**42.3**	(53.7)	(8.3)

During the next 12 months, we expect to reclassify $16.5 million of pretax net losses on cash flow hedges from accumulated other comprehensive loss to other–net, (income) expense. During the years ended December 31, 2021, 2020, and 2019, the amounts excluded from the assessment of hedge effectiveness recognized in other comprehensive income (loss) were not material.

Fair Value of Financial Instruments

The following tables summarize certain fair value information at 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: 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, 2021						
Cash equivalents	**$ 2,379.5**	**$ 2,379.5**	**$ 2,361.0**	**$ 18.5**	**$ —**	**$ 2,379.5**
Short-term investments:						
U.S. government and agency securities	**$ 25.7**	**$ 25.6**	**$ 25.7**	**$ —**	**$ —**	**$ 25.7**
Corporate debt securities	**43.7**	**43.7**	**—**	**43.7**	**—**	**43.7**
Mortgage-backed securities	**0.2**	**0.2**	**—**	**0.2**	**—**	**0.2**
Asset-backed securities	**6.2**	**6.2**	**—**	**6.2**	**—**	**6.2**
Other securities	**14.3**	**14.3**	**—**	**—**	**14.3**	**14.3**
Short-term investments	**$ 90.1**					
Noncurrent investments:						
U.S. government and agency securities	**$ 137.0**	**$ 136.8**	**$ 137.0**	**$ —**	**$ —**	**$ 137.0**
Corporate debt securities	**235.3**	**232.7**	**—**	**235.3**	**—**	**235.3**
Mortgage-backed securities	**109.8**	**108.1**	**—**	**109.8**	**—**	**109.8**
Asset-backed securities	**23.1**	**23.1**	**—**	**23.1**	**—**	**23.1**
Other securities	**108.1**	**22.2**	**—**	**—**	**108.1**	**108.1**
Marketable equity securities	**1,279.7**	**487.0**	**1,279.7**	**—**	**—**	**1,279.7**
Equity investments without readily determinable fair values[2]	**548.1**					
Equity method investments[2]	**771.5**					
Noncurrent investments	**$ 3,212.6**					
December 31, 2020						
Cash equivalents	$ 2,097.9	$ 2,097.9	$ 2,097.9	$ —	$ —	$ 2,097.9
Short-term investments:						
U.S. government and agency securities	$ 9.9	$ 9.9	$ 9.9	$ —	$ —	$ 9.9
Corporate debt securities	2.8	2.8	—	2.8	—	2.8
Asset-backed securities	1.2	1.2	—	1.2	—	1.2
Other securities	10.3	10.3	—	—	10.3	10.3
Short-term investments	$ 24.2					
Noncurrent investments:						
U.S. government and agency securities	$ 78.7	$ 74.3	$ 78.7	$ —	$ —	$ 78.7
Corporate debt securities	137.0	126.8	—	137.0	—	137.0
Mortgage-backed securities	106.4	101.4	—	106.4	—	106.4
Asset-backed securities	24.3	23.7	—	24.3	—	24.3
Other securities	110.5	31.8	—	—	110.5	110.5
Marketable equity securities	1,664.2	311.6	1,664.2	—	—	1,664.2
Equity investments without readily determinable fair values[2]	373.9					
Equity method investments[2]	471.8					
Noncurrent investments	$ 2,966.8					

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

(2) Fair value disclosures are not applicable for equity method investments and investments accounted for under the measurement alternative for equity investments.

Description	Carrying Amount	Fair Value Measurements Using: Quoted Prices in Active Markets for Identical Assets (Level 1)	Fair Value Measurements Using: Significant Other Observable Inputs (Level 2)	Fair Value Measurements Using: Significant Unobservable Inputs (Level 3)	Fair Value
Long-term debt, including current portion					
December 31, 2021	**$ (16,884.7)**	**$ —**	**$ (18,157.7)**	**$ —**	**$ (18,157.7)**
December 31, 2020	(16,595.3)	—	(19,038.9)	—	(19,038.9)

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, 2021					
Risk-management instruments					
Interest rate contracts designated as fair value hedges:					
Other receivables	**$ 4.8**	**$ —**	**$ 4.8**	**$ —**	**$ 4.8**
Other noncurrent assets	**78.3**	**—**	**78.3**	**—**	**78.3**
Other noncurrent liabilities	**(7.6)**	**—**	**(7.6)**	**—**	**(7.6)**
Interest rate contracts designated as cash flow hedges:					
Other noncurrent assets	**49.2**	**—**	**49.2**	**—**	**49.2**
Other noncurrent liabilities	**(31.7)**	**—**	**(31.7)**	**—**	**(31.7)**
Cross-currency interest rate contracts designated as net investment hedges:					
Other noncurrent assets	**31.3**	**—**	**31.3**	**—**	**31.3**
Other current liabilities	**(1.2)**	**—**	**(1.2)**	**—**	**(1.2)**
Cross-currency interest rate contracts designated as cash flow hedges:					
Other noncurrent assets	**33.2**	**—**	**33.2**	**—**	**33.2**
Other noncurrent liabilities	**(1.3)**	**—**	**(1.3)**	**—**	**(1.3)**
Foreign exchange contracts not designated as hedging instruments:					
Other receivables	**9.9**	**—**	**9.9**	**—**	**9.9**
Other current liabilities	**(35.3)**	**—**	**(35.3)**	**—**	**(35.3)**
Contingent consideration liabilities:					
Other noncurrent liabilities	**(70.5)**	**—**	**—**	**(70.5)**	**(70.5)**
December 31, 2020					
Risk-management instruments					
Interest rate contracts designated as fair value hedges:					
Other noncurrent assets	158.9	—	158.9	—	158.9
Interest rate contracts designated as cash flow hedges:					
Other noncurrent assets	38.1	—	38.1	—	38.1
Other noncurrent liabilities	(97.8)	—	(97.8)	—	(97.8)
Cross-currency interest rate contracts designated as net investment hedges:					
Other current liabilities	(92.6)	—	(92.6)	—	(92.6)
Other noncurrent liabilities	(97.2)	—	(97.2)	—	(97.2)
Cross-currency interest rate contracts designated as cash flow hedges:					
Other noncurrent assets	34.4	—	34.4	—	34.4
Other noncurrent liabilities	(2.9)	—	(2.9)	—	(2.9)
Foreign exchange contracts not designated as hedging instruments:					
Other receivables	41.1	—	41.1	—	41.1
Other current liabilities	(15.2)	—	(15.2)	—	(15.2)

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 enforceable master netting arrangements 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. Fair values are not readily available for certain equity investments measured under the measurement alternative. As of December 31, 2021, we had approximately $828 million of unfunded commitments to invest in venture capital funds, which we anticipate will be invested over a period of up to 10 years.

Contingent consideration liability relates to our liability arising in connection with the CVR issued as a result of the Prevail acquisition. The fair value of the CVR liability was estimated using a discounted cash flow analysis and Level 3 inputs, including projections representative of a market participant's view of the expected cash payment associated with the first potential regulatory approval of a Prevail compound in the applicable countries based on probabilities of technical success, timing of the potential approval events for the compounds, and an estimated discount rate. See Note 3 for additional information related to the CVR arrangement.

The table below summarizes the contractual maturities of our investments in debt securities measured at fair value as of December 31, 2021:

	Maturities by Period				
	Total	Less Than 1 Year	1-5 Years	6-10 Years	More Than 10 Years
Fair value of debt securities	$ 581.0	$ 75.9	$ 216.5	$ 126.4	$ 162.2

The net gains recognized in our consolidated statements of operations for equity securities were $176.9 million, $1.44 billion, and $401.2 million for the years ended December 31, 2021, 2020, and 2019, respectively. The net gains/losses recognized for the years ended December 31, 2021, 2020, and 2019 on equity securities sold during the respective periods were not material.

We adjust our equity investments without readily determinable fair values based upon changes in the equity instruments' values resulting from observable price changes in orderly transactions for an identical or similar investment of the same issuer. Downward adjustments resulting from an impairment are recorded based upon impairment considerations, including the financial condition and near term prospects of the issuer, general market conditions, and industry specific factors. Adjustments recorded for the years ended December 31, 2021, 2020, and 2019 were not material.

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

	2021	2020
Unrealized gross gains	**$ 9.7**	$ 20.9
Unrealized gross losses	**5.2**	0.5
Fair value of securities in an unrealized gain position	**250.7**	348.9
Fair value of securities in an unrealized loss position	**290.2**	11.4

We periodically assess our investment in available-for-sale securities for impairment losses and credit losses. 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. Impairment and credit

losses related to available-for-sale securities were not material for the years ended December 31, 2021, 2020, and 2019.

As of December 31, 2021, 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 97 percent of the fixed-rate debt securities in a loss position are investment-grade debt securities. As of December 31, 2021, 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 available-for-sale securities was as follows:

	2021	2020	2019
Proceeds from sales	**$ 174.7**	$ 264.8	$ 431.6
Realized gross gains on sales	**2.8**	4.5	4.9
Realized gross losses on sales	**1.7**	8.2	3.0

Realized gains and losses on sales of available-for-sale investments are computed based upon specific identification of the initial cost adjusted for any other-than-temporary declines in fair value that were recorded in earnings.

Accounts Receivable Factoring Arrangements

We have entered into accounts receivable factoring agreements with financial institutions to sell certain of our non-U.S. accounts receivable. These transactions are accounted for as sales and result in a reduction in accounts receivable because the agreements transfer effective control over and risk related to the receivables to the buyers. Our factoring agreements do not allow for recourse in the event of uncollectibility, and we do not retain any interest in the underlying accounts receivable once sold. We derecognized $550.5 million and $754.9 million of accounts receivable as of December 31, 2021 and 2020, respectively, under these factoring arrangements. The costs of factoring such accounts receivable on our consolidated results of operations for the years ended December 31, 2021, 2020, and 2019 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, or more frequently if impairment indicators are present, by first assessing qualitative factors to determine whether it is more likely than not that the fair value is less than its carrying amount. If we conclude it is more likely than not that the fair value is less than the carrying amount, a quantitative test that compares the fair value to its carrying value is performed to determine the amount of any impairment. The changes in goodwill during 2021 and 2020 were primarily related to our acquisitions of Prevail and Dermira, respectively. See Note 3 for additional information.

No impairments occurred with respect to the carrying value of goodwill for the years ended December 31, 2021, 2020, and 2019.

Other Intangibles

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

	2021			2020		
Description	Carrying Amount, Gross	Accumulated Amortization	Carrying Amount, Net	Carrying Amount, Gross	Accumulated Amortization	Carrying Amount, Net
Finite-lived intangible assets:						
Marketed products	**$ 7,987.2**	**$ (2,229.2)**	**$ 5,758.0**	$ 7,984.0	$ (1,659.5)	$ 6,324.5
Other	**69.4**	**(60.5)**	**8.9**	92.8	(68.3)	24.5
Total finite-lived intangible assets	**8,056.6**	**(2,289.7)**	**5,766.9**	8,076.8	(1,727.8)	6,349.0
Indefinite-lived intangible assets:						
Acquired IPR&D	**1,925.0**	**—**	**1,925.0**	1,101.0	—	1,101.0
Other intangibles	**$ 9,981.6**	**$ (2,289.7)**	**$ 7,691.9**	$ 9,177.8	$ (1,727.8)	$ 7,450.0

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 intangible assets 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 fair values of acquired IPR&D projects acquired in business combination, 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 as other intangible assets if the projects have an alternative future use; otherwise, they are expensed immediately. See Note 3 for acquired IPR&D projects that had no alternative future use.

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, analyst expectations, 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.

The change in marketed products in 2021 primarily related to the sale of rights to Qbrexza in 2021 as well as the impairment of a Phase I molecule related to a contract-based intangible. See Note 5 for additional information. These decreases were more than offset by the recognition of several milestones related to the COVID-19 therapies that occurred in 2021. The increase in the acquired IPR&D in 2021 is due to the acquisition of Prevail. See Note 3 for additional information regarding intangible assets acquired in a recent business combination and Note 4 for additional information regarding capitalized milestone payments.

Indefinite-lived intangible assets are reviewed for impairment at least annually, or more frequently if impairment indicators are present, by first assessing qualitative factors to determine whether it is more likely than not that the fair value of the asset is less than its carrying amount. If we conclude it is more

likely than not that the fair value is less than the carrying amount, a quantitative test that compares the fair value of the intangible asset to its carrying value is performed to determine the amount of any impairment. 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.

Intangible assets with finite lives are capitalized and are amortized primarily to cost of sales over their estimated useful lives, ranging from one to 20 years. As of December 31, 2021, the remaining weighted-average amortization period for finite-lived intangible assets was approximately 14 years.

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

	2021	2020	2019
Amortization expense	**$ 628.8**	$ 428.2	$ 225.8

The estimated amortization expense for each of the next five years associated with our finite-lived intangible assets as of December 31, 2021 is as follows:

	2022	2023	2024	2025	2026
Estimated amortization expense	$ 570.9	$ 483.5	$ 433.7	$ 417.1	$ 408.8

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:

	2021	2020
Land	**$ 258.7**	$ 226.8
Buildings	**7,588.1**	7,326.1
Equipment	**8,937.2**	8,560.9
Construction in progress	**2,177.8**	2,138.8
	18,961.8	18,252.6
Less accumulated depreciation	**(9,976.7)**	(9,570.7)
Property and equipment, net	**$ 8,985.1**	$ 8,681.9

Depreciation expense related to property and equipment was as follows:

	2021	2020	2019
Depreciation expense	**$ 787.0**	$ 765.2	$ 814.7

Capitalized interest costs were not material for the years ended December 31, 2021, 2020, and 2019.

The following table summarizes long-lived assets by geographical area:

	2021	2020
Long-lived assets[(1)]:		
U.S. and Puerto Rico	**$ 6,620.0**	$ 6,113.6
Ireland	**1,702.3**	1,786.9
Other foreign countries	**1,691.0**	1,747.7
Long-lived assets	**$ 10,013.3**	$ 9,648.2

[(1)] Long-lived assets consist of property and equipment, net, operating lease assets, and certain other noncurrent assets.

Note 10: Leases

We determine if an arrangement is a lease at inception. We have leases with terms up to 14 years primarily for corporate offices, research and development facilities, vehicles, and equipment, including some of which have options to extend and/or early-terminate the leases. We determine the lease term by assuming the exercise of any renewal and/or early-termination options that are reasonably assured.

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

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

Lease expense for operating lease assets, which is recognized on a straight-line basis over the lease term, was $159.4 million, $154.6 million, and $172.8 million during the years ended December 31, 2021, 2020, and 2019, respectively. Variable lease payments, which represent non-lease components such as maintenance, insurance and taxes, and which vary due to changes in facts or circumstances occurring after the commencement date other than the passage of time, are expensed in the period in which the payment obligation is incurred and were not material during the years ended December 31, 2021, 2020, and 2019. Short-term lease expense was not material during the years ended December 31, 2021, 2020, and 2019.

Supplemental balance sheet information related to operating leases as of December 31, 2021 and 2020 was as follows:

	2021		2020	
Weighted-average remaining lease term		**7 years**		7 years
Weighted-average discount rate	**3.0**	**%**	3.3	%

Supplemental cash flow information related to operating leases during the years ended December 31, 2021, 2020, and 2019 was as follows:

	2021	2020	2019
Operating cash flows from operating leases	**$ 156.7**	$ 160.9	$ 153.6
Right-of-use assets obtained in exchange for new operating lease liabilities	**163.5**	136.7	81.2

The annual minimum lease payments of our operating lease liabilities as of December 31, 2021 were as follows:

2022	$ 148.4
2023	117.6
2024	95.4
2025	79.7
2026	64.5
After 2026	270.2
Total lease payments	775.8
Less imputed interest	90.1
Total	$ 685.7

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

Note 11: Borrowings

Debt at December 31 consisted of the following:

	2021	2020
Long-term notes	**$ 16,741.2**	$ 16,348.7
Other long-term debt	**10.8**	14.8
Unamortized debt issuance costs	**(84.2)**	(89.1)
Fair value adjustment on hedged long-term notes	**216.9**	320.9
Total debt	**16,884.7**	16,595.3
Less current portion	**(1,538.3)**	(8.7)
Long-term debt	**$ 15,346.4**	$ 16,586.6

The following table summarizes long-term notes at December 31:

	2021	2020
2.35% notes due 2022	**$ 750.0**	$ 750.0
3.00% notes due 2022	**99.2**	99.2
1.00% euro denominated notes due 2022	**678.2**	737.9
0.15% Swiss franc denominated notes due 2024	**654.7**	679.7
7.125% notes due 2025	**217.5**	229.7
2.75% notes due 2025	**560.6**	560.6
1.625% euro denominated notes due 2026	**847.7**	922.4
5.5% notes due 2027	**364.3**	377.5
3.1% notes due 2027	**401.5**	401.5
0.45% Swiss franc denominated notes due 2028	**436.4**	453.2
3.375% notes due 2029	**930.6**	1,150.0
0.42% Japanese yen denominated notes due 2029	**199.0**	222.4
2.125% euro denominated notes due 2030	**847.7**	922.4
0.625% euro denominated notes due 2031	**678.2**	737.9
0.50% euro denominated notes due 2033	**678.2**	—
0.56% Japanese yen denominated notes due 2034	**80.5**	90.0
6.77% notes due 2036	**158.6**	174.4
5.55% notes due 2037	**444.7**	476.2
5.95% notes due 2037	**266.8**	284.1
3.875% notes due 2039	**240.3**	360.7
1.625% British pound denominated notes due 2043	**337.1**	—
4.65% notes due 2044	**38.3**	43.0
3.7% notes due 2045	**386.8**	412.5
3.95% notes due 2047	**347.0**	436.1
3.95% notes due 2049	**958.2**	1,500.0
1.70% euro denominated notes due 2049	**1,130.3**	1,229.9
0.97% Japanese yen denominated notes due 2049	**66.3**	74.1
2.25% notes due 2050	**1,250.0**	1,250.0
1.125% euro denominated notes due 2051	**565.2**	—
4.15% notes due 2059	**591.3**	1,000.0
2.50% notes due 2060	**850.0**	850.0
1.375% euro denominated notes due 2061	**791.2**	**—**
Unamortized note discounts	**(105.2)**	(76.7)
Total long-term notes	**$ 16,741.2**	$ 16,348.7

The weighted-average effective borrowing rate for each issuance of the long term-notes approximates the stated interest rate.

At December 31, 2021, we had a total of $5.26 billion of unused committed bank credit facilities, which consisted primarily of a $3.00 billion credit facility that expires in December 2026 and a $2.00 billion 364-day facility that expires in November 2022, 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 as of December 31, 2021. Of the remaining committed bank credit facilities, the outstanding balances as of December 31, 2021 and 2020 were not material. 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 September 2021, we issued euro-denominated notes consisting of €600.0 million of 0.50 percent fixed-rate notes due in September 2033, with interest to be paid annually. The net proceeds from the offering have been, and will continue to be, used to fund, in whole or in part, eligible projects designed to advance one or more of our environmental, social, and governance objectives.

In September 2021, we issued euro-denominated notes consisting of €500.0 million of 1.125 percent fixed-rate notes due in September 2051 and €700.0 million of 1.375 percent fixed-rate notes due in September 2061, with interest to be paid annually, and British pound-denominated notes consisting of £250.0 million of 1.625 percent fixed-rate notes due in September 2043, with interest to be paid annually. We paid $1.91 billion of the net cash proceeds from the offering to purchase and redeem certain higher interest rate U.S. dollar-denominated notes with an aggregate principal amount of $1.50 billion, resulting in a debt extinguishment loss of $405.2 million. This loss was included in other-net, (income) expense in our consolidated statement of operations for the year ended December 31, 2021. The $1.50 billion principal amount of higher interest rate U.S. dollar-denominated notes that were redeemed primarily included $541.8 million of 3.95 percent notes due 2049, $408.7 million of 4.15 percent notes due 2059, and $219.4 million of 3.375 percent notes due 2029. We used the remaining net proceeds from the offering to prefund certain 2022 debt maturities and for general corporate purposes.

In May 2020, we issued $1.00 billion of 2.25 percent fixed-rate notes due in May 2050, with interest to be paid semi-annually. We used the net cash proceeds from the offering of $988.6 million for general corporate purposes, including the repayment of outstanding commercial paper.

In August 2020, we issued $850.0 million of 2.50 percent fixed-rate notes due in September 2060 and an additional $250.0 million of our 2.25 percent fixed-rate notes due in May 2050, with interest to be paid semi-annually. We used the net cash proceeds from the offering of $1.07 billion for general corporate purposes, including the repayment of outstanding commercial paper.

In February 2019, we issued $1.15 billion of 3.375 percent fixed-rate notes due in March 2029, $850.0 million of 3.875 percent fixed-rate notes due in March 2039, $1.50 billion of 3.95 percent fixed-rate notes due in March 2049, and $1.00 billion of 4.15 percent fixed-rate notes due in March 2059, with interest to be paid semi-annually. We used the net cash proceeds of $4.45 billion from the offering to repay commercial paper that was issued in connection with the acquisition of Loxo and for general corporate purposes.

In November 2019, we issued euro-denominated notes consisting of €600.0 million of 0.625 percent fixed-notes due November 2031 and €1.00 billion of 1.70 percent fixed-rate notes due in November 2049 with interest to be paid annually. We paid $2.27 billion, comprised of $1.75 billion of net cash proceeds from the offering and proceeds from commercial paper, to purchase and redeem certain higher interest rate U.S. dollar denominated notes with an aggregate principal amount of $2.00 billion and a net carrying value of $2.01 billion, resulting in a debt extinguishment loss of $252.5 million. This loss was included in other-net, (income) expense in our consolidated statement of operations during the year ended December 31, 2019.

In November 2019, we issued Japanese Yen-denominated notes consisting of ¥22.92 billion of 0.42 percent fixed-rate notes due in November 2029, ¥9.28 billion of 0.56 percent fixed-rate notes due in November 2034, and ¥7.64 billion of 0.97 percent fixed-rate notes due in November 2049, with interest to be paid semi-annually. We used the net cash proceeds from the offering of $356.6 million for general corporate purposes, including the repayment of outstanding commercial paper.

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

	2022	2023	2024	2025	2026
Maturities on long-term debt	$ 1,531.5	$ 3.3	$ 657.1	$ 778.9	$ 847.9

We have converted approximately 13 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, 2021 and 2020, including the effects of interest rate swaps for hedged debt obligations, were 2.27 percent and 2.61 percent, respectively.

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

	2021	2020	2019
Cash payments for interest on borrowings	**$ 338.0**	$ 345.8	$ 305.5

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 12: Stock-Based Compensation

Our stock-based compensation expense consists of performance awards (PAs), shareholder value awards (SVAs), relative value awards (RVAs), 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, RVA, and RSU shares.

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

	2021	2020	2019
Stock-based compensation expense	**$ 342.8**	$ 308.1	$ 306.8
Tax benefit	**72.0**	64.7	64.4

At December 31, 2021, stock-based compensation awards may be granted under the 2002 Lilly Stock Plan for not more than 50.6 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, 2021, 2020, and 2019 were $198.57, $137.33, and $112.09, 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 0.7 million shares, 1.1 million shares, and 1.2 million shares were issued during the years ended December 31, 2021, 2020, and 2019, respectively. Approximately 0.7 million shares are expected to be issued in 2022. As of December 31, 2021, the total remaining unrecognized compensation cost related to nonvested PAs was $66.1 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, 2021, 2020, and 2019 were $230.19, $139.14, and $95.01, respectively, determined using the following assumptions:

(Percents)	2021	2020	2019
Expected dividend yield	**2.50 %**	2.50 %	2.50 %
Risk-free interest rate	**0.19**	1.38	2.46
Volatility	**31.42**	20.90	21.00

Pursuant to this program, approximately 1.0 million shares, 0.8 million shares, and 1.0 million shares were issued during the years ended December 31, 2021, 2020, and 2019, respectively. Approximately 0.5 million shares are expected to be issued in 2022. As of December 31, 2021, the total remaining unrecognized compensation cost related to nonvested SVAs was $47.0 million, which will be amortized over the weighted-average remaining requisite service period of 21 months.

Relative Value Award Program

Beginning in 2020, we granted RVAs to officers and management that are payable in shares of our common stock. The number of shares actually issued, if any, varies depending on the growth of our stock price at the end of the three-year vesting period compared to our peers. We measure the fair value of the RVA 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 our peers' 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 value of the RVA units granted during the years ended December 31, 2021 and 2020 were $286.71 and $179.90, respectively, determined using the following assumptions:

(Percents)	2021	2020
Expected dividend yield	**2.50 %**	2.50 %
Risk-free interest rate	**0.19**	1.38
Volatility	**30.95**	19.89

As of December 31, 2021, the total remaining unrecognized compensation cost related to nonvested RVAs was $18.6 million, which will be amortized over the weighted-average remaining requisite service period of 21 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, 2021, 2020, and 2019 were $196.30, $135.42, and $108.43, respectively. The number of shares ultimately issued for the RSU program remains constant with the exception of forfeitures. Pursuant to this program, 0.7 million, 1.1 million, and 1.5 million shares were granted and approximately 0.6 million, 0.6 million, and 0.8 million shares were issued during the years ended December 31, 2021, 2020, and 2019, respectively. Approximately 0.9 million shares are expected to be issued in 2022. As of December 31, 2021, the total remaining unrecognized compensation cost related to nonvested RSUs was $161.4 million, which will be amortized over the weighted-average remaining requisite service period of 25 months.

Note 13: Shareholders' Equity

In 2021, 2020, and 2019, we repurchased $1.25 billion, $500.0 million, and $4.40 billion, respectively, of shares associated with our share repurchase programs.

In 2021, we repurchased $1.00 billion of shares, which completed our $8.00 billion share repurchase program authorized in June 2018. Additionally, our board authorized a $5.00 billion share repurchase program in May 2021. In 2021, we repurchased $250.0 million of shares under the $5.00 billion share repurchase program. As of December 31, 2021, we had $4.75 billion remaining under the $5.00 billion share repurchase program.

We have 5.0 million authorized shares of preferred stock. As of December 31, 2021 and 2020, 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, 2021 and 2020, 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, 2021 and 2020, 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, 2021, 2020, and 2019.

Note 14: Income Taxes

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. Deferred taxes related to global intangible low-taxed income (GILTI) are also recognized for the future tax effects of temporary differences.

We recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position, based on its technical merits, will be sustained upon examination by the taxing authority. 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:

	2021	2020	2019
Current:			
Federal[1]	**$ 938.5**	$ 567.6	$ 280.2
Foreign	**466.0**	650.4	299.8
State	**(28.4)**	(47.3)	(14.4)
Total current tax expense	**1,376.1**	1,170.7	565.6
Deferred:			
Federal	**(977.5)**	(97.4)	141.3
Foreign	**174.6**	(16.6)	(24.1)
State	**0.6**	(20.5)	(54.8)
Total deferred tax (benefit) expense	**(802.3)**	(134.5)	62.4
Income taxes	**$ 573.8**	$ 1,036.2	$ 628.0

[1] The 2021, 2020, and 2019 current tax expense includes $64.7 million, $144.4 million, and $153.1 million of tax benefit, respectively, from utilization of net operating loss and tax credit carryforwards.

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

	2021	2020
Deferred tax assets:		
Purchases of intangible assets	**$ 2,347.4**	$ 2,560.6
Compensation and benefits	**634.7**	1,045.6
Tax credit carryforwards and carrybacks	**463.7**	523.5
Tax loss and other tax carryforwards and carrybacks	**645.4**	488.3
Sales rebates and discounts	**832.3**	461.3
Correlative tax adjustments	**560.8**	404.2
Foreign tax redeterminations	**274.9**	242.8
Operating lease liabilities	**150.0**	150.7
Capitalized research and development	**275.1**	135.2
Other	**477.9**	605.8
Total gross deferred tax assets	**6,662.2**	6,618.0
Valuation allowances	**(875.6)**	(816.3)
Total deferred tax assets	**5,786.6**	5,801.7
Deferred tax liabilities:		
Earnings of foreign subsidiaries	**(1,583.3)**	(1,905.3)
Intangibles	**(1,516.1)**	(1,465.7)
Inventories	**(596.4)**	(623.7)
Prepaid employee benefits	**(560.6)**	(410.1)
Property and equipment	**(338.7)**	(315.2)
Financial instruments	**(303.0)**	(216.9)
Operating lease assets	**(132.6)**	(134.3)
Total deferred tax liabilities	**(5,030.7)**	(5,071.2)
Deferred tax assets - net	**$ 755.9**	$ 730.5

The deferred tax asset and related valuation allowance amounts for U.S. federal, international, 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, 2021, based on filed tax returns we have tax credit carryforwards and carrybacks of $859.9 million available to reduce future income taxes; $148.8 million, if unused, will expire by 2026, and $21.5 million, if unused, will expire between 2030 and 2040. The remaining portion of the tax credit carryforwards is related to federal tax credits of $76.2 million, international tax credits of $115.3 million, and state tax credits of $498.1 million, all of which are fully reserved.

At December 31, 2021, based on filed tax returns we had net operating losses and other carryforwards for international and U.S. federal income tax purposes of $2.21 billion: $832.6 million will expire by 2026; $818.2 million will expire between 2027 and 2041; and $561.5 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 and other carryforwards of $230.0 million are fully reserved as of December 31, 2021.

Domestic and Puerto Rican companies contributed approximately 28 percent, 39 percent, and 44 percent for the years ended December 31, 2021, 2020, and 2019, 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.

Substantially all of the unremitted earnings of our foreign subsidiaries are considered not to be indefinitely reinvested for continued use in our foreign operations. At December 31, 2021 and December 31, 2020, we 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 U.S. federal, state, and foreign income taxes, net of refunds, were as follows:

	2021	2020	2019
Cash payments of income taxes	**$ 1,598.8**	$ 954.6	$ 1,180.5

In December 2017, the Tax Cuts and Job Act (2017 Tax Act) was signed into law. The 2017 Tax Act included significant changes to the U.S. corporate income tax system, including a one-time repatriation transition tax (also known as the 'Toll Tax') on unremitted foreign earnings. The 2017 Tax Act provided an election to taxpayers subject to the Toll Tax to make payments over an eight-year period beginning in 2018 through 2025. Having made this election, our future cash payments relating to the Toll Tax as of December 31, 2021 are as follows:

	Total	Less than 1 Year	1-3 Years	3-5 Years
2017 Tax Act Toll Tax	$ 2,149.5	$ 253.7	$ 1,109.9	$ 785.9

We have additional noncurrent income tax payables of $2.02 billion unrelated to the Toll Tax; we cannot reasonably estimate the timing of future cash outflows associated with these liabilities.

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

	2021	2020	2019
Income tax at the U.S. federal statutory tax rate	**$ 1,292.6**	$ 1,518.3	$ 1,105.8
Add (deduct):			
International operations, including Puerto Rico[(1)]	**(458.2)**	(297.2)	(242.0)
General business credits	**(100.5)**	(97.9)	(108.8)
Foreign-derived intangible income deduction	**(86.7)**	(71.5)	(15.5)
Other	**(73.4)**	(15.5)	(111.5)
Income taxes	**$ 573.8**	$ 1,036.2	$ 628.0

[(1)] Includes the impact of Puerto Rico Excise Tax, GILTI tax, and other U.S. taxation of foreign income.

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

	2021	2020	2019
Beginning balance at January 1	**$ 2,551.9**	$ 2,108.6	$ 2,034.6
Additions based on tax positions related to the current year	**310.3**	225.6	187.2
Additions for tax positions of prior years	**98.6**	310.8	425.3
Reductions for tax positions of prior years	**(8.1)**	(52.4)	(100.3)
Settlements	**(38.5)**	(72.0)	(260.5)
Lapses of statutes of limitation	**(49.7)**	(41.7)	(161.5)
Changes related to the impact of foreign currency translation	**(66.2)**	73.0	(16.2)
Ending balance at December 31	**$ 2,798.3**	$ 2,551.9	$ 2,108.6

The total amount of unrecognized tax benefits that, if recognized, would affect our effective tax rate was $1.70 billion and $1.67 billion at December 31, 2021 and 2020, respectively.

We file U.S. federal, foreign, and various state and local income tax returns. We are no longer subject to U.S. federal income tax examination for years before 2016. In most major foreign and state jurisdictions, we are no longer subject to income tax examination for years before 2012.

The U.S. examination of tax years 2016-2018 began in 2019 and remains ongoing; therefore, the resolution of this audit period will likely extend beyond the next 12 months. For tax years 2013-2015, all matters were effectively settled in 2019. As a result, our gross uncertain tax positions were reduced by approximately $200 million, we made a cash payment of approximately $125 million, and our consolidated results were benefited by an immaterial reduction in tax expense.

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:

	2021	2020	2019
Income tax (benefit) expense	**$ 20.5**	$ 34.0	$ (26.4)

At December 31, 2021 and 2020, our accruals for the payment of interest and penalties totaled $220.1 million and $196.7 million, respectively.

Note 15: 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	
	2021	**2020**	**2021**	**2020**
Change in benefit obligation:				
Benefit obligation at beginning of year	**$ 18,225.5**	$ 16,251.0	**$ 1,753.7**	$ 1,601.4
Service cost	**369.2**	325.5	**49.2**	40.8
Interest cost	**337.8**	425.8	**32.5**	43.7
Actuarial (gain) loss	**(564.3)**	1,563.1	**(86.1)**	142.1
Benefits paid	**(630.1)**	(587.2)	**(79.3)**	(75.1)
Curtailment loss	**—**	2.2	**—**	—
Foreign currency exchange rate changes and other adjustments	**(173.1)**	245.1	**(6.2)**	0.8
Benefit obligation at end of year	**17,565.0**	18,225.5	**1,663.8**	1,753.7
Change in plan assets:				
Fair value of plan assets at beginning of year	**14,579.0**	12,858.0	**3,227.0**	2,768.2
Actual return on plan assets	**2,458.1**	1,802.4	**202.6**	539.0
Employer contribution	**131.2**	318.8	**11.1**	(5.1)
Benefits paid	**(630.1)**	(587.2)	**(79.3)**	(75.1)
Foreign currency exchange rate changes and other adjustments	**(122.2)**	187.0	**—**	—
Fair value of plan assets at end of year	**16,416.0**	14,579.0	**3,361.4**	3,227.0
Funded status	**(1,149.0)**	(3,646.5)	**1,697.6**	1,473.3
Unrecognized net actuarial (gain) loss	**3,908.2**	6,515.5	**(497.2)**	(349.1)
Unrecognized prior service (benefit) cost	**11.2**	15.4	**(117.6)**	(177.6)
Net amount recognized	**$ 2,770.4**	$ 2,884.4	**$ 1,082.8**	$ 946.6
Amounts recognized in the consolidated balance sheet consisted of:				
Other noncurrent assets	**$ 668.5**	$ 299.6	**$ 1,910.2**	$ 1,697.0
Other current liabilities	**(68.3)**	(67.9)	**(7.9)**	(7.4)
Accrued retirement benefits	**(1,749.3)**	(3,878.2)	**(204.8)**	(216.3)
Accumulated other comprehensive (income) loss before income taxes	**3,919.5**	6,530.9	**(614.7)**	(526.7)
Net amount recognized	**$ 2,770.4**	$ 2,884.4	**$ 1,082.8**	$ 946.6

The unrecognized net actuarial (gain) loss and unrecognized prior service (benefit) cost have not yet been recognized in net periodic pension costs and were included in accumulated other comprehensive loss at December 31, 2021 and 2020.

The $750.4 million decrease in benefit obligation in 2021 was driven primarily by an increase in the discount rate. The $2.13 billion increase in the benefit obligation in 2020 was driven by a decrease in the discount rate.

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

	Defined Benefit Pension Plans			Retiree Health Benefit Plans		
(Percents)	2021	2020	2019	2021	2020	2019
Discount rate for benefit obligation	**2.8 %**	2.4 %	3.0 %	**3.0 %**	2.6 %	3.3 %
Discount rate for net benefit costs	**2.4**	3.0	4.0	**2.6**	3.3	4.4
Rate of compensation increase for benefit obligation	**3.5**	3.3	3.3			
Rate of compensation increase for net benefit costs	**3.3**	3.3	3.4			
Expected return on plan assets for net benefit costs	**6.8**	7.3	7.4	**5.0**	6.0	6.0

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:

	2022	2023	2024	2025	2026	2027-2031
Defined benefit pension plans	$ 631.9	$ 641.8	$ 669.4	$ 686.6	$ 707.5	$ 3,919.7
Retiree health benefit plans	89.4	89.5	93.1	93.9	94.5	477.7

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

	2021	2020
Projected benefit obligation	**$ 3,360.3**	$ 15,770.7
Fair value of plan assets	**1,542.8**	11,824.4

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	
	2021	2020	2021	2020
Accumulated benefit obligation	**$ 2,532.0**	$ 14,682.3	**$ 212.6**	$ 223.8
Fair value of plan assets	**973.4**	11,824.4	**—**	—

The total accumulated benefit obligation for our defined benefit pension plans was $16.44 billion and $17.03 billion at December 31, 2021 and 2020, respectively.

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

	Defined Benefit Pension Plans			Retiree Health Benefit Plans		
	2021	2020	2019	2021	2020	2019
Components of net periodic (benefit) cost:						
Service cost	**$ 369.2**	$ 325.5	$ 250.4	**$ 49.2**	$ 40.8	$ 36.3
Interest cost	**337.8**	425.8	486.0	**32.5**	43.7	58.0
Expected return on plan assets	**(949.3)**	(901.5)	(839.6)	**(146.2)**	(158.1)	(144.3)
Amortization of prior service (benefit) cost	**4.2**	4.5	6.1	**(59.6)**	(59.5)	(62.9)
Recognized actuarial (gain) loss	**487.7**	396.3	284.9	**3.2**	(3.0)	1.9
Curtailment loss	**—**	—	2.2	**—**	—	—
Net periodic (benefit) cost	**$ 249.6**	$ 250.6	$ 190.0	**$ (120.9)**	$ (136.1)	$ (111.0)

The following represents the amounts recognized in other comprehensive income (loss) for the years ended December 31, 2021, 2020, and 2019:

	Defined Benefit Pension Plans			Retiree Health Benefit Plans		
	2021	2020	2019	2021	2020	2019
Actuarial gain (loss) arising during period	**$ 2,072.4**	$ (663.0)	$ (1,461.0)	**$ 142.5**	$ 238.8	$ 246.1
Plan amendments during period	**—**	(2.2)	—	**—**	—	—
Curtailment gain	**—**	—	19.0	**—**	—	—
Amortization of prior service (benefit) cost included in net income	**4.2**	4.5	6.1	**(59.6)**	(59.5)	(62.9)
Amortization of net actuarial (gain) loss included in net income	**487.7**	396.3	284.9	**3.2**	(3.0)	1.9
Foreign currency exchange rate changes and other	**47.2**	(71.5)	(7.7)	**1.9**	2.4	3.6
Total other comprehensive income (loss) during period	**$ 2,611.5**	$ (335.9)	$ (1,158.7)	**$ 88.0**	$ 178.7	$ 188.7

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 $167.3 million, $164.3 million, and $145.2 million for the years ended December 31, 2021, 2020, and 2019, 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, 2021, 2020, and 2019 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 75 percent growth investments and 25 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, bank loans, 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 in fund-of-funds structures and directly into hedge funds. 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, special situations, private debt, and private real estate investments. 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 equity-like 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 public 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 a portion of the real estate holdings, 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, 2021 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.	$ 1,325.4	$ 430.4	$ 0.1	$ 1.2	$ 893.7
International	2,722.7	815.0	—	—	1,907.7
Fixed income:					
Developed markets	4,496.0	2.6	3,356.6	—	1,136.8
Developed markets - repurchase agreements	(1,376.2)	—	(1,376.2)	—	—
Emerging markets	611.0	11.3	250.5	0.1	349.1
Private alternative investments:					
Hedge funds	3,046.8	—	—	—	3,046.8
Equity-like funds	3,816.4	2.1	—	5.5	3,808.8
Real estate	630.3	363.8	7.5	10.7	248.3
Other	1,143.6	103.2	263.2	(2.1)	779.3
Total	$ 16,416.0	$ 1,728.4	$ 2,501.7	$ 15.4	$ 12,170.5
Retiree Health Benefit Plans					
Public equity securities:					
U.S.	$ 124.7	$ 40.9	$ —	$ 0.1	$ 83.7
International	180.6	47.7	—	—	132.9
Fixed income:					
Developed markets	102.2	—	80.5	—	21.7
Emerging markets	51.6	—	23.7	—	27.9
Private alternative investments:					
Hedge funds	275.4	—	—	—	275.4
Equity-like funds	317.8	—	—	0.5	317.3
Cash value of trust owned insurance contract	2,166.8	—	2,166.8	—	—
Real estate	36.2	34.5	0.7	1.0	—
Other	106.1	24.4	18.3	(0.1)	63.5
Total	$ 3,361.4	$ 147.5	$ 2,290.0	$ 1.5	$ 922.4

[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, 2021. The activity in the Level 3 investments during the year ended December 31, 2021 was not material.

The fair values of our defined benefit pension plan and retiree health plan assets as of December 31, 2020 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.	$ 737.6	$ 476.1	$ —	$ 1.0	$ 260.5
International	2,635.8	1,102.3	—	—	1,533.5
Fixed income:					
Developed markets	4,301.3	2.9	3,179.2	—	1,119.2
Developed markets - repurchase agreements	(1,670.8)	—	(1,670.8)	—	—
Emerging markets	631.0	14.2	262.7	0.1	354.0
Private alternative investments:					
Hedge funds	2,661.3	—	—	—	2,661.3
Equity-like funds	2,844.7	—	—	16.9	2,827.8
Real estate	558.9	259.6	6.9	5.8	286.6
Other	1,879.2	60.4	301.2	18.0	1,499.6
Total	$ 14,579.0	$ 1,915.5	$ 2,079.2	$ 41.8	$ 10,542.5
Retiree Health Benefit Plans					
Public equity securities:					
U.S.	$ 68.3	$ 45.0	$ —	$ 0.1	$ 23.2
International	162.3	58.1	—	—	104.2
Fixed income:					
Developed markets	101.5	—	80.3	—	21.2
Emerging markets	53.5	—	24.7	—	28.8
Private alternative investments:					
Hedge funds	229.7	—	—	—	229.7
Equity-like funds	223.4	—	—	1.6	221.8
Cash value of trust owned insurance contract	2,204.6	—	2,204.6	—	—
Real estate	25.8	24.5	0.7	0.6	—
Other	157.9	14.1	21.1	1.7	121.0
Total	$ 3,227.0	$ 141.7	$ 2,331.4	$ 4.0	$ 749.9

[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, 2020. The activity in the Level 3 investments during the year ended December 31, 2020 was not material.

In 2022, we expect to contribute approximately $40 million to our defined benefit pension plans to satisfy minimum funding requirements for the year. We do not currently expect to make material discretionary contributions in 2022.

Note 16: Contingencies

We are involved in various lawsuits, claims, government investigations and other legal proceedings that arise in the ordinary course of business. These claims or proceedings can involve various types of parties, including governments, competitors, customers, suppliers, service providers, licensees, employees, or shareholders, among others. These matters may involve patent infringement, antitrust, securities, pricing, sales and marketing practices, environmental, commercial, contractual rights, licensing obligations, health and safety matters, consumer fraud, employment matters, product liability and insurance coverage, among others. The resolution of these matters often develops over a long period of time and expectations can change as a result of new findings, rulings, appeals or settlement arrangements. Legal proceedings that are significant or that we believe could become significant or material are described below.

We believe the legal proceedings in which we are named as defendants are without merit and we are defending against them vigorously. It is not possible to determine the final 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 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.

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 litigation liability insurance, we are self-insured for litigation liability losses for all our currently and previously marketed products.

Patent Litigation

Alimta Patent Litigation

U.S. Patent Litigation

Alimta (pemetrexed) was protected by a vitamin regimen patent until November 2021, and since then has been protected by pediatric exclusivity through May 2022.

In December 2019, we settled a lawsuit we filed against Eagle Pharmaceuticals, Inc. (Eagle) in response to its application to market a product using an alternative form of pemetrexed. Per the settlement agreement, Eagle has a limited initial entry into the market with its product starting February 2022 (up to an approximate three-week supply) and subsequent unlimited entry starting April 2022.

European Patent Litigation

In Europe, Alimta was protected by the vitamin regimen patent through June 2021. Despite the recent patent expiration, a number of legal proceedings that were initiated prior to expiration are ongoing.

Emgality Patent Litigation

In September 2018, we were named as a defendant in litigation filed by Teva Pharmaceuticals International GMBH and Teva Pharmaceuticals USA, Inc. (collectively, Teva) in the U.S. District Court for the District of Massachusetts seeking a ruling that various claims in nine different Teva patents would be infringed by our launch and continued sales of Emgality for the prevention of migraine in adults. Trial is currently scheduled to begin in October 2022. In June 2021, we were named as a defendant in a second litigation filed by Teva in the U.S. District Court for the District of Massachusetts seeking a ruling that two

of Teva's patents, which are directed toward use of the active ingredient in Emgality to treat migraine, would be infringed by our continued sales of Emgality.

Jardiance Patent Litigation

In November 2018, Boehringer Ingelheim (BI), our partner in marketing and development of Jardiance, initiated U.S. patent litigation in the U.S. District Court of Delaware alleging infringement arising from submissions of Abbreviated New Drug Applications (ANDA) by a number of generic companies seeking approval to market generic versions of Jardiance, Glyxambi, and Synjardy in accordance with the procedures set out in the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act). Particularly with respect to Jardiance, the generic companies' ANDAs seek approval to market generic versions of Jardiance prior to the expiration of the relevant patents, and allege that certain patents, including in some allegations the compound patent, are invalid or would not be infringed. We are not a party to this litigation. This litigation has been stayed.

Taltz Patent Litigation

In April 2021, we petitioned the High Court of Ireland to declare invalid the patent that Novartis Pharma AG (Novartis) purchased from Genentech, Inc. in 2020. Novartis responded by filing a claim against us alleging patent infringement related to our commercialization of Taltz and seeking damages for past infringement and an injunction against future infringement. This matter is ongoing.

In April 2021 and November 2021, Novartis petitioned the Court of Rome Intellectual Property Division and the Swiss Federal Patent Court, respectively, in preliminary injunction (PI) and main infringement proceedings against us related to our commercialization of Taltz. In June 2021, the Court of Rome Intellectual Property Division dismissed Novartis' PI action. Novartis appealed the ruling and in October 2021, the panel hearing Novartis' appeal appointed a technical expert to assess the merits of the case. Both matters are ongoing. Hearings on the Italian and Swiss PI requests are scheduled for May 2022.

In June 2021, Novartis petitioned the Commercial Court of Vienna in PI proceedings and in November 2021, the Austrian court denied Novartis' request. Novartis did not appeal the ruling, and this matter is now closed.

Zyprexa Canada Patent Litigation

Beginning in the mid-2000s, several generic companies in Canada challenged the validity of our Zyprexa compound patent. In 2012, the Canadian Federal Court of Appeals denied our appeal of a lower court's decision that certain patent claims were invalid for lack of utility. In 2013, Apotex Inc. and Apotex Pharmachem Inc. (collectively, Apotex) brought claims against us in the Ontario Superior Court of Justice at Toronto for damages related to our enforcement of the Zyprexa compound patent under Canadian regulations governing patented drugs. Apotex seeks compensation based on novel legal theories under the Statute of Monopolies, Trade-Mark Act, and common law. In March 2021, the Ontario Superior Court granted our motion for summary judgement, thereby dismissing Apotex's case. Apotex appealed that ruling to the Court of Appeal for Ontario in April 2021 and a hearing occurred February 2022. We await a decision.

Product Liability Litigation

Actos® Product Liability

We are named along with Takeda Chemical Industries, Ltd. and Takeda affiliates (collectively, Takeda) as a defendant in four purported product liability class actions in Canada related to Actos, which we commercialized with Takeda in Canada until 2009, including one in Ontario filed December 2011 (*Casseres et al. v. Takeda Pharmaceutical North America, Inc., et al.*), one in Quebec filed July 2012 (*Whyte et al. v. Eli Lilly et al.*), one in Saskatchewan filed November 2017 (*Weiler v. Takeda Canada Inc. et al.*), and one in Alberta filed January 2013 (*Epp v. Takeda Canada Inc. et al.*). In general, plaintiffs in these actions alleged that Actos caused or contributed to their bladder cancer. An agreement to settle these actions became effective in May 2021. The relevant courts approved the settlement and the deadline for class members to seek settlement funds has now expired. The lawsuits have been dismissed or discontinued.

Byetta® Product Liability

We are named as a defendant in approximately 570 Byetta product liability lawsuits in the U.S. which were first initiated in March 2009 and involve approximately 805 plaintiffs. Approximately 55 of these lawsuits, covering about 285 plaintiffs, are filed in California state court and coordinated in a Los Angeles Superior Court. Approximately 515 of the lawsuits, covering about 515 plaintiffs, are filed in federal court, the majority of which are coordinated in a multi-district litigation (MDL) in the U.S. District Court for the Southern District of California. Two lawsuits, representing approximately two plaintiffs, have also been filed in various state courts. Approximately 565 of the lawsuits, involving approximately 800 plaintiffs, contain allegations that Byetta caused or contributed to the plaintiffs' cancer (primarily pancreatic cancer or thyroid cancer); while six plaintiffs allege Byetta caused or contributed to pancreatitis. In addition, one case alleges that Byetta caused or contributed to ampullary cancer. The federal and state trial courts granted summary judgment in favor of us and our co-defendants on the claims alleging pancreatic cancer. The plaintiffs appealed those rulings.

In November 2017, the U.S. Court of Appeals for the Ninth Circuit reversed the U.S. District Court for the Southern District of California's grant of summary judgment in the MDL based on that court's discovery rulings and remanded the cases back to the U.S. District Court for further proceedings. In March 2021, the U.S. District Court granted summary judgment for the defendants. In April 2021, the plaintiffs filed a notice of appeal to the U.S. Court of Appeals for the Ninth Circuit, but we have now been dismissed from that appeal. Certain plaintiffs have agreed to dismiss their lawsuits in exchange for a waiver of costs, and individual plaintiffs have begun dismissing their claims based upon this agreement. Approximately 311 of the MDL lawsuits have been dismissed as of February 2022. In the state court actions, in November 2018, the California Court of Appeal reversed the Los Angeles County Superior Court of California's grant of summary judgment based on that court's discovery rulings and remanded for further proceedings. In April 2021, the Los Angeles County Superior Court of California granted summary judgment for the defendants and the parties await entry of the order of judgment. Approximately 17 of the state court lawsuits have been dismissed as of February 2022.

We are aware of approximately 20 additional potential claimants who have not yet filed suit. These additional possible claims allege damages for pancreatic cancer or thyroid cancer.

Cialis Product Liability

We are named as a defendant in approximately 350 Cialis product liability lawsuits in the U.S. which were first initiated in August 2015. These cases, many of which were originally filed in various federal courts, contain allegations that Cialis caused or contributed to the plaintiffs' cancer (melanoma). In December 2016, the Judicial Panel on Multidistrict Litigation (JPML) granted the plaintiffs' petition to have filed cases and an unspecified number of future cases coordinated into a federal MDL in the U.S. District Court for the Northern District of California, alongside an existing coordinated proceeding involving Viagra®. The JPML ordered the transfer of the existing cases to the now-renamed MDL *In re: Viagra (Sildenafil Citrate) and Cialis (Tadalafil) Products Liability Litigation*. In April 2020, the MDL court granted summary judgment to the defendants on all of the claims brought against them by the plaintiffs. In May 2020, plaintiffs filed an appeal in the U.S. Court of Appeals for the Ninth Circuit. The parties have reached agreement to resolve the majority of claims pending in the appeal and expect those claims to soon be dismissed.

Jardiance Product Liability

First initiated in January 2019, we and Boehringer Ingelheim Pharmaceuticals, Inc., a subsidiary of BI, have been named as a defendant in 5 currently pending product liability lawsuits in Stamford Superior Court in Connecticut, alleging that Jardiance caused or contributed to plaintiffs' Fournier's gangrene. Our agreement with BI calls for BI to defend and indemnify us against any damages, costs, expenses, and certain other losses with respect to product liability claims in accordance with the terms of the agreement. All pending cases have been paused to allow for settlement negotiations and dismissals.

Environmental Proceedings

Under the Comprehensive Environmental Response, Compensation, and Liability Act, commonly known as "Superfund," we have been designated as one of several potentially responsible parties with respect to

the cleanup of fewer than 10 sites. Under Superfund, each responsible party may be jointly and severally liable for the entire amount of the cleanup.

Other Matters

340B Litigation and Investigations

We are the plaintiff in a lawsuit filed in January 2021 in the U.S. District Court for the Southern District of Indiana against the U.S. Department of Health and Human Services (HHS), the Secretary of HHS, the Health Resources and Services Administration (HRSA), and the Administrator of HRSA. The lawsuit challenges the HHS's December 30, 2020 advisory opinion stating that drug manufacturers are required to deliver discounts under the 340B program to all contract pharmacies. We seek a declaratory judgment that the defendants violated the Administrative Procedures Act and the U.S. Constitution, a preliminary injunction enjoining implementation of the administrative dispute resolution process created by defendants and, with it, their application of the advisory opinion, and other related relief. In March 2021, the court entered an order preliminarily enjoining the government's enforcement of the administrative dispute resolution process against us. In May 2021, HRSA notified us that it determined that our policy was contrary to the 340B statute. In response, in May 2021, we filed a motion for preliminary injunction and temporary restraining order requesting that the U.S. District Court for the Southern District of Indiana enjoin defendants from taking any action against us relating to the 340B drug pricing program until after the court issues a final judgment on the aforementioned litigation. In May 2021, the court denied our motion for a temporary restraining order but deferred resolution of our motion for preliminary injunction. In June 2021, the defendants withdrew the HHS December 30, 2020 advisory opinion. In July 2021, the court held oral argument on the parties' cross motions for summary judgment, the defendants' motion to dismiss, and our motion for preliminary injunction related to HRSA's May 2021 enforcement letter. In October 2021, the court denied the defendants' motion to dismiss, and granted in part and denied in part the parties' cross motions for summary judgment. We have filed a notice of appeal. This matter is ongoing.

In January 2021, we, along with other pharmaceutical manufacturers, were named as a defendant in a petition currently pending before the HHS Administrative Dispute Resolution Panel. Petitioner seeks declaratory and other injunctive relief related to the 340B program. As described above, the U.S. District Court for the Southern District of Indiana has entered a preliminary injunction enjoining the government's enforcement of this administrative dispute resolution process against us.

In July 2021, we, along with Sanofi-Aventis U.S., LLC (Sanofi), Novo Nordisk Inc. (Novo Nordisk), and AstraZeneca Pharmaceuticals LP, were named as a defendant in a purported class action lawsuit filed in the U.S. District Court for the Western District of New York by Mosaic Health, Inc. alleging antitrust and unjust enrichment claims related to the defendants' 340B distribution programs. We, with Sanofi and Novo Nordisk, filed a motion to dismiss the lawsuit. This matter is ongoing.

We received a civil investigative subpoena in February 2021 from the Office of the Attorney General for the State of Vermont relating to the sale of pharmaceutical products to Vermont covered entities under the 340B program. We are cooperating with this subpoena.

Branchburg Manufacturing Facility

In May 2021, we received a subpoena from the United States Department of Justice requesting the production of certain documents relating to our manufacturing site in Branchburg, New Jersey. We are cooperating with the subpoena.

Brazil Litigation – Cosmopolis Facility

Labor Attorney Litigation

First initiated in 2008, our subsidiary in Brazil, Eli Lilly do Brasil Limitada (Lilly Brasil), is named in a Public Civil Action brought by the Labor Attorney for the 15th Region in the Labor Court of Paulinia, State of Sao Paulo, Brazil, (the Labor Court) alleging possible harm to employees and former employees caused by alleged exposure to soil and groundwater contaminants 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, including some with unspecified financial impact, consisting primarily of paying lifetime health coverage for the employees and contractors who worked at the Cosmopolis facility for more than six months during the affected years and their children who were born during and after this period. We appealed this decision. In July 2018, the appeals court (TRT) generally affirmed the Labor Court's ruling, which included a liquidated award of 300 million Brazilian real. This 300 million Brazilian real liquidated award, when adjusted for inflation and the addition of pre and post judgment interest using the current Central Bank of Brazil's special system of clearance and custody rate, is approximately 950 million Brazilian real (approximately $170 million as of December 31, 2021). The TRT also restricted the broad health coverage awarded by the Labor Court to health problems that claimants could prove in a separate evidentiary proceeding arose from exposure to the alleged contamination. In August 2019, Lilly Brasil filed an appeal to the superior labor court (TST) and in June 2021, the TRT published its decision on the admissibility of Lilly Brasil's appeal, allowing the majority of the elements of the appeal to proceed; elements not proceeding are subject to an interlocutory appeal to the TST that was filed in June 2021. In September 2019, the TRT stayed a number of elements of its trial court decision pending the determination of Lilly Brasil's appeal to the TST.

In June 2019, the Labor Public Attorney (LPA) filed an application in the Labor Court for enforcement of the healthcare coverage granted by the TRT in its July 2018 ruling, requested restrictions on Lilly Brasil’s assets in Brazil, and required Lilly Brasil and Antibióticos do Brasil Ltda. (ABL) to submit a list of potential beneficiaries of the Public Civil Action for the LPA to identify and contact those individuals. In July 2019, the Labor Court issued a ruling requiring a freeze of Lilly Brasil’s immovable property or, alternatively, a security deposit or lien of 500 million Brazilian real. Lilly Brasil filed a writ of mandamus challenging this ruling. In June 2021, the court reduced the security deposit or lien to 100 million Brazilian real and limited the scope of the initial order. ABL and LPA appealed to the TST, which appeal is currently still under review. In addition, in September 2020, the LPA initiated a second preliminary enforcement of the portion of the July 2018 TRT decision in the Labor Court that prohibits the exposure of workers to the contaminated areas. The Labor Court is currently assessing the status of Lilly Brasil’s compliance with such portion of the July 2018 TRT decision. These matters are ongoing.

Individual Former Employee Litigation

Lilly Brasil is also named in approximately 25 pending lawsuits filed in the 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 more than half of the lawsuits by the trial courts, of which, approximately half of those judgements are on appeal in the labor courts.

China NDRC Antitrust Matter

The competition authority in China has investigated our distributor pricing practices in China in connection with a broader inquiry into pharmaceutical industry pricing. We cooperated with this investigation. In July 2021 Lilly divested Cialis in China. We consider this matter closed.

Puerto Rico Tax Matter

In May 2013, the Municipality of Carolina in Puerto Rico (Municipality) filed a lawsuit against us alleging noncompliance with respect to a contract with the Municipality and seeking a declaratory judgment. In December 2020, the Puerto Rico Appellate Court (AP) reversed the summary judgment previously granted by the Court of First Instance (CFI) in our favor, dismissing the Municipality's complaint in its entirety. The AP remanded the case to the CFI for trial on the merits.

In October 2021, the Municipality filed a motion to execute a purported judgment, and the CFI scheduled a hearing in March 2022 to consider the Municipality's motion. We have opposed the Municipality's motion. This matter is ongoing.

Eastern District of Pennsylvania Pricing (Average Manufacturer Price) Inquiry

In November 2014, we, along with another pharmaceutical manufacturer, were named as co-defendants in *United States et al. ex rel. Streck v. Takeda Pharm. Am., Inc., et al.*, which was filed in November 2014 and unsealed in the U.S. District Court for the Northern District of Illinois. The complaint alleges that the defendants should have treated certain credits from distributors as retroactive price increases and included such increases in calculating average manufacturer prices. In October 2021 the parties filed cross motions for summary judgment. Trial is scheduled for April 2022.

Health Choice Alliance

We are named as a defendant in a lawsuit filed in June 2017 in the U.S. District Court for the Eastern District of Texas seeking damages under the federal anti-kickback statute and state and federal false claims acts for certain patient support programs related to our products Humalog, Humulin, and Forteo. In September 2019, the U.S. District Court granted the U.S. Department of Justice's motion to dismiss the relator's second amended complaint. In January 2020, the relator appealed the District Court's dismissal to the U.S. Court of Appeals for the Fifth Circuit. In July 2021, the U.S. Court of Appeals for the Fifth Circuit affirmed the dismissal of the lawsuit, and the relator did not petition the U.S. Supreme Court for certiorari. We are also named as a defendant in two similar lawsuits filed in Texas and New Jersey state courts in October 2019 seeking damages under the Texas Medicaid Fraud Prevention Act and New Jersey Medicaid False Claims Act, respectively. In November 2020, the Texas state court action was stayed pending a final determination with respect to the aforementioned federal lawsuit. In April 2021, the New Jersey state court action was dismissed with prejudice and in June 2021, the relator appealed the state court's decision to the Appellate Division of the New Jersey Superior Court. In January 2022, the relator filed its appellate brief.

Pricing Litigation, Investigations, and Inquiries

Litigation

In December 2017, we, along with Sanofi and Novo Nordisk were named as defendants in a consolidated purported class action lawsuit, *In re. Insulin Pricing Litigation*, in the U.S. District Court for the District of New Jersey relating to insulin pricing seeking damages under various state consumer protection laws and the Federal Racketeer Influenced and Corrupt Organization Act (federal RICO Act). Separately, in February 2018, we, along with Sanofi and Novo Nordisk, were named as defendants in *MSP Recovery Claims, Series, LLC et al. v. Sanofi Aventis U.S. LLC et al.*, in the same court, seeking damages under various state consumer protection laws, common law fraud, unjust enrichment, and the federal RICO Act. In both *In re. Insulin Pricing Litigation* and the *MSP Recovery Claims* litigation, the court dismissed claims under the federal RICO Act and certain state laws. In April 2021, the plaintiffs in *In re. Insulin Pricing Litigation* amended their complaint to allege additional state law claims for civil conspiracy and violations of state RICO statutes. The court has allowed the Arizona RICO statute and certain state civil conspiracy law claims to proceed. Also, we, along with Sanofi, Novo Nordisk, CVS, Express Scripts, and Optum, have been sued in a purported class action, *FWK Holdings, LLC v. Novo Nordisk Inc., et al.,* filed in the same court in November 2020, for alleged violations of the federal RICO Act as well as the New Jersey RICO Act and antitrust law. That same group of defendants, along with Medco Health and United Health Group, also have been sued in other purported class actions in the same court, *Rochester Drug Co-Operative Inc. v. Eli Lilly & Co. et al.* and *Value Drug Co. v. Eli Lilly & Co. et al.* both initiated in March 2020, for alleged violations of the federal RICO Act. In September 2020, the U.S. District Court for the District of New Jersey

granted plaintiffs' motion to consolidate *FWK Holdings, LLC v. Novo Nordisk Inc., et al.*, *Rochester Drug Co-Operative Inc. v. Eli Lilly & Co. et al.*, and *Value Drug Co. v. Eli Lilly & Co. et al.* In July 2021, the U.S. District Court for the District of New Jersey dismissed the three antitrust claims alleged by plaintiffs in the consolidated litigation and denied dismissal of the RICO claims.

In October 2018, the Minnesota Attorney General's Office initiated litigation against us, Sanofi, and Novo Nordisk, *State of Minnesota v. Sanofi-Aventis U.S. LLC et al.,* in the U.S. District Court for the District of New Jersey, alleging unjust enrichment, violations of various Minnesota state consumer protection laws, and the federal RICO Act. In March 2021, the U.S. District Court for the District of New Jersey dismissed with prejudice the Minnesota Attorney General's federal RICO claims and false advertising claims under state law; the consumer fraud and other related state law claims remain ongoing. Additionally, in May 2019, the Kentucky Attorney General's Office filed a complaint against us, Sanofi, and Novo Nordisk, *Commonwealth of Kentucky v. Novo Nordisk, Inc. et al.*, in Kentucky state court, alleging violations of the Kentucky consumer protection law, false advertising, and unjust enrichment. In November 2019, Harris County in Texas initiated litigation against us, Sanofi, Novo Nordisk, Express Scripts, CVS, Optum, and Aetna, *County of Harris Texas v. Eli Lilly & Co., et al.*, in federal court in the Southern District of Texas alleging violations of the federal RICO Act, the state deceptive trade practices-consumer protection act, and common law claims such as fraud, unjust enrichment, and civil conspiracy. Harris County also alleged violations of federal and state antitrust law, but voluntarily dismissed them. This lawsuit relates to our insulin products as well as Trulicity.

In June 2021, the City of Miami, Florida initiated litigation against us, Sanofi, Novo Nordisk, ESI, CVS/Caremark/Aetna, and Optum, asserting state law antitrust, common law fraud, money had and received, unjust enrichment, and civil conspiracy claims. After removing the case to federal court, we, along with the other defendants, filed a motion to dismiss the lawsuit. In January 2022, the court granted the motion in part but has allowed the antitrust and conspiracy claims to proceed against us, Sanofi and Novo Nordisk. We, along with Sanofi and Novo Nordisk, have moved the court to reconsider its denial of our motion to dismiss the antitrust and conspiracy claims.

In June 2021, the Mississippi Attorney General's Office (Mississippi AG) initiated litigation against us, Sanofi, Novo Nordisk, Evernorth/ESI, CVS/Caremark, and United/Optum in the Hinds County, Mississippi Chancery Court, alleging state law consumer protection, unjust enrichment, and civil conspiracy claims. After the case was removed to federal court, we, along with the other defendants, filed a motion to dismiss the lawsuit. In response, the Mississippi AG filed a motion to amend its complaint, which the court granted. This matter is ongoing.

Investigations, Subpoenas, and Inquiries

We received subpoenas from the New York and Vermont Attorney General Offices and civil investigative demands from the Washington, New Mexico, and Colorado Attorney General Offices relating to the pricing and sale of our insulin products. The Offices of the Attorney General in Mississippi, Washington D.C., California, Florida, Hawaii, and Nevada have requested information relating to the pricing and sale of our insulin products. We also received interrogatories and a subpoena from the California Attorney General's Office regarding our competition in the long-acting insulin market, which was subsequently withdrawn in June 2021. In January 2022, the Michigan Attorney General filed against us in state court a petition seeking authorization to investigate Lilly for potential violations of the Michigan Consumer Protection Act (MCPA), and a complaint seeking a declaratory judgment that the MCPA applies to the conduct it seeks to investigate and allows it to conduct the investigation. The state court granted the State's petition to investigate, authorizing the State to issue civil investigative subpoenas. The State's complaint for declaratory judgment remains pending.

We received a request in January 2019 from the House of Representatives' Committee on Oversight and Reform seeking commercial information and business records related to the pricing of insulin products, among other issues. We also received requests from the Senate Finance Committee and the Senate Committee on Health, Education, Labor, and Pensions, and separate requests from the House Committee on Energy and Commerce majority and minority members. Those requests sought pricing and other commercial information regarding Lilly's insulin products. In January 2021, the Senate Finance Committee released a report summarizing the findings of its investigation. In December 2021 the House of Representatives' Committee on Oversight and Reform majority and minority staffs released separate reports with findings from their investigations into drug pricing, including of insulin products.

We are cooperating with all of these aforementioned investigations, subpoenas, and inquiries.

Research Corporation Technologies, Inc.

In April 2016, we were named as a defendant in litigation filed by Research Corporation Technologies, Inc. (RCT) in the U.S. District Court for the District of Arizona. RCT is seeking damages for breach of contract, unjust enrichment, and conversion related to processes used to manufacture certain products, including Humalog and Humulin. Both parties moved for summary judgment and hearing on the motions took place in August 2021. In October 2021, the Court issued a summary judgment decision finding in favor of RCT on certain issues, including with respect to a disputed royalty. Both parties filed motions for reconsideration, which are underway. Potential damages payable under the litigation, if finally awarded after an appeal, could be material but are not currently reasonably estimable. A trial date has not been set.

Note 17: 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, 2019[(1)]	$ (1,569.7)	$ (22.1)	$ (3,852.7)	$ (238.9)	$ (56.8)	$ (5,740.2)
Other comprehensive income (loss) before reclassifications	(46.2)	28.9	(967.6)	14.5	(27.2)	(997.6)
Net amount reclassified from accumulated other comprehensive loss	(62.1)	(1.9)	181.7	12.5	84.0	214.2
Net other comprehensive income (loss)	(108.3)	27.0	(785.9)	27.0	56.8	(783.4)
Balance at December 31, 2019	(1,678.0)	4.9	(4,638.6)	(211.9)	—	(6,523.6)
Other comprehensive income (loss) before reclassifications	250.5	6.8	(379.7)	(133.8)	—	(256.2)
Net amount reclassified from accumulated other comprehensive loss	—	3.1	267.3	13.0	—	283.4
Net other comprehensive income (loss)	250.5	9.9	(112.4)	(120.8)	—	27.2
Balance at December 31, 2020	(1,427.5)	14.8	(4,751.0)	(332.7)	—	(6,496.4)
Other comprehensive income (loss) before reclassifications	**(122.7)**	**(11.9)**	**1,823.4**	**106.6**	**—**	**1,795.4**
Net amount reclassified from accumulated other comprehensive loss	**—**	**0.8**	**344.0**	**13.1**	**—**	**357.9**
Net other comprehensive income (loss)	**(122.7)**	**(11.1)**	**2,167.4**	**119.7**	**—**	**2,153.3**
Ending balance at December 31, 2021	**$ (1,550.2)**	**$ 3.7**	**$ (2,583.6)**	**$ (213.0)**	**$ —**	**$ (4,343.1)**

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

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)	2021	2020	2019
Foreign currency translation gains/losses	**$ (136.2)**	$ 128.3	$ (18.4)
Unrealized net gains/losses on securities	**4.7**	(4.3)	(7.4)
Defined benefit pension and retiree health benefit plans	**(532.0)**	44.8	184.1
Effective portion of cash flow hedges	**(31.8)**	32.1	(7.3)
Benefit/(provision) for income taxes allocated to other comprehensive income (loss) items	**$ (695.3)**	$ 200.9	$ 151.0

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:

	Year Ended December 31,			
Details about Accumulated Other Comprehensive Loss Components	2021	2020	2019	Affected Line Item in the Consolidated Statements of Operations
Amortization of retirement benefit items:				
Prior service benefits, net	**$ (55.4)**	$ (55.0)	$ (56.8)	Other—net, (income) expense
Actuarial losses	**490.9**	393.3	286.8	Other—net, (income) expense
Total before tax	**435.5**	338.3	230.0	
Tax benefit	**(91.5)**	(71.0)	(48.3)	Income taxes
Net of tax	**344.0**	267.3	181.7	
Other, net of tax	**13.9**	16.1	(51.5)	Other—net, (income) expense
Reclassifications from continuing operations (net of tax)	**357.9**	283.4	130.2	
Reclassifications from discontinued operations (net of tax)	**—**	—	84.0	Net income from discontinued operations
Total reclassifications for the period, net of tax	**$ 357.9**	$ 283.4	$ 214.2	

Note 18: Other–Net, (Income) Expense

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

	2021	2020	2019
Interest expense	**$ 339.8**	$ 359.6	$ 400.6
Interest income	**(25.4)**	(33.0)	(80.4)
Net investment gains on equity securities (Note 7)	**(176.9)**	(1,442.2)	(401.2)
Debt extinguishment loss (Note 11)	**405.2**	—	252.5
Gain on sale of antibiotic business in China (Note 3)	**—**	—	(309.8)
Retirement benefit plans	**(289.7)**	(251.8)	(209.9)
Other (income) expense	**(51.4)**	195.5	56.6
Other–net, (income) expense	**$ 201.6**	$ (1,171.9)	$ (291.6)

Note 19: Discontinued Operations

On March 11, 2019, we completed the disposition of our remaining 80.2 percent ownership of Elanco common stock through a tax-free exchange offer. The earnings attributable to the divested, noncontrolling interest for the period from the initial public offering until disposition were not material.

As a result of the disposition, 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 financial statements for all periods presented.

Revenue and net income from discontinued operations in 2019 was $580.0 million and $3.68 billion, respectively. There were no discontinued operations in 2020 and 2021.

The gain related to the disposition of Elanco in the consolidated statement of cash flows includes the operating results of Elanco through the disposition date, which were not material. Net cash flows of our discontinued operations for operating and investing activities were not material for the year ended December 31, 2019.

We entered into a transitional services agreement (TSA) with Elanco to facilitate the orderly transfer of various services to Elanco. The TSA related primarily to administrative services, which were generally provided over 24 months from the date of disposition, and is now complete. This agreement was not material and did 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 available on our lilly.com website and on the internal LillyNow website to enable reporting of 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 (PCAOB ID: 42). 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 our Annual Report on Form 10-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. It is the audit committee's responsibility to appoint an independent registered public accounting firm subject to shareholder ratification, pre-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, operate under a code of conduct and are subject to 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 "Internal Control—Integrated Framework" (2013) 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, 2021. 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 effectiveness of internal control over financial reporting as of December 31, 2021 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their attestation report, which appears herein. Their responsibility is to evaluate whether internal control over financial reporting was designed and operating effectively.

David A. Ricks	Anat Ashkenazi
Chair, President, and Chief Executive Officer	*Senior Vice President and Chief Financial Officer*

February 23, 2022

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, 2021 and 2020, 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, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021, 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, 2021, 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 23, 2022 expressed an unqualified opinion thereon.

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.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Medicaid, Managed Care, and Medicare sales rebate accruals

Description of the Matter

As described in Note 2 to the consolidated financial statements under the caption "Net Product Revenue," the Company establishes provisions for sales rebate and discounts in the same period as the related sales occur. At December 31, 2021 the Company had $6,845.8 million in sales rebate and discount accruals. A large portion of these accruals are rebates associated with sales in the United States for which payment for purchase of the product is covered by Medicaid, Managed Care, and Medicare.

Auditing the Medicaid, Managed Care, and Medicare sales rebate and discount liabilities is challenging because of the subjectivity of certain assumptions required to estimate the rebate liabilities. In calculating the appropriate accrual amount, the Company considers historical Medicaid, Managed Care, and Medicare rebate payments by product as a percentage of their historical sales as well as any significant changes in sales trends, the lag in payment timing, an evaluation of the current Medicaid and Medicare laws and interpretations, the percentage of products that are sold via Medicaid, Managed Care, and Medicare, and product pricing. For Medicaid, there is significant complexity associated with calculating the legislated Medicaid rebates. Management utilizes employees with legislative experience and knowledge in developing assumptions used to calculate Medicaid rebates. Similarly, for Managed Care and Medicare, given variability in prescription drug costs, continued historical year over year increases in enrollees and variability in prescription data, historical rebate information may not be predictive for management to estimate the rebate accrual and thus, management supplements its historical data analysis with qualitative adjustments based upon current utilization.

How We Addressed the Matter in Our Audit

We tested the Company's controls addressing the identified risks of material misstatement related to the valuation of the sales rebate and discount liabilities. This included testing controls over management's review of the significant assumptions used to calculate the Medicaid, Managed Care, and Medicare rebate liabilities, including the significant assumptions discussed above. This testing also included management's control to compare actual activity to forecasted activity and controls to ensure the data used to evaluate the significant assumptions was complete and accurate.

Our audit procedures included, among others, evaluating for reasonableness the significant assumptions in light of economic trends, product profiles, and other regulatory factors. Our testing involved assessing the historical accuracy of management's estimates by comparing actual activity to previous estimates and performing analytical procedures, based on internal and external data sources, to evaluate the completeness of the reserves. Additionally, our procedures included reviewing a sample of contracts, testing a sample of rebate payments and testing the underlying data used in management's evaluation. For Medicaid, we involved our professionals with an understanding of the statutory reimbursement requirements to assess the consistency of the Company's calculation methodologies with the applicable government regulations and policy. For Medicare we evaluated the reasonableness of assumptions made by management in estimating the Medicare coverage gap liability.

Retirement Benefits - Valuation of Alternative Investments

Description of the Matter	As described in Note 15 to the consolidated financial statements under the caption "Benefit Plan Investments," the Company's benefit plan investment policies are set with specific consideration of return and risk requirements in relationship to the respective liabilities. At December 31, 2021 the Company had $19,777.4 million in plan assets related to the defined benefit pension plans and retiree health benefit plans. Approximately 38 percent of the total pension and retiree health assets are in hedge funds and private equity-like investment funds ("alternative investments"). These alternative investments are valued using significant unobservable inputs or are valued at net asset value (NAV) reported by the counterparty, adjusted as necessary. Auditing the fair value of these alternative investments is challenging because of the higher estimation uncertainty of the inputs to the fair value calculations, including the underlying net asset values ("NAVs"), discounted cash flow valuations, comparable market valuations, and adjustments for currency, credit, liquidity and other risks. Additionally, certain information regarding the fair value of these alternative investments is based on unaudited information available to management at the time of valuation.
How We Addressed the Matter in Our Audit	We tested the Company's controls addressing the risks of material misstatement relating to valuation of alternative investments. This included testing management's review controls over alternative investment valuation, which included a comparison of returns to benchmarks and in-person or telephonic meetings with investment firms to discuss valuation policies and procedures, as well as portfolio performance. Our audit procedures included, among others, comparing fund returns to selected relevant benchmarks and understanding variations, obtaining the latest audited financial statements and comparing to the Company's estimated fair values and reconciling any differences. We also inquired of management about changes to the investment portfolio and/or related investment strategies and considerations. We assessed the historical accuracy of management's estimates by comparing actual activity to previous estimates. We evaluated for contrary evidence by confirming the fair value of the investments and ownership interest directly with the trustees and a sample of managers at year end.

/s/ Ernst & Young LLP

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

Indianapolis, Indiana

February 23, 2022

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, 2021, 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, 2021, 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, 2021 and 2020, 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, 2021, and the related notes and our report dated February 23, 2022 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.

/s/ Ernst & Young LLP

Indianapolis, Indiana

February 23, 2022

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Under applicable Securities and Exchange Commission (SEC) regulations, management of a reporting company, with the participation of the principal executive officer and principal financial officer, must periodically evaluate the company's "disclosure controls and procedures," which are defined generally as controls and other procedures designed to ensure that information required to be disclosed by the reporting company in its periodic reports filed with the SEC (such as this Form 10-K) is recorded, processed, summarized, and reported on a timely basis.

Our management, with the participation of David A. Ricks, president and chief executive officer, and Anat Ashkenazi, senior vice president and chief financial officer, evaluated our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934) as of December 31, 2021, and concluded that they were effective.

Management's Report on Internal Control over Financial Reporting

Mr. Ricks and Ms. Ashkenazi provided a report on behalf of management on our internal control over financial reporting, in which management concluded that the company's internal control over financial reporting is effective at December 31, 2021 based on the framework in "Internal Control—Integrated Framework" (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Our internal control over financial reporting is 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 in the United States. Due to the inherent limitations, no evaluation over internal control can provide absolute assurance that no material misstatements or fraud exist.

In addition, Ernst & Young LLP, the company's independent registered public accounting firm, issued an attestation report on the company's internal control over financial reporting as of December 31, 2021.

You can find the full text of management's report and Ernst & Young's attestation report in Item 8.

Changes in Internal Control over Financial Reporting

During the fourth quarter of 2021, there were no changes in our internal control over financial reporting that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

Part III

Item 10. Directors, Executive Officers, and Corporate Governance

Directors and Executive Officers

Information relating to our board of directors is found in our Definitive Proxy Statement, to be dated on or about March 18, 2022 (Proxy Statement), under "Governance - Board Operations and Governance" and is incorporated in this Annual Report on Form 10-K by reference.

Information relating to our executive officers is found at Item 1, "Business - Executive Officers of the Company" and is incorporated by reference herein.

Code of Ethics

Information relating to our code of ethics is found in our Proxy Statement under "Governance - Board Oversight of Strategy, Compliance, and Risk Management - Code of Ethics" and is incorporated in this Annual Report on Form 10-K by reference.

Corporate Governance

Information about the procedures by which shareholders can recommend nominees to our board of directors is found in our Proxy Statement under "Shareholder Engagement on Governance Issues - Shareholder Recommendations and Nominations for Director Candidates" and is incorporated in this Annual Report on Form 10-K by reference.

The board of directors has appointed an audit committee consisting entirely of independent directors in accordance with applicable Securities and Exchange Commission and New York Stock Exchange requirements for audit committees. Information about our audit committee is found in our Proxy Statement under "Governance - Membership and Meetings of the Board and Its Committees - Audit Committee" and is incorporated in this Annual Report on Form 10-K by reference.

Item 11. Executive Compensation

Information on director compensation, executive compensation, and compensation committee matters can be found in the Proxy Statement under "Governance - Director Compensation," "- Membership and Meetings of the Board and Its Committees - Compensation Committee," "Compensation - Compensation Discussion and Analysis," and "- Executive Compensation." Such information is incorporated in this Annual Report on Form 10-K by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

Security Ownership of Certain Beneficial Owners and Management

Information relating to ownership of the company's common stock by management and by persons known by the company to be the beneficial owners of more than five percent of the outstanding shares of common stock is found in the Proxy Statement under "Ownership of Company Stock" and incorporated in this Annual Report on Form 10-K by reference.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table presents information as of December 31, 2021 regarding the company's compensation plans under which shares of the company's common stock have been authorized for issuance.

Plan category	(a) Number of securities to be issued upon exercise of outstanding options, warrants, and rights [1]	(b) Weighted-average exercise price of outstanding options, warrants, and rights	(c) Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders	—	$ —	50,646,706
Equity compensation plan not approved by security holders	—	—	—
Total	—	—	50,646,706

[1] 5,605,694 shares are underlying outstanding equity awards other than options.

Item 13. Certain Relationships and Related Transactions, and Director Independence

Related Person Transactions

Information relating to the policies and procedures for approval of related person transactions by our board of directors can be found in the Proxy Statement under "Governance - Highlights of the Company's Corporate Governance - Conflicts of Interest and Transactions with Related Persons." Such information is incorporated in this Annual Report on Form 10-K by reference.

Director Independence

Information relating to director independence can be found in the Proxy Statement under "Governance - Director Independence" and is incorporated in this Annual Report on Form 10-K by reference.

Item 14. Principal Accountant Fees and Services

Information related to the fees and services of our principal independent accountants, Ernst & Young LLP, can be found in the Proxy Statement under "Audit Matters - Item 3. Ratification of the Appointment of the Independent Auditor - Audit Committee Report - Services Performed by the Independent Auditor" and "-

Independent Auditor Fees." Such information is incorporated in this Annual Report on Form 10-K by reference.

Item 15. Exhibits and Financial Statement Schedules

(a)1. Financial Statements

The following consolidated financial statements of the company and its subsidiaries are found at Item 8:

- Consolidated Statements of Operations—Years Ended December 31, 2021, 2020, and 2019
- Consolidated Statements of Comprehensive Income (Loss)—Years Ended December 31, 2021, 2020, and 2019
- Consolidated Balance Sheets—December 31, 2021 and 2020
- Consolidated Statements of Shareholders' Equity—Years Ended December 31, 2021, 2020, and 2019
- Consolidated Statements of Cash Flows—Years Ended December 31, 2021, 2020, and 2019
- Notes to Consolidated Financial Statements

(a)2. Financial Statement Schedules

The consolidated financial statement schedules of the company and its subsidiaries have been omitted because they are not required, are inapplicable, or are adequately explained in the financial statements.

Financial statements of interests of 50 percent or less, which are accounted for by the equity method, have been omitted because they do not, considered in the aggregate as a single subsidiary, constitute a significant subsidiary.

(a)3. Exhibits

The following documents are filed as part of this report:

Exhibit		Location
3.1	Amended Articles of Incorporation	Incorporated by reference to Exhibit 3.1 to the Company's Annual Report on Form 10-K for the year ended December 31, 2013
3.2	Bylaws, as amended	Incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on December 16, 2021
4.1	Indenture, dated February 1, 1991, between the Company and Deutsche Bank Trust Company Americas, as successor trustee to Citibank, N.A., as Trustee	Incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-3, Registration No. 333-186979
4.2	Tripartite Agreement, dated September 13, 2007, appointing Deutsche Bank Trust Company Americas as Successor Trustee under the Indenture listed in Exhibit 4.1	Incorporated by reference to Exhibit 4.2 to the Company's Annual Report on Form 10-K for the year ended December 31, 2008
4.3	Description of the Company's Common Stock	Incorporated by reference to Exhibit 4.3 to the Company's Annual Report on Form 10-K for the year ended December 31, 2019
4.4	Description of the Company's 1.000% Notes due 2022, 1.625% Notes due 2026, and 2.125% Notes due 2030	Incorporated by reference to Exhibit 4.4 to the Company's Annual Report on Form 10-K for the year ended December 31, 2019
4.5	Description of the Company's 6.77% Notes due 2036	Incorporated by reference to Exhibit 4.5 to the Company's Annual Report on Form 10-K for the year ended December 31, 2019
4.6	Description of the Company's 7 1/8% Notes due 2025	Incorporated by reference to Exhibit 4.6 to the Company's Annual Report on Form 10-K for the year ended December 31, 2019

4.7	Description of the Company's 0.625% Notes due 2031 and 1.700% Notes due 2049	Incorporated by reference to Exhibit 4.7 to the Company's Annual Report on Form 10-K for the year ended December 31, 2019
4.8	Description of the Company's 0.500% Notes due 2033, 1.125% Notes due 2051, and 1.375% Notes due 2061	Attached
4.9	Description of the Company's 1.625% Notes due 2043	Attached
10.1	Amended and Restated 2002 Lilly Stock Plan(1)	Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2018
10.2	Form of Performance Award under the 2002 Lilly Stock Plan(1)	Attached
10.3	Form of Performance Award under the 2002 Lilly Stock Plan (with non-compete)(1)	Attached
10.4	Form of Performance Award under the 2002 Lilly Stock Plan (non-executive officer)(1)	Attached
10.5	Form of Shareholder Value Award under the 2002 Lilly Stock Plan(1)	Attached
10.6	Form of Shareholder Value Award under the 2002 Lilly Stock Plan (with non-compete)(1)	Attached
10.7	Form of Shareholder Value Award under the 2002 Lilly Stock Plan (non-executive officer)(1)	Attached
10.8	Form of Relative Value Award under the 2002 Lilly Stock Plan(1)	Attached
10.9	Form of Relative Value Award under the 2002 Lilly Stock Plan (with non-compete)(1)	Attached
10.10	Form of Relative Value Award under the 2002 Lilly Stock	Attached

10.18	2007 Change in Control Severance Pay Plan for Select Employees, as amended(1)	Incorporated by reference to Exhibit 10.15 to the Company's Annual Report on Form 10-K for the year ended December 31, 2020
21	List of Subsidiaries	Attached
23	Consent of Independent Registered Public Accounting Firm	Attached
31.1	Rule 13a-14(a) Certification of David A. Ricks, Chair, President, and Chief Executive Officer	Attached
31.2	Rule 13a-14(a) Certification of Anat Ashkenazi, Senior Vice President and Chief Financial Officer	Attached
32	Section 1350 Certification	Attached
101	Interactive Data File	Attached
104	Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101)	Attached

(1) Indicates management contract or compensatory plan.

Item 16. Form 10-K Summary

Not applicable.

Signatures

Pursuant to the requirements of Section 13 or 15(d) 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

By /s/ David A. Ricks

David A. Ricks
Chair, President, and Chief Executive Officer

February 23, 2022

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below on February 23, 2022 by the following persons on behalf of the Registrant and in the capacities indicated.

Signature	Title
/s/ David A. Ricks DAVID A. RICKS	Chair, President, and Chief Executive Officer (principal executive officer)
/s/ Anat Ashkenazi ANAT ASHKENAZI	Senior Vice President and Chief Financial Officer (principal financial officer)
/s/ Donald A. Zakrowski DONALD A. ZAKROWSKI	Vice President, Finance, and Chief Accounting Officer (principal accounting officer)
/s/ Ralph Alvarez RALPH ALVAREZ	Director
/s/ Katherine Baicker, Ph.D. KATHERINE BAICKER, Ph.D.	Director
/s/ Michael L. Eskew MICHAEL L. ESKEW	Director
/s/ J. Erik Fyrwald J. ERIK FYRWALD	Director
/s/ Jamere Jackson JAMERE JACKSON	Director
/s/ Kimberly H. Johnson KIMBERLY H. JOHNSON	Director
/s/ William G. Kaelin, Jr., M.D. WILLIAM G. KAELIN, JR., M.D.	Director
/s/ Juan R. Luciano JUAN R. LUCIANO	Director
/s/ Marschall S. Runge, M.D., Ph.D. MARSCHALL S. RUNGE, M.D., Ph.D.	Director
/s/ Gabrielle Sulzberger GABRIELLE SULZBERGER	Director
/s/ Jackson P. Tai JACKSON P. TAI	Director
/s/ Karen Walker KAREN WALKER	Director

Trademarks Used In This Report

Trademarks or service marks owned by Eli Lilly and Company or its affiliates, when first used in each item of this report, appear with an initial capital and are followed by the symbol ® or ™, as applicable. In subsequent uses of the marks in the item, the symbols may be omitted.

Actos® is a trademark of Takeda Pharmaceutical Company Limited.

Byetta® is a trademark of Amylin Pharmaceuticals, Inc.

Glyxambi®, Jardiance®, Jentadueto®, Synjardy®, Trajenta®, and Trijardy® are trademarks of Boehringer Ingelheim International GmbH.

Tyvyt® is a trademark of Innovent Biologics (Suzhou) Co., Ltd.

Viagra® is a trademark of G.D. Searle LLC, a Viatris Company.

United States
Securities and Exchange Commission
Washington, D.C. 20549

Form 10-K

Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
for the fiscal year ended December 31, 2020

Commission file number 001-06351

ELI LILLY AND COMPANY

(Exact name of Registrant as specified in its charter)

Indiana	35-0470950
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

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

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

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

Title of Each Class	Trading Symbol(s)
Common Stock (no par value)	LLY
1.000% Notes due 2022	LLY22
7 1/8% Notes due 2025	LLY25
1.625% Notes due 2026	LLY26
2.125% Notes due 2030	LLY30
0.625% Notes due 2031	LLY31
6.77% Notes due 2036	LLY36
1.700% Notes due 2049	LLY49A

Securities registered pursuant to Section 12(g) of the Exchange Act: None

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act. Yes ☐ No ☒

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

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files).
Yes ☒ No ☐

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company,” and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☒	Accelerated filer ☐
Non-accelerated filer ☐	Smaller reporting company ☐
	Emerging growth company ☐

If an emerging growth company, indicate by check mark if the Registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐
Indicate by check mark whether the Registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒
Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act):
Yes ☐ No ☒
Aggregate market value of the common equity held by non-affiliates computed by reference to the price at which the common equity was last sold as of the last business day of the Registrant’s most recently completed second fiscal quarter: approximately $138,907,000,000.

Number of shares of common stock outstanding as of February 12, 2021: 958,425,693

Portions of the Registrant’s Proxy Statement for the 2021 Annual Meeting of Shareholders have been incorporated by reference into Part III of this report.

Eli Lilly and Company

Form 10-K
For the Year Ended December 31, 2020

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Forward-Looking Statements

This Annual Report on Form 10-K and our other publicly available documents include forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 (Exchange Act), and are subject to the safe harbor created thereby under the Private Securities Litigation Reform Act of 1995. In particular, information appearing under “Business,” “Risk Factors,” and “Management's Discussion and Analysis of Results of Operations and Financial Condition” includes forward-looking statements. Forward-looking statements include all statements that do not relate solely to historical or current facts, and generally can be identified by the use of words such as “may,” “believe,” “will,” “expect,” “project,” “estimate,” “intend,” “anticipate,” “plan,” “continue,” or similar expressions or future or conditional verbs.

Forward-looking statements inherently involve many risks and uncertainties that could cause actual results to differ materially from those expressed in forward-looking statements. Where, in any forward-looking statement, we express an expectation or belief as to future results or events, it is based on management's current plans and expectations, expressed in good faith and believed to have a reasonable basis. However, we can give no assurance that any such expectation or belief will result or will be achieved or accomplished. Investors therefore should not place undue reliance on forward-looking statements. The following include some but not all of the factors that could cause actual results or events to differ materially from those anticipated:

- the impact of the evolving COVID-19 pandemic and the global response thereto;
- uncertainties related to our efforts to develop potential treatments for COVID-19;
- the significant costs and uncertainties in the pharmaceutical research and development process, including with respect to the timing and process of obtaining regulatory approvals;
- the impact of acquisitions and business development transactions and related integration costs;
- the expiration of intellectual property protection for certain of our products and competition from generic and/or biosimilar products;
- our ability to protect and enforce patents and other intellectual property;
- changes in patent law or regulations related to data package exclusivity;
- competitive developments affecting current products and our pipeline;
- market uptake of recently launched products;
- information technology system inadequacies, breaches, or operating failures;
- unauthorized access, disclosure, misappropriation, or compromise of confidential information or other data stored in our IT systems, networks, and facilities, or those of third parties with whom we share our data;
- unexpected safety or efficacy concerns associated with our products;
- litigation, investigations, or other similar proceedings involving past, current, or future products or commercial activities as we are largely self-insured;
- issues with product supply stemming from manufacturing difficulties or disruptions;
- reliance on third-party relationships and outsourcing arrangements;
- regulatory changes or other developments;
- regulatory actions regarding currently marketed products;
- continued pricing pressures and the impact of actions of governmental and private payers affecting pricing of, reimbursement for, and access to pharmaceuticals;
- devaluations in foreign currency exchange rates or changes in interest rates, and inflation;
- changes in tax law, tax rates, or events that differ from our assumptions related to tax positions;
- asset impairments and restructuring charges;
- the impact of global macroeconomic conditions and trade disruptions or disputes;
- changes in accounting and reporting standards promulgated by the Financial Accounting Standards Board and the Securities and Exchange Commission (SEC); and

- regulatory compliance problems or government investigations.

Investors should also carefully read the factors described under Item 1A, “Risk Factors” in this Annual Report on Form 10-K for a description of certain risks that could, among other things, cause our actual results to differ from those expressed in forward-looking statements. Investors should understand that it is not possible to predict or identify all such factors and should not consider the risks described above and under Item 1A, “Risk Factors” to be a complete statement of all potential risks and uncertainties.

All forward-looking statements speak only as of the date of this Annual Report and are expressly qualified in their entirety by the risk factors and cautionary statements included in this Annual 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 Annual Report.

Part I

Item 1. Business

Eli Lilly and Company (referred to as the company, Lilly, we, or us) was incorporated in 1901 in Indiana to succeed to the drug manufacturing business founded in Indianapolis, Indiana, in 1876 by Colonel Eli Lilly. We discover, develop, manufacture, and market products in a single business segment—human pharmaceutical products. In March 2019, we completed the disposition of our ownership in Elanco Animal Health Incorporated (Elanco), an animal health business.

Our purpose is to unite caring with discovery to create medicines that make life better for people around the world. Most of the products we sell today were discovered or developed by our own scientists, and our long-term success depends on our ability to continually discover or acquire, develop, and commercialize innovative new medicines.

We manufacture and distribute our products through facilities in the United States (U.S.), including Puerto Rico, and 8 other countries. Our products are sold in approximately 120 countries.

Products

Our products include:

Diabetes products, including:

- *Baqsimi*®, a nasal powder formulation for the treatment of severe hypoglycemia in patients with diabetes
- *Basaglar*®, a long-acting human insulin analog for the treatment of diabetes
- *Humalog*®, *Humalog Mix 75/25, Humalog U-100, Humalog U-200, Humalog Mix 50/50*, *insulin lispro, insulin lispro protamine*, and *insulin lispro mix 75/25,* human insulin analogs for the treatment of diabetes
- *Humulin*®, *Humulin 70/30, Humulin N, Humulin R,* and *Humulin U-500*, human insulins of recombinant DNA origin for the treatment of diabetes
- *Jardiance*®, for the treatment of type 2 diabetes and to reduce the risk of cardiovascular death in adult patients with type 2 diabetes and established cardiovascular disease
- *Lyumjev*®, a rapid-acting human insulin analog for the treatment of diabetes
- *Trajenta*®, for the treatment of type 2 diabetes
- *Trulicity*®, for the treatment of type 2 diabetes and to reduce the risk of major adverse cardiovascular events in adult patients with type 2 diabetes and established cardiovascular disease or multiple cardiovascular risk factors

Oncology products, including:

- *Alimta*®, for the first-line treatment, in combination with two other agents, of advanced non-small cell lung cancer (NSCLC) for patients with non-squamous cell histology and no EGFR or ALK genomic tumor aberrations; for the first-line treatment, in combination with another agent, of advanced non-squamous NSCLC; for the second-line treatment of advanced non-squamous NSCLC; as monotherapy for the maintenance treatment of advanced non-squamous NSCLC in patients whose disease has not progressed immediately following chemotherapy treatment; and in combination with another agent for the treatment of malignant pleural mesothelioma
- *Cyramza*®, for use as monotherapy or in combination with another agent as a second-line treatment of advanced or metastatic gastric cancer or gastro-esophageal junction adenocarcinoma; in combination with another agent as a second-line treatment of metastatic NSCLC; in combination with another agent as a second-line treatment of metastatic colorectal cancer; as a monotherapy as a second-line treatment of hepatocellular carcinoma; and in

combination with another agent as a first-line treatment of adult patients with metastatic NSCLC with activating epidermal growth factor receptor mutations

- *Erbitux*®, indicated both as monotherapy and in combination with another agent for the treatment of certain types of colorectal cancers; and as monotherapy, in combination with chemotherapy, or in combination with radiation therapy for the treatment of certain types of head and neck cancers

- *Retevmo*®, for the treatment of metastatic NSCLC in adult patients; for the treatment of advanced metastatic medullary thyroid cancer who require systemic therapy in adult and pediatric patients; and for the treatment of advanced metastatic thyroid cancer in adult and pediatric patients who require systemic therapy and are radioactive iodin-refractory
- *Tyvyt*®, for the treatment of relapsed or refractory classic Hodgkin's lymphoma and for the first-line treatment of non-squamous NSCLC in combination with Alimta and another agent in China
- *Verzenio*®, for use as monotherapy or in combination with endocrine therapy for the treatment of HR+, HER2- metastatic breast cancer

Immunology products, including:

- *Olumiant*®, for the treatment of adults with moderately-to-severely active rheumatoid arthritis
    - *Baricitinib* was granted Emergency Use Authorization (EUA) in 2020 for the treatment of suspected or laboratory confirmed COVID-19, in combination with remdesivir, in hospitalized adults and pediatric patients
- *Taltz*®, for the treatment of adults and pediatric patients aged 6 years or older with moderate-to-severe plaque psoriasis, adults with active psoriatic arthritis, adults with ankylosing spondylitis, and adults with active non-radiographic axial spondyloarthritis

Neuroscience products, including:

- *Cymbalta*®, for the treatment of major depressive disorder, diabetic peripheral neuropathic pain, generalized anxiety disorder, fibromyalgia, and chronic musculoskeletal pain due to chronic low back pain or chronic pain due to osteoarthritis
- *Emgality*®, for migraine prevention and the treatment of episodic cluster headache in adults
- *Reyvow*®, for the acute treatment of migraine, with or without aura, in adults
- *Zyprexa*®, for the treatment of schizophrenia, acute mixed or manic episodes associated with bipolar I disorder, and bipolar maintenance

Other therapies, including:

- *Bamlanivimab*, for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients with positive results of direct SARS-CoV-2 viral testing (EUA granted in 2020)
- *Bamlanivimab* and *etesevimab*, administered together, for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients with positive results of direct SARS-CoV-2 viral testing (EUA granted in 2021)
- *Cialis*®, for the treatment of erectile dysfunction and benign prostatic hyperplasia
- *Forteo*®, for the treatment of osteoporosis in postmenopausal women and men at high risk for fracture and for glucocorticoid-induced osteoporosis in men and postmenopausal women

Marketing and Distribution

We sell most of our products worldwide. We adapt our marketing methods and product emphasis in various countries to meet local customer needs and comply with local regulations.

U.S.

We promote our major products in the U.S. through sales representatives who call upon physicians and other health care professionals. We also promote to healthcare providers in medical journals and online health care channels, distribute literature and samples of certain products to physicians, and exhibit at medical meetings. In addition, we advertise certain products directly to consumers in the U.S. and we maintain websites with information about our major products. We supplement our employee sales force with contract sales organizations to leverage our resources and reach additional patients in need.

We maintain special business groups to service wholesalers, pharmacy benefit managers, managed care organizations, group purchasing organizations, government and long-term care institutions, hospitals, and

certain retail pharmacies. We enter into arrangements with these organizations providing for discounts or rebates on our products.

In the U.S., most of our products are distributed through wholesalers that serve pharmacies, physicians and other health care professionals, and hospitals. In 2020, 2019, and 2018, three wholesale distributors in the U.S.—McKesson Corporation, AmerisourceBergen Corporation, and Cardinal Health, Inc.—each accounted for between 15 percent and 20 percent of our consolidated revenue. No other customer accounted for more than 10 percent of our consolidated revenue in any of these years.

Outside the U.S.

Outside the U.S., we promote our products to healthcare providers primarily through sales representatives and online health care channels. While the products we market vary from country to country, diabetes products constitute the largest single group of our consolidated revenue. Distribution patterns for our products also vary from country to country. In most countries in which we operate, we maintain our own sales organizations, but in some smaller countries we market our products through independent distributors.

Marketing Collaborations

Certain of our products are marketed in arrangements with other pharmaceutical companies. For example, we and Boehringer Ingelheim have a global agreement to develop and commercialize a portfolio of diabetes products, including Trajenta, Jentadueto®, Jardiance, Glyxambi®, Synjardy®, Trijardy® XR, and Basaglar.

For additional information, see Item 8, "Financial Statements and Supplementary Data - Note 4, Collaborations and Other Arrangements."

Competition

Our products compete globally with many other pharmaceutical products in highly competitive markets.

Important competitive factors include effectiveness, safety, and ease of use; formulary placement, price, and demonstrated cost-effectiveness; marketing effectiveness; and research and development of new products, processes, modalities, and uses. Most new products that we introduce must compete with other branded or generic products already on the market or products that are later developed by competitors. When competitors introduce new products or delivery systems with therapeutic or cost advantages, including by developing new modalities, our products become subject to decreased sales, progressive price reductions, or both.

We believe our long-term competitive success depends on discovering and developing (either alone or in collaboration with others) or acquiring innovative, cost-effective products that provide improved outcomes for patients and deliver value to payers, and continuously improving the productivity of our operations in a highly competitive environment. There can be no assurance that our efforts will result in commercially successful products, and it is possible that our products will be, or will become, uncompetitive from time to time as a result of products developed by our competitors.

Generic Pharmaceuticals

One of the biggest competitive challenges we face is from generic pharmaceuticals. In the U.S. and Europe, the regulatory approval process for pharmaceuticals (other than biological products (biologics)) exempts generics from costly and time-consuming clinical trials to demonstrate their safety and efficacy, allowing generic manufacturers to rely on the safety and efficacy of the innovator product. As a result, generic manufacturers generally invest far fewer resources than we do in research and development and can price their products significantly lower than our branded products. Accordingly, when a branded non-biologic pharmaceutical loses its market exclusivity, it normally faces intense price competition from generic forms of the product, which can cause us to lose a significant portion of the product’s revenue in a very short period of time.

Further, public and private payers typically encourage the use of generics as alternatives to brand-name drugs in their healthcare programs. Laws in the U.S. generally allow, and in many cases require, pharmacists to substitute generic drugs that have been rated under government procedures to be essentially equivalent to a brand-name drug. Where substitution is mandatory, it must be made unless the

prescribing physician expressly forbids it. In many countries outside the U.S., intellectual property protection is weak, and we must compete with generic or counterfeit versions of our products.

Biosimilars

Several of our products and approximately half of the potential new medicines in our clinical-stage pipeline are biologics. In the U.S., the U.S. Food and Drug Administration (FDA) regulates biologics under the Federal Food, Drug and Cosmetic Act, the Public Health Service Act, and implementing regulations. Competition for Lilly's biologics may be affected by the approval of follow-on biologics, also known as biosimilars. A biosimilar is a subsequent version of an approved innovator biologic that, due to its analytical and clinical similarity to the innovator biologic, may be approved based on an abbreviated data package that relies in part on the full testing required of the innovator biologic. Approval by the FDA ultimately depends on many factors, including a showing that the biosimilar is "highly similar" to the original product and has no clinically meaningful differences from the original product in terms of safety, purity, and potency.

Globally, most governments have developed abbreviated regulatory pathways to approve biosimilars as follow-ons to innovator-developed biologics, including the Biologics Price Competition and Innovation Act of 2009 (the BPCIA) in the U.S., and a number of biosimilars have been licensed under the BPCIA and in Europe. The patent and regulatory exclusivity for the existing innovator biologic generally must expire in a given market before biosimilars may enter that market. However, in the U.S., the product exclusivity period under the BPCIA could be affected by recent government proposals and litigation. See "- Patents, Trademarks, and Other Intellectual Property Rights." In addition, the extent to which a biosimilar, once approved, will be substituted for the innovator biologic in a way that is similar to traditional generic substitution for non-biologic products is not yet entirely clear, and will depend on a number of regulatory and marketplace factors that are still developing. In the U.S., currently only a biosimilar product that is determined to be "interchangeable" will be considered substitutable for the original biologic product without the intervention of the health care provider who prescribed the original biologic product. To prove that a biosimilar product is interchangeable, the applicant must demonstrate that the product can be expected to produce the same clinical results as the original biologic product in any given patient, and if the product is administered more than once in a patient, that safety risks and potential for diminished efficacy of alternating or switching between the use of the interchangeable biosimilar biologic product and the original biologic product is no greater than the risk of using the original biologic product without switching.

Biosimilars may present both competitive challenges and opportunities. For example, a competitor company has developed a version of insulin lispro that competes with our product Humalog. On the other hand, in collaboration with Boehringer Ingelheim, we developed Basaglar, a new insulin glargine product, which has the same amino acid sequence as a product currently marketed by a competitor and has launched as a follow-on biologic in the U.S., and as a biosimilar in Europe and Japan. However, in March 2020, the FDA began regulating all of our insulin products as "biologics" rather than "drugs." Based on FDA draft guidance, this change may lower the requirements for competitor biosimilar products to enter the market, some of which could be designated as interchangeable and therefore substituted for our insulin products at U.S. pharmacies. As such, in June 2020, Mylan N.V. announced that the FDA approved its New Drug Application (NDA) for Semglee, a new insulin glargine product, which it launched as a follow-on biologic in the U.S. that competes with Basaglar. The laws regulating biosimilars continue to be interpreted and implemented by the FDA and remain subject to substantial uncertainty, including with respect to their impact on our business.

U.S. Private Sector Dynamics

In the U.S. private sector, consolidation and integration among healthcare providers significantly affects the competitive marketplace for pharmaceuticals. Health plans, pharmacy benefit managers, wholesalers, and other supply chain stakeholders have been consolidating into fewer, larger entities, thus enhancing their purchasing strength and importance. Private third-party insurers, as well as governments, typically maintain formularies that 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) to control costs by negotiating discounted prices in exchange for formulary inclusion.

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 efficacy, safety profile, or patient ease of use, but also by providing rebates. Value-based agreements, where pricing is based on achievement (or not) of specified outcomes, are another tool that 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. We expect these downward pricing pressures will continue to negatively affect our consolidated results of operations. In addition to formulary placement, changes in insurance designs continue to drive greater consumer cost-sharing through high deductible plans and higher co-insurance or co-pays. For additional information on pricing and reimbursement for our pharmaceutical products, see "- Regulations and Private Payer Actions Affecting Pharmaceutical Pricing, Reimbursement, and Access - U.S."

Patents, Trademarks, and Other Intellectual Property Rights

Overview

Intellectual property protection is critical to our ability to successfully commercialize our life sciences innovations and invest in the search for new medicines. We own, have applied for, or are licensed under, a large number of patents in the U.S. and many other countries relating to products, product uses, formulations, and manufacturing processes. In addition, as discussed below, for some products we have effective intellectual property protection in the form of data protection under pharmaceutical regulatory laws.

The patent protection anticipated to be of most relevance to pharmaceuticals is provided by national patents claiming the active ingredient (the compound patent), particularly those in major markets such as the U.S., various European countries, and Japan. These patents may be issued based upon the filing of international patent applications, usually filed under the Patent Cooperation Treaty (PCT). Patent applications covering compounds are generally filed during the Discovery Phase of the drug discovery process, which is described in the "Research and Development" section below. In general, national patents in each relevant country are available for a period of 20 years from the filing date of the PCT application, which is often years prior to the launch of a commercial product. Further patent term adjustments and restorations may extend the original patent term:

- Patent term adjustment is a statutory right available to all U.S. patent applicants to provide relief in the event that a patent grant is delayed during examination by the United States Patent and Trademark Office (USPTO).
- Patent term restoration is a statutory right provided to U.S. patent holders that claim inventions subject to review by the FDA. To make up for a portion of the time invested in clinical trials and the FDA review process, a single patent for a pharmaceutical product may be eligible for patent term restoration. Patent term restoration is limited by a formula and cannot be calculated until product approval due to uncertainty about the duration of clinical trials and the time it takes the FDA to review an application. There is a five-year cap on any restoration, and no patent's expiration date may be extended beyond 14 years from FDA approval. Some countries outside the U.S. also offer forms of patent term restoration. For example, Supplementary Protection Certificates are available to extend the life of a European patent up to an additional five years (subject to a 15-year cap from European Medicines Agency (EMA) approval). Similarly, in Japan, South Korea, and Australia, patent terms can be extended up to five years, depending on the length of regulatory review and other factors.

Loss of effective patent protection for pharmaceuticals, especially for non-biologic products, typically results in the loss of effective market exclusivity for the product, which often results in severe and rapid decline in revenues for the product. However, in some cases the innovator company may retain exclusivity despite approval of the generic, biosimilar, or other follow-on versions of a new medicine beyond the expiration of the compound patent through manufacturing trade secrets, later-expiring patents on

manufacturing processes, methods of use or formulations, or data protection that may be available under pharmaceutical regulatory laws. Changes to the laws and regulations governing these protections could result in earlier loss of effective market exclusivity. The primary forms of data protection are as follows:

- Regulatory authorities in major markets generally grant data package protection for a period of years following new drug approvals in recognition of the substantial investment required to complete clinical trials. Data package protection prohibits other manufacturers from submitting regulatory applications for marketing approval based on the innovator company's regulatory submission data for the drug. The base period of data package protection depends on the country. For example, the period is generally five years in the U.S. (12 years for new biologics as described below), effectively 10 years in Europe, and eight years in Japan. The period begins on the date of product approval and runs concurrently with the patent term for any relevant patent.
- Under the BPCIA, the FDA has the authority to approve biosimilars. A competitor seeking approval of a biosimilar must file an application to show its molecule is highly similar to an approved innovator biologic and include a certain amount of safety and efficacy data that the FDA will consider on a case-by-case basis. Under the data protection provisions of this law, the FDA cannot approve a biosimilar application until 12 years after initial marketing approval of the innovator biologic, subject to certain conditions. The BPCIA is part of the Affordable Care Act, the constitutionality of which is currently being litigated.
- In the U.S., the FDA has the authority to grant additional data protection for approved drugs where the sponsor conducts specified testing in pediatric or adolescent populations within a specified time period. If granted, this "pediatric exclusivity" provides an additional six months of exclusivity, which is added to the term of data protection as well as to the term of any relevant patents, to the extent these protections have not already expired. While the term of the pediatric exclusivity attaches to the term of any relevant patent, pediatric exclusivity is a regulatory exclusivity—i.e., a bar to generic approval, not a patent right.
- Under the U.S. orphan drug law, a specific use of a drug or biologic can receive "orphan" designation if it is intended to treat a disease or condition affecting fewer than 200,000 people in the U.S., or affecting more than 200,000 people but not reasonably expected to recover its development and marketing costs through U.S. sales. Among other benefits, orphan designation entitles the particular use of the drug to seven years of market exclusivity, meaning that the FDA cannot (with limited exceptions) approve another marketing application for the same drug for the same indication until expiration of the seven-year period. Unlike pediatric exclusivity, the orphan exclusivity period is independent of and runs in parallel with any applicable patents.

Outside the major markets, the adequacy and effectiveness of intellectual property protection for pharmaceuticals varies widely, and in a number of these markets we are unable to patent our products or to enforce the patents we receive for our products. Under the Trade-Related Aspects of Intellectual Property Agreement (TRIPs) administered by the World Trade Organization, more than 140 countries have agreed to provide non-discriminatory protection for most pharmaceutical inventions and to assure that adequate and effective rights are available to patent owners. Certain developing countries limit protection for biopharmaceutical products under their interpretation of "flexibilities" allowed under the agreement. Thus, some types of patents, such as those on new uses of compounds or new forms of molecules, are not available in certain developing countries. Further, many developing countries, and some developed countries, do not provide effective data package protection even though it is specified in TRIPs.

Our Intellectual Property Portfolio

We consider intellectual property protection for certain products, processes, uses, and formulations—particularly with respect to those products discussed below—to be important to our operations. In addition to the data protection and patents identified below, we may hold patents on manufacturing processes, formulations, devices, or uses that extend exclusivity beyond the dates shown below.

The most relevant U.S. patent protection or data protection and associated expiry dates for our top-selling or recently launched patent-protected marketed products are as follows:

- Alimta is protected by a vitamin regimen patent (2021) plus pediatric exclusivity (May 2022). See Item 8, "Financial Statements and Supplementary Data - Note 16, Contingencies," for information regarding our settlement agreement with Eagle Pharmaceuticals, Inc. (Eagle) and its impact on our exclusivity for Alimta.

- Baqsimi is protected by data protection (July 2022).
- Cyramza is protected by a compound patent and biologics data protection (2026).
- Emgality is protected by a compound patent (2033) and biologics data protection (2030).
- Jardiance, and the related combination product Glyxambi, is protected by a compound patent (2028).

- Olumiant is protected by a compound patent (2032).
- Retevmo is protected by a compound patent (2037) and by data protection (2025).
- Reyvow is protected by a compound patent (2025, not including possible patent extension).
- Taltz is protected by a compound patent (2030) and by biologics data protection (2028).
- Trulicity is protected by a compound patent (2027) and by biologics data protection (2026).
- Verzenio is protected by a compound patent (2031) and by data protection (2022).

Outside the U.S., important patent protection or data protection includes:

- Alimta is protected by patents covering its use to treat cancer in major European countries and in Japan (June 2021).
- Baqsimi is protected by data protection in Japan (2026).
- Cyramza is protected by a compound patent (2028) and by data protection (2024) in major European countries. Additionally, Cyramza is protected by a compound patent (2026) and by data protection (2023) in Japan.
- Emgality is protected by a compound patent (2033) and by data protection (2028) in major European countries, and by a compound patent (2031, not including possible patent extension) and by data protection (2029) in Japan.
- Jardiance is protected by a compound patent in major European countries (2029) and Japan (2030).
- Olumiant is protected by a compound patent (2032) and by data protection (2027) in major European countries, and by a compound patent (2033) and by data protection (2025) in Japan.
- Reyvow is protected by a compound patent (2023, not including possible patent extension) in major European countries. Reyvow is also protected by a compound patent (2023, not including possible patent extension) in Japan.
- Retsevmo® is protected by a compound patent (2037) and by data protection (2031) in major European countries. Retevmo is protected by a compound patent in Japan (2037, not including possible patent extension).
- Taltz is protected by a compound patent (2031) and data protection (2027) in major European countries and a compound patent (2030) and data protection (2024) in Japan.
- Trulicity is protected by a compound patent (2029) and by data protection (2024) in major European countries and by a compound patent (2029) and by data protection (2023) in Japan.
- Verzenio is protected by a compound patent (2033) and data protection (2028) in major European countries and by a compound patent (2034) and data protection (2026) in Japan.

Reyvow has been submitted for regulatory review in certain major European countries for the acute treatment of migraine, where it is expected to be protected by data protection upon approval (10 years). Additionally, Reyvow has been submitted for regulatory review in Japan for the acute treatment of migraine, where it is expected to be protected by data protection upon approval (8 years).

Retevmo has been submitted for regulatory review in Japan for the treatment of lung cancer, where it is expected to be protected by data protection upon approval (8 years).

Tanezumab is protected by a compound patent (2023, not including possible patent extension) in the U.S. Additionally, tanezumab has been submitted for regulatory review in the U.S. for the treatment of osteoarthritis pain, where it is expected to be protected by data protection upon approval (12 years).

Worldwide, we sell all of our major products under trademarks consisting of our product names, logos, and unique product appearances (e.g., the appearance of our Trulicity autoinjector) which we consider in the aggregate to be important to our operations. Trademark protection varies throughout the world, with protection continuing in some countries as long as the mark is used, and in other countries as long as it is

registered. Registrations are normally for fixed but renewable terms. Trademark protection often extends beyond the patent and data protection for a product.

Patent Licenses and Collaborations

Most of our major products are not subject to significant license and collaboration agreements. For information on our license and collaboration agreements, including our agreement with Incyte Corporation related to Olumiant, see Item 8, "Financial Statements and Supplementary Data - Note 4, Collaborations and Other Arrangements."

Patent Challenges

In the U.S., the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, authorizes the FDA to approve generic versions of innovative pharmaceuticals (other than biologics, which are discussed below in more detail) when the generic manufacturer has not conducted safety and efficacy studies but files an Abbreviated New Drug Application (ANDA). In an ANDA, the generic manufacturer must demonstrate only “bioequivalence” between the generic version and the NDA-approved drug—not safety and efficacy. Establishing bioequivalence is generally straightforward and inexpensive for the generic company.

Absent a patent challenge, the FDA cannot approve an ANDA until after certain of the innovator’s patents expire. However, after the innovator has marketed its product for four years, a generic manufacturer may file an ANDA alleging that one or more or all of the patents listed in the innovator’s NDA are invalid or not infringed. This allegation is commonly known as a “Paragraph IV certification.” If the innovator responds by filing suit against the generic manufacturer, the FDA is then prohibited from approving the generic company’s application for a 30-month period (which can be shortened or extended by the trial court judge hearing the patent challenge). If one or more of the NDA-listed patents are challenged, the first filer(s) of a Paragraph IV certification may be entitled to a 180-day period of market exclusivity over all other generic manufacturers.

Generic manufacturers use Paragraph IV certifications extensively to challenge patents on innovative pharmaceuticals. In addition, generic companies have shown willingness to launch “at risk,” i.e., after receiving ANDA approval but before final resolution of their patent challenge. We are currently in Hatch-Waxman litigation involving Alimta with a single generic manufacturer. For more information on Hatch-Waxman litigation involving the company, see Item 8, “Financial Statements and Supplementary Data - Note 16, Contingencies.”

Under the BPCIA, the FDA cannot approve an application for a biosimilar product until data protection expires, 12 years after initial marketing approval of the innovator biologic, and an application may not be submitted until four years following the date the innovator biologic was first approved. However, the BPCIA does provide a mechanism for a competitor to challenge the validity of an innovator’s patents as early as four years after initial marketing approval of the innovator biologic.

The patent litigation scheme under the BPCIA, and the BPCIA itself, is complex and continues to be interpreted and implemented by the FDA as well as courts. Courts have held that biosimilar applicants are not required to engage in the BPCIA patent litigation scheme and patent holders retain the right to bring suit under normal patent law procedures if a biosimilar applicant attempts to commercialize a product prior to patent expiration. Further, in the U.S., the increased likelihood of generic and biosimilar challenges to innovators’ intellectual property has increased the risk of loss of innovators’ market exclusivity. See also “- Competition - Biosimilars.”

In addition, there is a procedure in U.S. patent law, known as inter partes review (IPR), which allows any member of the public to file a petition with the USPTO seeking the review of any issued U.S. patent for validity. IPRs are conducted before Administrative Patent Judges in the USPTO using a lower standard of proof than used in federal district court. In addition, the challenged patents are not accorded the presumption of validity as they are in federal district court. Generic drug companies and even some investment firms have engaged in the IPR process in attempts to invalidate our patents.

Outside the U.S., the legal doctrines and processes by which pharmaceutical patents can be challenged vary widely. In recent years, we have experienced an increase in patent challenges from generic manufacturers in many countries outside the U.S.

For more information on administrative challenges and litigation involving our intellectual property rights, see Item 8, “Financial Statements and Supplementary Data - Note 16, Contingencies.”

Government Regulation of Our Operations

Our operations are regulated extensively by numerous national, state, and local agencies.

Regulation of Products

The lengthy process of laboratory and clinical testing, data analysis, manufacturing development, and regulatory review necessary for governmental approvals of our products is extremely costly and can significantly delay product introductions and revenue generation. In addition, our operations are subject to complex federal, state, local, and foreign laws and regulations concerning relationships with healthcare providers and suppliers, the environment, occupational health and safety, and data privacy. Compliance with the laws and regulations affecting the manufacture and sale of current products and the discovery, development, and introduction of new products will continue to require substantial effort, expense, and capital investment.

Of particular importance to our business is regulation by the FDA in the U.S. Pursuant to laws and regulations that include the Federal Food, Drug, and Cosmetic Act, the FDA has jurisdiction over all of our products and devices in the U.S. and administers requirements covering the testing, safety, effectiveness, manufacturing, quality control, distribution, labeling, marketing, promotion, advertising, dissemination of information, and post-marketing surveillance of those products.

Following approval, our products remain subject to regulation by various agencies in connection with labeling, import, export, storage, recordkeeping, advertising, promotion, and safety reporting. We conduct extensive post-marketing surveillance of the safety of the products we sell. The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after a product reaches the market. The FDA strictly regulates marketing, labeling, advertising, and promotion of products that are placed on the market. Pharmaceutical products may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

The FDA extensively regulates all aspects of manufacturing quality for pharmaceuticals under its current Good Manufacturing Practices (cGMP) regulations. Outside the U.S., our products and operations are subject to similar regulatory requirements, notably by the EMA in Europe and the Ministry of Health, Labor and Welfare in Japan. Specific regulatory requirements vary from country to country. Regulatory requirements and approval processes outside the U.S. may differ from those in the U.S. and may involve additional costs and uncertainties.

We make substantial investments of capital and operating expenses to implement comprehensive, company-wide quality systems and controls in our manufacturing, product development, and process development operations in an effort to ensure sustained compliance with cGMP and similar regulations. However, in the event we fail to adhere to these requirements, we become subject to potential government investigations, interruptions in production, fines and penalties, delays in new product approvals, and reputational harm. Certain of our products are manufactured by third parties, and their failure to comply with these regulations could adversely affect us through failure to supply product to us or delays in new product approvals. Any determination by the FDA or other regulatory authorities of manufacturing or other deficiencies could adversely affect our business.

We are also subject to a variety of federal, state, and local environmental, health and safety, and other laws and regulations that may affect our research, development or production efforts.

Emergency Use Authorizations

The Secretary of Health and Human Services may authorize unapproved medical products to be manufactured, marketed, and sold in the context of an actual or potential emergency that has been designated by the government. After an emergency has been announced, the Secretary of Health and Human Services may authorize EUAs for the use of specific products based on criteria established by statute, including that the product at issue may be effective in diagnosing, treating, or preventing serious or life-threatening diseases when there are no adequate, approved, and available alternatives. An EUA is subject to additional conditions and restrictions, such as the obligation to provide facts sheets for healthcare providers administering the product and those to whom it is administered, adverse event monitoring and reporting, and recordkeeping and reporting requirements by product manufacturers. The FDA may also establish additional discretionary conditions of authorization that the FDA deems necessary or appropriate to protect the public health, including conditions related to product distribution, product administration and data collection and analysis concerning the safety and effectiveness of the product. In issuing an EUA, the FDA considers the totality of available scientific evidence regarding quality, safety and efficacy, including the known and potential risks of such products and the adequacy and availability of approved alternatives, among other factors. An EUA is not a substitute for obtaining FDA approval, licensure, or clearance for use of a product. An EUA terminates when the emergency determination underlying the EUA terminates, and EUAs can be revoked under other circumstances, the timing of which may occur unexpectedly or be difficult to predict.

Outside the U.S., the emergency use of medical products is subject to regulatory processes and requirements that differ from those in the U.S.

The COVID-19 pandemic has been designated as a national emergency in the U.S. On the basis of such determination, the Secretary of Health and Human Services declared that circumstances exist justifying the authorization of emergency use of drugs and biologics during the COVID-19 pandemic. The FDA has granted EUAs for bamlanivimab, bamlanivimab and etesevimab administered together, and baricitinib in combination with remdesivir, and similar actions have been taken by other regulators in certain jurisdictions outside the U.S. We intend to submit bamlanivimab and etesevimab administered together to the FDA for approval in the second half of 2021.

Other Laws and Regulations

The marketing, promotional, and pricing practices of pharmaceutical manufacturers, as well as the manner in which manufacturers interact with purchasers, prescribers, and patients, are subject to various other U.S. federal and state laws, as well as analogous foreign laws and regulations, including the federal anti-kickback statute, the False Claims Act, and state laws governing kickbacks, false claims, unfair trade practices, and consumer protection. These laws are administered by, among others, the Department of Justice, the Office of Inspector General of the Department of Health and Human Services, the Federal Trade Commission, the Office of Personnel Management, and state attorneys general. Over the past several years, state and federal governments have increased their oversight, enforcement activities, and intra-agency coordination with respect to pharmaceutical companies. Further, several claims brought by these agencies against us and other companies under these and other laws have resulted in corporate criminal sanctions and very substantial civil settlements.

In December 2020, the Office of Inspector General of the U.S. Department of Health and Human Services and the Centers for Medicare & Medicaid Services issued final rules expanding and modifying existing, and adding new, regulatory “safe harbors” and exceptions, respectively, under the anti-kickback statute and the Ethics in Patient Referrals Act. We are currently evaluating the impact, if any, these regulatory amendments will have upon becoming effective on our consolidated results of operations, liquidity, and financial position, which is uncertain at this time.

The U.S. Foreign Corrupt Practices Act of 1977 (FCPA) prohibits certain individuals and entities, including U.S. publicly traded companies, from promising, offering, or giving anything of value to foreign officials with the corrupt intent of influencing the foreign official for the purpose of helping the company obtain or retain business or gain any improper advantage. The FCPA also imposes specific recordkeeping and internal controls requirements on U.S. publicly traded companies. As noted above, outside the U.S., our business is heavily regulated and therefore involves significant interaction with foreign officials.

Additionally, in many countries outside the U.S., healthcare providers who prescribe pharmaceuticals are employed by the government and purchasers of pharmaceuticals are government entities; therefore, our interactions with these prescribers and purchasers are subject to regulation under the FCPA.

In addition to the U.S. application and enforcement of the FCPA, the various jurisdictions in which we operate and supply our products have laws and regulations aimed at preventing and penalizing corrupt and anticompetitive behavior. In recent years, several jurisdictions have enhanced their laws and regulations in this area, increased their enforcement activities, and/or increased the level of cross-border coordination and information sharing.

We are and could in the future become subject to administrative and legal proceedings and actions, which could include claims for civil penalties (including treble damages under the False Claims Act), criminal sanctions, and administrative remedies, including exclusion from U.S. federal and other health care programs. It is possible that an adverse outcome in future actions could have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

We are also subject to a variety of federal, state, and local environmental, health and safety, and other laws and regulations that may affect our research, development or production efforts.

Regulations and Private Payer Actions Affecting Pharmaceutical Pricing, Reimbursement, and Access

U.S.

There continues to be considerable public and government scrutiny of pharmaceutical pricing, and measures to address the perceived high cost of pharmaceuticals are being considered at various levels of state and federal government. In addition, U.S. government action to reduce federal spending on entitlement programs, including Medicare and Medicaid, may affect payment for our products or services associated with the provision of our products. Additionally, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drug products. The regulatory priorities of the current U.S. presidential administration could further intensify these efforts, which could have a material adverse impact on our business.

In the U.S., we are required to provide rebates to the federal government and respective state governments on their purchases of our pharmaceuticals under various federal and state healthcare programs, including state Medicaid and Medicaid Managed Care programs (minimum of 23.1 percent plus adjustments for price increases over time) and discounts to private entities who treat patients in certain types of health care facilities intended to serve low-income and uninsured patients (known as 340B facilities). No rebates are required at this time in the Medicare Part B (physician and hospital outpatient) program where reimbursement is set on an “average sales price plus 4.3 percent” formula. Additionally, an annual fee is imposed on pharmaceutical manufacturers and importers that sell branded prescription drugs to specified government programs. Since 2019, the Bipartisan Budget Act has required manufacturers of brand-name drugs, biologics, and biosimilars to provide a discount of 70 percent of the cost of branded prescription drugs for Medicare Part D participants who are in the “doughnut hole” (the coverage gap in Medicare prescription drug coverage), an increase from the previous 50 percent discount.

Rebates are also negotiated in the private sector. We pay rebates to private payers who provide prescription drug benefits to seniors covered by Medicare and to private payers who provide prescription drug benefits to their customers. These rebates are affected by the introduction of competitive products and generics in the same class. Our approach to the rebates we offer to private payers who provide prescription drug benefits to seniors covered by Medicare may be impacted by recent regulatory amendments included in the anti-kickback statute final rule that will become effective on January 1, 2023.

Outside the U.S.

Globally, public and private payers are increasingly restricting access to pharmaceuticals based on assessments of comparative effectiveness and value, including through the establishment of formal health technology assessment processes. In addition, third-party organizations, including professional associations, academic institutions, and non-profit entities associated with payers, are conducting and publishing comparative effectiveness and cost/benefit analyses on medicines, the impact of which are uncertain at this time.

In most international markets, we operate in an environment of government-mandated cost-containment programs, which may include price controls, international reference pricing (to other countries' prices), discounts and rebates, therapeutic reference pricing (to other, often generic, pharmaceutical choices), restrictions on physician prescription levels, and mandatory generic substitution. We may experience additional pricing pressures resulting from the financial strain of the COVID-19 pandemic on government-funded healthcare systems around the world.

We cannot predict the extent to which our business may be affected by these or other potential future legislative, regulatory, or payer developments. However, in general we expect to see continued focus on regulating pricing resulting in additional state, federal, and international legislative and regulatory developments that could have further negative effects on pricing and reimbursement for our products.

See Item 7, "Management's Discussion and Analysis - Results of Operations - Executive Overview - Other Matters - Trends Affecting Pharmaceutical Pricing, Reimbursement, and Access" for additional information regarding recent legislative, administrative, and other pricing initiatives and their impact on our results.

Research and Development

Our commitment to research and development dates back more than 140 years. We invest heavily in research and development because we believe it is critical to our long-term competitiveness. At the end of 2020, we employed approximately 7,600 people in pharmaceutical research and development activities, including a substantial number of physicians, scientists holding graduate or postgraduate degrees, and highly skilled technical personnel.

Our internal pharmaceutical research focuses primarily on the areas of diabetes, oncology, immunology, neurodegeneration, and pain. During 2020, we also focused on researching and developing potential treatments for COVID-19. In addition to discovering and developing new medicines, we seek to expand the value of existing products through new uses, formulations, and therapeutic approaches that provide additional value to patients.

To supplement our internal efforts, we collaborate with others, including academic institutions and research-based pharmaceutical and biotechnology companies. We use the services of physicians, hospitals, medical schools, and other research organizations worldwide to conduct clinical trials to establish the safety and effectiveness of our medicines. We actively invest in external research and technologies that we believe complement and strengthen our own efforts. These investments can take many forms, including, among others, licensing arrangements, co-development agreements, co-promotion arrangements, joint ventures, acquisitions, and equity investments.

Pharmaceutical development is time-consuming, expensive, and risky. Very few of the candidates discovered by researchers ultimately become approved medicines. The process from discovery to regulatory approval can take over a decade. Candidates can fail at any stage of the process, and even late-stage candidates sometimes fail to receive regulatory approval or achieve commercial success. The following describes in more detail the research and development process for pharmaceutical products:

Phases of New Drug Development

- **Discovery Phase**

  In the discovery phase, scientists identify, design, and synthesize promising candidates by analyzing their effect on biological targets thought to play a role in disease. Targets are often unproven and only candidates that have the desired effect on the target and meet other design criteria move to the next phase of development, which includes the initiation of studies in animals to support regulatory and

safety requirements for clinical research in humans. The discovery phase can take years and the probability of any one candidate becoming a medicine is extremely low.

- **Early Development Phase**

  Early development includes initial testing for safety and efficacy and early analyses of manufacturing requirements. Safety testing is initially performed in laboratory tests and animals, as necessary. In general, the first human tests (often referred to as Phase I) are conducted in small groups of subjects to assess safety and evaluate the potential dosing range. Subsequently, larger populations of patients are studied (Phase II) to identify initial signs of efficacy while continuing to assess safety. In parallel, scientists work to identify safe, effective, and economical manufacturing processes. Long-term animal studies continue to test for potential safety issues. Of the candidates that enter the early development phase, approximately 10 percent move to the late development phase. The early development phase varies but can take several years to complete.

- **Late Development Phase**

  Late phase development projects (typically Phase III) have met initial safety requirements and shown initial evidence of efficacy in earlier studies. As a result, these candidates generally have a higher likelihood of success and trials include larger patient populations to demonstrate safety and efficacy in the disease. These studies are designed to demonstrate the benefit and risk of the potential new medicine and may be compared to competitive therapies, placebo, or both. Phase III studies are generally conducted globally and are designed to support regulatory filings for marketing approval. The duration of Phase III testing varies by disease and may take two to four years.

- **Submission Phase**

  Once a potential new medicine is submitted to regulatory agencies, the time to final marketing approval can vary from several months to several years, depending on the disease state, the strength and complexity of available data, the degree of unmet need, and the time required for the regulatory agency(ies) to evaluate the submission, which can depend on prioritization by regulators and other factors. There is no guarantee that a potential medicine will receive marketing approval, or that decisions on marketing approvals or indications will be consistent across geographic areas.

We believe our investments in research, both internally and in collaboration with others, have resulted in a robust pipeline of potential new medicines and new treatment indications in all stages of development. We currently have approximately 45 candidates in clinical development or under regulatory review, and a larger number of projects in the discovery phase. See Item 7, “Management's Discussion and Analysis - Results of Operations - Executive Overview - Late-Stage Pipeline,” for more information on certain of our product candidates.

Raw Materials and Product Supply

Most of the principal materials we use in our manufacturing operations are available from more than one source. However, we obtain certain raw or intermediate materials primarily from only one source. We generally seek to maintain sufficient inventory to supply the market until an alternative source of supply could be implemented, in the event one of these suppliers was unable to provide the materials or product. However, in the event of an extended failure of a supplier or significant unanticipated increases in demand on a supplier, it is possible that we could experience an interruption in supply until we established new sources or, in some cases, implemented alternative processes.

The majority of our revenue comes from products produced in our own facilities. Our principal active ingredient manufacturing occurs at sites we own in the U.S., including Puerto Rico, and Ireland. Finishing operations, including formulation, filling, assembling, delivery device manufacturing, and packaging, take place at a number of sites throughout the world. We utilize third parties for certain active ingredient manufacturing and finishing operations.

We manage our supply chain (including our own facilities, contracted arrangements, and inventory) in a way that is intended to allow us to meet all expected product demand while maintaining flexibility to reallocate manufacturing capacity to improve efficiency and respond to changes in supply and demand. To maintain a stable supply of our products, we use a variety of techniques including comprehensive quality systems, inventory management, and back-up sites.

However, pharmaceutical production processes are complex, highly regulated, and vary widely from product to product. Shifting or adding manufacturing capacity can be a very lengthy process requiring significant capital expenditures, process modifications, and regulatory approvals. Accordingly, if we were to experience unplanned plant shutdowns at one of our own facilities, significant failure of a contract supplier, or significant unanticipated increases in demand, we could experience an interruption in supply of certain products or product shortages until production could be resumed or expanded.

In addition, COVID-19 could also have an adverse impact on our manufacturing operations, global supply chain, and distribution systems, which could impact our ability to produce and distribute our products and affect the ability of third parties on which we rely to fulfill their obligations to us, and could increase our expenses. For more information, see Item 1A, "Risk Factors - Risks Related to Our Business - The COVID-19 pandemic and efforts to reduce its spread have impacted, and may in future periods negatively impact, our business and operations." and Item 7, "Management's Discussion and Analysis - Results of Operations - Executive Overview - COVID-19 Pandemic."

Quality Assurance

Our success depends in great measure on customer confidence in the quality of our products and in the integrity of the data that support their safety and effectiveness. Product quality arises from a total commitment to quality in all parts of our operations, including research and development, purchasing, facilities planning, manufacturing, distribution, and dissemination of information about our medicines.

Quality of production processes involves strict control of ingredients, equipment, facilities, manufacturing methods, packaging materials, and labeling. We perform tests at various stages of production processes and on the final product in an effort to ensure that the product meets all applicable regulatory requirements and our internal standards. These tests may involve chemical and physical chemical analyses, microbiological testing, testing in animals, or a combination thereof. Additional assurance of quality is provided by quality assurance groups that audit and monitor all aspects of quality related to pharmaceutical manufacturing procedures and systems in company operations and at third-party suppliers.

Executive Officers of the Company

The following table sets forth certain information regarding our current executive officers.

The term of office for each executive officer expires on the date of the annual meeting of the board of directors, to be held on May 3, 2021 in connection with the company's annual meeting of shareholders, or on the date his or her successor is chosen and qualified. No director or executive officer has a “family relationship” with any other director or executive officer of the company, as that term is defined for purposes of this disclosure requirement. There is no understanding between any executive officer or director and any other person pursuant to which the executive officer was selected.

Name	Age	Titles and Business Experience
David A. Ricks	53	Chairman, President, and Chief Executive Officer (CEO) (since 2017). Previously, Mr. Ricks held various leadership roles with Lilly, including senior vice president and president, Lilly Bio-Medicines. Mr. Ricks has 24 years of service with Lilly.
Anat Ashkenazi	48	Senior Vice President and Chief Financial Officer (since 2021). Previously, Ms. Ashkenazi held various leadership roles with Lilly, including senior vice president, controller and chief financial officer, Lilly Research Laboratories, and vice president, finance and chief financial officer, Lilly Diabetes and Lilly global manufacturing and quality. Ms. Ashkenazi has 19 years of service with Lilly.
Melissa S. Barnes	52	Senior Vice President, Enterprise Risk Management, and Chief Ethics and Compliance Officer (since 2013). Previously, Ms. Barnes held various leadership roles with Lilly, including vice president, deputy general counsel. Ms. Barnes has 26 years of service with Lilly.
Stephen F. Fry	55	Senior Vice President, Human Resources and Diversity (since 2011). Previously, Mr. Fry held various leadership roles with Lilly, including vice president, human resources. Mr. Fry has 33 years of service with Lilly.
Anat Hakim	51	Senior Vice President, General Counsel and Secretary (since 2020). Prior to joining Lilly, Ms. Hakim was senior vice president, general counsel and secretary of WellCare Health Plans, Inc. (WellCare) from 2016 to 2018, and executive vice president, general counsel and secretary of WellCare from 2018 to 2020. Prior to joining WellCare, she served as divisional vice president and associate general counsel of intellectual property litigation at Abbott Laboratories from 2010 to 2013 and divisional vice president and associate general counsel of litigation from 2013 to 2016. Ms. Hakim has one year of service with Lilly.
Patrik Jonsson	54	Senior Vice President, President, Lilly USA, and Chief Customer Officer (since 2020). Previously, Mr. Jonsson held various leadership roles with Lilly, including senior vice president and president, Lilly Bio-Medicines and president and general manager, Lilly Japan. Mr. Jonsson has 30 years of service with Lilly.
Michael B. Mason	54	Senior Vice President and President, Lilly Diabetes (since 2020). Previously, Mr. Mason held various leadership roles with Lilly, including senior vice president, connected care and insulins and vice president of U.S. Diabetes. Mr. Mason has 31 years of service with Lilly.
Johna L. Norton	54	Senior Vice President, Global Quality (since 2017). Previously, Ms. Norton held various leadership roles with Lilly, including vice president, global quality assurance API manufacturing and product research and development. Ms. Norton has 30 years of service with Lilly.
Myles O'Neill	62	Senior Vice President and President, Manufacturing Operations (since 2018). Previously, Mr. O'Neill held various leadership roles with Lilly, including senior vice president of global parenteral drug product, delivery devices, and regional manufacturing. Mr. O'Neill has 18 years of service with Lilly.
Leigh Ann Pusey	58	Senior Vice President, Corporate Affairs and Communications (since 2017). Prior to joining Lilly, Ms. Pusey was president and chief executive officer of the American Insurance Association from 2009 to 2017. Ms. Pusey has three years of service with Lilly.
Aarti Shah, Ph.D.	56	Senior Vice President and Chief Information and Digital Officer (since 2018). Previously, Dr. Shah held various leadership roles with Lilly, including senior vice president information technology and chief information officer and global brand development leader. Dr. Shah has 27 years of service with Lilly.
Daniel M. Skovronsky, M.D., Ph.D.	47	Senior Vice President, Chief Scientific Officer, and President, Lilly Research Laboratories (since 2018). Previously, Dr. Skovronsky held various leadership roles with Lilly, including senior vice president, clinical and product development. Dr. Skovronsky has 10 years of service with Lilly.
Anne E. White	52	Senior Vice President and President, Lilly Oncology (since 2018). Previously, Ms. White held various leadership roles with Lilly, including vice president of Portfolio Management, Chorus and Next Generation Research and Development. Ms. White has 25 years of service with Lilly.
Ilya Yuffa	46	Senior Vice President and President, Lilly Bio-Medicines (since 2020). Previously, Mr. Yuffa held various leadership roles with Lilly, including vice president of U.S. Diabetes general manager of Italy Hub, and vice president, global ethics and compliance officer since 2014. Mr. Yuffa has 24 years of service with Lilly.
Alfonso Zulueta	58	Senior Vice President and President, Lilly International (since 2014). Previously, Mr. Zulueta held various leadership roles with Lilly, including president of emerging markets and of Lilly Japan. Mr. Zulueta has 32 years of service with Lilly.

Human Capital Management

Our core values—integrity, excellence, and respect for people—shape our approach to attracting, retaining, engaging, and developing a highly skilled and ethical workforce, which is critical to executing our strategy. We believe the strength of our workforce significantly contributes to our financial performance and enables us to make life better for people around the world. For instance, most of the products we sell today were discovered or developed by our own scientists, and our long-term success depends on our ability to continually discover or acquire, develop, and commercialize innovative new medicines. We believe that fostering a positive culture that values the contributions of our talented colleagues helps drive our success.

We are committed to creating a safe, supportive, ethical, and rewarding work environment through strategic focus on our human capital management process, fairness and nondiscrimination in our employment practices, robust training and development opportunities, and competitive pay and benefits. We believe our dedication to promoting diversity and inclusion (D&I) within our company reflects our values and is a key driver of business success and growth.

We regularly conduct anonymous employee surveys to seek feedback from our workforce on a variety of topics. These results are reviewed and analyzed by our leaders in order to implement changes to our policies and benefits designed to improve our employees' well-being. As a result of our efforts, we believe that we have a highly performing, cohesive workforce and that our employee relations are good.

At the end of 2020, we employed approximately 35,000 people, including approximately 19,500 employees outside the U.S. Our employees include approximately 7,600 people engaged in research and development activities.

Strategy and Oversight

In order to build diverse and inclusive teams, our CEO and executive committee set expectations for inclusive leadership and hold leaders accountable for achieving results. Because dedication to human capital management is also a core component of our corporate governance, our board of directors regularly engages with management and facilitates a system of reporting designed to monitor human capital management initiatives and progress as part of the overarching framework that guides how we attract, retain, engage, and develop a workforce that aligns with our values and mission.

Diversity and Inclusion

We are committed to fairness and nondiscrimination in our employment practices, and we deeply value diverse backgrounds, skills, and global perspectives. To fulfill our purpose, we believe we must look at challenges from multiple viewpoints and understand the diverse experiences of the patients who depend on us.

We believe that fostering D&I begins with understanding. For example, our *Employee Journeys* research has yielded important insights about the experiences of women, Black/African American, Latinx, Asian, and lesbian, gay, bisexual, transgender, or queer (LGBTQ) employees at Lilly. The results of this research are reviewed by our senior leadership, and we deploy actions and activities in response to these insights to improve our workplace and corporate culture.

Since 2017, we have committed to increasing the number of women, Black/African American, Latinx, and Asian populations in leadership roles, and we actively monitor our progress. From the end of 2017 through the end of 2020, we increased the number of women in management globally from 41 percent to 46 percent. For minority group members (MGM) in the U.S. over the same period, we increased management representation from 16 percent to 22 percent. Across all levels of our workforce, from the end of 2017 through the end of 2020, we have seen increased representation for MGMs in the U.S. and women globally. Our focus on D&I is also evident at our executive committee and board of directors. Seven of 15 members (approximately 47 percent) of our executive committee (which includes our CEO) are women and two are MGM, including one MGM woman. In addition, the company’s 15-member board of directors includes six women and seven members of underrepresented groups (including MGM as well as LGBTQ individuals).

Our efforts in D&I and workplace benefits have garnered numerous recognitions, including, in 2020 and early 2021, Top 50 Companies for Diversity by DiversityInc., America's Best Employers for Diversity by Forbes, America's Most JUST Companies and Forbes JUST 100 by Forbes and JUST Capital, Perfect Score on the Human Rights Campaign Foundation Corporate Equality Index (2020 and 2021), World's Most Ethical Companies by Ethisphere, Leading Disability Employer by the National Organization on Disability, Top Employers by Science Magazine, America's Most Responsible Companies by Newsweek, and 100 Best Companies, Top 75 Companies for Executive Women, Best Companies for Dads, and Best Companies for Multicultural Women by Working Mother Magazine.

Employee Development

We believe talent begins with the hiring process. We therefore require hiring managers to consider a diverse pool of candidates and we strive to provide a diverse panel of interviewers for open positions. We believe that hiring in this way helps ensure that people from all backgrounds have equal opportunity to advance their careers.

We offer training to enable our employees to perform their duties in our highly regulated industry. We also strive to cultivate a culture that promotes ongoing learning by encouraging employees to seek further education and growth experiences, helping them build rewarding careers. We have introduced online programming to facilitate access to our learning and development offerings. Many training courses are designed to improve accessibility for people with disabilities and other unique needs. Across Lilly, we are working to design learning experiences to be more inclusive and effective.

To further improve our talent programs and processes, in 2019, we introduced *Explore Your Career*, a global framework of tools and resources for our employees. We believe *Explore Your Career* provides broader access and transparency about career development and advancement at Lilly. In 2018, we introduced *Emerge*, a three-day program led by our CEO that is designed to develop MGM talent at Lilly, and three cohorts comprising Black/African American women, Latinx and Asian women, and MGM men have participated in this enterprise-level program since its inception. Lilly also offers established leadership development programs for women and earlier career multi-cultural talent, as well as leaders at all levels.

Employee resource groups (ERGs) are another important component of developing talent at Lilly. We currently have 10 ERGs representing groups including women, MGMs, LGBTQ individuals, and people with disabilities. ERGs offer our diverse workforce opportunities to build relationships, engage with senior leaders, advance our caring community, and offer unique insights and perspectives to improve our business. Membership in our ERGs continues to grow, with an estimated 11,430 people participating worldwide at the end of 2020.

In furtherance of our efforts to create an inclusive workplace, in 2020 we expanded *Make it Safe to Thrive*, an education and awareness program to help employees and leaders understand how individual psychological safety can be created and enhanced, with the goal of ensuring that all employees feel safe to speak up and to share their ideas at work. The program includes live and online training and a monthly video series.

Employee Health and Safety

While we have consistently focused on protecting the health and safety of our employees, the COVID-19 pandemic has emphasized the importance of this critical priority. In response to the pandemic, we have taken measures to protect our workforce, maximize social distancing, and inform employees about our policies. For example, we instituted travel restrictions and remote working arrangements for employees whose roles do not require on-site presence. To support employee well-being in the U.S., we enhanced local benefits related to health care, childcare, and time off, and expanded reimbursement for home office ergonomic support expenditures. In the U.S., we provide full coverage for COVID-19 diagnostic testing and treatment, and at our corporate headquarters in Indianapolis, we provide free on-site testing for employees and members of their household. In addition, as part of our *Make it Safe to Thrive* program, we partnered with our ERGs to offer a series of programs highlighting and addressing challenges faced by ERG members during the COVID-19 pandemic, aiming to build understanding of different experiences and to offer ways to be inclusive.

Information Available on Our Website

Our company website is **www.lilly.com**. None of the information accessible on or through our website is incorporated into this Annual Report on Form 10-K. We make available through the website, free of charge, our company filings with the SEC as soon as reasonably practicable after we electronically file them with, or furnish them to, the SEC. These include our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, proxy statements, registration statements, and any amendments to those documents. The link to our SEC filings is **investor.lilly.com/financial-information/sec-filings**.

In addition, the Governance portion of our website includes our corporate governance guidelines, board of directors and committee information (including committee charters), and our articles of incorporation and bylaws. The link to our corporate governance information is **lilly.com/leadership/governance**.

Item 1A. Risk Factors

In addition to the other information contained in this Annual Report on Form 10-K, the following risk factors should be considered carefully in evaluating our company. It is possible that our business, financial condition, liquidity, cash flows, or results of operations could be materially adversely affected by any of these risks. Certain of these risks could also adversely affect the company's reputation. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial could also adversely affect our business and reputation.

Risks Related to Our Business

- **The COVID-19 pandemic and efforts to reduce its spread have impacted, and may in future periods negatively impact, our business and operations.**

  The COVID-19 pandemic has substantially burdened healthcare systems worldwide. The focus of resources on COVID-19 and widespread protective measures implemented to control the spread of the pandemic have impacted discovery, research, development, manufacturing, and sales of our medicines as well as those of the broader pharmaceutical industry. Significant delays or unexpected issues, such as higher discontinuation rates or delays accumulating data, affecting the timing, conduct, or regulatory review of our clinical trials, could adversely affect our ability to commercialize some assets in our product pipeline.

  Lack of normal access and fewer in-person interactions by patients and our employees with the healthcare system, along with concern about the continued supply of medications, has resulted, and may continue to result, in changes in buying patterns throughout the supply chain, impacting demand for our products and negatively impacting the consolidated operating results of our underlying business. In certain locations in the U.S and around the world with COVID-19 outbreaks, we temporarily halted in-person interactions by our employees with healthcare providers and increased virtual interactions. While in-person interactions have resumed in many locations, we may decide to halt such activity in the future and, in those cases, expect to resume such interactions as it is safe to do so and in compliance with applicable guidance and requirements. The COVID-19 pandemic could also have an adverse impact on our manufacturing operations, global supply chain, and distribution systems, which could impact our ability to produce and distribute our products and affect the ability of third parties on which we rely to fulfill their obligations to us, and could increase our expenses.

  We also face unique risks and uncertainties related to our development, manufacture, and uptake of potential treatments for COVID-19, including vulnerability to supply chain disruptions, higher manufacturing costs, difficulties in manufacturing sufficient quantities of our therapies, restrictions on administration that limit widespread and timely access to our therapies, and risks related to handling, return, and/or refund of product after delivery by us. Expedited authorization processes, including our EUAs for bamlanivimab and bamlanivimab and etesevimab administered together, have allowed restricted distribution of products with less than typical safety and efficacy data, and additional data that become available may call into question the safety or effectiveness of our COVID-19 therapies. Additionally, the availability of superior or competitive therapies, or preventative measures such as vaccines, coupled with the transient nature of pandemics, could negatively impact or eliminate demand for our COVID-19 therapies. In addition, we may be required to accept returns of certain product previously shipped pursuant to EUAs if the relevant EUA is revoked or terminated. Mutations or the spread of other variants of the coronavirus could also render our therapies ineffective. Any of these risks could prevent us from recouping our substantial investments in the research, development, and manufacture of our COVID-19 therapies.

  In addition, the conditions created by the COVID-19 pandemic intensify other risks inherent in our business, including, among other things, risks related to drug pricing and access, the conduct of clinical trials, workplace safety and productivity, intellectual property protection, product liability and other litigation, and the impact of adverse global and local economic conditions.

We have experienced negative impacts to our underlying business, including demand for our products, due to the COVID-19 pandemic but the pandemic has not negatively impacted our liquidity position. Given the evolving nature of the virus, the financial impact of the COVID-19 pandemic on our results of operations, financial condition, liquidity, and cash flows in future periods could change, perhaps materially. The degree to which the COVID-19 pandemic affects us will depend on developments that are highly uncertain and beyond our knowledge or control, including, but not limited to, the duration and severity of the pandemic, the actions taken to reduce its transmission, including widespread availability of vaccines, and the speed with which, and extent to which, more stable economic and operating conditions resume. Should the COVID-19 pandemic and any associated recession or depression continue for a prolonged period, our results of operations, financial condition, liquidity, and cash flows could be materially impacted by lower revenues and profitability and a lower likelihood of effectively and efficiently developing and launching new medicines.

- **Pharmaceutical research and development is very costly and highly uncertain; we may not succeed in developing, licensing, or acquiring commercially successful products sufficient in number or value to replace revenues of products that have lost or will soon lose intellectual property protection or are displaced by competing products or therapies.**

  There are many difficulties and uncertainties inherent in pharmaceutical research and development, the introduction of new products, and business development activities to expand our product pipeline.

  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 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 cannot state with certainty when or whether our products now under development will be approved or launched; whether, if initially granted, such approval will be maintained; whether we will be able to develop, license, or otherwise acquire additional product candidates or products; or whether our products, once launched, will be commercially successful.

  We must maintain a continuous flow of successful new products and successful new indications or brand extensions for existing products, both through our internal efforts and our business development activities, sufficient both to cover our substantial research and development costs and to replace revenues that are lost as profitable products lose intellectual property exclusivity or are displaced by competing products or therapies. Failure to do so in the short-term or long-term would have a material adverse effect on our business, results of operations, cash flows, and financial position. Our business development activities to enhance our product pipeline may include acquisitions, strategic alliances, collaborations, investments, and licensing arrangements. There are substantial risks associated with identifying business development targets and consummating related transactions, which may not be completed in a timely manner, if at all, may not result in successful commercialization of any product, and may give rise to legal proceedings or regulatory scrutiny.

  See Item 7, “Management’s Discussion and Analysis - Results of Operations - Executive Overview - Late-Stage Pipeline,” for more details about our current product pipeline.

- **We depend on products with intellectual property protection for most of our revenues, cash flows, and earnings; we have lost or will lose effective intellectual property protection for many of those products in the next few years, which has resulted and is likely to continue to result in rapid and severe declines in revenues.**

  A number of our top-selling products, including Alimta and Forteo, have recently lost, or will lose in the next few years, significant patent protection and/or data protection in the U.S. as well as key countries outside the U.S. We have faced and remain exposed to generic competition following the loss of such intellectual property protection. In particular, we expect that the entry of generic competition for Alimta in the U.S. following the loss of patent exclusivity will cause a rapid and severe decline in revenue for the product and have a material adverse effect on our consolidated results of operations and cash flows.

  Certain other significant products no longer have effective exclusivity through patent protection or data protection. For non-biologic products, loss of exclusivity (whether by expiration of legal rights or by termination thereof as a consequence of litigation) typically results in the entry of one or more generic competitors, leading to a rapid and severe decline in revenues, especially in the U.S. Historically, outside the U.S., the market penetration of generics following loss of exclusivity has not been as rapid or pervasive as in the U.S.; however, generic market penetration is increasing in many markets outside the U.S., including Japan, Europe, and many countries in emerging markets. For biologics (such as Humalog, Humulin, Erbitux, Cyramza, Trulicity, Taltz, and Emgality), loss of exclusivity may or may not result in the near-term entry of competitor versions (i.e., biosimilars) due to many factors, including development timelines, manufacturing challenges, and/or uncertainties regarding the regulatory pathways for approval of the competitor versions. Generic pharmaceutical companies could also introduce a generic product before resolution of any related patent litigation.

  There is no assurance that the patents we are seeking will be granted or that the patents we hold will be found valid and enforceable if challenged. Moreover, patents relating to particular products, uses, formulations, or processes do not preclude other manufacturers from employing alternative processes or marketing alternative products or formulations that compete with our patented products. In addition, competitors or other third parties may assert claims that our activities infringe patents or other intellectual property rights held by them, or allege a third-party right of ownership in our existing intellectual property. See Item 7, “Management’s Discussion and Analysis - Results of Operations - Executive Overview - Other Matters - Patent Matters,” and Item 1, "Business - Patents, Trademarks, and Other Intellectual Property Rights," for more details.

- **Our long-term success depends on intellectual property protection; if our intellectual property rights are invalidated, circumvented, or weakened, our business will be adversely affected.**

  Our long-term success depends on our ability to continually discover or acquire, develop, and commercialize innovative new medicines. Without strong intellectual property protection, we would be unable to generate the returns necessary to support our significant investments in research and development, as well as the other expenditures required to bring new drugs to the market.

  Intellectual property protection varies throughout the world and is subject to change over time, depending on local laws and regulations. Changes to such laws and regulations could reduce protections for our innovative products. In the U.S., in addition to the process for challenging patents set forth in the BPCIA, which applies to biologic products, the Hatch-Waxman Act provides generic companies powerful incentives to seek to invalidate our other pharmaceutical patents. As a result, we expect that our U.S. patents on major pharmaceutical products will continue to be routinely challenged in litigation and may not be upheld. In addition, a separate IPR process allows competitors to request review of issued patents by the USPTO without the protections of the Hatch-Waxman Act. Our patents may be invalidated through this expedited review process. Although such a decision can be appealed to the courts, in certain circumstances a loss in such a proceeding could result in a competitor entering the market, while a win provides no precedential value, meaning the same patent can be challenged by other competitors. We face many generic manufacturer challenges to our patents outside the U.S. as well. The entry of generic competitors typically results in rapid and severe declines in revenues. In addition, competitors or other third parties may claim that our activities infringe patents

or other intellectual property rights held by them. If successful, such claims could result in our being unable to market a product in a particular territory or being required to pay significant damages for past infringement or royalties on future sales. See Item 1, “Business - Patents, Trademarks, and Other Intellectual Property Rights,” and Item 8, "Financial Statements and Supplementary Data - Note 16, Contingencies," for more details.

- **We and our products face intense competition from multinational pharmaceutical companies, biotechnology companies, and lower-cost generic and biosimilar manufacturers, and such competition could have a material adverse effect on our business.**

  We compete with a large number of multinational pharmaceutical companies, biotechnology companies, and generic pharmaceutical companies. To compete successfully, we must continue to deliver to the market innovative, cost-effective products that meet important medical needs. Our product revenues can be adversely affected by the introduction by competitors of branded products that are perceived as superior by the marketplace, by generic or biosimilar versions of our branded products, and by generic or biosimilar versions of other products in the same therapeutic class as our branded products. Our revenues can also be adversely affected by treatment innovations that eliminate or minimize the need for treatment with our drugs.

  Regulation of generic and biosimilar products varies around the world and such regulation is complex and subject to ongoing interpretation and implementation by regulatory agencies and courts. Particularly for biosimilars, recent government proposals could make it easier, less expensive, and less time consuming for competitor products to enter the market, some of which could be substituted for our products by pharmacies. Given the importance of biologic products to our clinical-stage pipeline, such regulation could have a material adverse effect on our business. See Item 1, “Business - Competition” and "Business - Research and Development," for more details.

- **Failure, inadequacy, or breach of our IT systems or our business processes regarding confidential information and other data, unauthorized access to our confidential information or violations of data protection laws could result in material harm to our business and reputation.**

  A great deal of confidential information owned by us or our business partners or other third parties is stored in our information systems, networks, and facilities or those of third parties. This includes valuable trade secrets and intellectual property, clinical trial information, corporate strategic plans, marketing plans, customer information, and personally identifiable information, such as employee and patient information (collectively, confidential information). We also rely, to a large extent, on the efficient and uninterrupted operation of complex information technology systems, infrastructure, and hardware (together, IT systems), some of which are within our control and some of which are within the control of third parties, to accumulate, process, store, and transmit large amounts of confidential information and other data. We are subject to a variety of continuously evolving and developing laws and regulations around the world related to privacy, data protection, and data security. Maintaining the confidentiality, integrity and availability of our IT systems and confidential information is vital to our business.

  IT systems are vulnerable to system inadequacies, operating failures, service interruptions or failures, security breaches, malicious intrusions, or cyber-attacks from a variety of sources. Cyber-attacks are growing in their frequency, sophistication, and intensity, and are becoming increasingly difficult to detect, mitigate, or prevent. Cyber-attacks come in many forms, including the deployment of harmful malware, exploitation of vulnerabilities (including those third-party software or systems), denial-of-service attacks, the use of social engineering, and other means to compromise the confidentiality, integrity and availability of our IT systems, confidential information, and other data. Breaches resulting in the compromise, disruption, degradation, manipulation, loss, theft, destruction, or unauthorized disclosure or use of confidential information, or the unauthorized access to, disruption of, or interference with our products and services, can occur in a variety of ways, including but not limited to, negligent or wrongful conduct by employees or others with permitted access to our systems and information, or wrongful conduct by hackers, competitors, certain governments or nation-states, or other current or former company personnel. Our third-party partners, including third-party providers of data hosting or cloud services, as well as suppliers, distributors, alliances, and other third-party service providers, face similar risks, which could affect us directly or indirectly. The healthcare industry has been and continues to be a target for cyber-attacks, and the number of threats has only increased during the COVID-19 pandemic. Numerous federal agencies that monitor and regulate internet and cyber-crime have issued guidance, alerts and directives warning of software vulnerabilities that require immediate patching, malicious actors targeting healthcare related systems and nation-state sponsored hacking designed to steal valuable information, including related to potential COVID-19 treatments.

The failure or inadequacy of our IT systems or business processes, the compromise, disruption, degradation, manipulation, loss, theft, destruction, or unauthorized access to disclosure or use of confidential information, or the unauthorized access to, disruption of, or interference with our products and services that rely on IT systems or business processes, could impair our ability to secure and maintain intellectual property rights; result in a product manufacturing interruption or failure, or in the interruption or failure of products or services that rely on IT systems or business processes; damage our operations, customer relationships, or reputation; and cause us to lose trade secrets or other competitive advantages. Unauthorized disclosure of personally identifiable information could expose us to significant sanctions for violations of data privacy laws and regulations around the world and could damage public trust in our company.

To date, system inadequacies, operating failures, unauthorized access, service interruptions or failures, security breaches, malicious intrusions, cyber-attacks, and the compromise, disruption, degradation, manipulation, loss, theft, destruction, or unauthorized disclosure or use of confidential information have not had a material impact on our consolidated results of operations. We maintain cyber liability insurance; however, this insurance may not be sufficient to cover the financial, legal, business, or reputational losses that may result from an interruption or breach of our IT systems. We continue to implement measures in an effort to protect, detect, respond to, and minimize or prevent these risks and to enhance the resiliency of our IT systems; however, these measures may not be successful and we may fail to detect or remediate security breaches, malicious intrusions, cyber-attacks, or other compromises of our systems. Any of these events could result in material financial, legal, commercial, or reputational harm to our business.

- **Significant economic downturns or international trade disruptions or disputes could adversely affect our business and operating results.**

  While pharmaceuticals have not generally been sensitive to overall economic cycles, prolonged economic slowdowns, including as a result of COVID-19, could lead to decreased utilization of our products, affecting our sales volume. Declining tax revenues attributable to economic downturns increase the pressure on governments to reduce health care spending, leading to increasing government efforts to control drug prices and utilization. Additionally, some customers, including governments or other entities reliant upon government funding, may be unable to pay for our products in a timely manner. Also, if our customers, suppliers, or collaboration partners experience financial difficulties, we could experience slower customer collections, greater bad debt expense, and performance defaults by suppliers or collaboration partners. Similarly, in the event of a significant economic downturn, we could have difficulty accessing credit markets.

  Significant portions of our business are conducted in Europe, including the United Kingdom, Asia, and other international geographies. Trade disputes and interruptions in international relationships, including pandemic diseases, such as COVID-19, could result in changes to regulations governing our products and our intellectual property, or otherwise affect our ability to do business. While we do not expect either circumstance to materially affect our business in a direct manner, these and similar events could adversely affect us, or our business partners or customers.

- **Pharmaceutical products can develop unexpected safety or efficacy concerns, which could have a material adverse effect on our revenues, income, and reputation.**

  Pharmaceutical products receive regulatory approval based on data obtained in controlled clinical trials of limited duration. After approval, the products are used for longer periods of time by much larger numbers of patients. Accordingly, we and others (including regulatory agencies and private payers) collect extensive information on the efficacy and safety of our marketed products by continuously monitoring the use of our products in the marketplace. In addition, we or others may conduct post-marketing clinical studies on efficacy and safety of our marketed products. New safety or efficacy data from both market surveillance and post-marketing clinical studies may result in product label changes or other measures that could reduce the product's market acceptance and result in declining sales. Serious safety or efficacy issues that arise after product approval could result in voluntary or mandatory product recalls or withdrawals from the market. Safety issues could also result in costly product liability claims. See also “ - The COVID-19 pandemic and efforts to reduce its spread have impacted, and may in future periods negatively impact, our business and operations.”

- **We face litigation and investigations related to our products and our pricing practices and are self-insured; we could face large numbers of claims in the future, which could adversely affect our business.**

  We are subject to a substantial number of product liability claims involving various products, as well as litigation and investigations related to the pricing of our products. See Item 8, “Financial Statements and Supplementary Data - Note 16, Contingencies” for more information on our current product liability litigation, as well as pricing litigation, investigations, and inquiries. Because of the nature of pharmaceutical products, we are and could in the future become subject to large numbers of product liability claims for these or other products, or to further litigation or investigations, including related to pricing or other commercial practices. Such matters could affect our results of operations or require us to recognize substantial charges to resolve and, if involving marketed products, could adversely affect sales of the product. Due to a very restrictive market for liability insurance, we are self-insured for product liability losses for all our currently marketed products, as well as for litigation or investigations related to our pricing practices or other similar matters.

- **Manufacturing difficulties or disruptions could lead to product supply problems.**

  Pharmaceutical manufacturing is complex and highly regulated. Manufacturing or quality assurance difficulties at our facilities or contracted facilities, or the failure or refusal of a supplier or contract manufacturer to supply contracted quantities, could result in product shortages, leading to lost revenue. Such difficulties or disruptions could result from quality, oversight, or regulatory compliance problems; natural disasters or pandemic disease; equipment, mechanical, data, or information technology system vulnerabilities, such as system inadequacies, inadequate controls or procedures, operating failures, service interruptions or failures, security breaches, malicious intrusions, or cyber-attacks from a variety of sources; or inability to obtain single-source raw or intermediate materials. In addition, given the difficulties in predicting sales of new products and the very long lead times necessary for the expansion and regulatory qualification of pharmaceutical manufacturing capacity, it is possible that we could have difficulty meeting unanticipated demand for new products. See Item 1, “Business - Raw Materials and Product Supply,” for more details.

- **Reliance on third-party relationships and outsourcing arrangements could adversely affect our business.**

  We rely on third parties, including suppliers, distributors, alliances, and collaborations with other pharmaceutical and biotechnology companies, and third-party service providers, for selected aspects of product development, manufacturing, commercialization, support for information technology systems, product distribution, and certain financial transactional processes. For example, we outsource the day-to-day management and oversight of our clinical trials to contract research organizations. Outsourcing these functions involves the risk that the third parties may not perform to our standards or legal requirements; may not produce reliable results; may not perform in a timely manner; may not maintain the confidentiality, integrity, and availability of confidential and proprietary information relating to us, our clinical trial subjects, or patients; may experience disruption or fail to perform due to information technology system vulnerabilities, breaches, cyber-attacks, or inadequate controls or procedures; or may fail to perform at all. Failure of these third parties to meet their contractual, regulatory, confidentiality, privacy, security, or other obligations to us, our clinical trial subjects, and our patients could have a material adverse effect on our business.

Risks Related to Government Regulation

- **Our business is subject to increasing government price controls and other public and private restrictions on pricing, reimbursement, and access for our drugs, which could have a material adverse effect on our reputation or business.**

  Public and private payers continue to take aggressive steps to control their expenditures for pharmaceuticals by placing restrictions on pricing and reimbursement for, and patient access to, our medications. These pressures could continue to negatively affect our future revenues and net income.

We expect governments and private payers worldwide to intensify their scrutiny of, and actions intended to address, pricing, reimbursement, and access to pharmaceutical products. Additional regulations, legislation, or enforcement, including as a result of the current U.S. presidential administration, could adversely impact our revenue. However, we cannot predict the likelihood, nature, or extent of current and future health care reform efforts. We also may experience potential additional pricing pressures resulting from the financial strain of the COVID-19 pandemic on government-funded healthcare systems around the world.

For more details, see Item 1, “Business - Regulations and Private Payer Actions Affecting Pharmaceutical Pricing, Reimbursement, and Access,” and Item 7, “Management’s Discussion and Analysis - Results of Operations - Executive Overview - Other Matters - Trends Affecting Pharmaceutical Pricing, Reimbursement, and Access.”

- **Changes in foreign currency rates or interest rate risks could materially affect our revenue, cost of sales, and operating expenses.**

  As a global company with substantial operations outside the U.S., we face foreign currency risk exposure from fluctuating currency exchange rates. While we seek to manage a portion of these exposures through hedging and other risk management techniques, significant fluctuations in currency rates can have a material impact, either positive or negative, on our revenue, cost of sales, and operating expenses. In the event of an extreme devaluation of local currency, the price of our products could become unsustainable in the relevant market. See Item 7, “Management’s Discussion and Analysis - Financial Condition and Liquidity” for more details.

- **Unanticipated changes in our tax rates or exposure to additional tax liabilities could increase our income taxes and decrease our net income.**

  We are subject to income taxes in the U.S. and numerous foreign jurisdictions, and in the course of our business, we make judgments about the expected tax treatment of various transactions and events. Changes in relevant tax laws, regulations, administrative practices, principles, and interpretations, as well as events that differ from our expectations, could adversely affect our future effective tax rates. In addition, global tax authorities routinely examine our tax returns and are expected to become more aggressive in their examinations of profit allocations among jurisdictions which could affect our anticipated tax liabilities. In December 2017, the U.S. enacted tax reform legislation significantly revising U.S. tax laws, and a number of other countries are also actively considering or enacting tax changes. Significant uncertainty currently exists regarding proposed tax policies of the current U.S. presidential administration including repeal of certain aspects of the 2017 tax law. Modifications to key elements of the U.S. or international tax framework could have a material adverse effect on our consolidated operating results and cash flows. See Item 7, “Management’s Discussion and Analysis - Results of Operations - Executive Overview - Other Matters - Tax Matters” and Item 8, "Financial Statements and Supplementary Data - Note 14, Income Taxes," for more details.

  We have taken the position, based on an opinion of tax counsel, that our divestiture of Elanco common stock in connection with the 2019 separation of Elanco qualifies as a transaction that is tax-free for U.S. federal income tax purposes. If any facts, assumptions, representations, and undertakings from Lilly and Elanco regarding the past and future conduct of their respective businesses and other matters are incorrect or not otherwise satisfied, the divestiture may not qualify for tax-free treatment, which could result in significant U.S. federal income tax liabilities for us and our shareholders who exchanged their stock for Elanco stock.

- **Regulatory compliance problems could be damaging to the company.**

  The marketing, promotional, and pricing practices of pharmaceutical manufacturers, as well as the manner in which manufacturers interact with purchasers, prescribers, and patients, are subject to extensive regulation. Many companies, including us, have been subject to claims related to these practices asserted by federal, state, and foreign governmental authorities, private payers, and consumers. These claims have resulted in substantial expense and other significant consequences to us. We are and could in the future become subject to such investigations, the outcomes of which could include criminal charges and fines, penalties, or other monetary or non-monetary remedies, including exclusion from U.S. federal and other health care programs. Such investigations may intensify as a result of the regulatory priorities of the current U.S. presidential administration. In addition, regulatory issues concerning compliance with cGMP, quality assurance, and similar regulations (and comparable foreign regulations) for our products can lead to regulatory and legal actions, product recalls and seizures, fines and penalties, interruption of production leading to product shortages, import bans or denials of import certifications, delays or denials in the approvals of new products pending resolution of the issues, and reputational harm, any of which would adversely affect our business. See Item 1, “Business - Government Regulation of Our Operations,” for more details.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our principal domestic and international executive offices are located in Indianapolis. At December 31, 2020, we owned 9 production and distribution sites in the U.S., including Puerto Rico. Together with the corporate administrative offices, these facilities contain an aggregate of approximately 8.2 million square feet of floor area dedicated to production, distribution, and administration. Major production sites include Indianapolis, Indiana; Carolina, Puerto Rico; and Branchburg, New Jersey.

We own production and distribution sites in 8 countries outside the U.S., containing an aggregate of approximately 4.4 million square feet of floor area. Major production sites include facilities in Ireland, France, Spain, Italy, and China.

In the U.S., our research and development facilities contain an aggregate of approximately 4.2 million square feet of floor area, primarily consisting of owned facilities located in Indianapolis. We also lease smaller sites in San Diego, California; San Francisco, California; and New York, New York. Outside the U.S., we own a small research and development facility in Spain and lease a small site in Singapore.

We believe that none of our properties is subject to any encumbrance, easement, or other restriction that would detract materially from its value or impair its use in the operation of the business. The buildings we own are of varying ages and in good condition.

Item 3. Legal Proceedings

We are a party to various currently pending legal actions, government investigations, and environmental proceedings. Information pertaining to legal proceedings is described in Item 8, "Financial Statements and Supplementary Data - Note 16, Contingencies," and incorporated by reference herein.

Item 4. Mine Safety Disclosures

Not applicable.

Part II

Item 5. Market for the Registrant's Common Equity, Related Stockholder Matters, and Issuer Purchases of Equity Securities

Information relating to the principal market for our common stock and related stockholder matters is described in Item 7, "Management's Discussion and Analysis of Results of Operations and Financial Condition" and Item 12, "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters." This information is incorporated herein by reference.

As of February 12, 2021, there were approximately 21,650 holders of record of our common stock based on information provided by our transfer agent. Our common stock is listed under the ticker symbol LLY on the New York Stock Exchange (NYSE).

The following table summarizes the activity related to repurchases of our equity securities during the fourth quarter ended December 31, 2020:

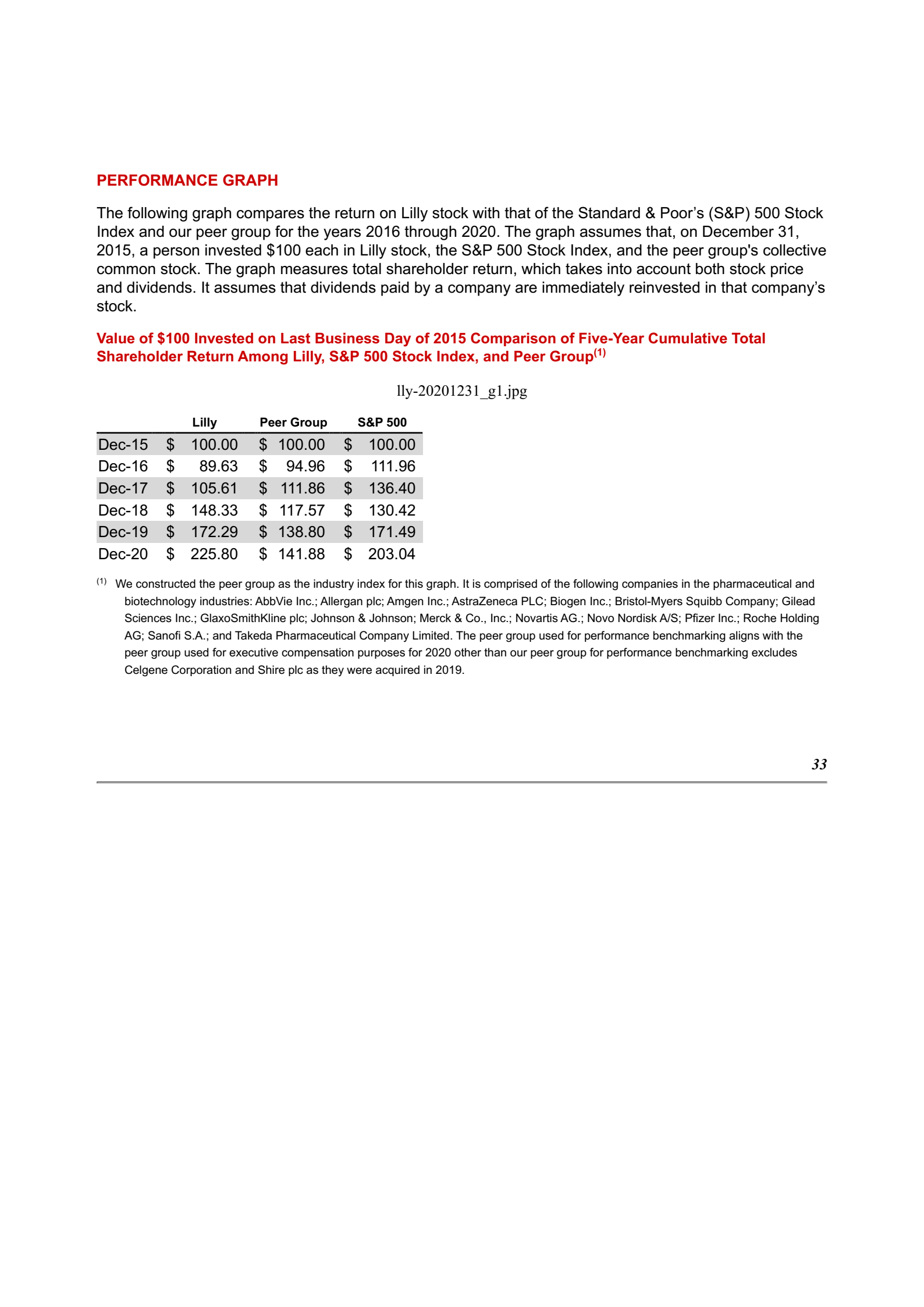
Period	Total Number of Shares Purchased (in thousands)	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs (in thousands)	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs (dollars in millions)
October 2020	—	$ —	—	$ 1,000.0
November 2020	—	—	—	1,000.0
December 2020	—	—	—	1,000.0
Total	—	—	—	

During the three months ended December 31, 2020, we did not repurchase any shares under the $8.00 billion share repurchase program authorized in June 2018.

PERFORMANCE GRAPH

The following graph compares the return on Lilly stock with that of the Standard & Poor's (S&P) 500 Stock Index and our peer group for the years 2016 through 2020. The graph assumes that, on December 31, 2015, a person invested $100 each in Lilly stock, the S&P 500 Stock Index, and the peer group's collective common stock. The graph measures total shareholder return, which takes into account both stock price and dividends. It assumes that dividends paid by a company are immediately reinvested in that company's stock.

Value of $100 Invested on Last Business Day of 2015 Comparison of Five-Year Cumulative Total Shareholder Return Among Lilly, S&P 500 Stock Index, and Peer Group[(1)]



	Lilly	Peer Group	S&P 500
Dec-15	$ 100.00	$ 100.00	$ 100.00
Dec-16	$ 89.63	$ 94.96	$ 111.96
Dec-17	$ 105.61	$ 111.86	$ 136.40
Dec-18	$ 148.33	$ 117.57	$ 130.42
Dec-19	$ 172.29	$ 138.80	$ 171.49
Dec-20	$ 225.80	$ 141.88	$ 203.04

(1) We constructed the peer group as the industry index for this graph. It is comprised of the following companies in the pharmaceutical and biotechnology industries: AbbVie Inc.; Allergan plc; Amgen Inc.; AstraZeneca PLC; Biogen Inc.; Bristol-Myers Squibb Company; Gilead Sciences Inc.; GlaxoSmithKline plc; Johnson & Johnson; Merck & Co., Inc.; Novartis AG.; Novo Nordisk A/S; Pfizer Inc.; Roche Holding AG; Sanofi S.A.; and Takeda Pharmaceutical Company Limited. The peer group used for performance benchmarking aligns with the peer group used for executive compensation purposes for 2020 other than our peer group for performance benchmarking excludes Celgene Corporation and Shire plc as they were acquired in 2019.

Item 6. [Reserved]

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 in Item 8 of Part II of this Annual Report on Form 10-K. Certain statements in this Item 7 of Part II of this Annual Report on Form 10-K constitute forward-looking statements. Various risks and uncertainties, including those discussed in "Forward-Looking Statements" and Item 1A, "Risk Factors," may cause our actual results, financial position, and cash generated from operations to differ materially from these forward-looking statements.

Executive Overview

This section provides an overview of our financial results, recent product and late-stage pipeline developments, and other matters affecting our company and the pharmaceutical industry. Earnings per share (EPS) data are presented on a diluted basis.

COVID-19 Pandemic

In response to the COVID-19 pandemic, we have been focused on maintaining a reliable supply of our medicines; reducing the strain on the medical system; developing treatments for COVID-19; protecting the health, safety, and well-being of our employees; supporting our communities; and ensuring affordability of and access to our medicines, particularly insulin.

We have experienced negative impacts to our underlying business due to the COVID-19 pandemic, including decreases in new prescriptions as a result of fewer patient visits to physician's offices to begin or change treatment, changes in payer segment mix, and the use of patient affordability programs in the United States (U.S.) due to rising unemployment. Additionally, we have experienced, and may continue to experience, decreased demand as a result of lack of normal access and fewer in-person interactions by patients and our employees with the healthcare system. In certain locations in the U.S. and around the world with COVID-19 outbreaks, we temporarily halted in-person interactions by our employees with healthcare providers and increased virtual interactions. While in-person interactions have resumed in many locations, we may decide to halt such activity in the future and, in those cases, expect to resume such interactions as it is safe to do so and in compliance with applicable guidance and requirements. We may experience additional pricing pressures resulting from the financial strain of the COVID-19 pandemic on government-funded healthcare systems around the world.

We remain committed to discovering and developing new treatments for the patients we serve. At the beginning of the COVID-19 pandemic, we paused new clinical trial starts and enrollment in new trials in order to reduce the strain on the medical system, and we have resumed this activity in our clinical trials. However, significant delays or unexpected issues, such as higher discontinuation rates or delays accumulating data, affecting the timing, conduct, or regulatory review of our clinical trials, could adversely affect our ability to commercialize some assets in our product pipeline if the COVID-19 pandemic continues for a protracted period.

In regards to COVID-19 therapies, the U.S. Food and Drug Administration (FDA) granted Emergency Use Authorizations (EUA) for bamlanivimab and bamlanivimab and etesevimab administered together for higher-risk patients who have been recently diagnosed with mild-to-moderate COVID-19 and for baricitinib in combination with remdesivir in hospitalized COVID-19 patients. We are actively working with a variety of organizations, including governmental agencies, to facilitate access to our COVID-19 treatments in various countries. However, we face unique risks and uncertainties in our development, manufacture, and uptake of potential treatments for COVID-19, including vulnerability to supply chain disruptions, higher manufacturing costs, difficulties in manufacturing sufficient quantities of our therapies, restrictions on administration that limit widespread and timely access to our therapies, and risks related to handling, return, and/or refund of product after delivery by us. Expedited authorization processes, including our EUAs for bamlanivimab and bamlanivimab and etesevimab administered together, have allowed restricted distribution of products with less than typical safety and efficacy data, and additional data that become available may call into question the safety or effectiveness of our COVID-19 therapies. Additionally, the availability of superior or competitive therapies, or preventative measures, such as vaccines, coupled with the transient nature of pandemics, could negatively impact or eliminate demand for our COVID-19 therapies. In addition, we may be required to accept returns of certain product previously shipped pursuant to EUAs if the relevant EUA is revoked or terminated. Mutations or the spread of other variants of the coronavirus could also render our therapies ineffective. Any of these risks could prevent us from recouping our substantial investments in the research, development, and manufacture of our COVID-19 therapies.

Our ability to continue to operate without significant negative impacts will in part depend on our ability to protect our employees and our supply chain. We have taken steps to protect our employees worldwide, with particular measures in place for those working in our manufacturing sites and distribution facilities. For 2020, we were able to largely maintain our normal operations. However, uncertainty resulting from the COVID-19 pandemic could have an adverse impact on our manufacturing operations, global supply chain, and distribution systems, which could impact our ability to produce and distribute our products and the ability of third parties on which we rely to fulfill their obligations to us, and could increase our expenses.

Although the COVID-19 pandemic has affected our operations and demand for our products, it has not negatively impacted our liquidity position. We expect to continue to generate cash flows to meet our short-term liquidity needs and to have access to liquidity via the short-term and long-term debt markets. We also have not observed any material impairments of our assets or significant changes in the fair value of assets due to the COVID-19 pandemic.

The degree to which the COVID-19 pandemic will continue to impact our business operations, financial results, and liquidity will depend on future developments, is highly uncertain, and cannot be predicted due to, among other things, the duration and severity of the pandemic, the actions taken to reduce its transmission, including widespread availability of vaccines, and the speed with which, and extent to which, more stable economic and operating conditions resume. Should the COVID-19 pandemic and any associated recession or depression continue for a prolonged period, our results of operations, financial condition, liquidity, and cash flows could be materially impacted by lower revenues and profitability and a lower likelihood of effectively and efficiently developing and launching new medicines. See “Risk Factors” in Part I, Item 1A of this Annual Report on Form 10-K for additional information on risk factors that could impact our results.

Elanco Animal Health (Elanco) Disposition

On March 11, 2019, we completed the disposition of our remaining 80.2 percent ownership of Elanco common stock through a tax-free exchange offer. As a result, we recognized a gain on the disposition of approximately $3.7 billion in the first quarter of 2019 and now operate as a single segment. See Note 19 to the consolidated financial statements for further discussion.

Financial Results

The following table summarizes our key operating results:

	Year Ended December 31		Percent Change
	2020	2019	
Revenue	**$ 24,539.8**	$ 22,319.5	10
Gross margin	**19,056.5**	17,598.3	8
Gross margin as a percent of revenue	**77.7 %**	78.8 %	
Operating expense	**$ 12,206.9**	$ 11,808.8	3
Acquired in-process research and development	**660.4**	239.6	NM
Asset impairment, restructuring, and other special charges	**131.2**	575.6	(77)
Income before income taxes	**7,229.9**	5,265.9	37
Income taxes	**1,036.2**	628.0	65
Net income from continuing operations	**6,193.7**	4,637.9	34
Net income	**6,193.7**	8,318.4	(26)
EPS from continuing operations	**6.79**	4.96	37
EPS	**6.79**	8.89	(24)

NM - not meaningful

Revenue increased in 2020 driven by increased volume, partially offset by lower realized prices. Operating expenses, defined as the sum of research and development and marketing, selling, and administrative expenses, increased in 2020, driven primarily by approximately $450 million of development expenses for COVID-19 therapies. The decreases in net income and EPS in 2020 were driven primarily by the approximately $3.7 billion gain recognized on the disposition of Elanco in 2019, partially offset by higher gross margin and higher other income in 2020.

The following highlighted items affect comparisons of our 2020 and 2019 financial results:

2020

Acquired in-process research and development (IPR&D) (Note 3 to the consolidated financial statements)

- We recognized acquired IPR&D charges of $660.4 million resulting from the acquisitions of Disarm Therapeutics, Inc. (Disarm) and a pre-clinical stage company as well as collaborations with Innovent Biologics, Inc. (Innovent), Sitryx Therapeutics Limited (Sitryx), Fochon Pharmaceuticals, Ltd. (Fochon), AbCellera Biologics Inc. (AbCellera), Evox Therapeutics Ltd (Evox), and Shanghai Junshi Biosciences Co., Ltd. (Junshi Biosciences).

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

- We recognized charges of $131.2 million primarily related to severance costs incurred as a result of actions taken worldwide to reduce our cost structure, as well as acquisition and integration costs incurred as part of the acquisition of Dermira, Inc. (Dermira).

Other-Net, (Income) Expense (Note 18 to the consolidated financial statements)

- We recognized $1.44 billion of net investment gains on equity securities.

2019

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

- We recognized acquired IPR&D charges of $239.6 million resulting from collaborations with AC Immune SA (AC Immune), Centrexion Therapeutics Corporation (Centrexion), ImmuNext, Inc. (ImmuNext), and Avidity Biosciences, Inc. (Avidity).

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

- We recognized charges of $575.6 million primarily associated with the accelerated vesting of Loxo Oncology, Inc. (Loxo) employee equity awards as part of the acquisition of Loxo.

Other-Net, (Income) Expense (Note 18 to the consolidated financial statements)

- We recognized $401.2 million of net investment gains on equity securities.
- We recognized a gain of $309.8 million on the sale of our antibiotics business in China.
- We recognized a debt extinguishment loss of $252.5 million related to the repurchase of debt.

Net Income from Discontinued Operations (Note 19 to the consolidated financial statements)

- We recognized a gain related to the disposition of Elanco of approximately $3.7 billion.

Late-Stage Pipeline

Our long-term success depends on our ability to continually discover or acquire, develop, and commercialize innovative new medicines. We currently have approximately 45 candidates in clinical development or under regulatory review, and a larger number of projects in the discovery phase.

The following new molecular entities (NMEs) and diagnostic agent are currently in Phase III clinical trials or have been submitted for regulatory review or have received first regulatory approval in the U.S., Europe, or Japan in 2020. In addition, the following table includes certain NMEs currently in Phase II clinical trials. The following table reflects the status of these NMEs and diagnostic agent, including certain other developments since January 1, 2020.

Compound	Indication	Status	Developments
COVID-19 Therapies			
Bamlanivimab	COVID-19	Emergency Use Authorization	The FDA granted EUA for higher-risk patients recently diagnosed with mild-to-moderate COVID-19 in the fourth quarter of 2020. Announced in January 2021 that a Phase III trial met the primary and all key secondary endpoints. Additional Phase III trials are ongoing.
Bamlanivimab and etesevimab administered together	COVID-19	Emergency Use Authorization	Announced in January 2021 that a Phase III trial met the primary and all key secondary endpoints. The FDA granted EUA for higher-risk patients recently diagnosed with mild-to-moderate COVID-19 in January 2021. Additional Phase III trials are ongoing. We intend to submit to the FDA for approval in the second half of 2021.
Endocrinology			
Ultra-rapid Lispro (Lyumjev®)	Type 1 and 2 diabetes	Launched	Launched in Japan in the second quarter of 2020 and in the U.S. and Europe in the third quarter of 2020.
Tirzepatide	Type 2 diabetes	Phase III	Announced in the fourth quarter of 2020 and in February 2021 that Phase III trials met the primary and all key secondary endpoints. Additional Phase III trials are ongoing.
	Obesity		Phase III trials are ongoing.
	Nonalcoholic steatohepatitis	Phase II	Phase II trial is ongoing.
Basal Insulin-Fc	Type 1 and 2 diabetes	Phase II	Phase II trials are ongoing.

Compound	Indication	Status	Developments
Immunology			
Lebrikizumab[1]	Atopic dermatitis	Phase III	Acquired in Dermira acquisition in February 2020. The FDA granted Fast Track designation[2]. Phase III trials are ongoing.
Mirikizumab	Crohn's Disease	Phase III	Phase III trials are ongoing.
	Psoriasis		Announced in the third quarter of 2020 that Phase III trials met the primary and all key secondary endpoints. Additional Phase III trials are ongoing.
	Ulcerative colitis		Phase III trials are ongoing.
CXCR1/2 Ligands Monoclonal Antibody	Hidradenitis Suppurativa	Phase II	Phase II trial initiated in the third quarter of 2020.
IL-2 Conjugate	Systemic Lupus Erythematosus	Phase II	Phase II trial is ongoing.
Neuroscience			
Lasmiditan (Reyvow®)	Acute treatment of migraine	Launched	Received Schedule V classification from the Drug Enforcement Agency and launched in the U.S. in the first quarter of 2020. Submitted in Europe and Japan in the fourth quarter of 2020.
Flortaucipir (Tauvid™)	Alzheimer's disease diagnostic	Launched	Launched in the U.S. in the fourth quarter of 2020.
Tanezumab[3]	Osteoarthritis pain	Submitted	Submitted to the FDA in 2019. The FDA intends to hold an Advisory Committee meeting, expected to occur in March 2021, to discuss the submission.
	Cancer pain	Phase III	Phase III trial is ongoing.
Solanezumab	Preclinical Alzheimer's disease	Phase III	Announced in the first quarter of 2020 that a Phase III trial for people with dominantly inherited Alzheimer's disease (DIAD) did not meet the primary endpoint. We do not plan to pursue submission for DIAD. Phase III trial is ongoing for Anti-Amyloid Treatment in Asymptomatic Alzheimer's.
Donanemab	Alzheimer’s disease	Phase II	Announced in January 2021 that a Phase II trial met the primary endpoint. Additional Phase II trials are ongoing.
Epiregulin/TGFa mAb	Chronic pain	Phase II	Phase II trials initiated in the third quarter of 2020.
PACAP38 Antibody	Chronic pain	Phase II	Phase II trial initiated in

(1) In collaboration with Almirall, S.A. (Almirall) in Europe.
(2) Fast Track designation is designated to expedite the development and review of new therapies to treat serious conditions and address unmet medical needs.
(3) In collaboration with Pfizer, Inc.
(4) Continued approval may be contingent on verification and description of clinical benefit in confirmatory Phase III trials.

As part of our collaboration with Innovent, we plan to pursue registration of sintilimab injection (Tyvyt®) in the U.S. and other markets.

Our pipeline also contains several new indication line extension (NILEX) products. The following certain NILEX products are currently in Phase II or Phase III clinical testing, have been submitted for regulatory review, or have received first regulatory approval in the U.S., Europe, or Japan for use in the indication described in 2020. The following table reflects the status of certain NILEX products, including certain other developments since January 1, 2020:

Compound	Indication	Status	Developments
Endocrinology			
Empagliflozin (Jardiance®)[(1)]	Heart failure with reduced ejection fraction	Submitted	Submitted in the U.S., Europe and Japan in the fourth quarter of 2020.
	Chronic kidney disease	Phase III	Granted FDA Fast Track designation[(2)]. Phase III trials are ongoing.
	Heart failure with preserved ejection fraction		
Immunology			
Baricitinib (Olumiant®)	Atopic dermatitis	Approved	Announced in the first quarter of 2020 that a Phase III trial met the primary and all key secondary endpoints. Submitted in the U.S. in the second quarter of 2020. Approved in Europe in the third quarter of 2020 and in Japan in the fourth quarter of 2020.
	COVID-19	Emergency Use Authorization	The FDA granted EUA in combination with remdesivir in hospitalized COVID-19 patients in the fourth quarter of 2020.
	Alopecia areata	Phase III	The FDA granted Breakthrough Therapy designation[(3)]. Phase III trials are ongoing.
	Systemic lupus erythematosus		Phase III trials are ongoing.
Oncology			
Abemaciclib (Verzenio®)	Adjuvant breast cancer	Submitted	Announced in the second quarter of 2020 that a Phase III trial met the primary endpoint. Submitted in the U.S. and Europe in the fourth quarter of 2020.
	Prostate cancer	Phase II	Phase II trials are ongoing.

(1) In collaboration with Boehringer Ingelheim.

(2) Fast Track designation is designated to expedite the development and review of new therapies to treat serious conditions and address unmet medical needs.

(3) 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.

There are many difficulties and uncertainties inherent in pharmaceutical research and development and the introduction of new products, as well as 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 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 potential new medicines. 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 any 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

Patent Matters

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

Our formulation patents for Forteo® expired in December 2018, and our use patents expired in August 2019 in major European markets and the U.S. Both the formulation patent and the use patent expired in August 2019 in Japan. We expect further volume decline as a result of the anticipated entry of generic and biosimilar competition following the loss of patent exclusivity in these markets. In the aggregate, we expect that the decline in revenue will have a material adverse effect on our consolidated results of operations and cash flows.

The Alimta® vitamin regimen patents, which we expect to provide us with patent protection for Alimta through June 2021 in Japan and major European countries, and through May 2022 in the U.S., have been challenged in each of these jurisdictions. In the U.S., most challenges have been finally resolved in our favor, and one remains in active litigation. We and Eagle Pharmaceuticals, Inc. (Eagle) reached an agreement in December 2019 to settle all pending litigation, allowing Eagle a limited initial entry into the market with its product starting February 2022 (up to an approximate three-week supply) and subsequent unlimited entry starting April 2022. We expect that the entry of generic competition in the U.S. either from an unfavorable outcome to the patent challenge or following the loss of patent exclusivity, will cause a rapid and severe decline in revenue and have a material adverse effect on our consolidated results of operations and cash flows.

We are aware that several companies have received approval to market generic versions of pemetrexed in major European markets and that generic competitors may choose to attempt a launch at risk. Following a final decision in the Supreme Court of Germany in July 2020 overturning the lower court and upholding the validity of our Alimta patent, several generics that were on the market at risk in Germany left. We have removed the remaining generics from the market in Germany by obtaining preliminary injunctions in our favor. In September 2020, the Paris Court of First Instance in France issued a final decision upholding the validity of our Alimta patent and found infringement by Fresenius Kabi France and Fresenius Kabi Groupe France's (collectively, Kabi) pemetrexed product. The court issued an injunction against Kabi and provisionally awarded us damages. In January 2021, that same court issued a preliminary injunction against Zentiva France S.A.S. (Zentiva), the last remaining company with a generic pemetrexed product on the French market, and provisionally awarded us damages. In October 2020, the Court of Appeal of the Netherlands overturned a lower court decision and ruled that our Alimta patent is valid and infringed and reinstated an injunction against Kabi, thereby removing Kabi's pemetrexed product from the Netherlands market. Kabi has appealed this decision to the Netherlands Supreme Court. Kabi's generic pemetrexed product was the only at risk generic on the market in the Netherlands. Our vitamin regimen patents have also been challenged in other smaller European jurisdictions.

We expect that further entry of generic competition for Alimta in major European markets following either the loss of effective patent protection or of patent exclusivity will cause a rapid and severe decline in revenue. See Note 16 to the consolidated financial statements for a more detailed account of the legal proceedings currently pending in the U.S., Europe, and Japan regarding, among others, our Alimta patents.

The compound patent for Humalog® (insulin lispro) has expired in major markets. Global regulators have different legal pathways to approve similar versions of insulin lispro. A competitor launched a similar version of insulin lispro in certain European markets in 2017 and in the U.S. in the second quarter of 2018. While it is difficult to estimate the severity of the impact of insulin lispro products entering the market, we do not expect and have not experienced a rapid and severe decline in revenue; however, we expect additional pricing pressure and some loss of market share that would continue over time.

Our compound patent protection for Cymbalta® expired in Japan in January 2020. We expect generics to enter the market in mid-2021. We expect that the entry of generic competition will cause a rapid and severe decline in revenue and will have a material adverse effect on our consolidated results of operations and cash flows.

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 seek to manage a portion of these exposures through hedging and other risk management techniques, significant fluctuations in currency rates can have a material impact, either positive or negative, on our revenue, cost of sales, and operating expenses. While there is uncertainty in the future movements in foreign exchange rates, fluctuations in these rates could negatively impact our future consolidated results of operations and cash flows.

Trends Affecting Pharmaceutical Pricing, Reimbursement, and Access

U.S.

In the U.S., public concern over access to and affordability of pharmaceuticals continues to drive the regulatory and legislative debate. These policy and political issues increase the risk that taxes, fees, rebates, or other cost control measures may be enacted to manage federal and state budgets. Key health policy initiatives affecting biopharmaceuticals include:

- the Coronavirus Aid, Relief, and Economic Security (CARES) Act and subsequent stimulus bills that focus on ensuring availability and access to lifesaving drugs during a public health crisis,
- foreign reference pricing in Medicare and private insurance,
- modifications to Medicare Parts B and D,

- provisions that would allow the Department of Health and Human Services (HHS) to negotiate prices for biologics and drugs in Medicare,
- a reduction in biologic data exclusivity,

- proposals related to Medicaid prescription drug coverage and manufacturer drug rebates,
- proposals that would require biopharmaceutical manufacturers to disclose proprietary drug pricing information, and
- state-level proposals related to prescription drug prices and reducing the cost of pharmaceuticals purchased by government health care programs.

On July 24, 2020 and September 13, 2020, former U.S. President Donald Trump signed Executive Orders related to the 340B Prescription Drug Program, rebate reform in Medicare Part D, drug importation including insulin, and foreign reference pricing in Medicare Part B and Part D. Although their current status is unclear given the change in presidential administration, these Executive Orders, if implemented, could have a material adverse impact on our future consolidated results of operations, liquidity, and financial position. On September 1, 2020, Lilly announced it would distribute all 340B ceiling priced products directly to covered entities and their child sites only. Lilly provides 340B discounts to a contract pharmacy only if it is a wholly owned subsidiary of a covered entity, if a covered entity does not have an in-house pharmacy or, in the case of insulin, if the subject covered entity and its contract pharmacies agree to pass along the discount to patients without any markup for dispensing fees and without billing insurance or collecting duplicate discounts. Lilly has been transparent with regulators on its distribution activity and continues to comply with all 340B program requirements. Certain covered entities and their trade associations have threatened litigation, questioning whether Lilly's program, and similar actions by other manufacturers, violate 340B program requirements. On October 9, 2020, three covered entities sued HHS and the Health Resources and Services Administration (HRSA) in the U.S. District Court for the District of Columbia seeking to compel the agencies to take enforcement action against Lilly and three other companies, among other requested relief. On October 21, 2020, a trade association representing certain covered entities sued HHS in the same court seeking to compel the agency to promulgate administrative dispute resolution regulations. On December 11, 2020, a number of associations and entities filed suit against HHS in the U.S. District Court for the Northern District of California requesting immediate enforcement of the contract pharmacy guidance. On December 31, 2020, the General Counsel of HHS issued an advisory opinion alleging that honoring contract pharmacy agreements is mandatory. In January 2021, Lilly filed suit against HHS, the Secretary of HHS, the HRSA, and the Administrator of the HRSA in the U.S. District Court for the Southern District of Indiana seeking a declaratory judgment that HHS's attempt to require manufacturers to permit contract pharmacy distribution is unlawful and a preliminary injunction enjoining implementation of the alternative dispute resolution process created by defendants and, with it, their application of the advisory opinion, and other related relief. The cases are pending and the impact of these cases and any subsequent litigation is uncertain. See Note 16 to the consolidated financial statements for additional information.

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. Several states have also passed importation legislation, including Colorado, Florida, Maine, New Hampshire, New Mexico, and Vermont. As of late 2020 several of these states were actively working with the former presidential administration to implement an importation program from Canada. On November 22, 2020, Florida announced it submitted a proposed importation plan to the U.S. In 2020, HHS and the FDA also took several actions to advance state importation initiatives, including issuing requests for proposals for personal importation and reimportation of insulin and a final rule on the Importation of Prescription Drugs. Additionally, on November 27, 2020, the Canadian Minister of Health issued an interim order to ensure that participation in bulk importation frameworks, such as the one recently established by the U.S., does not cause or exacerbate a drug shortage in Canada. We continue to review these state proposals and legislation, as well as federal rules and guidance published by HHS and the FDA, the impact of which is uncertain at this time. Currently, it is unclear if the current presidential administration will adopt any of the importation initiatives put forth by the former presidential administration. We will continue to monitor and assess these developments.

In the private sector, consolidation and integration among healthcare providers significantly affects the competitive marketplace for pharmaceuticals. Health plans, pharmacy benefit managers, wholesalers, and other supply chain stakeholders have been consolidating into fewer, larger entities, thus enhancing their purchasing strength and importance. Private third-party insurers, as well as governments, typically maintain formularies that 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) to control costs by negotiating discounted prices in exchange for formulary inclusion. 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 efficacy, safety profile, or patient ease of use, but also by providing rebates. Value-based agreements, where pricing is based on achievement (or not) of specified outcomes, are another tool that 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. We expect these downward pricing pressures will continue to negatively affect our consolidated results of operations. In addition to formulary placement, changes in insurance designs continue to drive greater consumer cost-sharing through high deductible plans and higher co-insurance or co-pays. We continue to invest in patient affordability solutions (resulting in lower revenue) in an effort to assist patients in affording their medicines.

The main coverage expansion provisions of the Affordable Care Act (ACA) are currently in effect through both state-based exchanges and the expansion of Medicaid. A trend has been the prevalence of benefit designs containing high out-of-pocket costs for patients, particularly for pharmaceuticals. In addition to the coverage expansions, many employers in the commercial market 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 pharmaceutical products. The COVID-19 pandemic is also creating additional pressure on health systems worldwide. As a result, cost containment and other measures may intensify as governments manage and emerge from the pandemic.

Tax Matters

We are subject to income taxes and various other taxes in the U.S. and in many foreign jurisdictions; therefore, changes in both domestic and international tax laws or regulations could affect our effective tax rate, results of operations, and cash flows. Countries around the world, including the U.S., are actively considering and enacting tax law changes. The current presidential administration's tax proposal contains significant changes, including the rate at which income of U.S. companies would be taxed. Further, actions taken with respect to tax-related matters by associations such as the Organisation for Economic Co-operation and Development and the European Commission could influence tax policy in countries in which we operate. In addition, global tax authorities routinely examine our tax returns and are expected to

become more aggressive in their examinations of profit allocations among jurisdictions, which could affect our anticipated tax liabilities.

Acquisitions

We strategically invest in external research and technologies that we believe complement and strengthen our own efforts. These investments can take many forms, including acquisitions, strategic alliances, collaborations, investments, and licensing arrangements. 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 continuously evaluate business development transactions that have the potential to strengthen our business.

In 2019, we acquired all shares of Loxo for a purchase price of $6.92 billion, net of cash acquired. Under the terms of the agreement, we acquired a pipeline of investigational medicines, including selpercatinib, an oral RET inhibitor, and LOXO-305, an oral BTK inhibitor. In the second quarter of 2020, the FDA approved selpercatinib (Retevmo) under its Accelerated Approval regulations and continued approval may be contingent upon verification and description of clinical benefit in confirmatory trials.

In 2020, we acquired all shares of Dermira for a purchase price of $849.3 million, net of cash acquired. Under terms of the agreement, we acquired lebrikizumab, a novel, investigational, monoclonal antibody being evaluated for the treatment of moderate-to-severe atopic dermatitis. Lebrikizumab was granted Fast Track designation from the FDA. We also acquired Qbrexza® cloth, a medicated cloth for the topical treatment of primary axillary hyperhidrosis (uncontrolled excessive underarm sweating).

In January 2021, we acquired all shares of Prevail Therapeutics Inc. (Prevail) for a purchase price of approximately $880 million in cash plus one non-tradable contingent value right (CVR). The CVR entitles Prevail stockholders to up to an additional approximately $160 million payable, subject to certain terms and conditions, upon the first regulatory approval of a Prevail product in one of the following countries: U.S., Japan, United Kingdom, Germany, France, Italy, or Spain. Under the terms of the agreement, we acquired a biotechnology company developing potentially disease-modifying AAV9-based gene therapies for patients with neurodegenerative diseases.

See Note 3 to the consolidated financial statements for further discussion regarding our recent acquisitions.

Operating Results—2020

Revenue

The following table summarizes our revenue activity by region:

	Year Ended December 31,		
	2020	2019	Percent Change
U.S.	**$ 14,229.3**	$ 12,722.6	12
Outside U.S.	**10,310.5**	9,596.8	7
Revenue	**$ 24,539.8**	$ 22,319.5	10

Numbers may not add due to rounding.

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

	2020 vs. 2019		
	U.S.	Outside U.S.	Consolidated
Volume	17 %	13 %	15 %
Price	(5)%	(6)%	(5)%
Foreign exchange rates	— %	— %	— %
Percent change	12 %	7 %	10 %

Numbers may not add due to rounding.

In the U.S., the revenue increase in 2020 was driven by increased volume primarily for Trulicity®, bamlanivimab, and Taltz®. Excluding bamlanivimab revenue, U.S. revenue grew 5 percent. The increase in revenue due to volume was partially offset by a decrease in realized prices. The decrease in realized prices in the U.S. was primarily driven by increased rebates to gain and maintain broad commercial access across the portfolio and, to a lesser extent, unfavorable segment mix and changes to estimates for rebates and discounts, most notably impacting Humalog. The decrease in realized prices in the U.S. was partially offset by modest list price increases and lower utilization in the 340B segment.

Outside the U.S., the revenue increase in 2020 was driven by increased volume primarily for Tyvyt, Trulicity, Alimta, and Olumiant. The increase in revenue due to volume was partially offset by lower realized prices primarily for Tyvyt and Alimta. The increase in volume and decrease in realized prices for Tyvyt and Alimta was driven primarily by their inclusion in government reimbursement programs in China.

The following table summarizes our revenue activity in 2020 compared with 2019:

	Year Ended December 31,				
	2020			2019	
Product	U.S.	Outside U.S.	Total	Total	Percent Change
Trulicity	**$ 3,835.9**	**$ 1,232.2**	**$ 5,068.1**	$ 4,127.8	23
Humalog[1]	**1,485.6**	**1,140.3**	**2,625.9**	2,820.7	(7)
Alimta	**1,265.3**	**1,064.7**	**2,329.9**	2,115.8	10
Taltz	**1,288.5**	**500.0**	**1,788.5**	1,366.4	31
Humulin®	**866.4**	**393.2**	**1,259.6**	1,290.1	(2)
Jardiance[2]	**620.8**	**533.0**	**1,153.8**	944.2	22
Basaglar®	**842.3**	**282.1**	**1,124.4**	1,112.6	1
Forteo	**510.3**	**536.0**	**1,046.3**	1,404.7	(26)
Cyramza®	**381.9**	**650.8**	**1,032.6**	925.1	12
Verzenio	**618.2**	**294.4**	**912.7**	579.7	57
Bamlanivimab[3]	**850.0**	**21.2**	**871.2**	—	NM
Cymbalta	**42.1**	**725.6**	**767.7**	725.4	6
Olumiant	**63.8**	**575.0**	**638.9**	426.9	50
Cialis®	**61.8**	**545.4**	**607.1**	890.5	(32)
Erbitux®	**480.1**	**56.3**	**536.4**	543.4	(1)
Zyprexa®	**46.1**	**360.5**	**406.5**	418.7	(3)
Emgality®	**325.9**	**37.0**	**362.9**	162.5	NM
Trajenta®[4]	**95.6**	**263.0**	**358.5**	590.6	(39)
Other products	**548.7**	**1,099.8**	**1,648.8**	1,874.4	(12)
Revenue	**$ 14,229.3**	**$ 10,310.5**	**$ 24,539.8**	$ 22,319.5	10

Numbers may not add due to rounding.

NM - Not meaningful

(1) Humalog revenue includes insulin lispro.

(2) Jardiance revenue includes Glyxambi®, Synjardy®, and Trijardy® XR.

(3) Bamlanivimab sales are pursuant to EUA.

(4) Trajenta revenue includes Jentadueto®.

Revenue of Trulicity, a treatment for type 2 diabetes and to reduce the risk of major adverse cardiovascular events in adult patients with type 2 diabetes and established cardiovascular disease or multiple cardiovascular risk factors, increased 22 percent in the U.S., driven by increased volume, partially offset by lower realized prices primarily due to higher contracted rebates. Revenue outside the U.S. increased 27 percent, primarily driven by increased volume.

Revenue of Humalog, an injectable human insulin analog for the treatment of diabetes, decreased 11 percent in the U.S., driven by lower realized prices, partially offset by higher demand. Revenue outside the U.S. decreased 1 percent, primarily driven by the unfavorable impact of foreign exchange rates. Included in the revenue of Humalog in the U.S. are our own insulin lispro authorized generics, which began launching in the second quarter of 2019 in order to lower out-of-pocket costs for patients. 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, due to the impact of competition and due to pricing pressure in the U.S. and some international markets, we expect some price decline and loss of market share to continue over time.

Revenue of Alimta, a treatment for various cancers, increased 4 percent in the U.S., primarily driven by higher realized prices. Revenue outside the U.S. increased 19 percent, primarily driven by increased volume in China and Germany, partially offset by lower realized prices. We will lose our patent protection

for Alimta in Japan and major European countries in June 2021. We expect the limited entry of generic competition in the U.S. starting February 2022 and subsequent unlimited entry starting April 2022. We expect that the entry of generic competition following the loss of exclusivity will cause a rapid and severe decline in revenue. See "Results of Operations - Executive Overview - Other Matters" for more information.

Revenue of Taltz, a treatment for moderate-to-severe plaque psoriasis, active psoriatic arthritis, ankylosing spondylitis, and active non-radiographic axial spondyloarthritis, increased 27 percent in the U.S., primarily driven by increased demand. Revenue outside the U.S. increased 43 percent, primarily driven by increased volume.

Revenue of Humulin, an injectable human insulin for the treatment of diabetes, decreased 2 percent in the U.S., driven by lower realized prices, partially offset by higher volume. Revenue outside the U.S. decreased 4 percent, driven by decreased volume and the unfavorable impact of foreign exchange rates, partially offset by higher realized prices.

Revenue of Jardiance, a treatment for type 2 diabetes and to reduce the risk of cardiovascular death in adult patients with type 2 diabetes and established cardiovascular disease, increased 10 percent in the U.S., driven by increased volume. Revenue outside the U.S. increased 41 percent, driven primarily by increased volume. See Note 4 to the consolidated financial statements for information regarding our collaboration with Boehringer Ingelheim involving Jardiance.

Revenue of Basaglar, a long-acting human insulin analog for the treatment of diabetes, decreased 4 percent in the U.S., driven by lower realized prices. Revenue outside the U.S. increased 19 percent, driven primarily by increased volume. See Note 4 to the consolidated financial statements for information regarding our collaboration with Boehringer Ingelheim involving Basaglar. A competitor launched a similar version of glargine in the U.S. in 2020. Due to the impact of competitive pressures, we expect some price decline and loss of market share over time.

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., primarily driven by decreased demand. Revenue outside the U.S. decreased 29 percent, driven by decreased volume and, to a lesser extent, lower realized prices. We expect further volume declines as a result of the anticipated entry of generic and biosimilar competition due to the loss of patent exclusivity in the U.S., Japan, and major European markets. See "Executive Overview - Other Matters - Patent Matters" for more information.

Revenue of Cyramza, a treatment for various cancers, increased 14 percent in the U.S., driven primarily by increased demand and, to a lesser extent, higher realized prices. Revenue outside the U.S. increased 10 percent, driven primarily by increased volume.

Revenue of Verzenio, a treatment for HR+, HER2- metastatic breast cancer, increased 36 percent in the U.S., driven by increased demand and, to a lesser extent, higher realized prices. Revenue outside the U.S. increased $169.5 million driven by higher volume.

Gross Margin, Costs, and Expenses

Gross margin as a percent of revenue was 77.7 percent in 2020, a decrease of 1.1 percentage points compared with 2019, primarily due to the impact of lower realized prices on revenue, the unfavorable effect of foreign exchange rates on international inventories sold, and higher intangibles amortization expense related to Retevmo, partially offset by charges in 2019 resulting from the withdrawal of Lartruvo® and greater manufacturing efficiencies. Gross margin percent for 2020 was also negatively impacted as a result of bamlanivimab sales in the fourth quarter of 2020.

Research and development expenses increased 9 percent to $6.09 billion in 2020, driven primarily by approximately $450 million of development expenses for COVID-19 therapies. Excluding these expenses related to COVID-19 therapies, research and development expenses were relatively flat.

Marketing, selling, and administrative expenses decreased 1 percent to $6.12 billion in 2020 primarily due to lower marketing activity.

We recognized acquired IPR&D charges of $660.4 million in 2020 resulting from the acquisitions of Disarm and a pre-clinical stage company as well as collaborations with Innovent, Sitryx, Fochon, AbCellera, Evox, and Junshi Biosciences. In 2019, we recognized acquired IPR&D charges of $239.6 million resulting from collaborations with AC Immune, Centrexion, ImmuNext, and Avidity.

We recognized asset impairment, restructuring, and other special charges of $131.2 million in 2020. The charges were primarily related to severance costs incurred as a result of actions taken worldwide to reduce our cost structure, as well as acquisition and integration costs incurred as part of the acquisition of Dermira. In 2019, we recognized $575.6 million of asset impairment, restructuring, and other special charges primarily associated with the accelerated vesting of Loxo employee equity awards as part of the acquisition of Loxo.

Other—net, (income) expense was income of $1.17 billion in 2020 compared to income of $291.6 million in 2019 primarily driven by higher net gains on investment securities.

Our effective tax rate was 14.3 percent in 2020, compared with an effective tax rate of 11.9 percent in 2019 driven by net discrete tax benefits in 2019.

Operating Results—2019

For a discussion of our results of operations pertaining to 2019 and 2018 see Item 7, "Management's Discussion and Analysis of Results of Operations and Financial Condition" in our Annual Report on Form 10-K for the year ended December 31, 2019.

FINANCIAL CONDITION AND LIQUIDITY

We believe our available cash and cash equivalents, together with our ability to generate operating cash flow and our access to short-term and long-term borrowings, are sufficient to fund our existing and planned capital requirements, which include:

- working capital requirements, including related to employee payroll, clinical trials, manufacturing materials, and taxes;
- capital expenditures;
- share repurchases and dividends;
- repayment of outstanding short-term and long-term borrowings;
- contributions to our defined benefit pension and retiree health benefit plans;
- milestone and royalty payments; and
- potential business development activities, including acquisitions, strategic alliances, collaborations, investments, and licensing arrangements.

Our management continuously evaluates our liquidity and capital resources, including our access to external capital, to ensure we can adequately and efficiently finance our capital requirements. As of December 31, 2020, our material cash requirements primarily related to purchases of goods and services to produce our products and conduct our operations, capital equipment expenditures, dividends, repayment of outstanding borrowings, the remaining obligations for the one-time repatriation transition tax (also known as the 'Toll Tax') from the Tax Cuts and Jobs Act (2017 Tax Act), leases, unfunded commitments to invest in venture capital funds, and retirement benefits (see Notes 11, 14, 10, 7, and 15 to the consolidated financial statements). We anticipate our cash requirements related to ordinary course purchases of goods and services and capital equipment expenditures will be consistent with our past levels relative to revenues.

Cash and cash equivalents increased to $3.66 billion as of December 31, 2020, compared with $2.34 billion at December 31, 2019. Net cash provided by operating activities was $6.50 billion in 2020, compared with $4.84 billion in 2019. Net cash provided by operating activities in 2019 included approximately $360 million of cash paid to settle the accelerated vesting of Loxo employee equity awards (see Note 5 to the consolidated financial statements). 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, 2020 and 2019.

In addition to our cash and cash equivalents, we held total investments of $2.99 billion and $2.06 billion as of December 31, 2020 and 2019, respectively. See Note 7 to the consolidated financial statements for additional details.

In February 2020, we completed our acquisition of Dermira for $18.75 per share, or approximately $1.1 billion, which was funded through cash on hand and the issuance of commercial paper. In February 2019, we completed our acquisition of Loxo for $235 per share or approximately $6.9 billion, which was funded through a mixture of cash and debt. See Note 3 to the consolidated financial statements for additional information.

As of December 31, 2020, total debt was $16.60 billion, an increase of $1.28 billion compared with $15.32 billion at December 31, 2019. The increase primarily related to the net proceeds from the issuance of $1.00 billion of 2.25 percent fixed-rate notes in May 2020, as well as the net proceeds from the issuance of an additional $250.0 million of 2.25 percent fixed-rate notes and the issuance of $850.0 million of 2.50 percent fixed-rate notes in August 2020. We used the net proceeds from the sale of these notes for general corporate purposes, which included the repayment of outstanding commercial paper used to fund a portion of the purchase price for our acquisition of Dermira. See Note 11 to the consolidated financial statements for additional information.

As of December 31, 2020, we had a total of $5.24 billion of unused committed bank credit facilities, $5.00 billion of which is available to support our commercial paper program. See Note 11 to the consolidated

financial statements for additional details. We believe that amounts accessible through existing commercial paper markets should be adequate to fund any short-term borrowing needs.

For the 135th consecutive year, we distributed dividends to our shareholders. Dividends of $2.96 per share and $2.58 per share were paid in 2020 and 2019, respectively. In the fourth quarter of 2020, effective for the dividend to be paid in the first quarter of 2021, the quarterly dividend was increased to $0.85 per share, resulting in an indicated annual rate for 2021 of $3.40 per share.

Capital expenditures of $1.39 billion during 2020, compared to $1.03 billion in 2019.

In 2020, we repurchased $500.0 million of shares under our $8.00 billion share repurchase program authorized in June 2018. As of December 31, 2020, we had $1.00 billion remaining under this program. See Note 13 to the consolidated financial statements for additional details.

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 January 2021, we completed our acquisition of Prevail for $22.50 per share, or approximately $880 million in cash, plus one non-tradable CVR that entitles Prevail stockholders to up to an additional $4.00 per share in cash (or an aggregate of approximately $160 million) payable, subject to certain terms and conditions. This acquisition was funded primarily through cash on hand and the issuance of commercial paper. 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.

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, currency values, and fair values of equity securities. 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 this risk management program 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, 2020 and 2019, 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, 2020 and 2019, 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, 2020 and 2019, 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.

Our fair value risk exposure relates primarily to our public equity investments and to equity investments that do not have readily determinable fair values. As of December 31, 2020 and 2019, our carrying values of these investments were $2.04 billion and $1.12 billion, respectively. A hypothetical 20 percent change in

fair value of the equity instruments would have impacted other-net, (income) expense by $407.6 million and $224.7 million as of December 31, 2020 and 2019, respectively.

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 product in the event that regulatory approval for marketing is obtained.

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 expense or aggregate milestone payments made could be material to our 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.

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. For product sales to customers, provisions for returns, rebates and discounts are established in the same period the related product sales are recognized. To determine the appropriate transaction price for our product sales at the time we recognize a sale to a direct customer, we 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 largest of our sales rebate and discount amounts are rebates associated with sales covered by managed care, Medicare, Medicaid, and chargeback contracts in the U.S. In determining the appropriate accrual amount, we consider our historical rebate payments for these programs by product as a percentage of our historical sales as well as any significant changes in sales trends (e.g., patent expiries and product launches), an evaluation of the current contracts for these programs, the percentage of our products that are sold via these programs, and our product pricing.

Refer to Note 2 to the consolidated financial statements for further information on revenue recognition and sales return, rebate, and discount accruals.

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.

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, 2020, a 5 percent change in our global sales return, rebate, and discount liability would have led to an approximate $313 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, 2020 and 2019.

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

(Dollars in millions)	2020	2019
Sales return, rebate, and discount liabilities, beginning of year	**$ 4,635.5**	$ 4,670.9
Reduction of net sales[(1)]	**18,668.4**	15,490.2
Cash payments	**(17,903.9)**	(15,525.6)
Sales return, rebate, and discount liabilities, end of year	**$ 5,400.0**	$ 4,635.5

[(1)] Adjustments of the estimates for these returns, rebates, and discounts to actual results were less than 2 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 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.

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 estimates and assumptions that are deemed reasonable by management. Significant estimates and assumptions include, but are not limited to, probability of technical success, revenue growth and discount rate. 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.

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, or more frequently if impairment indicators are present, by first assessing qualitative factors to determine whether it is more likely than not that the fair value of the intangible asset is less than its carrying amount. If we conclude it is more likely than not that the fair value is less than the carrying amount, a quantitative test that compares the fair value of the intangible asset to its carrying value 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 15 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 65 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.

Annually, we determine the fair value of the plan assets in our defined benefit pension and retiree health benefit plans. Approximately 35 percent of our plan assets are in hedge funds and private equity-like investment funds (collectively, alternative assets). We value these alternative investments using significant unobservable inputs or using the net asset value reported by the counterparty, adjusted as necessary. Inputs include underlying net asset values, discounted cash flows valuations, comparable market valuations, and adjustments for currency, credit, liquidity and other risks.

Financial Statement Impact

If the 2020 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 $21.6 million. If the 2020 expected return on plan assets for U.S. plans were to change by a quarter percentage point, income before income taxes would change by $28.8 million. If our assumption regarding the 2020 expected age of future retirees for U.S. plans were adjusted by one year, our income before income taxes would be affected by $52.0 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, 2020.

Adjustments to the fair value of plan assets are not recognized in pension and retiree health benefit expense in the year that the adjustments occur. Such changes are deferred, along with other actuarial gains and losses, and are amortized into expense over the expected remaining service life of employees.

Income Taxes

Background and Uncertainties

We prepare and file tax returns based upon our interpretation of tax laws and regulations, and we record estimates based upon these interpretations. Our tax returns are routinely subject to examination by various taxing authorities, which could result in future tax, interest, and penalty assessments. 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 changes to existing tax law, the issuance of regulations 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 future taxable income 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 to generate future taxable income in these jurisdictions could lead to the reversal of all or a portion of these valuation allowances and a reduction of income tax expense.

Financial Statement Impact

As of December 31, 2020, a 5 percent change in the amount of uncertain tax positions and the valuation allowance would result in a change in net income of $83.4 million and $40.8 million, respectively.

LEGAL AND REGULATORY MATTERS

Information relating to certain legal proceedings can be found in Note 16 to the consolidated financial statements and is incorporated here by reference.

FINANCIAL EXPECTATIONS FOR 2021

For the full year of 2021, we expect EPS to be in the range of $7.10 to $7.75, which excludes estimated acquisition and integration costs related to the acquisition of Prevail. We anticipate total revenue between $26.5 billion and $28.0 billion, including an estimated $1 billion to $2 billion of revenue from COVID-19 therapies. Revenue growth is expected to be driven by volume from Trulicity, Taltz, Verzenio, Jardiance, Olumiant, Cyramza, Emgality, Tyvyt, and Retevmo, as well as by COVID-19 therapies. Revenue growth is

expected to be partially offset by lower revenue for products that have lost patent exclusivity. We expect mid-single digit net price declines globally in 2021. In the U.S., we expect low-to-mid-single digit net price declines, driven primarily by increased rebates to maintain broad commercial access and segment mix, partially offset by lower utilization in the 340B segment. Outside the U.S., we expect net price declines in China, Japan, and Europe.

We anticipate that gross margin as a percent of revenue will be approximately 77 percent in 2021. Research and development expenses are expected to be in the range of $6.5 billion to $6.7 billion, including approximately $300 million to $400 million of continued investment in COVID-19 therapies. Marketing, selling, and administrative expenses are expected to be in the range of $6.2 billion to $6.4 billion. Other—net, (income) expense is expected to be expense in the range of $200 million to $300 million. The 2021 effective tax rate is expected to be approximately 15 percent.

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 and Liquidity.” That information is incorporated by reference herein.

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	2020	2019	2018
Revenue	**$ 24,539.8**	$ 22,319.5	$ 21,493.3
Costs, expenses, and other:			
Cost of sales	**5,483.3**	4,721.2	4,681.7
Research and development	**6,085.7**	5,595.0	5,051.2
Marketing, selling, and administrative	**6,121.2**	6,213.8	5,975.1
Acquired in-process research and development (Note 3)	**660.4**	239.6	1,983.9
Asset impairment, restructuring, and other special charges (Note 5)	**131.2**	575.6	266.9
Other—net, (income) expense (Note 18)	**(1,171.9)**	(291.6)	(145.6)
	17,309.9	17,053.6	17,813.2
Income before income taxes	**7,229.9**	5,265.9	3,680.1
Income taxes (Note 14)	**1,036.2**	628.0	529.5
Net income from continuing operations	**6,193.7**	4,637.9	3,150.6
Net income from discontinued operations (Note 19)	**—**	3,680.5	81.4
Net income	**$ 6,193.7**	$ 8,318.4	$ 3,232.0
Earnings per share:			
Earnings from continuing operations - basic	**$ 6.82**	$ 4.98	$ 3.07
Earnings from discontinued operations - basic	**—**	3.95	0.07
Earnings per share - basic	**$ 6.82**	$ 8.93	$ 3.14
Earnings from continuing operations - diluted	**$ 6.79**	$ 4.96	$ 3.05
Earnings from discontinued operations - diluted	**—**	3.93	0.08
Earnings per share - diluted	**$ 6.79**	$ 8.89	$ 3.13
Shares used in calculation of earnings per share:			
Basic	**907,634**	931,059	1,027,721
Diluted	**912,505**	935,684	1,033,667

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	2020	2019	2018
Net income	**$ 6,193.7**	$ 8,318.4	$ 3,232.0
Other comprehensive income (loss) from continuing operations:			
Change in foreign currency translation gains (losses)	**122.1**	(89.9)	(429.6)
Change in net unrealized gains (losses) on securities	**14.2**	34.4	(8.8)
Change in defined benefit pension and retiree health benefit plans (Note 15)	**(157.1)**	(970.0)	544.0
Change in effective portion of cash flow hedges	**(152.9)**	34.3	(6.0)
Other comprehensive income (loss) from continuing operations before income taxes	**(173.7)**	(991.2)	99.6
Benefit (provision) for income taxes related to other comprehensive income (loss) from continuing operations	**200.9**	151.0	(30.3)
Other comprehensive income (loss) from continuing operations, net of tax (Note 17)	**27.2**	(840.2)	69.3
Other comprehensive income from discontinued operations, net of tax (Note 17)	**—**	56.8	14.3
Other comprehensive income (loss), net of tax (Note 17)	**27.2**	(783.4)	83.6
Comprehensive income	**$ 6,220.9**	$ 7,535.0	$ 3,315.6

See notes to consolidated financial statements.

Consolidated Balance Sheets

ELI LILLY AND COMPANY AND SUBSIDIARIES

(Dollars in millions, shares in thousands) December 31	2020	2019
Assets		
Current Assets		
Cash and cash equivalents (Note 7)	**$ 3,657.1**	$ 2,337.5
Short-term investments (Note 7)	**24.2**	101.0
Accounts receivable, net of allowances of **$25.9 (2020)** and $22.4 (2019)	**5,875.3**	4,547.3
Other receivables	**1,053.7**	994.2
Inventories (Note 6)	**3,980.3**	3,190.7
Prepaid expenses and other	**2,871.5**	2,538.9
Total current assets	**17,462.1**	13,709.6
Investments (Note 7)	**2,966.8**	1,962.4
Goodwill (Note 8)	**3,766.5**	3,679.4
Other intangibles, net (Note 8)	**7,450.0**	6,618.0
Deferred tax assets (Note 14)	**2,830.4**	2,572.6
Property and equipment, net (Note 9)	**8,681.9**	7,872.9
Other noncurrent assets	**3,475.4**	2,871.2
Total assets	**$ 46,633.1**	$ 39,286.1
Liabilities and Equity		
Current Liabilities		
Short-term borrowings and current maturities of long-term debt (Note 11)	**$ 8.7**	$ 1,499.3
Accounts payable	**1,606.7**	1,405.3
Employee compensation	**997.2**	915.5
Sales rebates and discounts	**5,853.0**	4,933.6
Dividends payable	**770.6**	671.5
Income taxes payable (Note 14)	**495.1**	160.6
Other current liabilities	**2,750.3**	2,189.4
Total current liabilities	**12,481.6**	11,775.2
Other Liabilities		
Long-term debt (Note 11)	**16,586.6**	13,817.9
Accrued retirement benefits (Note 15)	**4,094.5**	3,698.2
Long-term income taxes payable (Note 14)	**3,837.8**	3,607.2
Other noncurrent liabilities	**1,707.5**	1,501.0
Deferred tax liabilities (Note 14)	**2,099.9**	2,187.5
Total other liabilities	**28,326.3**	24,811.8
Commitments and Contingencies (Note 16)		
Eli Lilly and Company Shareholders' Equity (Notes 12 and 13)		
Common stock—no par value Authorized shares: 3,200,000 Issued shares: **957,077 (2020)** and 958,056 (2019)	**598.2**	598.8
Additional paid-in capital	**6,778.5**	6,685.3
Retained earnings	**7,830.2**	4,920.4
Employee benefit trust	**(3,013.2)**	(3,013.2)
Accumulated other comprehensive loss (Note 17)	**(6,496.4)**	(6,523.6)
Cost of common stock in treasury	**(55.7)**	(60.8)
Total Eli Lilly and Company shareholders' equity	**5,641.6**	2,606.9
Noncontrolling interests	**183.6**	92.2
Total equity	**5,825.2**	2,699.1
Total liabilities and equity	**$ 46,633.1**	$ 39,286.1

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								
	Common Stock						Common Stock in Treasury		
	Shares	Amount	Additional Paid-in Capital	Retained Earnings	Employee Benefit Trust	Accumulated Other Comprehensive Loss	Shares	Amount	Noncontrolling Interest
Balance at January 1, 2018	1,100,672	$ 687.9	$ 5,817.8	$ 13,894.1	$ (3,013.2)	$ (5,718.6)	664	$ (75.8)	$ 75.7
Net income				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 1)				763.8		(105.2)			
Sale of Elanco Stock (Note 19)			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
Net income				8,318.4					37.7
Other comprehensive income (loss), net of tax						(794.4)			11.0
Cash dividends declared per share: $2.68				(2,430.5)					
Retirement of treasury shares	(102,640)	(64.1)		(12,363.4)			(102,640)	12,427.5	
Purchase of treasury shares							37,639	(4,400.0)	
Issuance of stock under employee stock plans, net	3,057	1.9	(210.7)				(74)	8.6	
Stock-based compensation			312.4						
Acquisition of common stock in exchange offer							65,001	(8,027.5)	
Deconsolidation of Elanco									(1,028.9)
Other									(8.0)
Balance at December 31, 2019	958,056	598.8	6,685.3	4,920.4	(3,013.2)	(6,523.6)	530	(60.8)	92.2
Net income				**6,193.7**					**126.6**
Other comprehensive income, net of tax						**27.2**			
Cash dividends declared per share: $3.07				**(2,786.2)**					
Retirement of treasury shares	**(3,627)**	**(2.3)**		**(497.7)**			**(3,627)**	**500.0**	
Purchase of treasury shares							**3,627**	**(500.0)**	
Issuance of stock under employee stock plans, net	**2,648**	**1.7**	**(212.7)**				**(43)**	**5.1**	
Stock-based compensation			**308.1**						
Other			**(2.2)**						**(35.2)**
Balance at December 31, 2020	**957,077**	**$ 598.2**	**$ 6,778.5**	**$ 7,830.2**	**$ (3,013.2)**	**$ (6,496.4)**	**487**	**$ (55.7)**	**$ 183.6**

See notes to consolidated financial statements.

Consolidated Statements of Cash Flows

ELI LILLY AND COMPANY AND SUBSIDIARIES (Dollars in millions)	Year Ended December 31 2020	2019	2018
Cash Flows from Operating Activities			
Net income	**$ 6,193.7**	$ 8,318.4	$ 3,232.0
Adjustments to Reconcile Net Income to Cash Flows from Operating Activities:			
Gain related to disposition of Elanco (Note 19)	**—**	(3,680.5)	—
Gain on sale of antibiotic business in China (Note 3)	**—**	(309.8)	—
Depreciation and amortization	**1,323.9**	1,232.6	1,609.0
Change in deferred income taxes	**(134.5)**	62.4	326.8
Stock-based compensation expense	**308.1**	312.4	279.5
Net investment gains	**(1,438.5)**	(403.1)	(27.0)
Acquired in-process research and development (Note 3)	**660.4**	239.6	1,983.9
Other non-cash operating activities, net	**333.9**	751.8	499.0
Other changes in operating assets and liabilities, net of acquisitions and divestitures:			
Receivables—(increase) decrease	**(1,350.2)**	(127.2)	(996.7)
Inventories—(increase) decrease	**(533.4)**	(258.7)	7.8
Other assets—(increase) decrease	**(457.1)**	(602.3)	(980.0)
Income taxes payable—increase (decrease)	**322.0**	(221.3)	(125.3)
Accounts payable and other liabilities—increase (decrease)	**1,271.3**	(477.7)	(284.5)
Net Cash Provided by Operating Activities	**6,499.6**	4,836.6	5,524.5
Cash Flows from Investing Activities			
Purchases of property and equipment	**(1,387.9)**	(1,033.9)	(1,210.6)
Proceeds from sales and maturities of short-term investments	**129.7**	136.6	2,552.5
Purchases of short-term investments	**(11.4)**	(42.7)	(112.2)
Proceeds from sales of noncurrent investments	**757.1**	609.8	3,509.5
Purchases of noncurrent investments	**(358.7)**	(247.5)	(837.9)
Purchases of in-process research and development	**(641.2)**	(319.6)	(1,807.6)
Cash paid for acquisitions, net of cash acquired (Note 3)	**(849.3)**	(6,917.7)	—
Cash distributed to Elanco upon disposition	**—**	(374.0)	—
Cash received for sale of antibiotic business in China	**—**	354.8	—
Other investing activities, net	**102.8**	(248.7)	(187.7)
Net Cash Provided by (Used for) Investing Activities	**(2,258.9)**	(8,082.9)	1,906.0
Cash Flows from Financing Activities			
Dividends paid	**(2,687.1)**	(2,409.8)	(2,311.8)
Net change in short-term borrowings	**(1,494.2)**	995.4	(2,197.9)
Proceeds from issuance of long-term debt	**2,062.3**	6,556.4	2,477.7
Repayments of long-term debt	**(276.5)**	(2,866.4)	(1,009.1)
Purchases of common stock	**(500.0)**	(4,400.0)	(4,150.7)
Net proceeds from Elanco initial public offering (Note 19)	**—**	—	1,659.7
Other financing activities, net	**(241.6)**	(200.1)	(372.8)
Net Cash Used for Financing Activities	**(3,137.1)**	(2,324.5)	(5,904.9)
Effect of exchange rate changes on cash and cash equivalents	**216.0**	(89.9)	(63.6)
Net increase (decrease) in cash and cash equivalents	**1,319.6**	(5,660.7)	1,462.0
Cash and cash equivalents at beginning of year (includes $677.5 (2019) and $324.4 (2018) of discontinued operations)	**2,337.5**	7,998.2	6,536.2
Cash and Cash Equivalents at End of Year (includes $677.5 (2018) of discontinued operations)	**$ 3,657.1**	$ 2,337.5	$ 7,998.2

See notes to consolidated financial statements.

Notes to Consolidated Financial Statements

ELI LILLY AND COMPANY AND SUBSIDIARIES
(Tables present dollars in millions, except per-share data)

Note 1: Summary of Significant Accounting Policies and Implementation of New Financial Accounting Standards

Basis of Presentation

The accompanying consolidated financial statements include Eli Lilly and Company and all subsidiaries and have been prepared in accordance with accounting principles generally accepted in the United States (GAAP). We consider majority voting interests, as well as effective economic or other control over an entity when deciding whether or not to consolidate an entity. We generally do not have control by means other than voting interests. 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 this Annual Report on Form 10-K.

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.

On March 11, 2019, we completed the disposition of our remaining 80.2 percent ownership of Elanco Animal Health Incorporated (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.

Research and Development Expenses and Acquired In-Process Research and Development (IPR&D)

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 IPR&D expense includes the initial costs of externally developed IPR&D projects, acquired directly in a transaction other than a business combination, that do not have an alternative future use.

Earnings Per Share (EPS)

We calculate basic 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 United States (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).

Advertising Expenses

Costs associated with advertising are expensed as incurred and are included in marketing, selling, and administrative expenses. Advertising expenses, comprised primarily of television, radio, print media, and Internet advertising, totaled approximately $1.1 billion, $1.1 billion, and $900 million in 2020, 2019, and 2018, respectively, which was less than 5 percent of revenue each year.

Other Significant Accounting Policies

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

Implementation of New Financial Accounting Standards

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

Effective January 1, 2018, we adopted Accounting Standards Update 2014-09, *Revenue from Contracts with Customers,* and other related updates. This standard 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. We applied this standard 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. We applied this standard through a cumulative effect adjustment to retained earnings as of the beginning of the year of adoption. Upon adoption, the cumulative effect of applying this standard resulted in an increase of approximately $5 million to retained earnings as of January 1, 2018. Adoption of this standard did not result in a material change in revenue or net income in the year of adoption.

Effective January 1, 2018, we adopted Accounting Standards Update 2016-01 (ASU 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). We applied the new standard through a cumulative effect adjustment to retained earnings as of the beginning of the 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 as of January 1, 2018. Adoption of this standard did not result in a material change in net income in the year of adoption.

Effective January 1, 2018, we adopted 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. We adopted this standard using a modified retrospective approach. Upon adoption, the cumulative effect of applying

this 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 as of January 1, 2018. Adoption of this standard did not result in a material change in net income in the year of adoption.

Change in Accounting Principle for Retirement Benefit Plan Assets

Effective during the third quarter of 2020, we adopted a voluntary change in our method of applying an accounting principle for certain of our retirement benefit plans. Refer to Note 15 for additional information.

Note 2: Revenue

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

	2020	2019	2018
Net product revenue	**$ 22,694.8**	$ 20,377.3	$ 19,866.4
Collaboration and other revenue[(1)]	**1,845.0**	1,942.2	1,626.9
Revenue	**$ 24,539.8**	$ 22,319.5	$ 21,493.3

[(1)] Collaboration and other revenue associated with prior period transfers of intellectual property was $135.6 million, $301.5 million, and $303.2 million during the years ended December 31, 2020, 2019, and 2018, respectively.

We recognize revenue primarily from two different types of contracts, product sales to customers (net product revenue) and collaborations and other arrangements. Revenue recognized from collaborations and other arrangements will include our share of profits from the collaboration, as well as royalties, 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, 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.

Most of our products are sold to wholesalers that serve pharmacies, physicians and other health care professionals, and hospitals. For the years ended December 31, 2020, 2019, and 2018, our three largest wholesalers each accounted for between 15 percent and 20 percent of consolidated revenue. Further, they each accounted for between 19 percent and 27 percent of accounts receivable as of December 31, 2020 and 2019.

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

Sales Rebates and Discounts - Background and Uncertainties

- 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, chargeback, and patient assistance programs in the U.S. In determining the appropriate accrual amount, we consider our historical rebate payments for these programs by product as a percentage of our historical sales as well as any significant changes in sales trends (e.g., patent expiries and product launches), an evaluation of the current contracts for these programs, the percentage of our products that are sold via these programs, and our product pricing. Although we accrue a liability for rebates related to these programs at the time we record the sale, the rebate related to that sale is typically paid up to six months later. Because of this time lag, in any particular period our rebate adjustments may incorporate revisions of accruals for several periods.
- Most of our rebates outside the U.S. are contractual or legislatively mandated and are estimated and recognized in the same period as the related sales. In some large European countries, government rebates are based on the anticipated budget for pharmaceutical payments in the country. An estimate of these rebates, updated as governmental authorities revise budgeted deficits, is recognized in the same period as the related sale.

Sales Returns - Background and Uncertainties

- When product sales occur, to determine the appropriate transaction price for our sales, we estimate a reserve for future product returns related to those sales using an expected value approach. This estimate is based on several factors, including: historical return rates, expiration date by product (on average, approximately 24 months after the initial sale of a product to our customer), and estimated levels of inventory in the wholesale and retail channels, as well as any other specifically-identified anticipated returns due to known factors such as the loss of patent exclusivity, product recalls and discontinuances, or a changing competitive environment. We maintain a returns policy that allows most 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. In the U.S. we allow bamlanivimab to be returned if the Emergency Use Authorization (EUA) is revoked. If the EUA were to be revoked, we could experience an elevated level of product returns of bamlanivimab, dependent on the amount of product remaining in the distribution channel. 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 at the 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 U.S. product returns have been less than 2 percent of our U.S. 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 increase revenue recognized as a result of changes in estimates for the judgments described above for our most significant U.S. sales returns, rebates, and discounts liability balances for products shipped in previous periods were approximately 1 percent, 2 percent and 1 percent of U.S revenue during 2020, 2019, and 2018, respectively.

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

The following table summarizes contract liability balances:

	2020	2019
Contract liabilities	**$ 276.8**	$ 264.6

The contract liabilities balances disclosed above as of December 31, 2020 and 2019 were primarily related to the remaining license period of symbolic intellectual property and obligations to perform research and development activities or supply product for a defined period of time.

During the years ended December 31, 2020, 2019, and 2018, revenue recognized from contract liabilities as of the beginning of the respective year 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.

Disaggregation of Revenue

The following table summarizes revenue by product:

	U.S.			Outside U.S.		
	2020	**2019**	**2018**	**2020**	**2019**	**2018**
Revenue—to unaffiliated customers:						
Diabetes:						
Trulicity®	**$ 3,835.9**	$ 3,155.2	$ 2,515.8	**$ 1,232.2**	$ 972.7	$ 683.3
Humalog® [1]	**1,485.6**	1,669.7	1,787.8	**1,140.3**	1,151.0	1,208.7
Humulin®	**866.4**	879.7	910.2	**393.2**	410.4	421.2
Jardiance [2]	**620.8**	565.9	400.2	**533.0**	378.3	258.1
Basaglar®	**842.3**	876.2	622.8	**282.1**	236.3	178.5
Trajenta [3]	**95.6**	224.8	224.2	**263.0**	365.8	350.5
Other Diabetes	**162.5**	158.0	146.0	**81.5**	88.1	112.2
Total Diabetes	**7,909.1**	7,529.5	6,607.0	**3,925.3**	3,602.6	3,212.5
Oncology:						
Alimta®	**1,265.3**	1,219.5	1,131.0	**1,064.7**	896.4	1,001.9
Cyramza®	**381.9**	335.3	291.5	**650.8**	589.9	529.9
Verzenio®	**618.2**	454.8	248.5	**294.4**	124.9	6.6
Erbitux®	**480.1**	487.9	531.6	**56.3**	55.4	103.8
Other Oncology	**46.6**	111.0	200.6	**461.0**	339.3	215.1
Total Oncology	**2,792.1**	2,608.5	2,403.2	**2,527.2**	2,005.9	1,857.3
Immunology:						
Taltz®	**1,288.5**	1,016.8	738.7	**500.0**	349.6	198.7
Olumiant®	**63.8**	42.2	6.7	**575.0**	384.7	195.9
Other Immunology	**20.0**	—	—	**14.6**	—	—
Total Immunology	**1,372.3**	1,059.0	745.4	**1,089.6**	734.3	394.6
Neuroscience:						
Cymbalta®	**42.1**	49.6	54.3	**725.6**	675.8	653.7
Zyprexa®	**46.1**	41.0	36.2	**360.5**	377.6	435.1
Emgality®	**325.9**	154.9	4.9	**37.0**	7.7	—
Other Neuroscience	**73.2**	111.0	182.0	**220.9**	305.3	454.5
Total Neuroscience	**487.3**	356.5	277.4	**1,344.0**	1,366.4	1,543.3
Other:						
Forteo®	**510.3**	645.5	757.9	**536.0**	759.1	817.7
Bamlanivimab [4]	**850.0**	—	—	**21.2**	—	—
Cialis®	**61.8**	231.7	1,129.2	**545.4**	658.8	722.7
Other	**246.4**	291.9	471.8	**321.8**	469.7	553.3
Total Other	**1,668.4**	1,169.1	2,358.8	**1,424.4**	1,887.7	2,093.7
Revenue	**$ 14,229.3**	$ 12,722.6	$ 12,391.9	**$ 10,310.5**	$ 9,596.8	$ 9,101.4

Numbers may not add due to rounding.

[1] Humalog revenue includes insulin lispro.

[2] Jardiance revenue includes Glyxambi® and Synjardy®, and Trijardy® XR.

[3] Trajenta revenue includes Jentadueto®.

[4] Bamlanivimab sales are pursuant to EUA.

The following table summarizes revenue by geographical area:

	2020	2019	2018
Revenue—to unaffiliated customers[1]:			
U.S.	**$ 14,229.3**	$ 12,722.6	$ 12,391.9
Europe	**4,187.7**	3,765.0	3,663.1
Japan	**2,583.1**	2,547.6	2,407.4
China	**1,116.9**	939.4	750.8
Other foreign countries	**2,422.7**	2,344.9	2,280.1
Revenue	**$ 24,539.8**	$ 22,319.5	$ 21,493.3

Numbers may not add due to rounding.

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

Note 3: Acquisitions and Divestiture

In February 2020 and 2019, we completed the acquisitions of Dermira, Inc. (Dermira) and Loxo Oncology, Inc. (Loxo), respectively. These transactions, as further discussed in this note below in Acquisitions of Businesses, were accounted for as business combinations under the acquisition method of accounting. Under this method, the assets acquired and liabilities assumed were recorded at their respective fair values as of the acquisition date in our consolidated financial statements. The determination of estimated fair value required management to make significant estimates and assumptions. The excess of the purchase price over the fair value of the acquired net assets, where applicable, has been recorded as goodwill. The results of operations of these acquisitions have been included in our consolidated financial statements from the date of acquisition.

We also acquired assets in development in 2020, 2019, and 2018, which are further discussed in this note below in Asset Acquisitions. Upon each acquisition, the cost allocated to acquired IPR&D was immediately expensed because the compound acquired had no alternative future use. For the years ended December 31, 2020, 2019, and 2018, we recorded acquired IPR&D charges of $660.4 million, $239.6 million, and $1.98 billion, respectively.

Acquisitions of Businesses

Dermira Acquisition

Overview of Transaction

In February 2020, we acquired all shares of Dermira for a purchase price of approximately $849.3 million, net of cash acquired. Under terms of the agreement, we acquired lebrikizumab, a novel, investigational, monoclonal antibody being evaluated for the treatment of moderate-to-severe atopic dermatitis. Lebrikizumab was granted Fast Track designation from the U.S. Food and Drug Administration (FDA). We also acquired Qbrexza® (glycopyrronium) cloth, a medicated cloth approved by the FDA for the topical treatment of primary axillary hyperhidrosis (uncontrolled excessive underarm sweating).

Assets Acquired and Liabilities Assumed

The fair values recognized related to the assets acquired and liabilities assumed in this acquisition included goodwill of $86.8 million, other intangibles of $1.20 billion primarily related to lebrikizumab, deferred income tax liabilities of $49.5 million, and long-term debt of $375.5 million. After the acquisition, we repaid $276.2 million of long-term debt assumed as part of our acquisition of Dermira.

Revenue attributable to assets acquired in the Dermira acquisition did not have a material impact on our consolidated statement of operations for the year ended December 31, 2020. We are unable to provide the results of operations for the year ended December 31, 2020 attributable to Dermira as those operations were substantially integrated into our legacy business.

Pro forma information has not been included because this acquisition did not have a material impact on our results of operations for the years ended December 31, 2020 and 2019.

Loxo Acquisition

Overview of Transaction

In February 2019, we acquired all shares of Loxo for a purchase price of $6.92 billion, net of cash acquired. The accelerated vesting of Loxo employee equity awards was recognized as transaction expense included in asset impairment, restructuring, and other special charges during the year ended December 31, 2019 (see Note 5).

Under the terms of the agreement, we acquired a pipeline of investigational medicines, including selpercatinib (LOXO-292), an oral RET inhibitor, and LOXO-305, an oral BTK inhibitor. In the second quarter of 2020, the FDA approved selpercatinib (Retevmo®) under its Accelerated Approval regulations and continued approval may be contingent upon verification and description of clinical benefit in confirmatory trials. At the time of approval, we reclassified our $4.60 billion intangible asset for selpercatinib (Retevmo) from indefinite-lived intangible assets to finite-lived intangible assets and began amortizing straight line over its estimated useful life.

Assets Acquired and Liabilities Assumed

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

Estimated Fair Value at February 15, 2019		
Acquired IPR&D[(1)]	$	4,670.0
Finite-lived intangibles[(2)]		980.0
Deferred income taxes		(1,032.8)
Other assets and liabilities - net		(26.4)
Total identifiable net assets		4,590.8
Goodwill[(3)]		2,326.9
Total consideration transferred - net of cash acquired	$	6,917.7

(1) $4.60 billion of the acquired IPR&D relates to selpercatinib (LOXO-292).

(2) Contract-based intangibles (primarily related to Vitrakvi) which are being amortized to cost of sales on a straight-line basis over their estimated useful lives, were expected to have a weighted average useful life of approximately 12 years from the acquisition date.

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

Our consolidated statement of operations for the year ended December 31, 2019 includes revenue attributable to assets acquired in the Loxo acquisition of $136.7 million, primarily due to regulatory approval and sales milestones received. We are unable to provide the results of operations for the year ended December 31, 2019 attributable to Loxo as those operations were substantially integrated into our legacy business.

Pro forma information has not been included because this acquisition did not have a material impact on our results of operations for the years ended December 31, 2019 and 2018.

Asset Acquisitions

The following table and narrative summarize our asset acquisitions during 2020, 2019, and 2018.

Counterparty	Compound(s),Therapy, or Asset	Acquisition Month	Phase of Development[1]	Acquired IPR&D Expense
Sitryx Therapeutics Limited	Pre-clinical targets that could lead to potential new medicines for autoimmune diseases	March 2020	Pre-clinical	$ 52.3
AbCellera Biologics Inc. (AbCellera)[2]	Neutralizing antibodies for the treatement and prevention of COVID-19	March 2020	Pre-clinical	25.0
Shanghai Junshi Biosciences Co., Ltd. (Junshi Biosciences)	Neutralizing antibodies for the treatment and prevention of COVID-19	May 2020	Pre-clinical	20.0

Undisclosed	Pre-clinical target that could lead to potential new medicine	May 2020	Pre-clinical	174.8
Evox Therapeutics Ltd	Pre-clinical research collaboration for the potential treatment of neurological disorders	June 2020	Pre-clinical	22.0
Innovent Biologics, Inc. (Innovent)	Sintilimab injection, an anti-PD-1 monoclonal antibody immuno-oncology medicine, for geographies outside of China	October 2020	Phase III	200.0
Disarm Therapeutics, Inc. (Disarm)	Disease-modifying therapeutics program for patients with axonal degeneration	October 2020	Pre-clinical	126.3
Fochon Pharmaceuticals, Ltd.	Pre-clinical molecule targeting hematological malignancies	November 2020	Pre-clinical	40.0
AC Immune SA	Tau aggregation inhibitor small molecules for the potential treatment of Alzheimer's disease and other neurodegenerative diseases	January 2019 & September 2019[(3)]	Pre-clinical	127.1
ImmuNext, Inc.	Novel immunometabolism target	March 2019	Pre-clinical	40.0
Avidity Biosciences, Inc.	Potential new medicines in immunology and other select indications	April 2019	Pre-clinical	25.0
Centrexion Therapeutics Corporation	CNTX-0290, a novel, small molecule somatostatin receptor type 4 agonist	July 2019	Phase I	47.5
Sigilon Therapeutics, Inc.	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 BioSciences, Inc. (ARMO)	Cancer therapy - pegilodecakin	June 2018	Phase III	1,475.8
Anima Biotech Inc.	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 Co., Ltd.	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[(4)]	28.1
Dicerna Pharmaceuticals Inc.	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

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

(2) We recognized the acquired IPR&D expense of $25.0 million in May 2020 upon closing of the transaction.

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

(4) This research and development collaboration agreement terminated effective March 2020.

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

Divestiture

In October 2019, we completed a transaction in which we sold the rights in China for two legacy antibiotic medicines, as well as a manufacturing facility in Suzhou, China to Eddingpharm, a China-based specialty pharmaceutical company. In connection with the sale, we received net cash proceeds of $354.8 million and $40.3 million from Eddingpharm in 2019 and 2020, respectively. We accounted for the transaction as the sale of a business. We recorded a gain of $309.8 million in Other—net, (income) expense upon closing the transaction in 2019.

Subsequent Events

Precision BioSciences, Inc. (Precision)

In January 2021, we entered into a research collaboration and exclusive license agreement with Precision to utilize Precision's proprietary ARCUS genome editing platform for the research and development of potential in vivo therapies for genetic disorders. Under terms of the agreement, we paid an upfront cash payment of $100.0 million and invested $35.0 million in Precision's common stock at a premium. As a result of the transaction, we will record an acquired IPR&D charge of $107.8 million in the first quarter of 2021.

Merus N.V. (Merus)

In January 2021, we entered into a research collaboration and exclusive license agreement with Merus to research and develop up to three CD3-engaging T-cell re-directing bispecific antibody therapies. Under the terms of the agreement, we paid Merus an upfront cash payment of $40.0 million and invested $20.0 million in Merus common shares at a premium. As a result of the transaction, we will record an acquired IPR&D charge of $46.5 million in the first quarter of 2021.

Prevail Therapeutics Inc. (Prevail)

In January 2021, we completed our acquisition of Prevail. Prevail is a biotechnology company developing potentially disease-modifying AAV9-based gene therapies for patients with neurodegenerative diseases. The acquisition establishes a new modality for drug discovery and development, extending our research efforts through the creation of a gene therapy program that will be anchored by Prevail’s portfolio of clinical-stage and preclinical neuroscience assets.

We acquired all shares of Prevail for $22.50 per share (approximately $880 million) in cash plus one non-tradable contingent value right (CVR). The CVR entitles Prevail stockholders to up to an additional $4.00 per share in cash (or an aggregate of approximately $160 million) payable, subject to terms and conditions, upon the first regulatory approval of a Prevail product in one of the following countries: U.S., Japan, United Kingdom (U.K.), Germany, France, Italy or Spain. To achieve the full value of the CVR, such regulatory approval must occur by December 31, 2024. If such regulatory approval occurs after December 31, 2024, the value of the CVR will be reduced by approximately 8.3 cents per month until December 1, 2028, at which point the CVR will expire.

The accounting impact of this acquisition and the results of the operations for Prevail will be included in our consolidated financial statements beginning in the first quarter of 2021.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.

Asahi Kasei Pharma Corporation (Asahi)

In January 2021, we entered into a license agreement with Asahi to acquire the exclusive rights for AK1780, an orally bioavailable P2X7 receptor antagonist that recently completed Phase 1 single and

multiple ascending dose and clinical pharmacology studies for the potential treatment of chronic pain conditions. As a result of the transaction, we will pay Asahi an upfront cash payment and record an acquired IPR&D charge of $20.0 million in the first quarter of 2021.

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 as well as 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 from or payments to the collaboration partner. See Note 2 for amounts of collaboration and other revenue recognized from these types of arrangements.

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

Boehringer Ingelheim Diabetes Collaboration

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

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

Product Family	Milestones (Deferred) Capitalized[1]
Trajenta[2]	$ 446.4
Jardiance[3]	289.0
Basaglar	(250.0)

[1] In connection with the regulatory approvals of Basaglar in the U.S., Europe, and Japan, milestone payments received were recorded as contract liabilities and are being amortized through the term of the collaboration (2029) to collaboration and other revenue. In connection with the regulatory approvals of Trajenta and Jardiance, milestone payments made were capitalized as intangible assets and are being amortized to cost of sales through the term of the collaboration. This represents the cumulative amounts that have been (deferred) or capitalized from the start of this collaboration through the end of the reporting period.

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

[3] The collaboration agreement with Boehringer Ingelheim for Jardiance ends upon expiration of the compound patent and any supplementary protection certificates or extensions thereto.

Through December 31, 2019, in the most significant markets, we and Boehringer Ingelheim shared equally the ongoing development costs, commercialization costs, and agreed upon gross margin for any product resulting from the collaboration. We recorded our portion of the gross margin associated with Boehringer Ingelheim's products as collaboration and other revenue. We recorded 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 recorded our portion of the development and commercialization costs as research and development expense and marketing, selling, and administrative expense, respectively. Each company was entitled to potential performance payments depending on the sales of the molecules it contributes to the collaboration. These performance payments may have resulted 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 have been reduced by any performance payments we made related to these products. Similarly, performance payments we may have received related to

Basaglar effectively reduced Boehringer Ingelheim's share of the gross margin, which reduced our cost of sales.

Effective January 1, 2020, we and Boehringer Ingelheim modernized the alliance. In the most significant markets, we and Boehringer Ingelheim share equally the ongoing development costs and commercialization costs for the Jardiance product family. We receive a royalty on net sales of Boehringer Ingelheim's products in the most significant markets and recognize the royalty as collaboration and other revenue. We pay to Boehringer Ingelheim a royalty on net sales for Basaglar in the U.S. We record our sales of Basaglar to third parties as net product revenue with the royalty payments made to Boehringer Ingelheim recorded as cost of sales. For the Jardiance product family, we record our portion of the development and commercialization costs as research and development expense and marketing, selling, and administrative expense, respectively. Boehringer Ingelheim is entitled to potential performance payments depending on the net sales of the Jardiance product family; therefore, our reported revenue for Jardiance may be reduced by any potential performance payments we make related to this product. Beginning January 1, 2021, the royalty received by us related to the Jardiance product family may also be increased or decreased depending on whether net sales for this product family exceed or fall below certain thresholds.

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

	2020	2019	2018
Basaglar	**$ 1,124.4**	$ 1,112.6	$ 801.2
Jardiance	**1,153.8**	944.2	658.3
Trajenta	**358.5**	590.6	574.7

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 (baricitinib), 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 global net sales with rates ranging up to 20 percent. The agreement calls for payments by us to Incyte associated with certain development, success-based regulatory, and sales-based milestones. In the first half of 2020, the agreement was amended to include the treatment of COVID-19, with Incyte obtaining the right to receive an additional royalty ranging up to the low teens on global net sales for the treatment of COVID-19 that exceed a specified aggregate global net sales threshold.

In connection with the regulatory approvals of Olumiant in the U.S., Europe, and Japan, milestone payments of $210.0 million and $180.0 million were capitalized as intangible assets as of December 31, 2020 and 2019, respectively, and are being amortized to cost of sales through the term of the collaboration. This represents the cumulative amounts that have been capitalized from the start of this collaboration through the end of each reporting period.

As of December 31, 2020, Incyte is eligible to receive up to $100.0 million of additional payments from us contingent upon certain success-based regulatory milestones. Incyte is also eligible to receive up to $150.0 million of potential sales-based milestones.

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

	2020	2019	2018
Olumiant	**$ 638.9**	$ 426.9	$ 202.5

COVID-19 antibody therapies

In 2020, we entered into a worldwide license and collaboration agreement with AbCellera to co-develop therapeutic antibodies for the potential prevention and treatment of COVID-19, including bamlanivimab, for which we hold development and commercialization rights. In connection with this transaction, we recognized an acquired IPR&D expense of $25.0 million in 2020. AbCellera has the right to receive tiered royalty payments on global net sales of bamlanivimab with percentages ranging in the mid-teens to mid-twenties. Royalty payments made to AbCellera are recorded as cost of sales. Pursuant to an EUA, we recognized $871.2 million of net product revenue associated with our sales of bamlanivimab to third parties during the year ended December 31, 2020.

In 2020, we entered into a license and collaboration agreement with Junshi Biosciences to co-develop therapeutic antibodies for the potential prevention and treatment of COVID-19, including etesevimab, for which we hold development and commercialization rights outside of Greater China (which includes mainland China, Hong Kong and Macau Special Administrative Regions and Taiwan) and Junshi Biosciences maintains all rights in Greater China. In connection with this transaction, we recognized an acquired IPR&D expense of $20.0 million in 2020. Junshi Biosciences has the right to receive royalty payments in the mid-teens on our future net sales of etesevimab. Junshi Biosciences also has the right to receive certain development, success-based regulatory and sales-based milestones. As of December 31, 2020, Junshi Biosciences is eligible to receive up to $75.0 million of additional payments contingent upon certain success-based regulatory milestones and up to $120.0 million of potential sales-based milestones, contingent upon the commercial success of etesevimab. During the year ended December 31, 2020, we recognized $50.0 million of research and development expenses related to development milestones.

Tyvyt®

We have a collaboration agreement with Innovent to jointly develop and commercialize Tyvyt (sintilimab injection) in China. In 2019, we and Innovent began co-commercializing Tyvyt in China. We record our sales of Tyvyt to third parties as revenue, with payments made to Innovent for its portion of the gross margin reported as cost of sales. We also report as revenue our portion of the gross margin for Tyvyt sales made by Innovent to third parties. Our Tyvyt revenue in China, which is primarily recorded as net product revenue, was $308.7 million and $134.0 million in 2020 and 2019, respectively.

In October 2020, we obtained an exclusive license for Tyvyt from Innovent for geographies outside of China and plan to pursue registration of Tyvyt in the U.S. and other markets. We recorded an acquired IPR&D charge of $200.0 million in 2020 associated with the upfront payment to Innovent.

As of December 31, 2020, Innovent is eligible to receive up to $825.0 million for geographies outside of China and up to $75.0 million in China in success-based regulatory and sales-based milestones. Innovent is also eligible to receive tiered double digit royalties on net sales for geographies outside of China.

Tanezumab

We have a collaboration agreement with Pfizer Inc. (Pfizer) to jointly develop and globally commercialize tanezumab for the treatment of osteoarthritis pain and cancer pain. The companies equally share the ongoing development costs and, if successful, in the U.S. will co-commercialize and equally share in gross margin and certain commercialization expenses. As a result of an amendment to the agreement in the third quarter of 2020, Pfizer will be responsible for commercialization activities and costs outside the U.S., and we have the right to receive tiered royalties in percentages from the high teens to mid-twenties for net sales in Japan as well as low double digit royalties on annual net sales greater than $150.0 million in all other territories outside of the U.S. and Japan. As of December 31, 2020, Pfizer is eligible to receive up to $147.5 million in success-based regulatory milestones based on current development plans and up to $1.23 billion in a series of sales-based milestones, contingent upon the commercial success of tanezumab.

Lebrikizumab

As a result of our acquisition of Dermira, we have a worldwide licensing agreement with F. Hoffmann-La Roche Ltd and Genentech, Inc. (collectively Roche), which provides us the global development and

commercialization rights to lebrikizumab. Roche has the right to receive tiered royalty payments on future global net sales ranging in percentages from high single digits to high teens if the product is successfully commercialized. As of December 31, 2020, Roche is eligible to receive up to $180.0 million of payments from us contingent upon the achievement of success-based regulatory milestones, and up to $1.03 billion in a series of sales-based milestones, contingent upon the commercial success of lebrikizumab.

As a result of our acquisition of Dermira, we have a license agreement with Almirall, S.A. (Almirall), under which Almirall licensed the rights to develop and commercialize lebrikizumab for the treatment or prevention of dermatology indications, including, but not limited to, atopic dermatitis in Europe. We have the right to receive tiered royalty payments on future net sales in Europe ranging in percentages from low double digits to low twenties if the product is successfully commercialized. As of December 31, 2020, we are eligible to receive additional payments of $85.0 million from Almirall contingent upon the achievement of success-based regulatory milestones and up to $1.25 billion in a series of sales-based milestones, contingent upon the commercial success of lebrikizumab.

As of December 31, 2020, $29.7 million was recorded as a contract liability on the consolidated balance sheet and is expected to be recognized as collaboration and other revenue over the remaining Phase III development period. During the twelve months ended December 31, 2020, milestones received and collaboration and other revenue recognized were not material.

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:

	2020	2019	2018
Severance	**$ 151.2**	$ 77.8	$ 127.8
Asset impairment (gain) and other special charges	**(20.0)**	497.8	139.1
Total asset impairment, restructuring, and other special charges	**$ 131.2**	$ 575.6	$ 266.9

Severance costs recognized during the years ended December 31, 2020, 2019 and 2018 were incurred as a result of actions taken worldwide to reduce our cost structure. Substantially all of the severance costs incurred during the year ended December 31, 2020 are expected to be paid in the next 12 months.

Asset impairment and other special charges recognized during the year ended December 31, 2019 resulted primarily from $400.7 million of other special charges related to the acquisition of Loxo, substantially all of which is associated with the accelerated vesting of Loxo employee equity awards.

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.

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:

	2020	2019
Finished products	**$ 758.9**	$ 647.3
Work in process	**2,535.4**	2,067.6
Raw materials and supplies	**651.2**	424.6
Total (approximates replacement cost)	**3,945.5**	3,139.5
Increase to LIFO cost	**34.8**	51.2
Inventories	**$ 3,980.3**	$ 3,190.7

Inventories valued under the LIFO method comprised $1.21 billion and $1.20 billion of total inventories at December 31, 2020 and 2019, 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. In accordance with documented corporate risk-management policies, we monitor the amount of credit exposure to any one financial institution or corporate issuer. We are exposed to credit-related losses in the event of nonperformance by counterparties to risk-management instruments but do not expect any counterparties to fail to meet their obligations given their high credit ratings.

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

Our equity investments are accounted for using three different methods depending on the type of equity investment:

- Investments in companies over which we have significant influence but not a controlling interest are accounted for using the equity method, with our share of earnings or losses reported in other-net, (income) expense.
- For equity investments that do not have readily determinable fair values, we measure these investments at cost, less any impairment, plus or minus changes resulting from observable price changes in orderly transactions for the identical or similar investment of the same issuer. Any change in recorded value is recorded in other-net, (income) expense.
- Our public equity investments are measured and carried at fair value. Any change in fair value is recognized in other-net, (income) expense.

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

Our derivative activities are initiated within the guidelines of documented corporate risk-management policies and are intended to offset losses and gains on the assets, liabilities, and transactions being hedged. Management reviews the correlation and effectiveness of our derivatives on a quarterly basis.

For derivative instruments that are designated and qualify as fair value hedges, the derivative instrument is marked to market with gains and losses recognized currently in income to offset the respective losses and gains recognized on the underlying exposure. For derivative instruments that are designated and qualify as cash flow hedges, gains and losses are reported as a component of accumulated other comprehensive loss and reclassified into earnings in the same period the hedged transaction affects earnings. For derivative and non-derivative instruments that are designated and qualify as net investment hedges, the foreign currency translation gains or losses due to spot rate fluctuations are reported as a component of accumulated other comprehensive loss. Derivative contracts that are not designated as hedging instruments are recorded at fair value with the gain or loss recognized in earnings during the period of change.

We may enter into foreign currency forward or option contracts to reduce the effect of fluctuating currency exchange rates (principally the euro, British pound, and the Japanese yen). Foreign currency derivatives used for hedging are put in place using the same or like currencies and duration as the underlying exposures. Forward and option contracts are principally used to manage exposures arising from subsidiary trade and loan payables and receivables denominated in foreign currencies. These contracts are recorded at fair value with the gain or loss recognized in other–net, (income) expense. We may enter into foreign currency forward and option contracts and currency swaps as fair value hedges of firm commitments. Forward contracts generally have maturities not exceeding 12 months. At December 31, 2020, we had outstanding foreign currency forward commitments to purchase 647.9 million U.S. dollars and sell 530.7 million euro; commitments to purchase 2.97 billion euro and sell 3.62 billion U.S. dollars;

commitments to purchase 180.7 million U.S. dollars and sell 18.64 billion Japanese yen, and commitments to purchase 272.2 million British pounds and sell 363.9 million U.S. dollars which all settled 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 $6.02 billion and $5.49 billion as of December 31, 2020 and 2019, respectively, of which $4.50 billion and $4.10 billion have been designated as, and are effective as, economic hedges of net investments in certain of our euro-denominated foreign operations as of December 31, 2020 and 2019, respectively. At December 31, 2020, we had outstanding cross currency swaps with notional amounts of $3.76 billion swapping U.S. dollars to euro and $1.00 billion swapping swiss francs to U.S. dollars which have settlement dates ranging through 2028. Our cross-currency interest rate swaps, for which a majority convert a portion of our U.S. dollar-denominated fixed rate debt to foreign-denominated fixed rate debt, have also been designated as, and are effective as, economic hedges of net investments.

In the normal course of business, our operations are exposed to fluctuations in interest rates which can vary the costs of financing, investing, and operating. We seek to address a portion of these risks through a controlled program of risk management that includes the use of derivative financial instruments. The objective of controlling these risks is to limit the impact of fluctuations in interest rates on earnings. Our primary interest-rate risk exposure results from changes in short-term U.S. dollar interest rates. In an effort to manage interest-rate exposures, we strive to achieve an acceptable balance between fixed- and floating-rate debt and investment positions and may enter into interest rate swaps or collars to help maintain that balance.

Interest rate swaps or collars that convert our fixed-rate debt to a floating rate are designated as fair value hedges of the underlying instruments. Interest rate swaps or collars that convert floating-rate debt to a fixed rate are designated as cash flow hedges. Interest expense on the debt is adjusted to include the payments made or received under the swap agreements. Cash proceeds from or payments to counterparties resulting from the termination of interest rate swaps are classified as operating activities in our consolidated statements of cash flows. At December 31, 2020, substantially all of our total long-term debt is at a fixed rate. We have converted approximately 9 percent of our long-term fixed-rate notes to floating rates through the use of interest rate swaps.

We also may enter into forward-starting interest rate swaps, which we designate as cash flow hedges, as part of any anticipated future debt issuances in order to reduce the risk of cash flow volatility from future changes in interest rates. The change in fair value of these instruments is recorded as part of other comprehensive income (loss), and upon completion of a debt issuance and termination of the swap, is amortized to interest expense over the life of the underlying debt. As of December 31, 2020, the total notional amounts of forward-starting interest rate contracts in designated cash flow hedging instruments were $1.75 billion, which have settlement dates ranging between 2023 and 2025.

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:

	2020	2019	2018
Fair value hedges:			
Effect from hedged fixed-rate debt	**$ 86.9**	$ 112.1	$ (40.9)
Effect from interest rate contracts	**(86.9)**	(112.1)	40.9
Cash flow hedges:			
Effective portion of losses on interest rate contracts reclassified from accumulated other comprehensive loss	**16.4**	15.9	14.8
Cross-currency interest rate swaps	**(102.4)**	(17.1)	—
Net (gains) losses on foreign currency exchange contracts not designated as hedging instruments	**(123.7)**	61.9	100.0
Total	**$ (209.7)**	$ 60.7	$ 114.8

During the years ended December 31, 2020, 2019 and 2018, the amortization of losses related to the portion of our risk management hedging instruments, fair value hedges, and cash flow hedges that was excluded from the assessment of effectiveness was not material.

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

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

	2020	2019	2018
Net investment hedges:			
Foreign currency-denominated notes	**$ (404.0)**	$ 40.1	$ 110.4
Cross-currency interest rate swaps	**(207.9)**	47.4	96.8
Foreign currency exchange contracts	**—**	—	5.7
Cash flow hedges:			
Forward-starting interest rate swaps	**(110.9)**	31.6	—
Cross-currency interest rate swaps	**(53.7)**	(8.3)	—

During the next 12 months, we expect to reclassify $16.8 million of net losses on cash flow hedges from accumulated other comprehensive loss to other–net, (income) expense. During the years ended December 31, 2020, 2019 and 2018, the amounts excluded from the assessment of hedge effectiveness recognized in other comprehensive income (loss) were not material.

Fair Value of Financial Instruments

The following tables summarize certain fair value information at 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: 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, 2020						
Cash equivalents	**$ 2,097.9**	**$ 2,097.9**	**$ 2,097.9**	**$ —**	**$ —**	**$ 2,097.9**
Short-term investments:						
U.S. government and agency securities	**$ 9.9**	**$ 9.9**	**$ 9.9**	**$ —**	**$ —**	**$ 9.9**
Corporate debt securities	**2.8**	**2.8**	**—**	**2.8**	**—**	**2.8**
Asset-backed securities	**1.2**	**1.2**	**—**	**1.2**	**—**	**1.2**
Other securities	**10.3**	**10.3**	**—**	**—**	**10.3**	**10.3**
Short-term investments	**$ 24.2**					
Noncurrent investments:						
U.S. government and agency securities	**$ 78.7**	**$ 74.3**	**$ 78.7**	**$ —**	**$ —**	**$ 78.7**
Corporate debt securities	**137.0**	**126.8**	**—**	**137.0**	**—**	**137.0**
Mortgage-backed securities	**106.4**	**101.4**	**—**	**106.4**	**—**	**106.4**
Asset-backed securities	**24.3**	**23.7**	**—**	**24.3**	**—**	**24.3**
Other securities	**110.5**	**31.8**	**—**	**—**	**110.5**	**110.5**
Marketable equity securities	**1,664.2**	**311.6**	**1,664.2**	**—**	**—**	**1,664.2**
Equity investments without readily determinable fair values[2]	**373.9**					
Equity method investments[2]	**471.8**					
Noncurrent investments	**$ 2,966.8**					
December 31, 2019						
Cash equivalents	$ 1,025.4	$ 1,025.4	$ 1,025.4	$ —	$ —	$ 1,025.4
Short-term investments:						
U.S. government and agency securities	$ 7.2	$ 7.2	$ 7.2	$ —	$ —	$ 7.2
Corporate debt securities	81.4	81.1	—	81.4	—	81.4
Asset-backed securities	2.6	2.6	—	2.6	—	2.6
Other securities	9.8	9.8	—	—	9.8	9.8
Short-term investments	$ 101.0					
Noncurrent investments:						
U.S. government and agency securities	$ 77.2	$ 76.3	$ 77.2	$ —	$ —	$ 77.2
Corporate debt securities	271.1	267.8	—	271.1	—	271.1
Mortgage-backed securities	101.1	99.6	—	101.1	—	101.1
Asset-backed securities	30.0	29.6	—	30.0	—	30.0
Other securities	60.0	27.4	—	—	60.0	60.0
Marketable equity securities	718.6	254.4	718.6	—	—	718.6
Equity investments without readily determinable fair values[2]	405.0					
Equity method investments[2]	299.4					
Noncurrent investments	$ 1,962.4					

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

[2] Fair value disclosures are not applicable for equity method investments and investments accounted for under the measurement alternative for equity investments.

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, 2020	**$ —**	**$ —**	**$ —**	**$ —**	**$ —**
December 31, 2019	(1,494.2)	—	(1,491.6)	—	(1,491.6)
Long-term debt, including current portion					
December 31, 2020	**$ (16,595.3)**	**$ —**	**$ (19,038.9)**	**$ —**	**$ (19,038.9)**
December 31, 2019	(13,823.0)	—	(15,150.0)	—	(15,150.0)

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, 2020					
Risk-management instruments					
Interest rate contracts designated as fair value hedges:					
Other noncurrent assets	**$ 158.9**	**$ —**	**$ 158.9**	**$ —**	**$ 158.9**
Interest rate contracts designated as cash flow hedges:					
Other noncurrent assets	**38.1**	**—**	**38.1**	**—**	**38.1**
Other noncurrent liabilities	**(97.8)**	**—**	**(97.8)**	**—**	**(97.8)**
Cross-currency interest rate contracts designated as net investment hedges:					
Other current liabilities	**(92.6)**	**—**	**(92.6)**	**—**	**(92.6)**
Other noncurrent liabilities	**(97.2)**	**—**	**(97.2)**	**—**	**(97.2)**
Cross-currency interest rate contracts designated as cash flow hedges:					
Other noncurrent assets	**34.4**	**—**	**34.4**	**—**	**34.4**
Other noncurrent liabilities	**(2.9)**	**—**	**(2.9)**	**—**	**(2.9)**
Foreign exchange contracts not designated as hedging instruments:					
Other receivables	**41.1**	**—**	**41.1**	**—**	**41.1**
Other current liabilities	**(15.2)**	**—**	**(15.2)**	**—**	**(15.2)**
December 31, 2019					
Risk-management instruments					
Interest rate contracts designated as fair value hedges:					
Other noncurrent assets	72.0	—	72.0	—	72.0
Interest rate contracts designated as cash flow hedges:					
Other noncurrent assets	43.3	—	43.3	—	43.3
Cross-currency interest rate contracts designated as net investment hedges:					
Other noncurrent assets	45.1	—	45.1	—	45.1
Other current liabilities	(21.4)	—	(21.4)	—	(21.4)
Other noncurrent liabilities	(5.7)	—	(5.7)	—	(5.7)
Cross-currency interest rate contracts designated as cash flow hedges:					
Other noncurrent assets	3.0	—	3.0	—	3.0
Other noncurrent liabilities	(20.1)	—	(20.1)	—	(20.1)
Foreign exchange contracts not designated as hedging instruments:					
Other receivables	18.4	—	18.4	—	18.4
Other current liabilities	(11.9)	—	(11.9)	—	(11.9)

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 enforceable master netting arrangements 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. As of December 31, 2020, we had approximately $687 million of unfunded commitments to invest in venture capital funds, which we anticipate will be paid over a period of up to 10 years.

The table below summarizes the contractual maturities of our investments in debt securities measured at fair value as of December 31, 2020:

	Maturities by Period				
	Total	Less Than 1 Year	1-5 Years	6-10 Years	More Than 10 Years
Fair value of debt securities	$ 360.3	$ 13.9	$ 135.6	$ 82.7	$ 128.1

The net gains recognized in our consolidated statements of operations for equity securities were $1,442.2 million, $401.2 million and $72.6 million for the years ended December 31, 2020, 2019 and 2018, respectively. The net gains/losses recognized for the years ended December 31, 2020, 2019 and 2018 on equity securities sold during the respective periods were not material.

We adjust our equity investments without readily determinable fair values based upon changes in the equity instruments' values resulting from observable price changes in orderly transactions for an identical or similar investment of the same issuer. Downward adjustments resulting from an impairment are recorded based upon impairment considerations, including the financial condition and near term prospects of the issuer, general market conditions, and industry specific factors. Adjustments recorded for the years ended December 31, 2020, 2019 and 2018 were not material.

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

	2020	2019
Unrealized gross gains	**$ 20.9**	$ 10.3
Unrealized gross losses	**0.5**	4.0
Fair value of securities in an unrealized gain position	**348.9**	429.5
Fair value of securities in an unrealized loss position	**11.4**	141.1

We periodically assess our investment in available-for-sale securities for impairment and credit losses. 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. Impairment and credit losses related to available-for-sale securities were not material for the years ended December 31, 2020, 2019 and 2018.

As of December 31, 2020, 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 86 percent of the fixed-rate debt securities in a loss position are investment-grade debt securities. As of December 31, 2020, 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 available-for-sale securities was as follows:

	2020	2019	2018
Proceeds from sales	**$ 264.8**	$ 431.6	$ 5,529.0
Realized gross gains on sales	**4.5**	4.9	3.6
Realized gross losses on sales	**8.2**	3.0	49.2

Realized gains and losses on sales of available-for-sale investments are computed based upon specific identification of the initial cost adjusted for any other-than-temporary declines in fair value that were recorded in earnings.

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 $754.9 million and $678.8 million of accounts receivable as of December 31, 2020 and 2019, respectively, under these factoring arrangements. The costs of factoring such accounts receivable on our consolidated results of operations for the years ended December 31, 2020, 2019, and 2018 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, or more frequently if impairment indicators are present, by first assessing qualitative factors to determine whether it is more likely than not that the fair value is less than its carrying amount. If we conclude it is more likely than not that the fair value is less than the carrying amount, a quantitative test that compares the fair value to its carrying value is performed to determine the amount of any impairment. The changes in goodwill during 2020 and 2019 were primarily related to our acquisitions of Dermira and Loxo, respectively. See Note 3 for further discussion.

No impairments occurred with respect to the carrying value of goodwill for the years ended December 31, 2020, 2019, and 2018.

Other Intangibles

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

Description	2020 Carrying Amount, Gross	2020 Accumulated Amortization	2020 Carrying Amount, Net	2019 Carrying Amount, Gross	2019 Accumulated Amortization	2019 Carrying Amount, Net
Finite-lived intangible assets:						
Marketed products	**$ 7,984.0**	**$ (1,659.5)**	**$ 6,324.5**	$ 3,150.2	$ (1,244.6)	$ 1,905.6
Other	**92.8**	**(68.3)**	**24.5**	94.2	(51.8)	42.4
Total finite-lived intangible assets	**8,076.8**	**(1,727.8)**	**6,349.0**	3,244.4	(1,296.4)	1,948.0
Indefinite-lived intangible assets:						
Acquired IPR&D	**1,101.0**	**—**	**1,101.0**	4,670.0	—	4,670.0
Other intangibles	**$ 9,177.8**	**$ (1,727.8)**	**$ 7,450.0**	$ 7,914.4	$ (1,296.4)	$ 6,618.0

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 intangible assets 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 fair values of acquired IPR&D projects acquired in business combination, 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 as other intangible assets if the projects have an alternative future use; otherwise, they are expensed immediately. See Note 3 for acquired IPR&D projects that had no alternative future use.

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, analyst expectations, 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.

The increase in marketed products and the decrease in acquired IPR&D in 2020 primarily relates to the reclassification of our $4.60 billion intangible asset for selpercatinib (Retevmo) from indefinite-lived to finite-lived as it was approved by the FDA in the second quarter of 2020. This decrease in acquired IPR&D in 2020 was partially offset by the addition of acquired IPR&D for lebrikizumab as a result of the Dermira acquisition. The increases in marketed products and acquired IPR&D intangible assets in 2019 were primarily related to our acquisition of Loxo. See Note 3 for further discussion of intangible assets acquired in recent business combinations and Note 4 for additional discussion of recent capitalized milestone payments.

Indefinite-lived intangible assets are reviewed for impairment at least annually, or more frequently if impairment indicators are present, by first assessing qualitative factors to determine whether it is more likely than not that the fair value of the asset is less than its carrying amount. If we conclude it is more likely than not that the fair value is less than the carrying amount, a quantitative test that compares the fair value of the intangible asset to its carrying value is performed to determine the amount of any impairment. 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.

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, 2020, the remaining weighted-average amortization period for finite-lived intangible assets was approximately 15 years.

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

	2020	2019	2018
Amortization expense	**$ 428.2**	$ 225.8	$ 361.3

The estimated amortization expense for each of the next five years associated with our finite-lived intangible assets as of December 31, 2020 is as follows:

	2021	2022	2023	2024	2025
Estimated amortization expense	$ 517.7	$ 513.0	$ 501.2	$ 449.1	$ 432.5

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:

	2020	2019
Land	**$ 226.8**	$ 169.5
Buildings	**7,326.1**	7,067.3
Equipment	**8,560.9**	7,913.3
Construction in progress	**2,138.8**	1,884.4
	18,252.6	17,034.5
Less accumulated depreciation	**(9,570.7)**	(9,161.6)
Property and equipment, net	**$ 8,681.9**	$ 7,872.9

Depreciation expense related to property and equipment was as follows:

	2020	2019	2018
Depreciation expense	**$ 765.2**	$ 814.7	$ 797.1

Capitalized interest costs were not material for the years ended December 31, 2020, 2019, and 2018.

The following table summarizes long-lived assets by geographical area:

	2020	2019
Long-lived assets[(1)]:		
U.S. and Puerto Rico	**$ 6,113.6**	$ 5,595.4
Ireland	**1,786.9**	1,454.8
Other foreign countries	**1,747.7**	1,758.3
Long-lived assets	**$ 9,648.2**	$ 8,808.5

[(1)] Long-lived assets consist of property and equipment, net, operating lease assets, and certain other noncurrent assets.

Note 10: Leases

We determine if an arrangement is a lease at inception. We have leases with terms up to 12 years primarily for corporate offices, research and development facilities, vehicles, and equipment, including some of which have options to extend and/or early-terminate the leases. We determine the lease term by assuming the exercise of any renewal and/or early-termination options that are reasonably assured.

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

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

Lease expense for operating lease assets, which is recognized on a straight-line basis over the lease term, was $154.6 million and $172.8 million during the years ended December 31, 2020 and 2019, respectively. Variable lease payments, which represent non-lease components such as maintenance, insurance and taxes, and which vary due to changes in facts or circumstances occurring after the commencement date other than the passage of time, are expensed in the period in which the payment obligation is incurred and were not material during the years ended December 31, 2020 and 2019. Short-term lease expense was not material during the years ended December 31, 2020 and 2019.

Supplemental balance sheet information related to operating leases as of December 31, 2020 and 2019 was as follows:

	2020		2019	
Weighted-average remaining lease term		**7 years**		8 years
Weighted-average discount rate	**3.3**	**%**	3.6	%

Supplemental cash flow information related to operating leases during the years ended December 31, 2020 and 2019 was as follows:

	2020	2019
Operating cash flows from operating leases	**$ 160.9**	$ 153.6
Right-of-use assets obtained in exchange for new operating lease liabilities	**136.7**	81.2

The annual minimum lease payments of our operating lease liabilities as of December 31, 2020 were as follows:

Year 1	$ 150.9
Year 2	120.7
Year 3	94.1
Year 4	73.3
Year 5	63.4
After Year 5	258.7
Total lease payments	761.1
Less imputed interest	97.4
Total	$ 663.7

Rental expense for all leases, including contingent rentals (not material), was $175.7 million for the year ended December 31, 2018.

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

Note 11: Borrowings

Debt at December 31 consisted of the following:

	2020	2019
Short-term commercial paper borrowings	**$ —**	$ 1,494.2
Long-term notes	**16,348.7**	13,638.5
Other long-term debt	**14.8**	12.9
Unamortized debt issuance costs	**(89.1)**	(73.6)
Fair value adjustment on hedged long-term notes	**320.9**	245.2
Total debt	**16,595.3**	15,317.2
Less current portion	**(8.7)**	(1,499.3)
Long-term debt	**$ 16,586.6**	$ 13,817.9

The following table summarizes long-term notes at December 31:

	2020	2019
2.35% notes due 2022	**$ 750.0**	$ 750.0
3.00% notes due 2022	**99.2**	—
1.00% Euro denominated notes due 2022	**737.9**	671.8
0.15% Swiss Franc denominated notes due 2024	**679.7**	618.3
7.125% notes due 2025	**229.7**	229.7
2.75% notes due 2025	**560.6**	560.6
1.625% Euro denominated notes due 2026	**922.4**	839.7
5.5% notes due 2027	**377.5**	377.5
3.1% notes due 2027	**401.5**	401.5
0.45% Swiss Franc denominated notes due 2028	**453.2**	412.2
3.375% notes due 2029	**1,150.0**	1,150.0
0.42% Japanese Yen denominated notes due 2029	**222.4**	209.9
2.125% Euro denominated notes due 2030	**922.4**	839.7
0.625% Euro denominated notes due 2031	**737.9**	671.8
0.56% Japanese Yen denominated notes due 2034	**90.0**	85.0
6.77% notes due 2036	**174.4**	174.4
5.55% notes due 2037	**476.2**	476.2
5.95% notes due 2037	**284.1**	284.1
3.875% notes due 2039	**360.7**	360.7
4.65% notes due 2044	**43.0**	43.0
3.7% notes due 2045	**412.5**	412.5
3.95% notes due 2047	**436.1**	436.1
3.95% notes due 2049	**1,500.0**	1,500.0
1.7% Euro denominated notes due 2049	**1,229.9**	1,119.6
0.97% Japanese Yen denominated notes due 2049	**74.1**	70.0
2.25% notes due 2050	**1,250.0**	—
4.15% notes due 2059	**1,000.0**	1,000.0
2.5% notes due 2060	**850.0**	—
Unamortized note discounts	**(76.7)**	(55.8)
Total long-term notes	**$ 16,348.7**	$ 13,638.5

The weighted-average effective borrowing rate on outstanding commercial paper at December 31, 2019 was 1.65 percent. The weighted-average effective borrowing rate for each issuance of the long term-notes approximates the stated interest rate.

At December 31, 2020, we had a total of $5.24 billion of unused committed bank credit facilities, which consisted primarily of a $3.00 billion credit facility that expires in December 2024 and a $2.00 billion 364-day facility that expires in December 2021, 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 as of December 31, 2020. Of the remaining committed bank credit facilities, the outstanding balances as of December 31, 2020 and 2019 were not material. 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 2020, we issued $1.00 billion of 2.25 percent fixed-rate notes due in May 2050, with interest to be paid semi-annually. We used the net cash proceeds from the offering of $988.6 million for general corporate purposes, including the repayment of outstanding commercial paper.

In August 2020, we issued $850.0 million of 2.50 percent fixed-rate notes due in September 2060 and an additional $250.0 million of our 2.25 percent fixed-rate notes due in May 2050, with interest to be paid semi-annually. We used the net cash proceeds from the offering of $1.07 billion for general corporate purposes, including the repayment of outstanding commercial paper.

In February 2019, we issued $1.15 billion of 3.375 percent fixed-rate notes due in March 2029, $850.0 million of 3.875 percent fixed-rate notes due in March 2039, $1.50 billion of 3.95 percent fixed-rate notes due in March 2049, and $1.00 billion of 4.15 percent fixed-rate notes due in March 2059, with interest to be paid semi-annually. We used the net cash proceeds of $4.45 billion from the offering to repay commercial paper that was issued in connection with the acquisition of Loxo and for general corporate purposes.

In November 2019, we issued euro-denominated notes consisting of €600.0 million of 0.625 percent fixed-notes due November 2031 and €1.00 billion of 1.70 percent fixed-rate notes due in November 2049 with interest to be paid annually. We paid $2.27 billion, comprised of $1.75 billion of net cash proceeds from the offering and proceeds from commercial paper, to purchase and redeem certain higher interest rate U.S. dollar denominated notes with an aggregate principal amount of $2.00 billion and a net carrying value of $2.01 billion, resulting in a debt extinguishment loss of $252.5 million. This loss was included in other-net, (income) expense in our consolidated statement of operations during the year ended December 31, 2019.

In November 2019, we issued Japanese Yen-denominated notes consisting of ¥22.92 billion of 0.42 percent fixed-rate notes due in November 2029, ¥9.28 billion of 0.56 percent fixed-rate notes due in November 2034, and ¥7.64 billion of 0.97 percent fixed-rate notes due in November 2049, with interest to be paid semi-annually. We used the net cash proceeds from the offering of $356.6 million for general corporate purposes, including the repayment of outstanding commercial paper.

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

	2021	2022	2023	2024	2025
Maturities on long-term debt	$ 6.0	$ 1,590.2	$ 2.3	$ 681.1	$ 790.3

We have converted approximately 9 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, 2020 and 2019, including the effects of interest rate swaps for hedged debt obligations, were 2.61 percent and 2.88 percent, respectively.

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

	2020	2019	2018
Cash payments for interest on borrowings	**$ 345.8**	$ 305.5	$ 223.8

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 12: Stock-Based Compensation

Our stock-based compensation expense consists of performance awards (PAs), shareholder value awards (SVAs), relative value awards (RVAs), 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, RVA, and RSU shares.

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

	2020	2019	2018
Stock-based compensation expense	**$ 308.1**	$ 306.8	$ 253.5
Tax benefit	**64.7**	64.4	53.2

At December 31, 2020, stock-based compensation awards may be granted under the 2002 Lilly Stock Plan for not more than 53.9 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, 2020, 2019, and 2018 were $137.33, $112.09, and $71.63, 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 1.1 million shares, 1.2 million shares, and 0.9 million shares were issued during the years ended December 31, 2020, 2019, and 2018, respectively. Approximately 0.8 million shares are expected to be issued in 2021. As of December 31, 2020, the total remaining unrecognized compensation cost related to nonvested PAs was $77.3 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, 2020, 2019, and 2018 were $139.14, $95.01, and $48.51, respectively, determined using the following assumptions:

(Percents)	2020	2019	2018
Expected dividend yield	**2.50 %**	2.50 %	2.50 %
Risk-free interest rate	**1.38**	2.46	2.31
Volatility	**20.90**	21.00	22.26

Pursuant to this program, approximately 0.8 million shares, 1.0 million shares, and 0.7 million shares were issued during the years ended December 31, 2020, 2019, and 2018, respectively. Approximately 1.0 million shares are expected to be issued in 2021. As of December 31, 2020, the total remaining

unrecognized compensation cost related to nonvested SVAs was $48.8 million, which will be amortized over the weighted-average remaining requisite service period of 20 months.

Relative Value Award Program

Beginning in 2020, we granted RVAs to officers and management and are payable in shares of our common stock. The number of shares actually issued, if any, varies depending on the growth of our stock price at the end of the three-year vesting period compared to our peers. We measure the fair value of the RVA 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 our peers' 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 value of the RVA units granted during the year ended December 31, 2020 was $179.90, determined using the following assumptions:

(Percents)	2020
Expected dividend yield	2.50 %
Risk-free interest rate	1.38
Volatility	19.89

As of December 31, 2020, the total remaining unrecognized compensation cost related to nonvested RVAs was $13.7 million, which will be amortized over the weighted-average remaining requisite service period of 24 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, 2020, 2019, and 2018 were $135.42, $108.43, and $70.95, respectively. The number of shares ultimately issued for the RSU program remains constant with the exception of forfeitures. Pursuant to this program, 1.1 million, 1.5 million, and 1.3 million shares were granted and approximately 0.6 million, 0.8 million, and 1.0 million shares were issued during the years ended December 31, 2020, 2019, and 2018, respectively. Approximately 0.6 million shares are expected to be issued in 2021. As of December 31, 2020, the total remaining unrecognized compensation cost related to nonvested RSUs was $179.2 million, which will be amortized over the weighted-average remaining requisite service period of 31 months.

Note 13: Shareholders' Equity

During 2020, 2019, and 2018, we repurchased $500.0 million, $4.40 billion and $4.15 billion, respectively, of shares associated with our share repurchase programs. As of December 31, 2020, we had $1.00 billion remaining under our $8.00 billion share repurchase program that our board authorized in June 2018.

We have 5.0 million authorized shares of preferred stock. As of December 31, 2020 and 2019, 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, 2020 and 2019, 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, 2020 and 2019, 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, 2020, 2019, and 2018.

Note 14: Income Taxes

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. Deferred taxes related to GILTI, global intangible low-taxed income, are also recognized for the future tax effects of temporary differences.

We recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position, based on its technical merits, will be sustained upon examination by the taxing authority. 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.

In December 2017, the Tax Cuts and Job Act (the 2017 Tax Act) was signed into law. 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 and GILTI, a new U.S. minimum tax on the earnings of our foreign subsidiaries. In 2018, we recorded $313.3 million of income tax benefit, mainly attributable to measurement period adjustments to the Toll Tax and GILTI.

Following is the composition of income tax expense:

	2020	2019	2018
Current:			
Federal[1]	**$ 567.6**	$ 280.2	$ 169.6
Foreign	**650.4**	299.8	106.8
State	**(47.3)**	(14.4)	4.7
Total current tax expense	**1,170.7**	565.6	281.1
Deferred:			
Federal[2]	**(97.4)**	141.3	(3.7)
Foreign	**(16.6)**	(24.1)	248.7
State	**(20.5)**	(54.8)	3.4
Total deferred tax (benefit) expense	**(134.5)**	62.4	248.4
Income taxes	**$ 1,036.2**	$ 628.0	$ 529.5

[1] The 2020 and 2019 current tax expense includes $144.4 million and $153.1 million of tax benefit, respectively, from utilization of net operating loss and tax credit carryforwards. The 2018 current tax expense includes $201.5 million of tax expense related to effects of the 2017 Tax Act.

[2] The 2018 deferred tax benefit includes $26.2 million of tax benefit related to effects of the 2017 Tax Act.

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

	2020	2019
Deferred tax assets:		
Purchases of intangible assets	**$ 2,560.6**	$ 2,512.4
Compensation and benefits	**1,045.6**	934.3
Tax credit carryforwards and carrybacks	**523.5**	455.8
Tax loss carryforwards and carrybacks	**488.3**	318.8
Sales rebates and discounts	**461.3**	197.3
Correlative tax adjustments	**404.2**	219.1
Foreign tax redeterminations	**242.8**	156.8
Operating lease liabilities	**150.7**	140.6
Capitalized research and development	**135.2**	75.7
Other	**605.8**	595.7
Total gross deferred tax assets	**6,618.0**	5,606.5
Valuation allowances	**(816.3)**	(616.5)
Total deferred tax assets	**5,801.7**	4,990.0
Deferred tax liabilities:		
Earnings of foreign subsidiaries	**(1,905.3)**	(1,776.4)
Intangibles	**(1,465.7)**	(1,298.0)
Inventories	**(623.7)**	(686.4)
Prepaid employee benefits	**(410.1)**	(305.9)
Property and equipment	**(315.2)**	(274.1)
Financial instruments	**(216.9)**	(139.4)
Operating lease assets	**(134.3)**	(124.7)
Total deferred tax liabilities	**(5,071.2)**	(4,604.9)
Deferred tax assets - net	**$ 730.5**	$ 385.1

The deferred tax asset and related valuation allowance amounts for U.S. federal, international, 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, 2020, based on filed tax returns we have tax credit carryforwards and carrybacks of $887.3 million available to reduce future income taxes; $148.8 million, if unused, will expire by 2026, and $16.1 million, if unused, will expire between 2029 and 2039. The remaining portion of the tax credit carryforwards is related to federal tax credits of $84.8 million, international tax credits of $121.9 million, and state tax credits of $515.7 million, all of which are fully reserved.

At December 31, 2020, based on filed tax returns we had net operating losses and other carryforwards for international and U.S. federal income tax purposes of $1.52 billion: $162.6 million will expire by 2025; $781.7 million will expire between 2026 and 2040; and $576.3 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 and other carryforwards of $175.6 million are fully reserved as of December 31, 2020.

Domestic and Puerto Rican companies contributed approximately 39 percent, 44 percent, and 15 percent for the years ended December 31, 2020, 2019, and 2018, 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.

Substantially all of the unremitted earnings of our foreign subsidiaries are considered not to be indefinitely reinvested for continued use in our foreign operations. At December 31, 2020 and December 31, 2019, we 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 U.S. federal, state, and foreign income taxes, net of refunds, were as follows:

	2020	2019	2018
Cash payments of income taxes	**$ 954.6**	$ 1,180.5	$ 1,076.7

The 2017 Tax Act provided an election to taxpayers subject to the Toll Tax to make payments over an eight year period beginning in 2018 through 2025. Having made this election, our future cash payments relating to the Toll Tax as of December 31, 2020 are as follows:

	Total	Less than 1 Year	1-3 Years	3-5 Years
2017 Tax Act Toll Tax	$2,403.1	$253.7	$729.3	$1,420.1

We have additional noncurrent income tax payables of $1.69 billion unrelated to the Toll Tax; we cannot reasonably estimate the timing of future cash outflows associated with these liabilities.

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

	2020	2019	2018
Income tax at the U.S. federal statutory tax rate	**$ 1,518.3**	$ 1,105.8	$ 772.8
Add (deduct):			
International operations, including Puerto Rico	**(297.1)**	(242.0)	(627.1)
General business credits	**(97.9)**	(108.8)	(87.4)
Non-deductible acquired IPR&D[(1)]	**63.2**	—	309.9
2017 Tax Act	**—**	—	175.3
Other	**(150.3)**	(127.0)	(14.0)
Income taxes	**$ 1,036.2**	$ 628.0	$ 529.5

[(1)] Non-deductible acquired IPR&D was related to the acquisitions of Disarm and a pre-clinical stage company in 2020 and ARMO in 2018. 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:

	2020	2019	2018
Beginning balance at January 1	**$ 2,108.6**	$ 2,034.6	$ 1,000.8
Additions based on tax positions related to the current year	**225.6**	187.2	798.2
Additions for tax positions of prior years	**310.8**	425.3	410.9
Reductions for tax positions of prior years	**(52.4)**	(100.3)	(115.4)
Settlements	**(72.0)**	(260.5)	(33.2)
Lapses of statutes of limitation	**(41.7)**	(161.5)	(20.5)
Changes related to the impact of foreign currency translation	**73.0**	(16.2)	(6.2)
Ending balance at December 31	**$ 2,551.9**	$ 2,108.6	$ 2,034.6

The total amount of unrecognized tax benefits that, if recognized, would affect our effective tax rate was $1.67 billion and $1.53 billion at December 31, 2020 and 2019, respectively.

We file U.S. federal, foreign, and various state and local income tax returns. We are no longer subject to U.S. federal income tax examination for years before 2016. In most major foreign and state jurisdictions, we are no longer subject to income tax examination for years before 2012.

The U.S. examination of tax years 2016-2018 began in the fourth quarter of 2019 and remains ongoing; therefore, the resolution of this audit period will likely extend beyond the next 12 months. For tax years 2013-2015, all matters were effectively settled in 2019. As a result, our gross uncertain tax positions were reduced by approximately $200 million, we made a cash payment of approximately $125 million, and our consolidated results were benefited by an immaterial reduction in tax expense.

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:

	2020	2019	2018
Income tax (benefit) expense	**$ 34.0**	$ (26.4)	$ 25.1

At December 31, 2020 and 2019, our accruals for the payment of interest and penalties totaled $196.7 million and $150.8 million, respectively.

Note 15: 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	
	2020	2019	2020	2019
Change in benefit obligation:				
Benefit obligation at beginning of year	**$ 16,251.0**	$ 13,427.1	**$ 1,601.4**	$ 1,540.0
Service cost	**325.5**	250.4	**40.8**	36.3
Interest cost	**425.8**	486.0	**43.7**	58.0
Actuarial loss	**1,563.1**	2,631.7	**142.1**	54.3
Benefits paid	**(587.2)**	(584.2)	**(75.1)**	(87.3)
Curtailment (gain) loss	**2.2**	(16.8)	**—**	(0.5)
Foreign currency exchange rate changes and other adjustments	**245.1**	56.8	**0.8**	0.6
Benefit obligation at end of year	**18,225.5**	16,251.0	**1,753.7**	1,601.4
Change in plan assets:				
Fair value of plan assets at beginning of year	**12,858.0**	10,932.6	**2,768.2**	2,398.1
Actual return on plan assets	**1,802.4**	2,012.0	**539.0**	444.1
Employer contribution	**318.8**	429.9	**(5.1)**	13.2
Benefits paid	**(587.2)**	(584.2)	**(75.1)**	(87.3)
Foreign currency exchange rate changes and other adjustments	**187.0**	67.7	**—**	0.1
Fair value of plan assets at end of year	**14,579.0**	12,858.0	**3,227.0**	2,768.2
Funded status	**(3,646.5)**	(3,393.0)	**1,473.3**	1,166.8
Unrecognized net actuarial (gain) loss	**6,515.5**	6,177.6	**(349.1)**	(111.6)
Unrecognized prior service (benefit) cost	**15.4**	17.4	**(177.6)**	(236.4)
Net amount recognized	**$ 2,884.4**	$ 2,802.0	**$ 946.6**	$ 818.8
Amounts recognized in the consolidated balance sheet consisted of:				
Other noncurrent assets	**$ 299.6**	$ 163.3	**$ 1,697.0**	$ 1,381.3
Other current liabilities	**(67.9)**	(65.3)	**(7.4)**	(7.3)
Accrued retirement benefits	**(3,878.2)**	(3,491.0)	**(216.3)**	(207.2)
Accumulated other comprehensive (income) loss before income taxes	**6,530.9**	6,195.0	**(526.7)**	(348.0)
Net amount recognized	**$ 2,884.4**	$ 2,802.0	**$ 946.6**	$ 818.8

The unrecognized net actuarial loss (gain) and unrecognized prior service cost (benefit) have not yet been recognized in net periodic pension costs and were included in accumulated other comprehensive loss at December 31, 2020 and 2019.

Effective during the third quarter of 2020, we adopted a voluntary change in our method of applying an accounting principle for certain of our retirement benefit plans. The new accounting method changes the computation of expected returns on U.S. dollar denominated investment grade debt securities and derivatives in such plans from a calculated value that includes changes in the fair values over a period of five years to actual fair value. This change in accounting principle is preferable because changes in the fair value of this class of assets will be amortized into net periodic pension and retiree health cost sooner. No change is being made to the accounting principle for the other classes of pension assets. The impact of the adoption of this change in accounting method was not material to our historical and current consolidated financial statements.

A decrease in the discount rate was the primary driver for the $2.13 billion and $2.89 billion increase in the benefit obligation in 2020 and 2019, respectively.

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.

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

	Defined Benefit Pension Plans			Retiree Health Benefit Plans		
(Percents)	**2020**	**2019**	**2018**	**2020**	**2019**	**2018**
Discount rate for benefit obligation	**2.4 %**	3.0 %	4.0 %	**2.6 %**	3.3 %	4.4 %
Discount rate for net benefit costs	**3.0**	4.0	3.4	**3.3**	4.4	3.7
Rate of compensation increase for benefit obligation	**3.3**	3.3	3.4			
Rate of compensation increase for net benefit costs	**3.3**	3.4	3.4			
Expected return on plan assets for net benefit costs	**7.3**	7.4	7.4	**6.0**	6.0	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:

	2021	2022	2023	2024	2025	2026-2030
Defined benefit pension plans	$ 639.2	$ 635.3	$ 645.8	$ 673.1	$ 689.6	$ 3,800.8
Retiree health benefit plans	91.2	91.2	91.2	94.9	95.7	481.8

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

	2020	2019
Projected benefit obligation	**$ 15,770.7**	$ 14,039.7
Fair value of plan assets	**11,824.4**	10,483.4

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	
	2020	2019	2020	2019
Accumulated benefit obligation	**$ 14,682.3**	$ 13,063.7	**$ 223.8**	$ 214.4
Fair value of plan assets	**11,824.4**	10,483.4	**—**	—

The total accumulated benefit obligation for our defined benefit pension plans was $17.03 billion and $15.17 billion at December 31, 2020 and 2019, respectively.

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

	Defined Benefit Pension Plans			Retiree Health Benefit Plans		
	2020	2019	2018	2020	2019	2018
Components of net periodic (benefit) cost:						
Service cost	**$ 325.5**	$ 250.4	$ 292.7	**$ 40.8**	$ 36.3	$ 41.5
Interest cost	**425.8**	486.0	458.5	**43.7**	58.0	57.3
Expected return on plan assets	**(901.5)**	(839.6)	(842.1)	**(158.1)**	(144.3)	(177.9)
Amortization of prior service (benefit) cost	**4.5**	6.1	4.6	**(59.5)**	(62.9)	(79.5)
Recognized actuarial loss (gain)	**396.3**	284.9	332.5	**(3.0)**	1.9	6.1
Curtailment (gain) loss	**—**	2.2	1.3	**—**	—	(29.3)
Net periodic (benefit) cost	**$ 250.6**	$ 190.0	$ 247.5	**$ (136.1)**	$ (111.0)	$ (181.8)

The following represents the amounts recognized in other comprehensive income (loss) for the years ended December 31, 2020, 2019, and 2018:

	Defined Benefit Pension Plans			Retiree Health Benefit Plans		
	2020	2019	2018	2020	2019	2018
Actuarial gain (loss) arising during period	**$ (663.0)**	$ (1,461.0)	$ 182.8	**$ 238.8**	$ 246.1	$ 37.5
Plan amendments during period	**(2.2)**	—	(17.6)	**—**	—	14.1
Curtailment gain (loss)	**—**	19.0	45.2	**—**	—	(31.8)
Amortization of prior service (benefit) cost included in net income	**4.5**	6.1	4.6	**(59.5)**	(62.9)	(79.5)
Amortization of net actuarial loss included in net income	**396.3**	284.9	332.5	**(3.0)**	1.9	6.1
Foreign currency exchange rate changes and other	**(71.5)**	(7.7)	47.1	**2.4**	3.6	(0.1)
Total other comprehensive income (loss) during period	**$ (335.9)**	$ (1,158.7)	$ 594.6	**$ 178.7**	$ 188.7	$ (53.7)

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 $164.3 million, $145.2 million, and $132.6 million for the years ended December 31, 2020, 2019, and 2018, 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, 2020, 2019, and 2018 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 65 percent growth investments and 35 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, bank loans, 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 in fund-of-funds structures and directly into hedge funds. 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, special situations, private debt, and private real estate investments. 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 equity-like 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 public 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 a portion of the real estate holdings, 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, 2020 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.	$ 737.6	$ 476.1	$ —	$ 1.0	$ 260.5
International	2,635.8	1,102.3	—	—	1,533.5
Fixed income:					
Developed markets	4,301.3	2.9	3,179.2	—	1,119.2
Developed markets - repurchase agreements	(1,670.8)	—	(1,670.8)	—	—
Emerging markets	631.0	14.2	262.7	0.1	354.0
Private alternative investments:					
Hedge funds	2,661.3	—	—	—	2,661.3
Equity-like funds	2,844.7	—	—	16.9	2,827.8
Real estate	558.9	259.6	6.9	5.8	286.6
Other	1,879.2	60.4	301.2	18.0	1,499.6
Total	$ 14,579.0	$ 1,915.5	$ 2,079.2	$ 41.8	$ 10,542.5
Retiree Health Benefit Plans					
Public equity securities:					
U.S.	$ 68.3	$ 45.0	$ —	$ 0.1	$ 23.2
International	162.3	58.1	—	—	104.2
Fixed income:					
Developed markets	101.5	—	80.3	—	21.2
Emerging markets	53.5	—	24.7	—	28.8
Private alternative investments:					
Hedge funds	229.7	—	—	—	229.7
Equity-like funds	223.4	—	—	1.6	221.8
Cash value of trust owned insurance contract	2,204.6	—	2,204.6	—	—
Real estate	25.8	24.5	0.7	0.6	—
Other	157.9	14.1	21.1	1.7	121.0
Total	$ 3,227.0	$ 141.7	$ 2,331.4	$ 4.0	$ 749.9

[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, 2020. The activity in the Level 3 investments during the year ended December 31, 2020 was not material.

The fair values of our defined benefit pension plan and retiree health plan assets as of December 31, 2019 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.	$ 794.2	$ 532.4	$ —	$ —	$ 261.7
International	2,439.2	1,046.8	—	—	1,392.4
Fixed income:					
Developed markets	3,661.4	4.8	2,658.9	—	997.7
Developed markets - repurchase agreements	(1,659.1)	—	(1,659.1)	—	—
Emerging markets	648.0	18.5	277.4	4.1	348.0
Private alternative investments:					
Hedge funds	2,897.9	—	—	—	2,897.9
Equity-like funds	2,279.3	—	—	16.8	2,262.5
Real estate	570.3	166.2	—	—	404.1
Other	1,226.8	62.9	222.6	6.6	934.7
Total	$ 12,858.0	$ 1,831.7	$ 1,499.8	$ 27.5	$ 9,499.0
Retiree Health Benefit Plans					
Public equity securities:					
U.S.	$ 76.5	$ 52.1	$ —	$ —	$ 24.4
International	152.6	60.8	—	—	91.8
Fixed income:					
Developed markets	82.7	—	56.3	—	26.4
Emerging markets	58.5	—	27.0	0.4	31.1
Private alternative investments:					
Hedge funds	250.8	—	—	—	250.8
Equity-like funds	187.4	—	—	1.6	185.8
Cash value of trust owned insurance contract	1,832.2	—	1,832.2	—	—
Real estate	31.3	16.2	—	—	15.1
Other	96.2	11.4	7.9	0.7	76.2
Total	$ 2,768.2	$ 140.5	$ 1,923.4	$ 2.7	$ 701.6

[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, 2019. The activity in the Level 3 investments during the year ended December 31, 2019 was not material.

In 2021, we expect to contribute approximately $40 million to our defined benefit pension plans to satisfy minimum funding requirements for the year. We expect to contribute approximately $10 million in additional discretionary contributions in 2021.

Note 16: Contingencies

We are involved in various lawsuits, claims, government investigations and other legal proceedings that arise in the ordinary course of business. These claims or proceedings can involve various types of parties, including governments, competitors, customers, suppliers, service providers, licensees, employees, or shareholders, among others. These matters may involve patent infringement, antitrust, securities, pricing, sales and marketing practices, environmental, commercial, contractual rights, licensing obligations, health and safety matters, consumer fraud, employment matters, product liability and insurance coverage, among others. The resolution of these matters often develops over a long period of time and expectations can change as a result of new findings, rulings, appeals or settlement arrangements. Legal proceedings that are significant or that we believe could become significant or material are described below.

We believe the legal proceedings in which we are named as defendants are without merit and we are defending against them vigorously. 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 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.

Because of the nature of pharmaceutical products, it is possible that we could become subject to large numbers of additional product liability and related claims in the future. Due to a very restrictive market for product liability insurance, we are self-insured for product liability losses for all our currently and previously marketed products.

Patent Litigation

Alimta Patent Litigation

A number of manufacturers are seeking approvals in the U.S., a number of countries in Europe, and Japan to market generic forms of Alimta prior to the expiration of our vitamin regimen patents, alleging that those patents are invalid, not infringed, or both. We believe our Alimta vitamin regimen patents are valid and enforceable against these generic manufacturers. However, it is not possible to determine the ultimate outcome of the proceedings, and accordingly, we can provide no assurance that we will prevail. An unfavorable outcome in the U.S. could have a material adverse impact on our future consolidated results of operations and cash flows. We expect that a loss of exclusivity for Alimta in any of the below jurisdictions would result in a rapid and severe decline in future revenue for the product in the relevant market.

U.S. Patent Litigation

Alimta (pemetrexed) is protected by a vitamin regimen patent until 2021, plus pediatric exclusivity through May 2022.

In August 2017, we filed a lawsuit in the U.S. District Court for the Southern District of Indiana against Apotex Inc. (Apotex) alleging infringement of Alimta's vitamin regimen patent for its application to market a pemetrexed product. In December 2019, the U.S. District Court for the Southern District of Indiana granted our motion for summary judgment of infringement, and in December 2020, the U.S. Court of Appeals for

the Federal Circuit affirmed that ruling. Apotex did not request reconsideration or a rehearing of that ruling. However, Apotex could petition the U.S. Supreme Court to review the case.

In December 2019, we settled a lawsuit we filed against Eagle Pharmaceuticals, Inc. (Eagle) in response to its application to market a product using an alternative form of pemetrexed. Per the settlement agreement, Eagle has a limited initial entry into the market with its product starting February 2022 (up to an approximate three-week supply) and subsequent unlimited entry starting April 2022.

European Patent Litigation

Legal proceedings are ongoing regarding our Alimta patents in various national courts throughout Europe. We are aware that several companies have received approval to market generic versions of pemetrexed in major European markets and that generic competitors may choose to launch at risk. Following a final decision in the Supreme Court of Germany in July 2020 overturning the lower court and upholding the validity of our Alimta patent, several generics that were on the market at risk left. We have removed the remaining generics from the market by obtaining preliminary injunctions in our favor. In September 2020, the Paris Court of First Instance in France issued a final decision upholding the validity of our Alimta patent and found infringement by Fresenius Kabi France and Fresenius Kabi Groupe France's (collectively, Kabi) pemetrexed product. The court issued an injunction against Kabi and provisionally awarded us damages. In January 2021, that same court issued a preliminary injunction against Zentiva France S.A.S. (Zentiva), the last remaining company with a generic pemetrexed product on the French market, and provisionally awarded us damages. In October 2020, the Court of Appeal of the Netherlands overturned a lower court decision and ruled that our Alimta patent is valid and infringed and reinstated an injunction against Kabi, thereby removing Kabi's pemetrexed product from the Netherlands market. Kabi has appealed this decision to the Netherlands Supreme Court. Kabi's generic pemetrexed product was the only at risk generic on the market in the Netherlands.

Our vitamin regimen patents have also been challenged in other smaller European jurisdictions. We will continue to seek to remove any generic pemetrexed products launched at risk in other European markets, seek damages with respect to such launches, and defend our patents against validity challenges.

Japanese Administrative Proceedings

In October 2020, the Japanese Patent Office (JPO) issued notices closing Hopira Inc.'s (Hospira) invalidation against our Japanese Alimta patents. As a result, Hospira filed a withdrawal notice with the JPO and the JPO accepted the withdrawal in November. This matter is now closed.

Emgality Patent Litigation

In September 2018, we were named as a defendant in litigation filed by Teva Pharmaceuticals International GMBH and Teva Pharmaceuticals USA, Inc. (collectively, Teva) in the U.S. District Court for the District of Massachusetts seeking a ruling that various claims in nine different Teva patents would be infringed by our launch and continued sales of Emgality for the prevention of migraine in adults. Trial is expected in December 2021. Separately, the U.S. Patent and Trademark Office (USPTO) granted our request to initiate an *inter partes review* (IPR) to reexamine the validity of the nine Teva patents asserted against us in the litigation. In February 2020, the USPTO ruled in our favor and found that the claims asserted against us in six of Teva's nine patents were invalid. In March 2020, the USPTO ruled against us on the remaining three Teva patents, finding that we failed to show that the remaining three patents were unpatentable based on the subset of invalidity arguments available in an IPR proceeding. In April 2020, we appealed the USPTO's March 2020 ruling, and Teva appealed the USPTO's February 2020 ruling to the U.S. Court of Appeals for the Federal Circuit. The district court litigation will proceed in parallel with the IPR appeals.

Jardiance Patent Litigation

In November 2018, Boehringer Ingelheim (BI), our partner in marketing and development of Jardiance, initiated U.S. patent litigation in the U.S. District Court of Delaware alleging infringement arising from Alkem Laboratories Ltd.'s (Alkem) and Ascend Laboratories, LLC's (Ascend) submissions of Abbreviated New Drug Applications (ANDA) seeking approval to market generic versions of Jardiance, Glyxambi, and Synjardy in accordance with the procedures set out in the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act). Particularly with respect to Jardiance, Alkem's and Ascend's ANDAs seek approval to market generic versions of Jardiance prior to the expiration of the relevant patents, and allege that certain patents, including in some allegations the compound patent, are invalid or would not be infringed. We are not a party to this litigation. Trial was scheduled for April 2021 but has been postponed.

Taltz Patent Litigation

In July 2018, we were named as a defendant in litigation filed by Genentech, Inc. (Genentech) in Germany seeking a ruling that Genentech's patent would be infringed by our continued sales of Taltz in Germany. After it sold its patent rights to Novartis Pharma AG (Novartis) in June 2020, Genentech withdrew its infringement litigation and Novartis subsequently filed litigation against us in Germany asserting infringement based on sales of Taltz. In January 2021, we entered into a settlement agreement with Novartis whereby all pending litigation in Germany related to the Taltz patent has been withdrawn and this matter has concluded. We were also named in litigation in the U.K. in which Genentech asserted similar claims regarding its corresponding U.K. patent. Novartis purchased Genentech's U.K. patent rights for Taltz, sought substitution for Genentech in the U.K. litigation and then sought dismissal of all appeals. Orders to this effect were issued by the Patents Court and Court of Appeal in November 2020 and these matters have concluded.

Zyprexa Canada Patent Litigation

Beginning in the mid-2000's, several generic companies in Canada challenged the validity of our Zyprexa compound patent. In 2012, the Canadian Federal Court of Appeals denied our appeal of a lower court's decision that certain patent claims were invalid for lack of utility. In 2013, Apotex Inc. and Apotex Pharmachem Inc. (collectively, Apotex) brought claims against us in the Ontario Superior Court of Justice at Toronto for damages related to our enforcement of the Zyprexa compound patent under Canadian regulations governing patented drugs. Apotex seeks compensation based on novel legal theories under the Statute of Monopolies, Trade-Mark Act, and common law. Trial is expected in 2021 or 2022.

Product Liability Litigation

Actos® Product Liability

We are named along with Takeda Chemical Industries, Ltd. and Takeda affiliates (collectively, Takeda) as a defendant in four purported product liability class actions in Canada related to Actos, which we commercialized with Takeda in Canada until 2009, including one in Ontario filed December 2011 (*Casseres et al. v. Takeda Pharmaceutical North America, Inc., et al.*), one in Quebec filed July 2012 (*Whyte et al. v. Eli Lilly et al.*), one in Saskatchewan filed November 2017 (*Weiler v. Takeda Canada Inc. et al.*), and one in Alberta filed January 2013 (*Epp v. Takeda Canada Inc. et al.*). In general, plaintiffs in these actions alleged that Actos caused or contributed to their bladder cancer.

Byetta® Product Liability

First initiated in March 2009, we are named as a defendant in approximately 570 Byetta product liability lawsuits in the U.S. involving approximately 810 plaintiffs. Approximately 55 of these lawsuits, covering about 285 plaintiffs, are filed in California state court and coordinated in a Los Angeles Superior Court. Approximately 515 of the lawsuits, covering about 515 plaintiffs, are filed in federal court, the majority of which are coordinated in a multi-district litigation (MDL) in the U.S. District Court for the Southern District of California. Three lawsuits, representing approximately four plaintiffs, have also been filed in various state courts. Approximately 565 of the lawsuits, involving approximately 800 plaintiffs, contain allegations that Byetta caused or contributed to the plaintiffs' cancer (primarily pancreatic cancer or thyroid cancer); while six plaintiffs allege Byetta caused or contributed to pancreatitis. In addition, one case alleges that Byetta caused or contributed to ampullary cancer. The federal and state trial courts granted summary judgment in favor of us and our co-defendants on the claims alleging pancreatic cancer. The plaintiffs appealed those rulings. In November 2017, the U.S. Court of Appeals for the Ninth Circuit reversed the U.S. District Court's grant of summary judgment based on that court's discovery rulings and remanded the cases for further proceedings. In November 2018, the California Court of Appeal reversed the state court's grant of summary judgment based on that court's discovery rulings and remanded for further proceedings. We are aware of approximately 20 additional claimants who have not yet filed suit. These additional claims allege damages for pancreatic cancer or thyroid cancer.

Cialis Product Liability

First initiated in August 2015, we are named as a defendant in approximately 350 Cialis product liability lawsuits in the U.S. These cases, many of which were originally filed in various federal courts, contain allegations that Cialis caused or contributed to the plaintiffs' cancer (melanoma). In December 2016, the Judicial Panel on Multidistrict Litigation (JPML) granted the plaintiffs' petition to have filed cases and an unspecified number of future cases coordinated into a federal multidistrict litigation (MDL) in the U.S. District Court for the Northern District of California, alongside an existing coordinated proceeding involving Viagra®. The JPML ordered the transfer of the existing cases to the now-renamed MDL *In re: Viagra (Sildenafil Citrate) and Cialis (Tadalafil) Products Liability Litigation*. In April 2020, the MDL court granted summary judgment to the defendants on all of the claims brought against them by the plaintiffs. In May 2020, plaintiffs filed an appeal in the U.S. Court of Appeals for the Ninth Circuit.

Jardiance Product Liability

First initiated in January 2019, we and Boehringer Ingelheim Pharmaceuticals, Inc., a subsidiary of BI, have been named as a defendant in approximately 95 product liability lawsuits in the U.S., mostly in Stamford Superior Court in Connecticut, alleging that Jardiance caused or contributed to plaintiffs' Fournier's gangrene. Our agreement with BI calls for BI to defend and indemnify us against any damages, costs, expenses, and certain other losses with respect to product liability claims in accordance with the terms of the agreement.

Environmental Proceedings

Under the Comprehensive Environmental Response, Compensation, and Liability Act, commonly known as "Superfund," we have been designated as one of several potentially responsible parties with respect to the cleanup of fewer than 10 sites. Under Superfund, each responsible party may be jointly and severally liable for the entire amount of the cleanup.

Other Matters

340B Litigation

We are the plaintiff in a lawsuit filed in January 2021 in the U.S. District Court for the Southern District of Indiana against the U.S. Department of Health and Human Services (HHS), the Secretary of HHS, the Health Resources and Services Administration (HRSA), and the Administrator of HRSA. The lawsuit challenges the HHS's December 30, 2020 advisory opinion stating that drug manufacturers are required to deliver discounts under the 340B program to all contract pharmacies. We seek a declaratory judgment that the defendants violated the Administrative Procedures Act and the U.S. Constitution, a preliminary injunction enjoining implementation of the alternative dispute resolution process created by defendants and, with it, their application of the advisory opinion, and other related relief. A hearing on our motion for preliminary injunction has been scheduled for February 26, 2021.

In January 2021, we, along with other pharmaceutical manufacturers, were named as a defendant in a petition currently pending before the HHS Administration Dispute Resolution Panel. Petitioner seeks declaratory and other injunctive relief related to the 340B program.

Brazil Litigation – Cosmopolis Facility

Labor Attorney Litigation

First initiated in 2008, our subsidiary in Brazil, Eli Lilly do Brasil Limitada (Lilly Brasil), is named in a lawsuit brought by the Labor Attorney for the 15th Region in the Labor Court of Paulinia, State of Sao Paulo, Brazil, alleging possible harm to employees and former employees caused by exposure to heavy metals at a former Lilly Brasil manufacturing facility in Cosmopolis, Brazil, operated by the company between 1977 and 2003. In May 2014, the labor court judge ruled against Lilly Brasil, ordering it to undertake several actions of unspecified financial impact, including paying lifetime health coverage for the employees and contractors who worked at the Cosmopolis facility more than six months during the affected years and their children born during and after this period. We appealed this decision. In July 2018, the appeals court affirmed the labor court's ruling with a liquidated award of 300 million Brazilian real (for moral damages, donation of equipment, and creation of a foundation) which, adjusted for inflation and interest using the current Central Bank of Brazil's special system of clearance and custody rate (SELIC), is approximately 950 million Brazilian real (approximately $180 million as of December 31, 2020). The appeals court restricted the broad health coverage awarded by the labor court to health problems that claimants could show arose from exposure to the alleged contamination. In August 2019, Lilly Brasil filed an appeal to the superior labor court. In September 2019, the appeals court stayed a number of elements of its prior decision, including the obligation to provide health coverage for contractors, their children, and children of employees who worked at the Cosmopolis facility, pending the determination of Lilly Brasil's appeal to the superior labor court. The cost of any such health coverage has not been determined.

In June 2019, the Labor Attorney filed an application in the labor court for enforcement of the healthcare coverage granted by the appeals court in its July 2018 ruling and requested restrictions on Lilly Brasil's assets in Brazil. In July 2019, the labor court issued a ruling requiring either a freeze of Lilly Brasil's immovable property or, alternatively, a security deposit of 500 million Brazilian real. Lilly Brasil filed a writ of mandamus challenging this ruling, but the court has stayed its decision on this writ and instead directed the parties to attend conciliation hearings, a process that concluded unsuccessfully in September 2020. Consequently, the partial stay of the proceedings relating to Lilly Brasil's application to appeal in the main proceedings has been lifted. In addition, the Labor Attorney's application for preliminary enforcement of the July 2018 healthcare coverage ruling was granted. As the conciliation hearings have been unsuccessful, we have filed a brief to strike the Labor Attorney's application to enforce the previous healthcare coverage. Lilly Brasil is currently awaiting a determination as to whether its application seeking leave to appeal to the superior labor court has been successful.

Individual Former Employee Litigation

First initiated in 2003, we have also been 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.

China NDRC Antitrust Matter

The competition authority in China has investigated our distributor pricing practices in China in connection with a broader inquiry into pharmaceutical industry pricing. We have cooperated with this investigation.

Eastern District of Pennsylvania Pricing (Average Manufacturer Price) Inquiry

In November 2014, we, along with another pharmaceutical manufacturer, are named as co-defendants in *United States et al. ex rel. Streck v. Takeda Pharm. Am., Inc., et al.*, which was filed in November 2014 and unsealed in the U.S. District Court for the Northern District of Illinois. The complaint alleges that the defendants should have treated certain credits from distributors as retroactive price increases and included such increases in calculating average manufacturer prices. Trial is scheduled for February 2022.

Health Choice Alliance

We are named as a defendant in a lawsuit filed in June 2017 in the U.S. District Court for the Eastern District of Texas seeking damages under the federal anti-kickback statute and state and federal false claims acts for certain patient support programs related to our products Humalog, Humulin, and Forteo. In September 2019, the U.S. District Court granted the U.S. Department of Justice's motion to dismiss the relator's second amended complaint. In January 2020, the relator appealed the District Court's dismissal to the U.S. Court of Appeals for the Fifth Circuit. We are also named as a defendant in two similar lawsuits filed in Texas and New Jersey state courts in October 2019 seeking damages under the Texas Medicaid Fraud Prevention Act and New Jersey Medicaid False Claims Act, respectively. In November 2020, the Texas state court action was stayed pending a decision by the U.S. Court of Appeals for the Fifth Circuit on the aforementioned District Court appeal.

Pricing Litigation, Investigations, and Inquires

Litigation

In December 2017, we, along with Sanofi-Aventis U.S. LLC (Sanofi) and Novo Nordisk, Inc. (Novo Nordisk) were named as defendants in a consolidated purported class action lawsuit, *In re. Insulin Pricing Litigation*, in the U.S. District Court for the District of New Jersey relating to insulin pricing seeking damages under various state consumer protection laws and the Federal Racketeer Influenced and Corrupt Organization Act (federal RICO Act). Separately, in February 2018, we, along with Sanofi and Novo Nordisk, were named as defendants in *MSP Recovery Claims, Series, LLC et al. v. Sanofi Aventis U.S. LLC et al.*, in the same court, seeking damages under various state consumer protection laws, common law fraud, unjust enrichment, and the federal RICO Act. In both *In re. Insulin Pricing Litigation* and the *MSP Recovery Claims* litigation, the court dismissed claims under the federal RICO Act and certain state laws. Also, filed in the same court in November 2020, we, along with Sanofi, Novo Nordisk, CVS, Express Scripts, and Optum, have been sued in a purported class action, *FWK Holdings, LLC v. Novo Nordisk Inc., et al.*, for alleged violations of the federal RICO Act as well as the New Jersey RICO Act and anti-trust law. That same group of defendants, along with Medco Health and United Health Group, also have been sued in other purported class actions in the same court, *Rochester Drug Co-Operative Inc. v. Eli Lilly & Co. et al.* and *Value Drug Co. v. Eli Lilly & Co. et al.* both initiated in March 2020, for alleged violations of the federal RICO Act. In September 2020, the U.S. District Court for the District of New Jersey granted plaintiffs' motion to consolidate *FWK Holdings, LLC v. Novo Nordisk Inc., et al.*, *Rochester Drug Co-Operative Inc. v. Eli Lilly & Co. et al.*, and *Value Drug Co. v. Eli Lilly & Co. et al.*

In October 2018, the Minnesota Attorney General's Office initiated litigation against us, Sanofi, and Novo Nordisk, *State of Minnesota v. Sanofi-Aventis U.S. LLC et al.,* in the U.S. District Court for the District of New Jersey, alleging unjust enrichment, violations of various Minnesota state consumer protection laws, and the federal RICO Act. Additionally, in May 2019, the Kentucky Attorney General's Office filed a complaint against us, Sanofi, and Novo Nordisk, *Commonwealth of Kentucky v. Novo Nordisk, Inc. et al.*, in Kentucky state court, alleging violations of the Kentucky consumer protection law, false advertising, and unjust enrichment. In November 2019, Harris County in Texas initiated litigation against us, Sanofi, Novo Nordisk, Express Scripts, CVS, Optum, and Aetna, *County of Harris Texas v. Eli Lilly & Co., et al.*, in federal court in the Southern District of Texas alleging violations of the federal RICO Act, federal and state anti-trust law, and the state deceptive trade practices-consumer protection act. Harris County also alleges common law claims such as fraud, unjust enrichment, and civil conspiracy. This lawsuit relates to our insulin products as well as Trulicity.

Investigations, Subpoenas, and Inquiries

We received a subpoena from the New York and Vermont Attorney General Offices and civil investigative demands from the Washington, New Mexico, and Colorado Attorney General Offices relating to the pricing and sale of our insulin products. The Offices of the Attorney General in Mississippi, Washington D.C., California, Florida, Hawaii, and Nevada have requested information relating to the pricing and sale of our insulin products. We also received interrogatories and a subpoena from the California Attorney General's Office regarding our competition in the long-acting insulin market. We received two requests from the House of Representatives' Committee on Energy and Commerce and a request from the Senate's Committee on Health, Education, Labor, and Pensions seeking certain information related to the pricing of insulin products, among other issues. We also received requests from the House of Representatives' Committee on Oversight and Reform and the Senate's Committee on Finance, which seek detailed commercial information and business records. In January 2021, the Senate's Committee on Finance released a report summarizing the findings of its investigation. We are cooperating with all of these aforementioned investigations, subpoenas, and inquiries.

Research Corporation Technologies, Inc.

In April 2016, we were named as a defendant in litigation filed by Research Corporation Technologies, Inc. (RCT) in the U.S. District Court for the District of Arizona. RCT is seeking damages for breach of contract, unjust enrichment, and conversion related to processes used to manufacture certain products, including Humalog and Humulin. A trial date has not been set.

Note 17: 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, 2018 [1]	$ (1,191.7)	$ 113.5	$ (4,311.3)	$ (234.3)	$ (71.1)	$ (5,694.9)
Reclassification due to adoption of new accounting standard[2]	—	(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
Balance at December 31, 2018[3]	(1,569.7)	(22.1)	(3,852.7)	(238.9)	(56.8)	(5,740.2)
Other comprehensive income (loss) before reclassifications	(46.2)	28.9	(967.6)	14.5	(27.2)	(997.6)
Net amount reclassified from accumulated other comprehensive loss	(62.1)	(1.9)	181.7	12.5	84.0	214.2
Net other comprehensive income (loss)	(108.3)	27.0	(785.9)	27.0	56.8	(783.4)
Balance at December 31, 2019	(1,678.0)	4.9	(4,638.6)	(211.9)	—	(6,523.6)
Other comprehensive income (loss) before reclassifications	**250.5**	**6.8**	**(379.7)**	**(133.8)**	**—**	**(256.2)**
Net amount reclassified from accumulated other comprehensive loss	**—**	**3.1**	**267.3**	**13.0**	**—**	**283.4**
Net other comprehensive income (loss)	**250.5**	**9.9**	**(112.4)**	**(120.8)**	**—**	**27.2**
Ending balance at December 31, 2020	**$ (1,427.5)**	**$ 14.8**	**$ (4,751.0)**	**$ (332.7)**	**$ —**	**$ (6,496.4)**

[1] Accumulated other comprehensive loss as of January 1, 2018 consists of $5.72 billion of accumulated other comprehensive loss attributable to controlling interest and $23.7 million of accumulated other comprehensive income attributable to noncontrolling interest.

[2] This reclassification consists of $105.2 million of accumulated other comprehensive income attributable to controlling interest and $23.7 million of accumulated other comprehensive income attributable to noncontrolling interest. Refer to Note 1 for further details regarding the reclassification due to the adoption of ASU 2016-01.

[3] 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)	2020	2019	2018
Foreign currency translation gains/losses	**$ 128.3**	$ (18.4)	$ 51.6
Unrealized net gains/losses on securities	**(4.3)**	(7.4)	2.1
Defined benefit pension and retiree health benefit plans	**44.8**	184.1	(85.3)
Effective portion of cash flow hedges	**32.1**	(7.3)	1.3
Benefit/(provision) for income taxes allocated to other comprehensive income (loss) items	**$ 200.9**	$ 151.0	$ (30.3)

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:

	Year Ended December 31,			
Details about Accumulated Other Comprehensive Loss Components	2020	2019	2018	Affected Line Item in the Consolidated Statements of Operations
Amortization of retirement benefit items:				
Prior service benefits, net	**$ (55.0)**	$ (56.8)	$ (74.9)	Other—net, (income) expense
Actuarial losses	**393.3**	286.8	338.6	Other—net, (income) expense
Total before tax	**338.3**	230.0	263.7	
Tax benefit	**(71.0)**	(48.3)	(55.8)	Income taxes
Net of tax	**267.3**	181.7	207.9	
Other, net of tax	**16.1**	(51.5)	(19.5)	Other—net, (income) expense
Reclassifications from continuing operations (net of tax)	**283.4**	130.2	188.4	
Reclassifications from discontinued operations (net of tax)	**—**	84.0	2.1	Net income from discontinued operations
Total reclassifications for the period, net of tax	**$ 283.4**	$ 214.2	$ 190.5	

Note 18: Other–Net, (Income) Expense

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

	2020	2019	2018
Interest expense	**$ 359.6**	$ 400.6	$ 242.5
Interest income	**(33.0)**	(80.4)	(159.3)
Debt extinguishment loss (Note 11)	**—**	252.5	—
Gain on sale of antibiotic business in China (Note 3)	**—**	(309.8)	—
Retirement benefit plans	**(251.8)**	(209.9)	(240.5)
Other (income) expense	**(1,246.7)**	(344.6)	11.7
Other–net, (income) expense	**$ (1,171.9)**	$ (291.6)	$ (145.6)

For the years ended December 31, 2020 and 2019, other income was primarily related to net gains on investments (Note 7).

Note 19: Discontinued Operations

On September 24, 2018, Elanco completed its initial public offering (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.

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 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. We completed the disposition of our remaining 80.2 percent ownership of Elanco common stock through a tax-free exchange offer that closed on March 11, 2019 (the disposition date). The earnings attributable to the divested, noncontrolling interest for the period from the IPO until disposition were not material.

As a result of the disposition, 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 financial statements for all periods presented.

The following table sets summarizes revenue and net income from discontinued operations:

	2019	2018
Revenue from discontinued operations	$ 580.0	$ 3,062.4
Net income from discontinued operations	3,680.5	81.4

The gain related to the disposition of Elanco in the consolidated statement of cash flows includes the operating results of Elanco through the disposition date, which were not material. Net cash flows of our discontinued operations for operating activities were not material for the year ended December 31, 2019. Net cash provided by operating activities related to our discontinued operations was approximately $500 million for the year ended December 31, 2018. The net cash flows of our discontinued operations for investing activities were not material for any period presented.

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

are generally to be provided over 24 months from 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 available on our lilly.com website and on the internal LillyNow website to enable reporting of 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 our annual report on Form 10-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. It is the audit committee's responsibility to appoint an independent registered public accounting firm subject to shareholder ratification, pre-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, operate under a code of conduct and are subject to 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 "Internal Control—Integrated Framework" (2013) 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, 2020. 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 effectiveness of internal control over financial reporting as of December 31, 2020 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their attestation report, which appears herein. Their responsibility is to evaluate whether internal control over financial reporting was designed and operating effectively.

David A. Ricks	Anat Ashkenazi
Chairman, President, and Chief Executive Officer	*Senior Vice President and Chief Financial Officer*

February 17, 2021

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, 2020 and 2019, 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, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, 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, 2020, 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 17, 2021 expressed an unqualified opinion thereon.

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.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Medicaid, Managed Care, and Medicare sales rebate accruals

Description of the Matter

As described in Note 2 to the consolidated financial statements under the caption "Net Product Revenue," the Company establishes provisions for sales rebate and discounts in the same period as the related sales occur. At December 31, 2020 the Company had $5,853.0 million in sales rebate and discount accruals. A large portion of these accruals are rebates associated with sales in the United States for which payment for purchase of the product is covered by Medicaid, Managed Care, and Medicare.

Auditing the Medicaid, Managed Care, and Medicare sales rebate and discount liabilities is challenging because of the subjectivity of certain assumptions required to estimate the rebate liabilities. In calculating the appropriate accrual amount, the Company considers historical Medicaid, Managed Care, and Medicare rebate payments by product as a percentage of their historical sales as well as any significant changes in sales trends, the lag in payment timing, an evaluation of the current Medicaid and Medicare laws and interpretations, the percentage of products that are sold via Medicaid, Managed Care, and Medicare, and product pricing. For Medicaid, there is significant complexity associated with calculating the legislated Medicaid rebates. Management utilizes employees with legislative experience and knowledge in developing assumptions used to calculate Medicaid rebates. Similarly, for Managed Care and Medicare, given variability in prescription drug costs, continued historical year over year increases in enrollees and variability in prescription data, historical rebate information may not be predictive for management to estimate the rebate accrual and thus, management supplements its historical data analysis with qualitative adjustments based upon current utilization.

How We Addressed the Matter in Our Audit

We tested the Company's controls addressing the identified risks of material misstatement related to the valuation of the sales rebate and discount liabilities. This included testing controls over management's review of the significant assumptions used to calculate the Medicaid, Managed Care, and Medicare rebate liabilities, including the significant assumptions discussed above. This testing also included management's control to compare actual activity to forecasted activity and controls to ensure the data used to evaluate the significant assumptions was complete and accurate.

Our audit procedures included, among others, evaluating for reasonableness the significant assumptions in light of economic trends, product profiles, and other regulatory factors. Our testing involved assessing the historical accuracy of management's estimates by comparing actual activity to previous estimates and performing analytical procedures, based on internal and external data sources, to evaluate the completeness of the reserves. Additionally, our procedures included reviewing a sample of contracts, testing a sample of rebate payments and testing the underlying data used in management's evaluation. For Medicaid, we involved our professional with an understanding of the statutory reimbursement requirements to assess the consistency of the Company's calculation methodologies with the applicable government regulations and policy. For Medicare we evaluated the reasonableness of assumptions made by management in estimating the Medicare coverage gap liability.

Retirement Benefits - Valuation of Alternative Investments

Description of the Matter

As described in Note 15 to the consolidated financial statements under the caption "Benefit Plan Investments," the Company's benefit plan investment policies are set with specific consideration of return and risk requirements in relationship to the respective liabilities. At December 31, 2020 the Company had $17,806.0 million in plan assets related to the defined benefit pension plans and retiree health benefit plans. Approximately 33% of the total pension and retiree health assets are in hedge funds and private equity-like investment funds ("alternative investments"). These alternative investments are valued using significant unobservable inputs or are valued at net asset value (NAV) reported by the counterparty, adjusted as necessary.

Auditing the fair value of these alternative investments is challenging because of the higher estimation uncertainty of the inputs to the fair value calculations, including the underlying net asset values ("NAVs"), discounted cash flow valuations, comparable market valuations, and adjustments for currency, credit, liquidity and other risks. Additionally, certain information regarding the fair value of these alternative investments is based on unaudited information available to management at the time of valuation.

How We Addressed the Matter in Our Audit	We tested the Company's controls addressing the risks of material misstatement relating to valuation of alternative investments. This included testing management's review controls over alternative investment valuation, which included a comparison of returns to benchmarks and in-person or telephonic meetings with investment firms to discuss valuation policies and procedures, as well as portfolio performance. Our audit procedures included, among others, comparing fund returns to selected relevant benchmarks and understanding variations, obtaining the latest audited financial statements and comparing to the Company's estimated fair values and reconciling any differences. We also inquired of management about changes to the investment portfolio and/or related investment strategies and considerations. We assessed the historical accuracy of management's estimates by comparing actual activity to previous estimates. We evaluated for contrary evidence by confirming the fair value of the investments and ownership interest directly with the trustees and a sample of managers at year end.

/s/ Ernst & Young LLP

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

Indianapolis, Indiana

February 17, 2021

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, 2020, 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, 2020, 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, 2020 and 2019, 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, 2020, and the related notes and our report dated February 17, 2021 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.

/s/ Ernst & Young LLP

Indianapolis, Indiana

February 17, 2021

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Under applicable Securities and Exchange Commission (SEC) regulations, management of a reporting company, with the participation of the principal executive officer and principal financial officer, must periodically evaluate the company's "disclosure controls and procedures," which are defined generally as controls and other procedures designed to ensure that information required to be disclosed by the reporting company in its periodic reports filed with the SEC (such as this Form 10-K) is recorded, processed, summarized, and reported on a timely basis.

Our management, with the participation of David A. Ricks, president and chief executive officer, and Anat Ashkenazi, senior vice president and chief financial officer, evaluated our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31, 2020, and concluded that they were effective.

Management's Report on Internal Control over Financial Reporting

Mr. Ricks and Ms. Ashkenazi provided a report on behalf of management on our internal control over financial reporting, in which management concluded that the company's internal control over financial reporting is effective at December 31, 2020 based on the framework in "Internal Control—Integrated Framework" (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Our internal control over financial reporting is 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 in the United States. Due to the inherent limitations, no evaluation over internal control can provide absolute assurance that no material misstatements or fraud exist.

In addition, Ernst & Young LLP, the company's independent registered public accounting firm, issued an attestation report on the company's internal control over financial reporting as of December 31, 2020.

You can find the full text of management's report and Ernst & Young's attestation report in Item 8.

Changes in Internal Control over Financial Reporting

During the fourth quarter of 2020, there were no changes in our internal control over financial reporting that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

Part III

Item 10. Directors, Executive Officers, and Corporate Governance

Directors and Executive Officers

Information relating to our board of directors is found in our Definitive Proxy Statement, to be dated on or about March 19, 2021 (Proxy Statement), under “Governance - Board Operations and Governance” and is incorporated in this Annual Report on Form 10-K by reference.

Information relating to our executive officers is found at Item 1, “Business - Executive Officers of the Company” and is incorporated by reference herein.

Code of Ethics

Information relating to our code of ethics is found in our Proxy Statement under “Governance - Board Oversight of Strategy, Compliance, and Risk Management - Code of Ethics” and is incorporated in this Annual Report on Form 10-K by reference.

Corporate Governance

Information about the procedures by which shareholders can recommend nominees to our board of directors is found in our Proxy Statement under “Shareholder Engagement on Governance Issues - Shareholder Recommendations and Nominations for Director Candidates" is incorporated in this Annual Report on Form 10-K by reference.

The board of directors has appointed an audit committee consisting entirely of independent directors in accordance with applicable SEC and New York Stock Exchange requirements for audit committees. Information about our audit committee is found in our Proxy Statement under “Governance - Membership and Meetings of the Board and Its Committees - Audit Committee” and is incorporated in this Annual Report on Form 10-K by reference.

Item 11. Executive Compensation

Information on director compensation, executive compensation, and compensation committee matters can be found in the Proxy Statement under “Governance - Director Compensation,” “- Membership and Meetings of the Board and Its Committees - Compensation Committee,” “Compensation - Compensation Discussion and Analysis,” and “- Executive Compensation.” Such information is incorporated in this Annual Report on Form 10-K by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

Security Ownership of Certain Beneficial Owners and Management

Information relating to ownership of the company's common stock by management and by persons known by the company to be the beneficial owners of more than five percent of the outstanding shares of common stock is found in the Proxy Statement under "Ownership of Company Stock" and incorporated in this Annual Report on Form 10-K by reference.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table presents information as of December 31, 2020 regarding the company's compensation plans under which shares of the company's common stock have been authorized for issuance.

Plan category	(a) Number of securities to be issued upon exercise of outstanding options, warrants, and rights [1]	(b) Weighted-average exercise price of outstanding options, warrants, and rights	(c) Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders	—	$ —	49,510,908
Equity compensation plan not approved by security holders	—	—	—
Total	—	—	49,510,908

[1] 9,192,921 shares are underlying outstanding equity awards other than options.

Item 13. Certain Relationships and Related Transactions, and Director Independence

Related Person Transactions

Information relating to the policies and procedures for approval of related person transactions by our board of directors can be found in the Proxy Statement under "Governance - Highlights of the Company's Corporate Governance - Conflicts of Interest and Transactions with Related Persons." Such information is incorporated in this Annual Report on Form 10-K by reference.

Director Independence

Information relating to director independence can be found in the Proxy Statement under "Governance - Director Independence" and is incorporated in this Annual Report on Form 10-K by reference.

Item 14. Principal Accountant Fees and Services

Information related to the fees and services of our principal independent accountants, Ernst & Young LLP, can be found in the Proxy Statement under "Audit Matters - Item 3. Ratification of the Appointment of the Independent Auditor - Audit Committee Report - Services Performed by the Independent Auditor" and "- Independent Auditor Fees." Such information is incorporated in this Annual Report on Form 10-K by reference.

Item 15. Exhibits and Financial Statement Schedules

(a)1. Financial Statements

The following consolidated financial statements of the company and its subsidiaries are found at Item 8:

- Consolidated Statements of Operations—Years Ended December 31, 2020, 2019, and 2018
- Consolidated Statements of Comprehensive Income (Loss)—Years Ended December 31, 2020, 2019, and 2018
- Consolidated Balance Sheets—December 31, 2020 and 2019
- Consolidated Statements of Shareholders' Equity—Years Ended December 31, 2020, 2019, and 2018
- Consolidated Statements of Cash Flows—Years Ended December 31, 2020, 2019, and 2018
- Notes to Consolidated Financial Statements

(a)2. Financial Statement Schedules

The consolidated financial statement schedules of the company and its subsidiaries have been omitted because they are not required, are inapplicable, or are adequately explained in the financial statements.

Financial statements of interests of 50 percent or less, which are accounted for by the equity method, have been omitted because they do not, considered in the aggregate as a single subsidiary, constitute a significant subsidiary.

(a)3. Exhibits

2.1	Agreement and Plan of Merger, dated January 5, 2019, among the Company, Bowfin Acquisition Corporation and Loxo Oncology, Inc.
3.1	Amended Articles of Incorporation
3.2	Bylaws, as amended
4.1	Indenture, dated February 1, 1991, between the Company and Deutsche Bank Trust Company Americas, as successor trustee to Citibank, N.A., as Trustee
4.2	Tripartite Agreement dated September 13, 2007, appointing Deutsche Bank Trust Company Americas as Successor Trustee under the Indenture listed in Exhibit 4.1
4.3	Description of the Company's Common Stock
4.4	Description of the Company's 1.000% Notes due 2022, 1.625% Notes due 2026, and 2.125% Notes due 2030
4.5	Description of the Company's 6.77% Notes due 2036
4.6	Description of the Company's 7 1/8% Notes due 2025
4.7	Description of the Company's 0.625% Notes due 2031 and 1.700% Notes due 2049
10.1	Amended and Restated 2002 Lilly Stock Plan[(1)]
10.2	Form of Performance Award under the 2002 Lilly Stock Plan[(1)]
10.3	Form of Performance Award under the 2002 Lilly Stock Plan (with non-compete)[(1)]
10.4	Form of Performance Award under the 2002 Lilly Stock Plan (non-executive officer)[(1)]
10.5	Form of Shareholder Value Award under the 2002 Lilly Stock Plan[(1)]
10.6	Form of Shareholder Value Award under the 2002 Lilly Stock Plan (with non-compete)[(1)]
10.7	Form of Shareholder Value Award under the 2002 Lilly Stock Plan (non-executive officer)[(1)]
10.8	Form of Relative Value Award under the 2002 Lilly Stock Plan[(1)]
10.9	Form of Relative Value Award under the 2002 Lilly Stock Plan (with non-compete)[(1)]
10.10	Form of Restricted Stock Unit Award under the 2002 Lilly Stock Plan[(1)]
10.11	Restricted Stock Unit Award to Michael Harrington under the 2002 Lilly Stock Plan[(1)]
10.12	The Lilly Deferred Compensation Plan, as amended[(1)]
10.13	The Lilly Directors' Deferral Plan, as amended[(1)]
10.14	The Eli Lilly and Company Bonus Plan, as amended[(1)]
10.15	2007 Change in Control Severance Pay Plan for Select Employees, as amended[(1)]
21	List of Subsidiaries
23	Consent of Independent Registered Public Accounting Firm
31.1	Rule 13a-14(a) Certification of David A. Ricks, Chairman, President, and Chief Executive Officer
31.2	Rule 13a-14(a) Certification of Anat Ashkenazi, Senior Vice President and Chief Financial Officer
32	Section 1350 Certification
101	Interactive Data File
104	Cover Page Interactive Data File (formatted Inline XBRL and contained in Exhibit 101)

[(1)] Indicates management contract or compensatory plan.

Item 16. Form 10-K Summary

Not applicable.

Index to Exhibits

The following documents are filed as part of this report:

Exhibit		Location
2.1	Agreement and Plan of Merger, dated January 5, 2019, among the Company, Bowfin Acquisition Corporation and Loxo Oncology, Inc.	Incorporated by reference to Exhibit 2.1 to the Current Report on Form 8-K filed by Loxo Oncology, Inc. on January 7, 2019
3.1	Amended Articles of Incorporation	Incorporated by reference to Exhibit 3.1 to the Company's Annual Report on Form 10-K for the year ended December 31, 2013
3.2	Bylaws, as amended	Incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on February 9, 2021
4.1	Indenture, dated February 1, 1991, between the Company and Deutsche Bank Trust Company Americas, as successor trustee to Citibank, N.A., as Trustee	Incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-3, Registration No. 333-186979
4.2	Tripartite Agreement, dated September 13, 2007, appointing Deutsche Bank Trust Company Americas as Successor Trustee under the Indenture listed in Exhibit 4.1	Incorporated by reference to Exhibit 4.2 to the Company's Annual Report on Form 10-K for the year ended December 31, 2008
4.3	Description of the Company's Common Stock	Incorporated by reference to Exhibit 4.3 to the Company's Annual Report on Form 10-K for the year ended December 31, 2019
4.4	Description of the Company's 1.000% Notes due 2022, 1.625% Notes due 2026, and 2.125% Notes due 2030	Incorporated by reference to Exhibit 4.4 to the Company's Annual Report on Form 10-K for the year ended December 31, 2019
4.5	Description of the Company's 6.77% Notes due 2036	Incorporated by reference to Exhibit 4.5 to the Company's Annual Report on Form 10-K for the year ended December 31, 2019
4.6	Description of the Company's 7 1/8%	Incorporated by reference to Exhibit

10.6	Form of Shareholder Value Award under the 2002 Lilly Stock Plan (with non-compete)	Attached
10.7	Form of Shareholder Value Award under the 2002 Lilly Stock Plan (non-executive officer)	Attached
10.8	Form of Relative Value Award under the 2002 Lilly Stock Plan	Attached
10.9	Form of Relative Value Award under the 2002 Lilly Stock Plan (with non-compete)	Attached
10.10	Form of Restricted Stock Unit Award under the 2002 Lilly Stock Plan	Attached
10.11	Restricted Stock Unit Award to Michael Harrington under the 2002 Lilly Stock Plan	Incorporated by reference to Exhibit 10.5 to the Company's Annual Report on Form 10-K for the year ended December 31, 2019
10.12	The Lilly Deferred Compensation Plan, as amended	Incorporated by reference to Exhibit 10.5 to the Company's annual report on Form 10-K for the year ended December 31, 2013
10.13	The Lilly Directors' Deferral Plan, as amended	Incorporated by reference to Exhibit 10 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2017
10.14	The Eli Lilly and Company Bonus Plan, as amended	Attached
10.15	2007 Change in Control Severance Pay Plan for Select Employees, as amended	Attached
21	List of Subsidiaries	Attached
23	Consent of Independent Registered Public Accounting Firm	Attached
31.1	Rule 13a-14(a) Certification of David A. Ricks, Chairman, President, and Chief Executive Officer	Attached
31.2	Rule 13a-14(a)	Attached

Signatures

Pursuant to the requirements of Section 13 or 15(d) 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

By /s/ David A. Ricks

David A. Ricks

Chairman, President, and Chief Executive Officer

February 17, 2021

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below on February 17, 2021 by the following persons on behalf of the Registrant and in the capacities indicated.

Signature	Title
/s/ David A. Ricks DAVID A. RICKS	Chairman, President, and Chief Executive Officer (principal executive officer)
/s/ Anat Ashkenazi ANAT ASHKENAZI	Senior Vice President and Chief Financial Officer (principal financial officer)
/s/ Donald A. Zakrowski DONALD A. ZAKROWSKI	Vice President, Finance, and Chief Accounting Officer (principal accounting officer)
/s/ Ralph Alvarez RALPH ALVAREZ	Director
/s/ Katherine Baicker, Ph.D. KATHERINE BAICKER, Ph.D.	Director
/s/ Carolyn R. Bertozzi, Ph.D. CAROLYN R. BERTOZZI, Ph.D.	Director
/s/ Michael L. Eskew MICHAEL L. ESKEW	Director
/s/ J. Erik Fyrwald J. ERIK FYRWALD	Director
/s/ Jamere Jackson JAMERE JACKSON	Director
 KIMBERLY H. JOHNSON	Director
/s/ William G. Kaelin, Jr., M.D. WILLIAM G. KAELIN, JR., M.D.	Director
/s/ Juan R. Luciano JUAN R. LUCIANO	Director
/s/ Marschall S. Runge, M.D., Ph.D. MARSCHALL S. RUNGE, M.D., Ph.D.	Director
/s/ Kathi P. Seifert KATHI P. SEIFERT	Director
/s/ Gabrielle Sulzberger GABRIELLE SULZBERGER	Director
/s/ Jackson P. Tai JACKSON P. TAI	Director
/s/ Karen Walker KAREN WALKER	Director

Trademarks Used In This Report

Trademarks or service marks owned by Eli Lilly and Company or its affiliates, when first used in each item of this report, appear with an initial capital and are followed by the symbol ® or ™, as applicable. In subsequent uses of the marks in the item, the symbols may be omitted.

Actos® is a trademark of Takeda Pharmaceutical Company Limited.

Byetta® is a trademark of Amylin Pharmaceuticals, Inc.

Glyxambi®, Jardiance®, Jentadueto®, Synjardy®, Trajenta®, and Trijardy® are trademarks of Boehringer Ingelheim GmbH.

Posilac® is a trademark of Union Agener and Elanco US Inc.

Tyvyt® is a trademark of Innovent Biologics (Suzhou) Co., Ltd.

Viagra® is a trademark of Pfizer Inc.

United States
Securities and Exchange Commission
Washington, D.C. 20549

Form 10-K

Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
for the fiscal year ended December 31, 2019

Commission file number 001-06351

Eli Lilly and Company

An Indiana corporation — I.R.S. employer identification no. 35-0470950

Lilly Corporate Center, Indianapolis, Indiana 46285 (317) 276-2000

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

Title of Each Class	Trading Symbol(s)	Name of Each Exchange On Which Registered
Common Stock (no par value)	LLY	New York Stock Exchange
1.000% Notes due 2022	LLY22	New York Stock Exchange
7 1/8% Notes due 2025	LLY25	New York Stock Exchange
1.625% Notes due 2026	LLY26	New York Stock Exchange
2.125% Notes due 2030	LLY30	New York Stock Exchange
0.625% Notes due 2031	LLY31	New York Stock Exchange
6.77% Notes due 2036	LLY36	New York Stock Exchange
1.700% Notes due 2049	LLY49A	New York Stock Exchange

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 under the Securities Act. Yes ☑ No ☐

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act. Yes ☐ No ☑

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

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files).
Yes ☑ No ☐

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company,” and "emerging growth company" in Rule 12b-2 under the Exchange Act.

Large accelerated filer ☒	Accelerated filer ☐
Non-accelerated filer ☐	Smaller reporting company ☐
	Emerging growth company ☐

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

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Act):
Yes ☐ No ☑

Aggregate market value of the common equity held by non-affiliates computed by reference to the price at which the common equity was last sold as of the last business day of the Registrant’s most recently completed second fiscal quarter (Common Stock): approximately $93,167,000,000.

Number of shares of common stock outstanding as of February 13, 2020: 956,382,203

Portions of the Registrant’s Proxy Statement to be filed on or about March 20, 2020 have been incorporated by reference into Part III of this report.

Securities registered pursuant to Section 12(g) of the Exchange Act: None

Eli Lilly and Company

Form 10-K
For the Year Ended December 31, 2019

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Forward-Looking Statements

This Annual Report on Form 10-K includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934 (Exchange Act), and the Private Securities Litigation Reform Act of 1995. Forward-looking statements include all statements that do not relate solely to historical or current facts, and can generally be identified by the use of words such as “may,” “believe,” “will,” “expect,” “project,” “estimate,” “intend,” “anticipate,” “plan,” “continue,” or similar expressions.

In particular, information appearing under “Business,” “Risk Factors,” and “Management's Discussion and Analysis of Results of Operations and Financial Condition” includes forward-looking statements. Forward-looking statements inherently involve many risks and uncertainties that could cause actual results to differ materially from those projected in these statements. Where, in any forward-looking statement, we express an expectation or belief as to future results or events, it is based on management's current plans and expectations, expressed in good faith and believed to have a reasonable basis. However, we can give no assurance that any such expectation or belief will result or will be achieved or accomplished. The following include some but not all of the factors that could cause actual results or events to differ materially from those anticipated:

- uncertainties in the pharmaceutical research and development process, including with respect to the timing of anticipated regulatory approvals and launches of new products;
- market uptake of recently launched products;
- competitive developments affecting current products and our pipeline;
- the expiration of intellectual property protection for certain of our products;
- our ability to protect and enforce patents and other intellectual property;
- the impact of actions of governmental and private payers affecting pricing of, reimbursement for, and access to pharmaceuticals;
- regulatory compliance problems or government investigations;
- regulatory actions regarding currently marketed products;
- unexpected safety or efficacy concerns associated with our products;
- issues with product supply stemming from manufacturing difficulties or disruptions;
- regulatory changes or other developments;
- changes in patent law or regulations related to data-package exclusivity;
- litigation, investigations, or other similar proceedings involving past, current, or future products or commercial activities as we are largely self-insured;
- unauthorized disclosure, misappropriation, or compromise of trade secrets or other confidential data stored in our information systems, networks, and facilities, or those of third parties with whom we share our data;
- changes in tax law, including the impact of United States tax reform legislation enacted in December 2017 and related guidance, or events that differ from our assumptions related to tax positions;
- changes in foreign currency exchange rates, interest rates, and inflation;
- asset impairments and restructuring charges;

- changes in accounting and reporting standards promulgated by the Financial Accounting Standards Board and the Securities and Exchange Commission;
- acquisitions and business development transactions and related integration costs;
- information technology system inadequacies or operating failures;
- reliance on third-party relationships and outsourcing arrangements; and
- the impact of global macroeconomic conditions.

Investors should not place undue reliance on forward-looking statements. You should carefully read the factors described in the “Risk Factors” section of this Annual Report on Form 10-K for a description of certain risks that could, among other things, cause our actual results to differ from these forward-looking statements.

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

Part I

Item 1. Business

Eli Lilly and Company (the “company” or “registrant” or "Lilly") was incorporated in 1901 in Indiana to succeed to the drug manufacturing business founded in Indianapolis, Indiana, in 1876 by Colonel Eli Lilly. We discover, develop, manufacture, and market products in a single business segment—human pharmaceutical products.

Our purpose is to unite caring with discovery to create medicines that make life better for people around the world. Most of the products we sell today were discovered or developed by our own scientists, and our success depends to a great extent on our ability to continue to discover or acquire, develop, and bring to market innovative new medicines.

In September 2018 Elanco Animal Health Incorporated (Elanco), an animal health business previously wholly owned by the company, completed an initial public offering of its common stock, which trades on the New York Stock Exchange, and in March 2019, we completed the disposition of our remaining ownership of Elanco common stock. For more information on the exchange offer, see Item 7, “Management’s Discussion and Analysis - Results of Operations - Executive Overview”.

We manufacture and distribute our products through facilities in the United States (U.S.), Puerto Rico, and 8 other countries. Our products are sold in approximately 120 countries.

Products

Our products include:

Diabetes and other endocrinology products, including:

- *Baqsimi*® (glucagon), a nasal powder formulation for the treatment of severe hypoglycemia in patients with diabetes (approved in the U.S. and Europe in 2019)
- *Basaglar*® (insulin glargine injection), a long-acting human insulin analog for the treatment of diabetes (launched in Japan and Europe under the trade name Abasaglar™)
- *Forteo*®, for the treatment of osteoporosis in postmenopausal women and men at high risk for fracture and for glucocorticoid-induced osteoporosis in men and postmenopausal women
- *Humalog*®, *Humalog Mix 75/25, Humalog U-100, Humalog U-200, Humalog Mix 50/50*, and *insulin lispro,* insulin analogs for the treatment of diabetes
- *Humatrope*®, for the treatment of human growth hormone deficiency and certain pediatric growth conditions
- *Humulin*®, *Humulin 70/30, Humulin N, Humulin R,* and *Humulin U-500,* human insulins of recombinant DNA origin for the treatment of diabetes
- *Jardiance*®, for the treatment of type 2 diabetes and to reduce the risk of cardiovascular death in adult patients with type 2 diabetes and established cardiovascular disease
- *Trajenta*®, for the treatment of type 2 diabetes
- *Trulicity*®, for the treatment of type 2 diabetes

Immunology products, including:

- *Olumiant®,* for the treatment of adults with moderately-to-severely active rheumatoid arthritis (approved in Europe and Japan in 2017, and in the U.S. in 2018)

- *Taltz®*, for the treatment of moderate-to-severe plaque psoriasis, active psoriatic arthritis (approved in the U.S. in 2017, and in Europe in 2018), and ankylosing spondylitis (approved in the U.S. in 2019)

Neuroscience products, including:

- *Cymbalta®*, for the treatment of major depressive disorder, diabetic peripheral neuropathic pain, generalized anxiety disorder, fibromyalgia, and chronic musculoskeletal pain due to chronic low back pain or chronic pain due to osteoarthritis

- *Emgality*®, a once-monthly subcutaneously injected calcitonin gene-related peptide (CGRP) antibody for migraine prevention (approved in the U.S. and Europe in 2018) and the treatment of episodic cluster headache (approved in the U.S. in 2019)

- *Reyvow*™, an oral medicine for the acute treatment of migraine (launched in the U.S. in 2020)

- *Strattera*®*,* for the treatment of attention-deficit hyperactivity disorder

- *Zyprexa*®*,* for the treatment of schizophrenia, acute mixed or manic episodes associated with bipolar I disorder, and bipolar maintenance

Oncology products, including:

- *Alimta*®*,* for the first-line treatment, in combination with another agent, of advanced non-small cell lung cancer (NSCLC) for patients with non-squamous cell histology; for the second-line treatment of advanced non-squamous NSCLC; as monotherapy for the maintenance treatment of advanced non-squamous NSCLC in patients whose disease has not progressed immediately following chemotherapy treatment; and in combination with another agent, for the treatment of malignant pleural mesothelioma

- *Cyramza*®*,* for use as a single agent or in combination with another agent as a second-line treatment of advanced or metastatic gastric cancer or gastro-esophageal junction adenocarcinoma; in combination with another agent as a second-line treatment of metastatic NSCLC; in combination with another agent as a second-line treatment of metastatic colorectal cancer; as a single agent as a second-line treatment of hepatocellular carcinoma (approved in the U.S. in 2019); and in combination with another agent as a first-line treatment of adult patients with metastatic NSCLC with activating epidermal growth factor receptor (EGFR) mutations (approved in Europe in 2020)

- *Erbitux*®*,* indicated both as a single agent and in combination with another chemotherapy agent for the treatment of certain types of colorectal cancers; and as a single agent, in combination with chemotherapy, or in combination with radiation therapy for the treatment of certain types of head and neck cancers

- *Verzenio*®*,* for use as a single agent and in combination with endocrine therapy for the treatment of a certain type of metastatic breast cancer (approved in the U.S. in 2017 and in Europe and Japan in 2018)

Other products, including:

- *Cialis*®*,* for the treatment of erectile dysfunction and benign prostatic hyperplasia

Marketing

We sell most of our products worldwide. We adapt our marketing methods and product emphasis in various countries to meet local customer needs.

U.S.

In the U.S., most of our products are distributed through wholesalers that serve pharmacies, physicians and other health care professionals, and hospitals. In 2019, 2018, and 2017, three wholesale distributors in the U.S. - McKesson Corporation, AmerisourceBergen Corporation, and Cardinal Health, Inc. - each accounted for between 14 percent and 21 percent of our consolidated total revenue. No other distributor accounted for more than 10 percent of our consolidated total revenue in any of those years.

We promote our major products in the U.S. through sales representatives who call upon physicians and other health care professionals. We also promote to healthcare providers in medical journals and on-line health care channels, distribute literature and samples of certain products to physicians, and exhibit at medical meetings. In addition, we advertise certain products directly to consumers in the U.S., and we

maintain websites with information about our major products. We supplement our employee sales force with contract sales organizations to leverage our own resources.

We maintain special business groups to service wholesalers, pharmacy benefit managers, managed care organizations, group purchasing organizations, government and long-term care institutions, hospitals, and certain retail pharmacies. We enter into arrangements with these organizations providing for discounts or rebates on our products.

Outside the U.S.

Outside the U.S., we promote our products to healthcare providers primarily through sales representatives and on-line health care channels. While the products marketed vary from country to country, diabetes and other endocrinology products constitute the largest single group in consolidated revenue. Distribution patterns vary from country to country. In most countries in which we operate, we maintain our own sales organizations, but in some smaller countries we market our products through independent distributors.

Marketing Collaborations

Certain of our products are marketed in arrangements with other pharmaceutical companies, including the following:

- We and Boehringer Ingelheim have a global agreement to develop and commercialize a portfolio of diabetes products, including Trajenta, Jentadueto®, Jardiance, Glyxambi®, Synjardy®, Trijardy® XR, and Basaglar.

For additional information, see Item 8, "Financial Statements and Supplementary Data - Note 4, Collaborations and Other Arrangements."

Competition

Our products compete globally with products of many other companies in highly competitive markets.

Important competitive factors include effectiveness, safety, and ease of use; price and demonstrated cost-effectiveness; marketing effectiveness; and research and development of new products, processes, and uses. Most new products that we introduce must compete with other branded or generic products already on the market or products that are later developed by competitors. If competitors introduce new products or delivery systems with therapeutic or cost advantages, our products can be subject to decreased sales, progressive price reductions, or both.

We believe our long-term competitive success depends upon discovering and developing (either alone or in collaboration with others) or acquiring innovative, cost-effective products that provide improved outcomes and deliver value to payers, and continuously improving the productivity of our operations in a highly competitive environment. There can be no assurance that our efforts will result in commercially successful products, and it is possible that our products will be, or become, uncompetitive from time to time as a result of products developed by our competitors.

Generic Pharmaceuticals

One of the biggest competitive challenges we face is from generic pharmaceuticals. In the U.S. and Europe, the regulatory approval process for pharmaceuticals (other than biological products (biologics)) exempts generics from costly and time-consuming clinical trials to demonstrate their safety and efficacy, allowing generic manufacturers to rely on the safety and efficacy of the innovator product. Therefore, generic manufacturers generally invest far less than we do in research and development and can price their products much lower than our branded products. Accordingly, when a branded non-biologic pharmaceutical loses its market exclusivity, it normally faces intense price competition from generic forms of the product. Public and private payers typically encourage the use of generics as alternatives to brand-name drugs in their healthcare programs. Laws in the U.S. generally allow, and in many cases require, pharmacists to substitute generic drugs that have been rated under government procedures to be essentially equivalent to a brand-name drug. Where substitution is mandatory, it must be made unless the prescribing physician expressly forbids it. In many countries outside the U.S., intellectual property protection is weak, and we must compete with generic or counterfeit versions of our products.

Biosimilars

Several of our current products, including Cyramza, Emgality, Erbitux, Taltz, and Trulicity and many of the new molecular entities (NMEs) in our research pipeline are biologics. Competition for Lilly's biologics may be affected by the approval of follow-on biologics, also known as biosimilars. A biosimilar is a subsequent version of an approved innovator biologic that, due to its functional and structural similarity to the innovator biologic, is approved based on an abbreviated data package that relies in part on the full testing required of the innovator biologic. Globally, most governments have developed regulatory pathways to approve

biosimilars as alternatives to innovator-developed biologics, but the patent and regulatory exclusivity for the existing innovator biologic must expire in a given market before biosimilars may enter that market. The extent to which a biosimilar, once approved, will be substituted for the innovator biologic in a way that is similar to traditional generic substitution for

non-biologic products, is not yet entirely clear, and will depend on a number of regulatory and marketplace factors that are still developing.

Biosimilars may present both competitive challenges and opportunities. For example, a competitor company has developed a version of insulin lispro which competes with our product Humalog. On the other hand, with our partner Boehringer Ingelheim, we developed Basaglar, a new insulin glargine product, which has the same amino acid sequence as a product currently marketed by a competitor and has launched as a follow-on biologic in the U.S., and as a biosimilar in Europe and Japan. In March 2020, the U.S. regulatory status of all of our insulin products will transition to become regulated as “biologics” rather than “drugs.” Based on recent U.S. Food and Drug Administration (FDA) draft guidance, this change may lower the requirements for competitor biosimilar products to enter the market, some of which could be designated as interchangeable and therefore substituted for our insulin products at U.S. pharmacies.

U.S. Private Sector Dynamics

In the U.S. private sector, consolidation and integration among healthcare providers is also a major factor in the competitive marketplace for pharmaceuticals. Health plans and pharmacy benefit managers have been consolidating into fewer, larger entities, thus enhancing their purchasing strength and importance. For example, in 2018 CVS Health, a large pharmacy benefit manager and pharmacy chain, acquired Aetna, a large national insurer, and Cigna Corporation acquired Express Scripts in a similar transaction. More recently, in December 2019, Express Scripts signed a three-year partnership agreement with another pharmacy benefit manager, Prime Therapeutics.

Payers typically maintain formularies which specify coverage (the conditions under which drugs are included on a plan's formulary) and reimbursement (the associated out-of-pocket cost to the consumer). Formulary placement can lead to reduced usage of a drug for the relevant patient population due to coverage restrictions, such as prior authorizations and formulary exclusions, or due to reimbursement limitations which result in higher consumer out-of-pocket cost, such as non-preferred co-pay tiers, increased co-insurance levels, and higher deductibles. Consequently, pharmaceutical companies compete for formulary placement not only on the basis of product attributes such as efficacy, safety profile, or patient ease of use, but also by providing rebates. Value-based agreements, where pricing is based on achievement, or not, of specified outcomes, 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 are expected to continue to negatively affect our future consolidated results of operations.

Patents, Trademarks, and Other Intellectual Property Rights

Overview

Intellectual property protection is critical to our ability to successfully commercialize our life sciences innovations and invest in the search for new medicines. We own, have applied for, or are licensed under, a large number of patents in the U.S. and many other countries relating to products, product uses, formulations, and manufacturing processes. In addition, as discussed below, for some products we have effective intellectual property protection in the form of data protection under pharmaceutical regulatory laws.

The patent protection anticipated to be of most relevance to pharmaceuticals is provided by national patents claiming the active ingredient (the compound patent), particularly those in major markets such as the U.S., various European countries, and Japan. These patents may be issued based upon the filing of international patent applications, usually filed under the Patent Cooperation Treaty (PCT). Patent applications covering compounds are generally filed during the Discovery Phase of the drug discovery process, which is described in the “Research and Development” section below. In general, national patents in each relevant country are available for a period of 20 years from the filing date of the PCT application, which is often years prior to the launch of a commercial product. Further patent term adjustments and restorations may extend the original patent term:

- Patent term adjustment is a statutory right available to all U.S. patent applicants to provide relief in the event that a patent grant is delayed during examination by the United States Patent and Trademark Office (USPTO).

- Patent term restoration is a statutory right provided to U.S. patent holders that claim inventions subject to review by the FDA. To make up for a portion of the time invested in clinical trials and the FDA review

process, a single patent for a pharmaceutical product may be eligible for patent term restoration. Patent term restoration is limited by a formula and cannot be calculated until product approval due to uncertainty about the duration of clinical trials and the time it takes the FDA to review an application. There is a five-year cap on any restoration, and no patent's expiration date may be extended beyond 14 years from FDA approval. Some countries outside the U.S. also offer forms of patent term restoration. For example, Supplementary Protection Certificates are available to extend the life of a European patent up to an additional five years (subject to a 15-year cap from European Medicines Agency (EMA) approval). Similarly, in Japan, South Korea, and Australia, patent terms can be extended up to five years, depending on the length of regulatory review and other factors.

Loss of effective patent protection for pharmaceuticals, especially for non-biologic products, typically results in the loss of effective market exclusivity for the product, which often results in severe and rapid decline in revenues for the product. However, in some cases the innovator company may be protected from approval of generic, biosimilar, or other follow-on versions of a new medicine beyond the expiration of the compound patent through manufacturing trade secrets, later-expiring patents on manufacturing processes, methods of use or formulations, or data protection that may be available under pharmaceutical regulatory laws. Changes to the laws and regulations governing these protections could result in earlier loss of effective market exclusivity. The primary forms of data protection are as follows:

- Regulatory authorities in major markets generally grant data package protection for a period of years following new drug approvals in recognition of the substantial investment required to complete clinical trials. Data package protection prohibits other manufacturers from submitting regulatory applications for marketing approval based on the innovator company’s regulatory submission data for the drug. The base period of data package protection depends on the country. For example, the period is generally five years in the U.S. (12 years for new biologics as described below), effectively 10 years in Europe, and eight years in Japan. The period begins on the date of product approval and runs concurrently with the patent term for any relevant patent.

- Under the Biologics Price Competition and Innovation Act of 2009 (the BPCI Act), the FDA has the authority to approve biosimilars. A competitor seeking approval of a biosimilar must file an application to show its molecule is highly similar to an approved innovator biologic and include a certain amount of safety and efficacy data that the FDA will consider on a case-by-case basis. Under the data protection provisions of this law, the FDA cannot approve a biosimilar application until 12 years after initial marketing approval of the innovator biologic, subject to certain conditions. The BPCI Act is part of the Affordable Care Act, the constitutionality of which is currently being litigated.

- In the U.S., the FDA has the authority to grant additional data protection for approved drugs where the sponsor conducts specified testing in pediatric or adolescent populations within a specified time period. If granted, this “pediatric exclusivity” provides an additional six months of exclusivity, which is added to the term of data protection as well as to the term of any relevant patents, to the extent these protections have not already expired. While the term of the pediatric exclusivity attaches to the term of any relevant patent, pediatric exclusivity is a regulatory exclusivity, a bar to generic approval, not a patent right.

- Under the U.S. orphan drug law, a specific use of a drug or biologic can receive "orphan" designation if it is intended to treat a disease or condition affecting fewer than 200,000 people in the U.S., or affecting more than 200,000 people but not reasonably expected to recover its development and marketing costs through U.S. sales. Among other benefits, orphan designation entitles the particular use of the drug to seven years of market exclusivity, meaning that the FDA cannot (with limited exceptions) approve another marketing application for the same drug for the same indication until expiration of the seven-year period. Unlike pediatric exclusivity, the orphan exclusivity period is independent of and runs in parallel with any applicable patents.

Outside the major markets, the adequacy and effectiveness of intellectual property protection for pharmaceuticals varies widely, and in a number of these markets we are unable to patent our products or to enforce the patents we receive for our products. Under the Trade-Related Aspects of Intellectual

Property Agreement (TRIPs) administered by the World Trade Organization, more than 140 countries have agreed to provide non-discriminatory protection for most pharmaceutical inventions and to assure that adequate and effective rights are available to patent owners. Certain developing countries limit protection for biopharmaceutical products under their interpretation of “flexibilities” allowed under the agreement. Thus, some types of patents, such as those on new uses of compounds or new forms of molecules, are not available in certain developing countries. Further, many developing countries, and some developed countries, do not provide effective data package protection even though it is specified in TRIPs.

Our Intellectual Property Portfolio

We consider intellectual property protection for certain products, processes, uses, and formulations—particularly with respect to those products discussed below—to be important to our operations. In addition to the data protection and patents identified below, we may hold patents on manufacturing processes, formulations, devices, or uses that extend exclusivity beyond the dates shown below.

The most relevant U.S. patent protection or data protection and associated expiry dates for our top-selling or recently launched patent-protected marketed products are as follows:

- Alimta is protected by a vitamin regimen patent (2021) plus pediatric exclusivity (May 2022).
- Baqsimi is protected by data protection (July 2022).
- Cyramza is protected by a compound patent and biologics data protection (2026).
- Emgality is protected by a compound patent (2033).
- Jardiance, and the related combination products Glyxambi and Synjardy, are protected by a compound patent (2025, not including possible patent extension).
- Olumiant is protected by a compound patent (2030, not including possible patent extension).
- Reyvow is protected by a compound patent (2025, not including possible patent extension).
- Taltz is protected by a compound patent (2026, not including possible patent extension) and by biologics data protection (2028).
- Trajenta and Jentadueto are protected by a compound patent (2023, not including possible patent extension).
- Trulicity is protected by a compound patent (2027).
- Verzenio is protected by a compound patent (2029, not including possible patent extension).

Outside the U.S., important patent protection or data protection includes:

- Alimta is protected by a vitamin regimen patent in major European countries (June 2021) and by patents covering use to treat cancer concomitantly with vitamins in Japan (June 2021).
- Cyramza is protected by a compound patent in major European countries (2028) and Japan (2026).
- Emgality in is protected by a compound patent in major European countries (2033) and Japan (2031, not including possible patent extension).
- Olumiant is protected by a compound patent in major European countries (2029, not including possible patent extension) and Japan (2033).
- Taltz is protected by a compound patent in major European countries (2031) and Japan (2030).
- Trulicity is protected by a compound in major European countries and Japan (2029).
- Verzenio is protected by a compound in major European countries and Japan (2029).

Baqsimi has been submitted for regulatory review in Japan, where it is expected to be protected by data protection upon approval (6 years).

Flortaucipir has been submitted for regulatory review in the U.S. for use as a positron emission tomography (PET) imaging agent and is protected by a compound patent (2029, not including possible patent extension).

Selpercatinib has been submitted for regulatory review in the U.S. for the treatment of cancers in certain patients and is protected by a U.S. compound patent (2037, not including possible patent extension).

Tanezumab has been submitted for regulatory review in the U.S. for the treatment of osteoarthritis pain and is expected to be protected by data protection upon approval (12 years).

Worldwide, we sell all of our major products under trademarks for names and unique product appearance (e.g., the appearance of our Trulicity autoinjector) which we consider in the aggregate to be important to our operations. Trademark protection varies throughout the world, with protection continuing in some countries as long as the mark is used, and in other countries as long as it is registered. Registrations are normally for fixed but renewable terms. Trademark protection often extends beyond the patent and data protection for a product.

Patent Licenses

Most of our major products are not subject to significant license agreements. For information on our license and collaboration agreement with Incyte Corporation related to Olumiant, see Item 8, "Financial Statements and Supplementary Data - Note 4, Collaborations."

Patent Challenges

In the U.S., the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, authorizes the FDA to approve generic versions of innovative pharmaceuticals (other than biologics) when the generic manufacturer has not conducted safety and efficacy studies but files an Abbreviated New Drug Application (ANDA). In an ANDA, the generic manufacturer must demonstrate only “bioequivalence” between the generic version and the New Drug Application (NDA)-approved drug—not safety and efficacy. Establishing bioequivalence is generally straightforward and inexpensive for the generic company.

Absent a patent challenge, the FDA cannot approve an ANDA until after certain of the innovator’s patents expire. However, after the innovator has marketed its product for four years, a generic manufacturer may file an ANDA alleging that one or more or all of the patents listed in the innovator’s NDA are invalid or not infringed. This allegation is commonly known as a “Paragraph IV certification.” If the innovator responds by filing suit against the generic manufacturer, the FDA is then prohibited from approving the generic company’s application for a 30-month period (which can be shortened or extended by the trial court judge hearing the patent challenge). If one or more of the NDA-listed patents are challenged, the first filer(s) of a Paragraph IV certification may be entitled to a 180-day period of market exclusivity over all other generic manufacturers.

Generic manufacturers use Paragraph IV certifications extensively to challenge patents on innovative pharmaceuticals. In addition, generic companies have shown willingness to launch “at risk,” i.e., after receiving ANDA approval but before final resolution of their patent challenge. We are currently in Hatch-Waxman litigation involving Alimta with five generic manufacturers. For more information on Hatch-Waxman litigation involving the company, see Item 8, “Financial Statements and Supplementary Data - Note 16, Contingencies” and Item 3, "Legal Proceedings."

Under the BPCI Act, the FDA cannot approve a biosimilar application until data protection expires, 12 years after initial marketing approval of the innovator biologic. However, the BPCI Act does provide a mechanism for a competitor to challenge the validity of an innovator’s patents as early as four years after initial marketing approval of the innovator biologic. The patent litigation scheme under the BPCI Act is complex and courts have held that biosimilar applicants are not required to engage in it. Patent holders still have the right to bring suit under normal patent law procedures if a biosimilar applicant attempts to commercialize a product prior to patent expiration.

In addition, there is a procedure in U.S. patent law known as inter partes review (IPR), which allows any member of the public to file a petition with the USPTO seeking the review of any issued U.S. patent for validity. IPRs are conducted before Administrative Patent Judges in the USPTO using a lower standard of proof than used in federal district court. In addition, the challenged patents are not accorded the presumption of validity as they are in federal district court. Generic drug companies and even some investment firms have engaged in the IPR process in attempts to invalidate our patents.

Outside the U.S., the legal doctrines and processes by which pharmaceutical patents can be challenged vary widely. In recent years, we have experienced an increase in patent challenges from generic manufacturers in many countries outside the U.S. For more information on administrative challenges and litigation involving our Alimta patents in Europe and Japan, see Item 8, “Financial Statements and Supplementary Data - Note 16, Contingencies.”

Government Regulation of Our Operations

Our operations are regulated extensively by numerous national, state, and local agencies. The lengthy process of laboratory and clinical testing, data analysis, manufacturing development, and regulatory review necessary for governmental approvals is extremely costly and can significantly delay product introductions. Promotion, marketing, manufacturing, and distribution of pharmaceutical products are extensively regulated in all major markets. We conduct extensive post-marketing surveillance of the safety of the products we sell. In addition, our operations are subject to complex federal, state, local, and foreign

laws and regulations concerning the environment, occupational health and safety, and privacy. Compliance with the laws and regulations affecting the manufacture and sale of current products and the discovery, development, and introduction of new products will continue to require substantial effort, expense, and capital investment.

Of particular importance to our business is the FDA in the U.S. Pursuant to the Federal Food, Drug, and Cosmetic Act, the FDA has jurisdiction over all of our products and devices in the U.S. and administers requirements covering the testing, safety, effectiveness, manufacturing, quality control, distribution, labeling, marketing, advertising, dissemination of information, and post-marketing surveillance of those products.

The FDA extensively regulates all aspects of manufacturing quality for pharmaceuticals under its current Good Manufacturing Practices (cGMP) regulations. Outside the U.S., our products and operations are subject to similar regulatory requirements, notably by the EMA in Europe and the Ministry of Health, Labor and Welfare in Japan. Specific regulatory requirements vary from country to country. We make substantial investments of capital and operating expenses to implement comprehensive, company-wide quality systems in our manufacturing, product development, and process development operations in an effort to ensure sustained compliance with cGMP and similar regulations. However, in the event we fail to adhere to these requirements in the future, we could be subject to interruptions in production, fines and penalties, and delays in new product approvals. Certain of our products are manufactured by third parties, and their failure to comply with these regulations could adversely affect us through failure to supply product to us or delays in new product approvals.

The marketing, promotional, and pricing practices of pharmaceutical manufacturers, as well as the manner in which manufacturers interact with purchasers, prescribers, and patients, are subject to various other U.S. federal and state laws, including the federal anti-kickback statute and the False Claims Act and state laws governing kickbacks, false claims, unfair trade practices, and consumer protection. These laws are administered by, among others, the Department of Justice (DOJ), the Office of Inspector General of the Department of Health and Human Services, the Federal Trade Commission, the Office of Personnel Management, and state attorneys general. Over the past several years, state and federal governments have increased their oversight, enforcement activities, and intra-agency coordination with respect to pharmaceutical companies. Several claims brought by these agencies against us and other companies under these and other laws have resulted in corporate criminal sanctions and very substantial civil settlements.

The U.S. Foreign Corrupt Practices Act of 1977 (FCPA) prohibits certain individuals and entities, including U.S. publicly traded companies, from promising, offering, or giving anything of value to foreign officials with the corrupt intent of influencing the foreign official for the purpose of helping the company obtain or retain business or gain any improper advantage. The FCPA also imposes specific recordkeeping and internal controls requirements on U.S. publicly traded companies. As noted above, outside the U.S., our business is heavily regulated and therefore involves significant interaction with foreign officials. Additionally, in many countries outside the U.S., the health care providers who prescribe pharmaceuticals are employed by the government and the purchasers of pharmaceuticals are government entities; therefore, our interactions with these prescribers and purchasers are subject to regulation under the FCPA.

In addition to the U.S. application and enforcement of the FCPA, the various jurisdictions in which we operate and supply our products have laws and regulations aimed at preventing and penalizing corrupt and anticompetitive behavior. In recent years, several jurisdictions, including China, Brazil, and the United Kingdom (U.K.), have enhanced their laws and regulations in this area, increased their enforcement activities, and/or increased the level of cross-border coordination and information sharing.

We are and could in the future become subject to administrative and legal proceedings and actions, which could include claims for civil penalties (including treble damages under the False Claims Act), criminal sanctions, and administrative remedies, including exclusion from U.S. federal and other health care programs. It is possible that an adverse outcome in future actions could have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

Regulations and Private Payer Actions Affecting Pharmaceutical Pricing, Reimbursement, and Access

In the U.S., we are required to provide rebates to the federal government and respective state governments on their purchases of our pharmaceuticals under state Medicaid and Medicaid Managed Care programs (minimum of 23.1 percent plus adjustments for price increases over time) and rebates to private payers who cover patients in certain types of health care facilities that serve low-income and uninsured patients (known as 340B facilities). No rebates are required at this time in the Medicare Part B

(physician and hospital outpatient) program where reimbursement is set on an "average selling price plus 4.3 percent" formula. Additionally, an annual fee is imposed on pharmaceutical manufacturers and importers that sell branded prescription drugs to specified government programs. Since 2019, the Bipartisan Budget Act has required manufacturers of brand-name drugs, biologics, and biosimilars to provide a discount of 70 percent of the cost of branded prescription drugs for Medicare Part D participants who are in the “doughnut hole” (the coverage gap in Medicare prescription drug coverage), up from the previous 50-percent discount.

Rebates are also negotiated in the private sector. We give rebates to private payers who provide prescription drug benefits to seniors covered by Medicare and to private payers who provide prescription drug benefits to their customers. These rebates are affected by the introduction of competitive products and generics in the same class.

In 2019, the White House signed into law targeted amendments to the Medicaid Drug Rebate Program statute, as well as the Fair and Accurate Medicaid Pricing Act, which was part of the Continuing Appropriations Act. We do not believe either will have a material impact to our business. Several states have passed importation legislation, including Colorado, Florida, Maine, and Vermont. Specifically, the state of Florida is working with the Administration to implement an importation program from Canada as early as 2020. We are currently reviewing the state legislation, as well as corresponding proposed federal rulemaking and guidance recently published by the Department of Health and Human Services and the FDA, the impact of which is uncertain at this time.

In most international markets, we operate in an environment of government-mandated cost-containment programs, which may include price controls, international reference pricing (to other countries' prices), discounts and rebates, therapeutic reference pricing (to other, often generic, pharmaceutical choices), restrictions on physician prescription levels, and mandatory generic substitution.

Globally, public and private payers are increasingly restricting access to pharmaceuticals based on assessments of comparative effectiveness and value, including through the establishment of formal health technology assessment processes. In addition, third party organizations, including professional associations, academic institutions, and non-profit entities associated with payers, are conducting and publishing comparative effectiveness and cost/benefit analyses on medicines, the impact of which are uncertain at this time.

We cannot predict the extent to which our business may be affected by these or other potential future legislative, regulatory, or payer developments. However, in general we expect that state, federal, and international legislative and regulatory developments could have further negative effects on pricing and reimbursement for our products.

Research and Development

Our commitment to research and development dates back more than 140 years. We invest heavily in research and development because we believe it is critical to our long-term competitiveness. At the end of 2019, we employed approximately 7,810 people in pharmaceutical research and development activities, including a substantial number of physicians, scientists holding graduate or postgraduate degrees, and highly skilled technical personnel.

Our internal pharmaceutical research focuses primarily on the areas of oncology, diabetes, neurodegeneration, immunology, and pain. We believe that we have a strong biotechnology research program, with more than half of our clinical-stage pipeline currently consisting of biologics. In addition to discovering and developing NMEs, we seek to expand the value of existing products through new uses, formulations, and therapeutic approaches that provide additional value to patients.

To supplement our internal efforts, we collaborate with others, including academic institutions and research-based pharmaceutical and biotechnology companies. We use the services of physicians, hospitals, medical schools, and other research organizations worldwide to conduct clinical trials to establish the safety and effectiveness of our pharmaceutical products. We actively invest in external research and technologies that we believe complement and strengthen our own efforts. These investments can take many forms, including licensing arrangements, co-development and co-marketing agreements, co-promotion arrangements, joint ventures, and acquisitions.

Pharmaceutical development is time-consuming, expensive, and risky. On average, only one out of many thousands of molecules discovered by researchers ultimately becomes an approved medicine. The process from discovery to regulatory approval can take over a decade. Drug candidates can fail at any stage of the process, and even late-stage drug candidates sometimes fail to receive regulatory approval or achieve commercial success. The rate of innovation cycles leading to medical improvements over initial inventions is accelerating, which has increased the risk that we opt not to develop a late-stage asset or that new products fail to achieve commercial success due to technical obsolescence - displacement by follow-on competitor products - before the period of exclusivity has ended. After approval and launch of a product, we expend considerable resources on post-marketing surveillance and additional clinical studies to collect data and understand the benefits and potential risks of medicines as they are used as therapeutics. Consistent with their purpose, these studies have the potential to identify information about problems with product safety or efficacy that result in product withdrawal. The following describes in more detail the research and development process for pharmaceutical products:

Phases of New Drug Development

- **Discovery Phase**

  The earliest phase of new drug research and development, the discovery phase, can take many years. Scientists identify, design, and synthesize promising molecules, screening tens of thousands of molecules for their effect on biological targets that appear to play an important role in one or more diseases. Targets can be part of the body, such as a protein, receptor, or gene; or foreign, such as a virus or bacteria. Some targets have been proven to affect disease processes, but often the target is unproven and may later prove to be irrelevant to the disease or to yield insufficient clinical benefit. Molecules that have the desired effect on the target and meet other design criteria become candidate molecules and move to the next phase of development. The probability of any one candidate molecule becoming a commercial product is extremely low.

- **Early Development Phase**

  The early development phase involves refining candidate molecules, understanding how to manufacture them efficiently, and completing initial testing for safety and efficacy. Safety testing is done first in laboratory tests and animals, as necessary, to identify toxicity and other potential safety issues that would preclude use in humans. In general, the first human tests (often referred to as Phase I) are conducted in small groups of healthy volunteers or patients to assess safety and find the potential dosing range. After a safe dose range has been established, the drug is typically administered to small populations of patients (Phase II) to look for initial signs of efficacy in treating the targeted disease, or biomarkers of the disease, and to continue to assess safety. In parallel, scientists work to identify safe, effective, and economical manufacturing processes. Long-term animal studies continue to test for potential safety issues. Of the molecules that enter the early development phase, approximately 10 percent move on to the product phase. The early development phase can take several years to complete.

- **Product Phase**

  Product phase (Phase III) molecules have met initial safety requirements and, typically, shown initial evidence of efficacy. As a result, these molecules generally have a higher likelihood of success. The molecules are tested in much larger patient populations to demonstrate efficacy to a predetermined level of statistical significance and to continue to develop the safety profile. These trials are generally global in nature and are designed to generate the data necessary to submit the molecule to regulatory agencies for marketing approval. The potential new drug is generally compared with existing competitive therapies, placebo, or both. The resulting data is compiled and may be submitted to regulatory agencies around the world. Phase III testing varies by disease state, but can often last from three to four years.

- **Submission Phase**

  Once a molecule is submitted to regulatory agencies, the time to final marketing approval can vary from several months to several years, depending on variables such as the disease state, the strength

and complexity of the data presented, the novelty of the target or compound, and the time required for the agency(ies) to evaluate the submission. There is no guarantee that a potential medicine will receive marketing approval, or that decisions on marketing approvals or indications will be consistent across geographic areas.

We believe our investments in research, both internally and in collaboration with others, have been rewarded by the large number of new molecules and new indications for existing molecules that we have in all stages of development. We currently have approximately 45 drug candidates across all stages of human testing and a larger number of projects in preclinical development. Among our new investigational molecules currently in the product phase of development or awaiting regulatory approval or launch are potential therapies for various cancers; Alzheimer's disease; pain; migraine; cluster headache; diabetes; obesity; and autoimmune diseases, including alopecia areata, systemic lupus erythematosus, psoriasis, atopic dermatitis, Crohn's disease, and ulcerative colitis. We are studying many other drug candidates in the earlier stages of development in our chosen priority areas. We are also developing new uses, formulations, or delivery methods for many of these molecules as well as several currently marketed products. See Item 7, "Management's Discussion and Analysis - Results of Operations - Executive Overview - Late-Stage Pipeline," for more information on certain of our product candidates.

Raw Materials and Product Supply

Most of the principal materials we use in our manufacturing operations are available from more than one source. However, we obtain certain raw or intermediate materials primarily from only one source. We generally seek to maintain sufficient inventory to supply the market until an alternative source of supply could be implemented, in the event one of these suppliers was unable to provide the materials or product. However, in the event of an extended failure of a supplier, it is possible that we could experience an interruption in supply until we established new sources or, in some cases, implemented alternative processes.

The majority of our revenue comes from products produced in our own facilities. Our principal active ingredient manufacturing occurs at sites we own in the U.S., Ireland, and Puerto Rico. Finishing operations, including formulation, filling, assembling, delivery device manufacturing, and packaging, take place at a number of sites throughout the world. We utilize third parties for certain active ingredient manufacturing and finishing operations.

We manage our supply chain (including our own facilities, contracted arrangements, and inventory) in a way that is intended to allow us to meet all expected product demand while maintaining flexibility to reallocate manufacturing capacity to improve efficiency and respond to changes in supply and demand. To maintain a stable supply of our products, we use a variety of techniques including comprehensive quality systems, inventory management, and back-up sites.

However, pharmaceutical production processes are complex, highly regulated, and vary widely from product to product. Shifting or adding manufacturing capacity can be a very lengthy process requiring significant capital expenditures, process modifications, and regulatory approvals. Accordingly, if we were to experience unplanned plant shutdowns at one of our own facilities, significant failure of a contract supplier, or significant unanticipated increases in demand, we could experience an interruption in supply of certain products or product shortages until production could be resumed or expanded.

Quality Assurance

Our success depends in great measure upon customer confidence in the quality of our products and in the integrity of the data that support their safety and effectiveness. Product quality arises from a total commitment to quality in all parts of our operations, including research and development, purchasing, facilities planning, manufacturing, distribution, and dissemination of information about our medicines.

Quality of production processes involves strict control of ingredients, equipment, facilities, manufacturing methods, packaging materials, and labeling. We perform tests at various stages of production processes and on the final product in an effort to assure that the product meets all regulatory requirements and Lilly internal standards. These tests may involve chemical and physical chemical analyses, microbiological testing, testing in animals, or a combination thereof. Additional assurance of quality is provided by corporate quality-assurance groups that audit and monitor all aspects of quality related to pharmaceutical manufacturing procedures and systems in company operations and at third-party suppliers.

Executive Officers of the Company

The following table sets forth certain information regarding our executive officers. Except as otherwise noted, all executive officers have been employed by the company in management or executive positions during the last five years.

The term of office for each executive officer expires on the date of the annual meeting of the Board of Directors, to be held on May 4, 2020 in connection with the company's annual shareholders meeting, or on the date his or

her successor is chosen and qualified. No director or executive officer has a “family relationship” with any other director or executive officer of the company, as that term is defined for purposes of this disclosure requirement. There is no understanding between any executive officer or director and any other person pursuant to which the executive officer was selected.

Name	Age	Offices and Business Experience
David A. Ricks	52	President, Chief Executive Officer, director (since January 2017) and board chair (since June 2017)
Melissa S. Barnes	51	Senior Vice President, Enterprise Risk Management and Chief Ethics and Compliance Officer (since January 2013)
Stephen F. Fry	54	Senior Vice President, Human Resources and Diversity (since February 2011)
Anat Hakim	50	Senior Vice President and General Counsel (since February 2020). Prior to joining Lilly Ms. Hakim was Executive Vice President, General Counsel and Secretary of Wellcare Health Plans, a managed care company. Prior to joining Wellcare, she served as Divisional Vice President and Associate General Counsel at Abbott Laboratories, a health care company.
Patrik Jonsson	53	Senior Vice President and President, Lilly Bio-Medicines (since September 2019)
Michael B. Mason	53	Senior Vice President and President, Lilly Diabetes (since January 2020)
Johna L. Norton	53	Senior Vice President, Global Quality (since April 2017)
Myles O'Neill	61	Senior Vice President and President, Manufacturing Operations (since January 2018)
Leigh Ann Pusey	57	Senior Vice President, Corporate Affairs and Communications (since June 2017). Prior to joining Lilly, Ms. Pusey served as president and CEO of the American Insurance Association.
Aarti Shah, Ph.D.	55	Senior Vice President and Chief Information and Digital Officer (since January 2018)
Daniel Skovronsky, M.D., Ph.D.	46	Senior Vice President, Chief Scientific Officer, and President, Lilly Research Laboratories (since June 2018)
Joshua L. Smiley	50	Senior Vice President and Chief Financial Officer (since January 2018)
Anne E. White	51	Senior Vice President and President, Lilly Oncology (since September 2018)
Alfonso Zulueta	57	Senior Vice President and President, Lilly International (since January 2014)

Employees

At the end of 2019, we employed approximately 33,625 people, including approximately 18,915 employees outside the U.S. A substantial number of our employees have long records of continuous service.

Information Available on Our Website

Our company website is **https://www.lilly.com.** None of the information accessible on or through our website is incorporated into this Form 10-K. We make available through the website, free of charge, our company filings with the Securities and Exchange Commission (SEC) as soon as reasonably practicable after we electronically file them with, or furnish them to, the SEC. These include our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements, registration statements, and any amendments to those documents. The company website link to our SEC filings is **https://investor.lilly.com/financial-information/sec-filings.**

In addition, the Corporate Governance portion of our website includes our corporate governance guidelines, board and committee information (including committee charters), and our articles of incorporation and bylaws. The link to our corporate governance information is **https://www.lilly.com/about/corporate-governance/Pages/corporate-governance.aspx.**

We will provide paper copies of our SEC filings free of charge upon request to the company’s secretary at the address listed on the front of this Form 10-K.

Item 1A. Risk Factors

In addition to the other information contained in this Form 10-K, the following risk factors should be considered carefully in evaluating our company. It is possible that our business, financial condition, liquidity, cash flows, or results of operations could be materially adversely affected by any of these risks. Certain of these risks could also adversely affect the company's reputation.

- **Pharmaceutical research and development is very costly and highly uncertain; we may not succeed in developing or acquiring commercially successful products sufficient in number or value to replace revenues of products that have lost or will soon lose intellectual property protection or are displaced by competing products or therapies.**

  There are many difficulties and uncertainties inherent in 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 cannot state with certainty when or whether our products now under development will be approved or launched; whether, if initially granted, such approval will be maintained; whether we will be able to develop, license, or otherwise acquire additional product candidates or products; or whether our products, once launched, will be commercially successful. We must maintain a continuous flow of successful new products and successful new indications or brand extensions for existing products sufficient both to cover our substantial research and development costs and to replace revenues that are lost as profitable products lose intellectual property exclusivity or are displaced by competing products or therapies. Failure to do so in the short-term or long-term would have a material adverse effect on our business, results of operations, cash flows, and financial position. See Item 7, “Management’s Discussion and Analysis - Results of Operations - Executive Overview - Late-Stage Pipeline,” for more details.

- **We depend on products with intellectual property protection for most of our revenues, cash flows, and earnings; we have lost or will lose effective intellectual property protection for many of those products in the next several years, which has resulted and is likely to continue to result in rapid and severe declines in revenues.**

  A number of our top-selling products have recently lost, or will lose in the next several years, significant patent protection and/or data protection in the U.S. as well as key countries outside the U.S., as illustrated in the tables below:

Product	U.S. Revenues (2019) ($ in millions)	Percent of Worldwide Revenues (2019)	Patent / Data Protection - U.S.
Alimta	$ 1,219.5	5%	Vitamin regimen patent plus pediatric exclusivity will expire in May 2022
Forteo	645.5	3%	Formulation and related process patents expired in December 2018 and use patents expired in August 2019

Product	Revenues Outside U.S. (2019) ($ in millions)	Percent of Worldwide Revenues (2019)	Patent / Data Protection - Major Europe / Japan
Alimta	$ 896.4	4%	Major European countries: vitamin regimen patent will expire in June 2021 Japan: use patents to treat cancer concomitantly with vitamins will expire in June 2021
Forteo	759.1	3%	Japan: data package protection expired in July 2018; formulation and use patents expired in August 2019
Cymbalta	675.8	3%	Japan: data package protection expired in January 2020

Certain other significant products no longer have effective exclusivity through patent protection or data protection. For non-biologic products, loss of exclusivity (whether by expiration of legal rights or by termination thereof as a consequence of litigation) typically results in the entry of one or more generic competitors, leading to a rapid and severe decline in revenues, especially in the U.S. Historically, outside the U.S. the market penetration of generics following loss of exclusivity has not been as rapid or pervasive as in the U.S.; however, generic market penetration is increasing in many markets outside the U.S., including Japan, Europe, and many countries in the emerging markets. For biologics (such as Humalog, Humulin, Erbitux, Cyramza, Trulicity, Taltz, and Emgality), loss of exclusivity may or may not result in the near-term entry of competitor versions (i.e., biosimilars) due to many factors including development timelines, manufacturing challenges, and/or uncertainties in the regulatory pathways for approval of the competitor versions.

There is no assurance that the patents we are seeking will be granted or that the patents we hold will be found valid and enforceable if challenged. Moreover, patents relating to particular products, uses, formulations, or processes do not preclude other manufacturers from employing alternative processes or marketing alternative products or formulations that compete with our patented products. In addition, competitors or other third parties may assert claims that our activities infringe patents or other intellectual property rights held by them, or allege a third-party right of ownership in our existing intellectual property. See Item 7, “Management’s Discussion and Analysis - Results of Operations - Executive Overview - Other Matters - Patent Matters,” and Item 1, "Business - Patents, Trademarks, and Other Intellectual Property Rights," for more details.

- **Our long-term success depends on intellectual property protection; if our intellectual property rights are invalidated, circumvented, or weakened, our business will be adversely affected.**

Our long-term success depends on our ability to continually discover or acquire, develop, and commercialize innovative new pharmaceutical products. Without strong intellectual property protection, we would be unable to generate the returns necessary to support the enormous investments in research and development and capital as well as other expenditures required to bring new drugs to the market.

Intellectual property protection varies throughout the world and is subject to change over time, depending on local laws and regulations. Changes to such laws and regulations could reduce protections for our innovative products. In the U.S., in addition to the process for challenging patents set forth in the BPCI Act, which applies to our biologic products, the Hatch-Waxman Act provides generic companies powerful incentives to seek to invalidate our other pharmaceutical patents. As a result, we expect that our U.S. patents on major pharmaceutical products will continue to be routinely challenged in litigation and may not be upheld. In addition, a separate IPR process allows competitors to request review of issued patents by the USPTO without the protections of the Hatch-Waxman Act. Our patents may be invalidated via this review process. Although such a decision can be appealed to the courts, in certain circumstances a loss in such a proceeding could result in a competitor entering the market, while a win provides no precedential value - the same patent can still be challenged by other competitors. We face many generic manufacturer challenges to our patents outside the U.S. as well. The entry of generic competitors typically results in rapid and severe declines in revenues. In

addition, competitors or other third parties may claim that our activities infringe patents or other intellectual property rights held by them. If successful, such claims could result in our being unable to market a product in a particular territory or being required to pay significant damages for past infringement or royalties on future sales. See Item 1, “Business - Patents, Trademarks, and Other Intellectual Property Rights,” Item 3, "Legal Proceedings," and Item 8, "Financial Statements and Supplementary Data - Note 16, Contingencies," for more details.

- **Our business is subject to increasing government price controls and other public and private restrictions on pricing, reimbursement, and access for our drugs, which could have a material adverse effect on our reputation or business.**

  Public and private payers are taking increasingly aggressive steps to control their expenditures for pharmaceuticals by placing restrictions on pricing and reimbursement for, and patient access to, our medications. These pressures could continue to negatively affect our future revenues and net income.

  We expect pricing, reimbursement, and access pressures from both governments and private payers inside and outside the U.S. to become more severe. For more details, see Item 1, “Business - Regulations and Private Payer Actions Affecting Pharmaceutical Pricing, Reimbursement, and Access,” and Item 7, “Management’s Discussion and Analysis - Results of Operations - Executive Overview - Other Matters - Trends Affecting Pharmaceutical Pricing, Reimbursement, and Access.”

- **We face intense competition from multinational pharmaceutical companies, biotechnology companies, and lower-cost generic and biosimilar manufacturers, and such competition could have a material adverse effect on our business.**

  We compete with a large number of multinational pharmaceutical companies, biotechnology companies, and generic pharmaceutical companies. To compete successfully, we must continue to deliver to the market innovative, cost-effective products that meet important medical needs. Our product revenues can be adversely affected by the introduction by competitors of branded products that are perceived as superior by the marketplace, by generic or biosimilar versions of our branded products, and by generic or biosimilar versions of other products in the same therapeutic class as our branded products. Regulation of generic and biosimilar products varies around the world. Particularly for biosimilars, changes to such regulations could make it easier, less expensive, and less time consuming for competitor products to enter the market, some of which could be substituted for our products at the pharmacy. Our revenues can also be adversely affected by treatment innovations that eliminate or minimize the need for treatment with our drugs. See Item 1, “Business - Competition” and "Business - Research and Development," for more details.

- **Changes in foreign currency rates or devaluation of a foreign currency can materially affect our revenue, cost of sales, and operating expenses.**

  As a global company with substantial operations outside the U.S., we face foreign currency risk exposure from fluctuating currency exchange rates. While we seek to manage a portion of these exposures through hedging and other risk management techniques, significant fluctuations in currency rates can have a material impact, either positive or negative, on our revenue, cost of sales, and operating expenses. In the event of an extreme devaluation of local currency, the price of our products could become unsustainable in the relevant market. See Item 7, “Management’s Discussion and Analysis - Financial Condition” for more details.

- **Unanticipated changes in our tax rates or exposure to additional tax liabilities could increase our income taxes and decrease our net income.**

  We are subject to income taxes in the U.S. and numerous foreign jurisdictions, and in the course of our business, we make judgments about the expected tax treatment of various transactions and events, including the separation of Elanco. Changes in the relevant tax laws, regulations, administrative practices, principles, and interpretations, as well as events that differ from our expectations, could adversely affect our future effective tax rates. The U.S. enacted tax reform legislation significantly revising the U.S. tax law, effective January 2018, and a number of other countries are actively considering or enacting tax changes. Modifications to key elements of the U.S. or international tax framework could have a material adverse effect on our consolidated operating results and cash flows. See Item 7, “Management’s Discussion and Analysis - Results of Operations - Executive Overview - Other Matters - Tax Matters” and Item 8, "Financial Statements and Supplementary Data - Note 14, Income Taxes," for more details. Lilly has taken the position on the separation from Elanco, based on an opinion of tax counsel, that the divestiture of Elanco common stock qualifies as a transaction that is tax-free for U.S. federal income tax purposes. If any facts,

assumptions, representations, and undertakings from Lilly and Elanco regarding the past and future conduct of their respective businesses and other matters are incorrect or not otherwise satisfied, the divestiture may not qualify for tax-free treatment, which could result in significant U.S. federal income tax liabilities for both Lilly and its shareholders who exchanged their stock for Elanco stock.

- **Failure, inadequacy, or breach of our information technology systems, infrastructure, and business information or violations of data protection laws could result in material harm to our business and reputation.**

  A great deal of confidential information owned by both us and our business partners is stored in our information systems, networks, and facilities or those of third parties. This includes valuable trade secrets and intellectual property, clinical trial information, corporate strategic plans, marketing plans, customer information, and personally identifiable information, such as employee and patient information (collectively, "confidential information"). We also rely to a large extent on the efficient and uninterrupted operation of complex information technology systems, infrastructure, and hardware (together "IT systems"), some of which are within the company's control and some of which are within the control of third parties, to accumulate, process, store, and transmit large amounts of confidential information and other data. We are subject to a variety of continuously evolving and developing laws and regulations around the world related to privacy, data protection, and data security. Maintaining the confidentiality, integrity and availability of our IT systems and confidential information is vital to our business.

  IT systems are vulnerable to system inadequacies, operating failures, service interruptions or failures, security breaches, malicious intrusions, or cyber-attacks from a variety of sources. Cyber-attacks are growing in their frequency, sophistication, and intensity, and are becoming increasingly difficult to detect, mitigate, or prevent. Cyber-attacks come in many forms, including the deployment of harmful malware, exploitation of vulnerabilities, denial-of-service attacks, the use of social engineering, and other means to compromise the confidentiality, integrity and availability of our IT systems, confidential information, and other data. Breaches resulting in the compromise, disruption, degradation, manipulation, loss, theft, destruction, or unauthorized disclosure or use of confidential information, or the unauthorized access to, disruption of, or interference with our products and services, can occur in a variety of ways, including but not limited to, negligent or wrongful conduct by employees or others with permitted access to our systems and information, or wrongful conduct by hackers, competitors, certain governments, or other current or former company personnel. Our third party partners face similar risks.

  The failure or inadequacy of our IT systems, the compromise, disruption, degradation, manipulation, loss, theft, destruction, or unauthorized disclosure or use of confidential information, or the unauthorized access to, disruption of, or interference with our products and services that rely on IT systems, could impair our ability to secure and maintain intellectual property rights; result in a product manufacturing interruption or failure, or in the interruption or failure of products or services that rely on IT systems; damage our operations, customer relationships, or reputation; and cause us to lose trade secrets or other competitive advantages. Unauthorized disclosure of personally identifiable information could expose us to significant sanctions for violations of data privacy laws and regulations around the world and could damage public trust in our company.

  To date, system inadequacies, operating failures, unauthorized access, service interruptions or failures, security breaches, malicious intrusions, cyber-attacks, and the compromise, disruption, degradation, manipulation, loss, theft, destruction, or unauthorized disclosure or use of confidential information have not had a material impact on our consolidated results of operations. We maintain cyber liability insurance; however, this insurance may not be sufficient to cover the financial, legal, business, or reputational losses that may result from an interruption or breach of our IT systems. We continue to implement measures in an effort to protect, detect, respond to, and minimize or prevent these risks and to enhance the resiliency of our IT systems; however, these measures may not be successful. If they are not successful, any of these events could result in material financial, legal, business, or reputational harm to our business.

- **Significant economic downturns or international trade disruptions or disputes could adversely affect our business and operating results.**

  While pharmaceuticals have not generally been sensitive to overall economic cycles, prolonged economic slowdowns could lead to decreased utilization of our products, affecting our sales volume. Declining tax revenues attributable to economic downturns increase the pressure on governments to reduce health care spending, leading to increasing government efforts to control drug prices and utilization. Additionally, some customers, including governments or other entities reliant upon government funding, may be unable to pay in a timely manner for our products. Also, if our customers, suppliers, or collaboration partners experience financial difficulties, we could experience slower customer collections, greater bad debt expense, and performance defaults by suppliers or collaboration partners. Similarly, in the event of a significant economic downturn, we could have difficulty accessing credit markets.

  Significant portions of our business are conducted in Europe, including the U.K.; Asia; and other international geographies. Trade disputes and interruptions in international relationships, including pandemic diseases, such as the coronavirus, could result in changes to regulations governing our products and our intellectual property, or otherwise affect our ability to do business. While we do not expect either circumstance to materially affect our business in a direct manner, these and similar events could adversely affect us, or our business partners or customers.

- **Pharmaceutical products can develop unexpected safety or efficacy concerns, which could have a material adverse effect on revenues, income, and reputation.**

  Pharmaceutical products receive regulatory approval based on data obtained in controlled clinical trials of limited duration. After approval, the products are used for longer periods of time by much larger numbers of patients; we and others (including regulatory agencies and private payers) collect extensive information on the efficacy and safety of our marketed products by continuously monitoring the use of our products in the marketplace. In addition, we or others may conduct post-marketing clinical studies on efficacy and safety of our marketed products. New safety or efficacy data from both market surveillance and post-marketing clinical studies may result in product label changes or other measures that could reduce the product's market acceptance and result in declining sales. Serious safety or efficacy issues that arise after product approval could result in voluntary or mandatory product recalls or withdrawals from the market. Safety issues could also result in costly product liability claims.

- **We face litigation and investigations related to our products and our pricing practices and are self-insured; we could face large numbers of claims in the future, which could adversely affect our business.**

  We are subject to a substantial number of product liability claims involving Actos®, Axiron®, Byetta®, Cialis, and Cymbalta among other products, as well as litigation and investigations related to the pricing of our products. See Item 8, “Financial Statements and Supplementary Data - Note 16, Contingencies,” and Item 3, “Legal Proceedings,” for more information on our current product liability litigation, as well as pricing litigation, investigations, and inquiries. Because of the nature of pharmaceutical products, we are and could in the future become subject to large numbers of product liability claims for these or other products, or to further litigation or investigations into pricing or other commercial practices. Such matters require substantial expenditures to resolve and, if involving marketed products, could adversely affect sales of the product. Due to a very restrictive market for liability insurance, we are self-insured for product liability losses for all our currently marketed products, as well as for litigation or investigations related to our pricing practices or other similar matters.

- **Regulatory compliance problems could be damaging to the company.**

  The marketing, promotional, and pricing practices of pharmaceutical manufacturers, as well as the manner in which manufacturers interact with purchasers, prescribers, and patients, are subject to extensive regulation. Many companies, including us, have been subject to claims related to these practices asserted by federal, state, and foreign governmental authorities, private payers, and consumers. These claims have resulted in substantial expense and other significant consequences to us. We are and could in the future become subject to such investigations, the outcomes of which could include criminal charges and fines, penalties, or other monetary or non-monetary remedies, including exclusion from U.S. federal and other health care programs. In addition, regulatory issues concerning compliance with cGMP regulations (and comparable foreign regulations) for our products can lead to product recalls and seizures, fines and penalties, interruption of production leading to product shortages, and delays in the approvals of new products pending resolution of the issues. See Item 1, “Business - Government Regulation of Our Operations,” for more details.

- **Manufacturing difficulties or disruptions could lead to product supply problems.**

  Pharmaceutical manufacturing is complex and highly regulated. Manufacturing difficulties at our facilities or contracted facilities, or the failure or refusal of a contract manufacturer to supply contracted quantities, could result in product shortages, leading to lost revenue. Such difficulties or disruptions could result from quality or regulatory compliance problems; natural disasters or pandemic disease; mechanical or information technology system vulnerabilities, such as system inadequacies, operating failures, service interruptions or failures, security breaches, malicious intrusions, or cyber-attacks from a variety of sources; or inability to obtain sole-source raw or intermediate materials. In addition, given the difficulties in predicting sales of new products and the very long lead times necessary for the expansion and regulatory qualification of pharmaceutical manufacturing capacity, it is possible that we could have difficulty meeting unanticipated demand for new products. See Item 1, “Business - Raw Materials and Product Supply,” for more details.

- **Reliance on third-party relationships and outsourcing arrangements could adversely affect our business.**

  We rely on third parties, including suppliers, distributors, alliances with other pharmaceutical and biotechnology companies, and third-party service providers, for selected aspects of product development, manufacture, commercialization, support for information technology systems, product distribution, and certain financial transactional processes. For example, we outsource the day-to-day management and oversight of our clinical trials to contract research organizations. Outsourcing these functions involves the risk that the third parties may not perform to our standards or legal requirements; may not produce reliable results; may not perform in a timely manner; may not maintain the confidentiality, integrity, and availability of our confidential and proprietary information; may experience disruption or fail to perform due to information technology system vulnerabilities, breaches, or cyber-attacks; or may fail to perform at all. Failure of these third parties to meet their contractual, regulatory, confidentiality, privacy, security, or other obligations to us could have a material adverse effect on our business.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our principal domestic and international executive offices are located in Indianapolis. At December 31, 2019, we owned 9 production and distribution sites in the U.S. and Puerto Rico. Together with the corporate administrative offices, these facilities contain an aggregate of approximately 8.2 million square feet of floor area dedicated to production, distribution, and administration. Major production sites include Indianapolis, Indiana; Carolina, Puerto Rico; and Branchburg, New Jersey.

We own production and distribution sites in 8 countries outside the U.S. and Puerto Rico, containing an aggregate of approximately 4.4 million square feet of floor area. Major production sites include facilities in Ireland, France, Spain, Italy, and China.

In the U.S., our research and development facilities contain an aggregate of approximately 4.2 million square feet of floor area, primarily consisting of owned facilities located in Indianapolis. We also lease smaller sites in San Diego, California and New York City, New York. Outside the U.S., we own smaller research and development facilities in the U.K. and Spain, and lease smaller sites in Singapore.

We believe that none of our properties is subject to any encumbrance, easement, or other restriction that would detract materially from its value or impair its use in the operation of the business. The buildings we own are of varying ages and in good condition.

Item 3. Legal Proceedings

We are a party to various currently pending legal actions, government investigations, and environmental proceedings, and we anticipate that such actions could be brought against us in the future. The most significant of these matters are described below or, as noted, in Item 8, "Financial Statements and Supplementary Data - Note 16, Contingencies." While it is not possible to determine the outcome of the legal actions, investigations, and proceedings brought against us, we believe that, except as otherwise specifically noted in Item 8, "Financial Statements and Supplementary Data - Note 16, Contingencies," the resolution of all such matters will not have a material adverse effect on our consolidated financial position or liquidity, but could be material to our consolidated results of operations in any one reporting period.

Legal Proceedings Described in Note 16 to the Consolidated Financial Statements

See Item 8, "Financial Statements and Supplementary Data - Note 16, Contingencies," for information on various legal proceedings, including but not limited to:

- The patent litigation and administrative proceedings involving Alimta, Jardiance, Taltz, and Emgality;
- The product liability litigation involving Cymbalta;
- The litigation related to the Cosmopolis facility in Brazil; and
- Pricing litigation, investigations, and inquiries.

That information is incorporated into this Item by reference.

Other Product Liability Litigation

We are named along with Takeda Chemical Industries, Ltd. and Takeda affiliates (collectively, Takeda) as a defendant in four purported product liability class actions in Canada related to Actos, which we commercialized with Takeda in Canada until 2009, including one in Ontario *(Casseres et al. v. Takeda Pharmaceutical North America, Inc., et al.*), one in Quebec (*Whyte et al. v. Eli Lilly et al.*), one in Saskatchewan (*Weiler v. Takeda Canada Inc. et al.*), and one in Alberta (*Epp v. Takeda Canada Inc. et al.*). In general, plaintiffs in these actions alleged that Actos caused or contributed to their bladder cancer. We believe these lawsuits are without merit, and we and Takeda are defending against them vigorously.

We are named as a defendant in approximately 565 Byetta product liability lawsuits in the U.S. involving approximately 815 plaintiffs. Approximately 60 of these lawsuits, covering about 305 plaintiffs, are filed in California state court and coordinated in a Los Angeles Superior Court. Approximately 500 of the lawsuits, covering about 510 plaintiffs, are filed in federal court, the majority of which are coordinated in a multi-district litigation (MDL) in the U.S. District Court for the Southern District of California. Three lawsuits, representing approximately four plaintiffs, have also been filed in various state courts. Approximately 555 of the lawsuits,

involving approximately 790 plaintiffs, contain allegations that Byetta caused or contributed to the plaintiffs' cancer (primarily pancreatic cancer or thyroid cancer); most others allege Byetta caused or contributed to pancreatitis. In addition, two suits involving approximately nine plaintiffs allege that Byetta caused or contributed to renal injuries and one case alleges that Byetta caused or contributed to ampullary cancer. The federal and state trial courts granted summary judgment in favor of us and our co-defendants on the claims alleging pancreatic cancer. The plaintiffs appealed those rulings. In November 2017, the U.S. Court of Appeals for the Ninth Circuit reversed the U.S. District Court's grant of summary judgment based on that court's discovery rulings and remanded the cases for further proceedings. In November 2018, the California Court of Appeal reversed the state court's grant of summary judgment based on that court's discovery rulings and remanded for further proceedings. We are aware of approximately 20 additional claimants who have not yet filed suit. These additional claims allege damages for pancreatic cancer or thyroid cancer. We believe these lawsuits are without merit and are defending against them vigorously.

We are named as a defendant in approximately 50 Axiron personal injury/product liability lawsuits in the U.S. involving approximately 50 plaintiffs. In some of the cases, other manufacturers of testosterone are named as co-defendants. All of these lawsuits have been consolidated in a federal MDL in the U.S. District Court for the Northern District of Illinois. The cases generally allege cardiovascular and related injuries. We have reached agreement on a settlement framework that provides for a comprehensive resolution of all of these personal injury claims alleging cardiovascular and related injuries from Axiron treatment. We have also been engaged in litigation with Medical Mutual of Ohio (MMO), which filed a class action complaint against multiple manufacturers of testosterone products, including Lilly, in the U.S. District Court for the Northern District of Illinois, on behalf of third-party payers who paid for those products and is seeking damages under the Federal Racketeer Influenced and Corrupt Organizations Act. MMO's motion for class certification was denied, and in February 2019, the District Court granted summary judgment in favor of defendants, dismissing MMO's lawsuit with prejudice. In November 2019, the U.S. Court of Appeals for the Seventh Circuit affirmed the District Court's ruling, concluding this case.

We are named as a defendant in approximately 350 Cialis product liability lawsuits in the U.S. These cases, many of which were originally filed in various federal courts, contain allegations that Cialis caused or contributed to the plaintiffs' cancer (melanoma). In December 2016, the Judicial Panel on Multidistrict Litigation (JPML) granted the plaintiffs' petition to have filed cases and an unspecified number of future cases coordinated into a federal MDL in the U.S. District Court for the Northern District of California, alongside an existing coordinated proceeding involving Viagra®. The JPML ordered the transfer of the existing cases to the now-renamed multidistrict litigation *In re: Viagra (Sildenafil Citrate) and Cialis (Tadalafil) Products Liability Litigation*. We believe these lawsuits are without merit and are defending against them vigorously.

Other Patent Litigation

In Canada, several generic companies previously challenged the validity of our Zyprexa compound patent. In 2012, the Canadian Federal Court of Appeals denied appeal of the lower court's decision that certain patent claims were invalid for lack of utility. In 2013, our petition for leave to appeal the decision to the Supreme Court of Canada was denied. Apotex Inc. and Apotex Pharmachem Inc. (collectively, Apotex) pursued claims for damages arising from our enforcement of the patent under Canadian regulations. Apotex's claims seek compensation based on novel legal theories under the Statute of Monopolies, Trade-Mark Act, and common law. We believe these claims are without merit and are defending against them vigorously. Trial is scheduled to begin in April 2021.

Other Matters

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

We are named as a defendant in a lawsuit in the U.S. District Court for the Eastern District of Texas seeking damages under the federal anti-kickback statute and state and federal false claims acts for certain

patient support programs related to our products Humalog, Humulin, and Forteo. In September 2019, the U.S. District Court granted the DOJ's motion to dismiss the relator’s second amended complaint. In January 2020, the relator appealed the District Court’s dismissal to the U.S. Court of Appeals for the Fifth Circuit. We believe this lawsuit is without merit and are defending against it vigorously.

The competition authority in China has investigated our distributor pricing practices in China in connection with a broader inquiry into pharmaceutical industry pricing. We have cooperated with this investigation.

We, along with another pharmaceutical manufacturer, are named as co-defendants in *United States et al. ex rel. Streck v. Takeda Pharm. Am., Inc., et al.*, which was unsealed in the U.S. District Court for the Northern District of Illinois. The complaint alleges that the defendants should have treated certain credits from distributors as retroactive price increases and included such increases in calculating Average Manufacturer Prices. We believe these claims are without merit and are defending against them vigorously.

Under the Comprehensive Environmental Response, Compensation, and Liability Act, commonly known as "Superfund," we have been designated as one of several potentially responsible parties with respect to the cleanup of fewer than 10 sites. Under Superfund, each responsible party may be jointly and severally liable for the entire amount of the cleanup.

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

Item 4. Mine Safety Disclosures

Not applicable.

Part II

Item 5. Market for the Registrant's Common Equity, Related Stockholder Matters, and Issuer Purchases of Equity Securities

You can find information relating to the principal market for our common stock and related stockholder matters at Item 6, "Selected Financial Data (unaudited)", Item 7, "Management's Discussion and Analysis of Results of Operations and Financial Condition", and Item 8, "Financial Statements and Supplementary Data - Note 20, Selected Quarterly Data (unaudited)." That information is incorporated here by reference.

The following table summarizes the activity related to repurchases of our equity securities during the fourth quarter ended December 31, 2019:

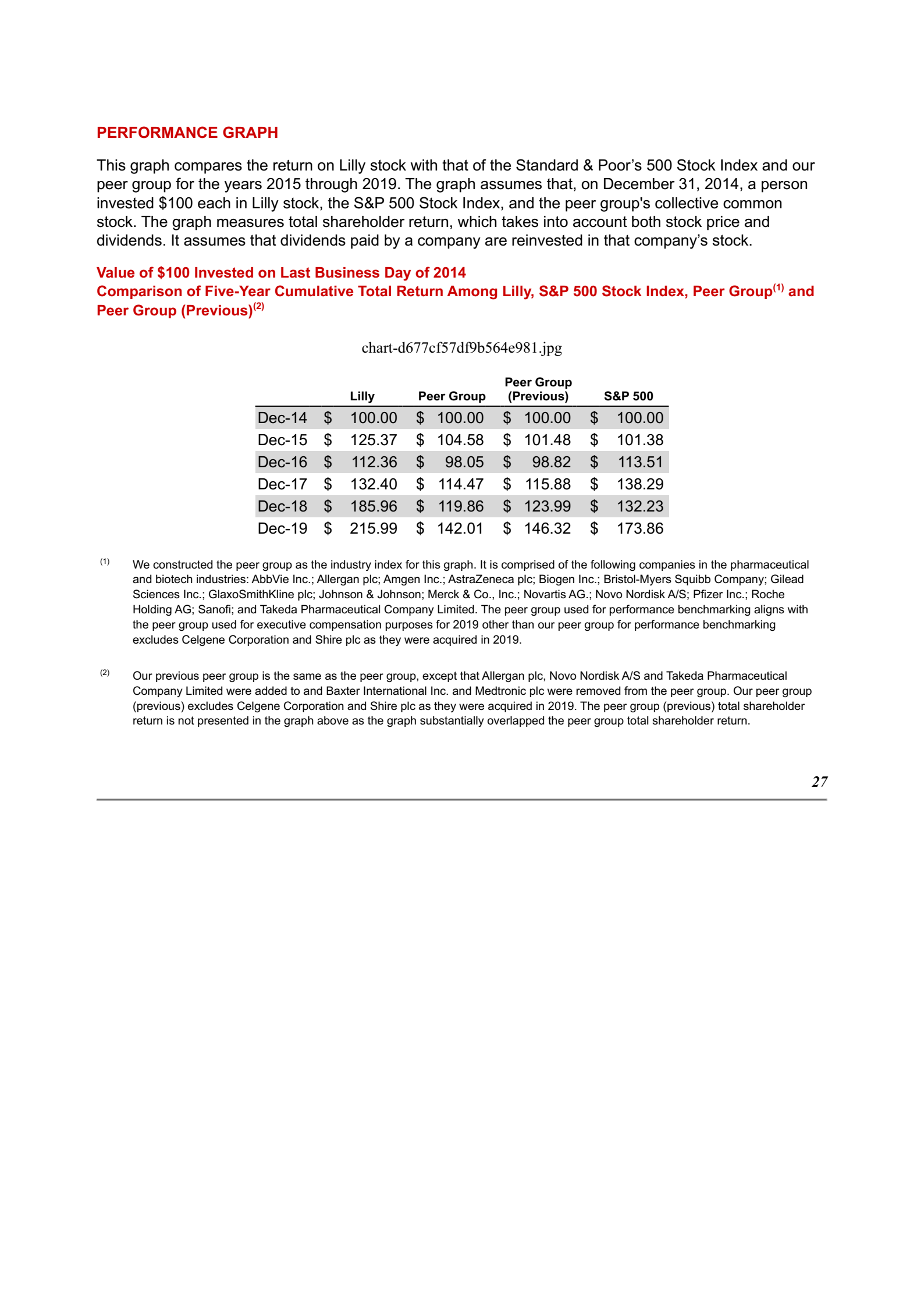
Period	Total Number of Shares Purchased (in thousands)	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs (in thousands)	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs (dollars in millions)
October 2019	2,079	$ 114.10	2,079	$ 1,562.8
November 2019	318	114.80	318	1,526.2
December 2019	225	116.65	225	1,500.0
Total	2,622	114.41	2,622	

During the three months ended December 31, 2019, we repurchased $300.0 million of shares under the $8.00 billion share repurchase program authorized in June 2018.

PERFORMANCE GRAPH

This graph compares the return on Lilly stock with that of the Standard & Poor's 500 Stock Index and our peer group for the years 2015 through 2019. The graph assumes that, on December 31, 2014, a person invested $100 each in Lilly stock, the S&P 500 Stock Index, and the peer group's collective common stock. The graph measures total shareholder return, which takes into account both stock price and dividends. It assumes that dividends paid by a company are reinvested in that company's stock.

Value of $100 Invested on Last Business Day of 2014
Comparison of Five-Year Cumulative Total Return Among Lilly, S&P 500 Stock Index, Peer Group[1] and Peer Group (Previous)[2]



	Lilly	Peer Group	Peer Group (Previous)	S&P 500
Dec-14	$ 100.00	$ 100.00	$ 100.00	$ 100.00
Dec-15	$ 125.37	$ 104.58	$ 101.48	$ 101.38
Dec-16	$ 112.36	$ 98.05	$ 98.82	$ 113.51
Dec-17	$ 132.40	$ 114.47	$ 115.88	$ 138.29
Dec-18	$ 185.96	$ 119.86	$ 123.99	$ 132.23
Dec-19	$ 215.99	$ 142.01	$ 146.32	$ 173.86

(1) We constructed the peer group as the industry index for this graph. It is comprised of the following companies in the pharmaceutical and biotech industries: AbbVie Inc.; Allergan plc; Amgen Inc.; AstraZeneca plc; Biogen Inc.; Bristol-Myers Squibb Company; Gilead Sciences Inc.; GlaxoSmithKline plc; Johnson & Johnson; Merck & Co., Inc.; Novartis AG.; Novo Nordisk A/S; Pfizer Inc.; Roche Holding AG; Sanofi; and Takeda Pharmaceutical Company Limited. The peer group used for performance benchmarking aligns with the peer group used for executive compensation purposes for 2019 other than our peer group for performance benchmarking excludes Celgene Corporation and Shire plc as they were acquired in 2019.

(2) Our previous peer group is the same as the peer group, except that Allergan plc, Novo Nordisk A/S and Takeda Pharmaceutical Company Limited were added to and Baxter International Inc. and Medtronic plc were removed from the peer group. Our peer group (previous) excludes Celgene Corporation and Shire plc as they were acquired in 2019. The peer group (previous) total shareholder return is not presented in the graph above as the graph substantially overlapped the peer group total shareholder return.

Item 6. Selected Financial Data (unaudited)

ELI LILLY AND COMPANY AND SUBSIDIARIES (Dollars in millions, except revenue per employee and per-share data)	2019	2018	2017	2016	2015
Operations[1]					
Revenue	**$ 22,319.5**	$ 21,493.3	$ 19,973.8	$ 18,312.8	$ 17,050.5
Cost of sales	**4,721.2**	4,681.7	4,447.7	4,160.5	3,373.1
Research and development	**5,595.0**	5,051.2	5,096.2	5,040.0	4,514.2
Marketing, selling, and administrative	**6,213.8**	5,975.1	5,982.4	5,841.9	5,732.4
Other[2]	**523.6**	2,105.2	2,142.7	(5.9)	538.9
Income before income taxes	**5,265.9**	3,680.1	2,304.8	3,276.3	2,891.9
Income taxes[3]	**628.0**	529.5	2,391.2	551.4	379.7
Net income (loss) from continuing operations	**4,637.9**	3,150.6	(86.4)	2,724.9	2,512.2
Net income (loss)[4]	**8,318.4**	3,232.0	(204.1)	2,737.6	2,408.4
Earnings (loss) per share from continuing operations—diluted	**4.96**	3.05	(0.08)	2.57	2.36
Earnings (loss) per share—diluted[4]	**8.89**	3.13	(0.19)	2.58	2.26
Dividends declared per share	**2.68**	2.33	2.12	2.05	2.01
Weighted-average number of shares outstanding—diluted (thousands)	**935,684**	1,033,667	1,052,023	1,061,825	1,065,720
Financial Position[1]					
Total assets	**$ 39,286.1**	$ 43,908.4	$ 44,981.0	$ 38,805.9	$ 35,568.9
Long-term debt	**13,817.9**	9,196.4	9,940.0	8,367.4	7,971.4
Supplementary Data[1]					
Return on total equity[4]	**184.9 %**	25.7 %	(1.5 %)	18.5 %	16.1 %
Return on assets[4]	**21.0 %**	7.3 %	(0.5 %)	7.5 %	6.8 %
Revenue per employee	**$ 664,000**	$ 650,000	$ 575,000	$ 510,000	$ 490,000
Number of employees	**33,625**	33,090	34,750	35,910	34,790
Number of shareholders of record	**22,600**	24,000	25,300	26,800	28,000

[1] On March 11, 2019, we completed the disposition of our remaining 80.2 percent ownership of Elanco Animal Health (Elanco) common stock through a tax-free exchange offer. As a result, Elanco has been presented as discontinued operations in our consolidated financial statements for all periods presented. See Note 19 to the consolidated financial statements for discussion regarding discontinued operations.

[2] 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.

[3] See Note 14 to the consolidated financial statements for discussion regarding income taxes.

(4) The 2019 increase was primarily driven by a gain of approximately $3.7 billion related to the disposition of Elanco. The 2019 increase in earnings (loss) per share and return on equity were also driven by the reduction of common stock related to the disposition of Elanco. See Note 19 to the consolidated financial statements for discussion regarding discontinued operations.

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 in Item 8 of Part II of this Annual Report on Form 10-K. Certain statements in this Item 7 of Part II of this Annual Report on Form 10-K constitute forward-looking statements. Various risks and uncertainties, including those discussed in "Forward-Looking Statements" and Item 1A, "Risk Factors", may cause our actual results, financial position, and cash generated from operations to differ materially from these forward-looking statements.

Executive Overview

This section provides an overview of our financial results, recent product and late-stage pipeline developments, and other matters affecting our company and the pharmaceutical industry. Earnings per share (EPS) data are presented on a diluted basis.

On March 11, 2019, we completed the disposition of our remaining 80.2 percent ownership of Elanco Animal Health Incorporated (Elanco) common stock through a tax-free exchange offer. As a result, we recognized a gain on the disposition of approximately $3.7 billion in the first quarter of 2019 and now operate as a single segment. See Note 19 to the consolidated financial statements for further discussion.

Financial Results

The following table summarizes our key operating results:

	Year Ended December 31,		Percent Change
	2019	2018	
Revenue	**$ 22,319.5**	$ 21,493.3	4
Gross margin	**17,598.3**	16,811.6	5
Gross margin as a percent of revenue	**78.8 %**	78.2 %	
Operating expense	**$ 11,808.8**	$ 11,026.3	7
Acquired in-process research and development	**239.6**	1,983.9	(88)
Asset impairment, restructuring, and other special charges	**575.6**	266.9	NM
Income before income taxes	**5,265.9**	3,680.1	43
Income taxes	**628.0**	529.5	19
Net income from continuing operations	**4,637.9**	3,150.6	47
Net income	**8,318.4**	3,232.0	NM
EPS from continuing operations	**4.96**	3.05	63
EPS	**8.89**	3.13	NM

NM - not meaningful

Revenue increased in 2019 driven by increased volume, partially offset by lower realized prices and the unfavorable impact of foreign exchange rates. Operating expenses increased in 2019, reflecting higher late-stage development expenses and increased marketing expenses for recently launched products, partially offset by lower marketing expenses for late life-cycle products. The increases in net income and EPS in 2019 were driven primarily by the gain recognized on the disposition of Elanco and, to a lesser

extent, lower acquired in-process research and development (IPR&D) charges. In addition to the increase in net income, EPS in 2019 significantly benefited from lower weighted-average shares outstanding as a result of the Elanco exchange offer and share repurchases.

The following highlighted items affect comparisons of our 2019 and 2018 financial results:

2019

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

- We recognized acquired IPR&D charges of $239.6 million primarily related to collaborations with AC Immune SA (AC Immune), Centrexion Therapeutics Corporation (Centrexion), ImmuNext, Inc. (ImmuNext), and Avidity Biosciences, Inc. (Avidity).

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

- We recognized charges of $575.6 million primarily associated with the accelerated vesting of Loxo Oncology, Inc. (Loxo) employee equity awards as a result of the closing of the acquisition of Loxo, and, to a lesser extent, charges associated with the decision to close and sell a research and development facility located in the United Kingdom (U.K).

Other–Net, (Income) Expense (Note 18 to the consolidated financial statements)

- We recognized a gain of $309.8 million on the sale of the company's antibiotics business in China.
- We recognized a debt extinguishment loss of $252.5 million related to the repurchase of debt.

Net Income from Discontinued Operations (Note 19 to the consolidated financial statements)

- We recognized a gain related to the disposition of Elanco of approximately $3.7 billion.

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, Inc. (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 Taxes (Note 14 to the consolidated financial statements)

- We recognized $313.3 million of income tax benefit primarily due 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).

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

Galcanezumab* (Emgality®) (Q3 2018)—a once-monthly subcutaneously injected calcitonin gene-related peptide (CGRP) antibody for migraine prevention and for the treatment of episodic cluster headache. See Note 16 to the consolidated financial statements for discussion of the legal

proceedings involving Teva Pharmaceuticals International GMBH and Teva Pharmaceuticals USA, Inc.

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

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

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

Flortaucipir (Q3 2019)**—a positron emission tomography (PET) tracer intended to image tau (or neurofibrillary) tangles in the brain, which are an indicator of Alzheimer's disease.

Selpercatinib (Q4 2019)—an oral drug for the treatment of patients with cancers that harbor abnormalities in the rearranged during transfection (RET) kinase, specifically thyroid cancer and lung cancer.

Tanezumab* (Q4 2019)—an anti-nerve growth factor monoclonal antibody for the treatment of osteoarthritis pain (in collaboration with Pfizer Inc. (Pfizer)).

Ultra-rapid Lispro* (Q1 2019)—an ultra-rapid insulin for the treatment of type 1 and type 2 diabetes.

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

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

Solanezumab* (Q2 2009)—an anti-amyloid beta monoclonal antibody for the treatment of preclinical Alzheimer’s disease.

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 and obesity.

* Biologic molecule subject to the United States (U.S.) Biologics Price Competition and Innovation Act

** Diagnostic agent

The following table reflects the status of the recently approved products, NMEs, and diagnostic agent set forth above, as well as certain other developments to our late-stage pipeline since January 1, 2019:

Compound	Indication	U.S.	Europe	Japan	Developments
Endocrinology					
Baqsimi	Severe hypoglycemia	Launched	Approved	Submitted	Launched in the U.S. in third quarter of 2019. Approved in Europe in the fourth quarter of 2019. Submitted to the Japan regulatory authorities in 2019.
Tirzepatide	Type 2 diabetes	Phase III			Phase III trials are ongoing.
	Obesity	Phase III			Phase III trials were initiated in the fourth quarter of 2019.
Ultra-rapid Lispro	Type 1 and 2 diabetes	Submitted			Submitted to regulatory authorities in Europe and Japan in the first quarter of 2019. Submitted to the U.S. Food and Drug Administration (FDA) in the third quarter of 2019. In January 2020, the European regulatory authorities issued a positive opinion recommending approval.
Immunology					

Mirikizumab	Crohn's Disease	Phase III	Phase III trials were initiated during the third quarter of 2019.
	Psoriasis	Phase III	Phase III trials are ongoing.
	Ulcerative colitis	Phase III	Phase III trials are ongoing.

Compound	Indication	U.S.	Europe	Japan	Developments
Neuroscience					
Emgality	Cluster headache	Launched	Submitted	Phase III	Submitted to European regulatory authorities in the first quarter of 2019. Approved and launched in the U.S. in the second quarter of 2019.
	Migraine prevention	Launched		Submitted	Launched in Europe in the first quarter of 2019. Submitted to Japanese regulatory authorities in January 2020.
Flortaucipir	Alzheimer's disease diagnostic	Submitted	Phase III		Submitted to the FDA in the third quarter of 2019.
Reyvow	Acute treatment of migraine	Launched	Phase III		Approved by the FDA in the fourth quarter of 2019. Received Schedule V classification from the Drug Enforcement Agency and launched in the U.S. in January 2020.
Solanezumab	Preclinical Alzheimer's disease	Phase III			Announced in February 2020 that a Phase III trial for people with dominantly inherited Alzheimer's disease (DIAD) did not meet the primary endpoint. We do not plan to pursue submission for DIAD. Phase III trial is ongoing for Anti-Amyloid Treatment in Asymptomatic Alzheimer's.
Tanezumab	Osteoarthritis pain	Submitted	Phase III		In the third quarter of 2018 and the first quarter of 2019, announced multiple Phase III trials met several primary endpoints. In the second quarter of 2019, announced the results of the long-term Phase III study in which the 5mg dose met two of the three co-primary endpoints and the 2.5mg dose did not meet any of the three co-primary endpoints. In partnership with Pfizer, we submitted to the FDA in the fourth quarter of 2019 and are pursuing submission in Europe and Japan in 2020.
	Chronic low back pain	Phase III			In the first quarter of 2019, announced Phase III trial met primary endpoint for the 10mg dose and did not meet primary endpoint on the 5mg dose. In the third quarter of 2019, announced results from a Phase III study evaluating long-term safety and efficacy in Japan. In partnership with Pfizer, announced in the third quarter of 2019 that we are not planning regulatory submissions. We plan to maintain an open dialogue with regulatory authorities on potential future regulatory pathways.
	Cancer pain	Phase III			Phase III trial is ongoing.

Compound	Indication	U.S.	Europe	Japan	Developments
Oncology					
Lartruvo®	Soft tissue sarcoma	Withdrawn	Withdrawing	Not Submitting	In the first quarter of 2019, announced confirmatory phase III trial did not meet primary endpoint. As this trial did not confirm clinical benefit, we suspended promotion globally and withdrew the product in the U.S. in the third quarter of 2019. For countries in Europe, we have withdrawn or are in the process of withdrawing the product.
Pegilodecakin	Pancreatic cancer	Not Submitting			In the fourth quarter of 2019, announced phase III trial did not meet primary endpoint of overall survival. Phase II trials for other indications also did not meet primary endpoint. We do not plan to initiate any new trials.
Selpercatinib (LOXO-292)	Thyroid Cancer	Submitted		Phase III	In the fourth quarter of 2019, submitted to the FDA and European regulatory authorities based on Phase II data. Granted Breakthrough Therapy Designation(1). Granted Priority Review(2) from the FDA in first quarter of 2020. Phase III trials were initiated in the fourth quarter of 2019 in all major geographies.
	Lung Cancer	Submitted		Phase III	

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

(2) 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 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

Patent Matters

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

We lost our patent exclusivity for Strattera® in the U.S. in May 2017, and generic versions of Strattera were approved in the same month. Following a settlement related to the compound patent challenge for Effient®, generic products launched in the U.S. in the third quarter of 2017. The entry of generic competition for these products has caused a rapid and severe decline in revenue, which, in the aggregate, 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. Another later expiring patent (October 2020) was the subject of U.S. patent litigation and pursuant to a settlement agreement related thereto, generic tadalafil entered the U.S. market in September 2018. We have faced and remain exposed to generic competition following the loss of exclusivity, which has rapidly and severely eroded revenue and is likely to continue to erode revenue.

Our formulation patents for Forteo® expired in December 2018, and our use patents expired in August 2019 in major European markets and the U.S. Both the formulation patent and the use patent expired in August 2019 in Japan. We expect further volume decline as a result of the entry of generic and biosimilar competition following the loss of patent exclusivity in these markets. In the aggregate, we expect that the decline in revenue will have a material adverse effect on our consolidated results of operations and cash flows.

The Alimta® vitamin regimen patents, which we expect to provide us with patent protection for Alimta through June 2021 in Japan and major European countries, and through May 2022 in the U.S., have been challenged in each of these jurisdictions. In the U.S., we and Eagle Pharmaceuticals, Inc. (Eagle) reached an agreement in December 2019 to settle all pending litigation, allowing Eagle a limited initial entry into the market with its product starting February 2022 (up to an approximate three-week supply) and subsequent unlimited entry starting April 2022. Our vitamin regimen patents have also been challenged in other smaller European jurisdictions. Our compound patent for Alimta expired in the U.S. in January 2017, and expired in major European countries and Japan in December 2015. We are aware that several companies have received approval to market generic versions of pemetrexed in major European markets (including Germany, France, and the Netherlands) and that additional generic competitors may choose to launch at risk. Although we will continue to seek to remove any such products, generic product entry is resulting in some loss in revenue in these jurisdictions. We expect that further entry of generic competition for Alimta following the loss of effective patent protection will cause a rapid and severe decline in revenue for the product, which will, in the aggregate, have a material adverse effect on our consolidated results of operations and cash flows. See Note 16 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 competitor launched a similar version of insulin lispro in certain European markets in 2017 and in the U.S. in the second quarter of 2018. While it is difficult to estimate the severity of the impact of insulin lispro products entering the market, we do not expect and have not experienced a rapid and severe decline in revenue; however, we expect additional pricing pressure and some loss of market share that would continue over time.

Foreign Currency Exchange Rates

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

Trends Affecting Pharmaceutical Pricing, Reimbursement, and Access

U.S.

In the U.S., public concern over access to and affordability of pharmaceuticals continues to drive the regulatory and legislative debate. These policy and political issues increase the risk that taxes, fees, rebates, or other cost control measures may be enacted to manage federal and state budgets. Key health policy initiatives affecting biopharmaceuticals include:

- foreign reference pricing in Medicare and private insurance,
- modifications to Medicare Parts B and D,
- provisions that would allow the Department of Health and Human Services to negotiate prices for biologics and drugs in Medicare,
- a reduction in biologic data exclusivity,
- proposals related to Medicaid prescription drug coverage and manufacturer drug rebates,
- proposals that would require biopharmaceutical manufacturers to disclose proprietary drug pricing information; and
- state-level proposals related to prescription drug prices and reducing the cost of pharmaceuticals purchased by government health care programs.

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

In the private sector, consolidation and integration among healthcare providers is also a major factor in the competitive marketplace for 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. In addition to formulary placement, changes in insurance designs continue to drive greater consumer cost sharing through high deductible plans and higher co-insurance or co-pays (including co-pay accumulator and

maximizer programs). We continue to invest in patient affordability solutions (resulting in lower revenue) in an effort to assist patients in affording their medicines.

The main coverage expansion provisions of the Affordable Care Act (ACA) are currently in effect through both state-based exchanges and the expansion of Medicaid. A trend has been the prevalence of benefit designs containing high out-of-pocket costs for patients, particularly for pharmaceuticals. In addition to the coverage expansions, many employers in the commercial market 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 and various other taxes in the U.S. and in many foreign jurisdictions; therefore, changes in both domestic and international tax laws or regulations could adversely affect our effective tax rate, results of operations, and cash flows. Countries around the world, including the U.S., actively consider and enact tax law changes. Further, actions taken with respect to tax-related matters by associations such as the Organisation for Economic Co-operation and Development and the European Commission could influence tax policy in countries in which we operate. Modifications to U.S. and foreign tax laws or regulations are frequently enacted and could result in material impacts to our results of operations and financial position.

Acquisitions

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

In February 2019, we acquired all shares of Loxo for a purchase price of $6.92 billion, net of cash acquired. Under the terms of the agreement, we acquired a pipeline of investigational medicines, including selpercatinib (LOXO-292), an oral RET inhibitor that has been granted Breakthrough Therapy designation by the FDA, and LOXO-305, an oral BTK inhibitor.

On January 10, 2020, we announced an agreement to acquire Dermira, Inc. for a purchase price of $18.75 per share, or approximately $1.1 billion.The acquisition will expand our immunology pipeline with the addition of lebrikizumab, a novel, investigational, monoclonal antibody designed to bind IL-13 with high affinity that is being evaluated in a Phase III clinical development program for the treatment of moderate-to-severe atopic dermatitis. Lebrikizumab was granted Fast Track designation from the FDA. 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.The acquisition will also expand our portfolio of marketed dermatology medicines with the addition of Qbrexza® (glycopyrronium) cloth, a medicated cloth approved by the FDA for the topical treatment of primary axillary hyperhidrosis (uncontrolled excessive underarm sweating). The transaction is not subject to any financing condition and is expected to close by the end of the first quarter of 2020, subject to customary closing conditions, including receipt of required regulatory approvals and the tender of a majority of the outstanding shares of Dermira's common stock.

See Note 3 to the consolidated financial statements for further discussion regarding our recent acquisitions.

Operating Results—2019

Revenue

The following table summarizes our revenue activity by region:

	Year Ended December 31,		
	2019	2018	Percent Change
U.S.[1]	**$ 12,722.6**	$ 12,391.9	3
Outside U.S.	**9,596.8**	9,101.4	5
Revenue	**$ 22,319.5**	$ 21,493.3	4

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:

	2019 vs. 2018		
	U.S.	Outside U.S.	Consolidated
Volume	6 %	10 %	8 %
Price	(3)%	(1)%	(3)%
Foreign exchange rates	— %	(3)%	(1)%
Percent change	3 %	5 %	4 %

Numbers may not add due to rounding.

In the U.S., the revenue increase in 2019 was driven by increased volume for Trulicity®, Taltz®, Verzenio®, Jardiance®, Emgality, and Basaglar®. The increase in revenue was partially offset by decreased volume for products that have lost exclusivity, primarily Cialis, lower volume for Forteo, and the impact from the product withdrawal of Lartruvo®. Additionally, the increase in revenue was partially offset by lower realized prices for several products, primarily Trulicity.

Outside the U.S., the revenue increase in 2019 was primarily driven by increased volume for Trulicity, Olumiant®, Taltz, and Jardiance. The increase in revenue was partially offset by the unfavorable impact of foreign exchange rates and, to a lesser extent, lower realized prices.

The following table summarizes our revenue activity in 2019 compared with 2018:

	Year Ended December 31,				
	2019			2018	
Product	U.S.[1]	Outside U.S.	Total	Total	Percent Change
Trulicity	**$ 3,155.2**	**$ 972.7**	**$ 4,127.8**	$ 3,199.1	29
Humalog[2]	**1,669.7**	**1,151.0**	**2,820.7**	2,996.5	(6)
Alimta	**1,219.5**	**896.4**	**2,115.8**	2,132.9	(1)
Forteo	**645.5**	**759.1**	**1,404.7**	1,575.6	(11)
Taltz	**1,016.8**	**349.6**	**1,366.4**	937.5	46
Humulin®	**879.7**	**410.4**	**1,290.1**	1,331.4	(3)
Basaglar	**876.2**	**236.3**	**1,112.6**	801.2	39
Jardiance[3]	**565.9**	**378.3**	**944.2**	658.3	43
Cyramza®	**335.3**	**589.9**	**925.1**	821.4	13
Cialis	**231.7**	**658.8**	**890.5**	1,851.8	(52)
Cymbalta®	**49.6**	**675.8**	**725.4**	708.0	2
Trajenta®[4]	**224.8**	**365.8**	**590.6**	574.7	3
Verzenio	**454.8**	**124.9**	**579.7**	255.0	NM
Erbitux®	**487.9**	**55.4**	**543.4**	635.3	(14)
Olumiant	**42.2**	**384.7**	**426.9**	202.5	NM
Zyprexa®	**41.0**	**377.6**	**418.7**	471.3	(11)
Strattera	**30.8**	**211.7**	**242.5**	450.8	(46)
Emgality	**154.9**	**7.7**	**162.5**	4.9	NM
Other products	**641.1**	**990.7**	**1,631.9**	1,885.1	(13)
Revenue	**$ 12,722.6**	**$ 9,596.8**	**$ 22,319.5**	$ 21,493.3	4

Numbers may not add due to rounding.

NM - Not meaningful

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

[2] Humalog revenue includes insulin lispro.

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

[4] Trajenta revenue includes Jentadueto®.

Revenue of Trulicity, a treatment for type 2 diabetes, increased 25 percent in the U.S., driven by higher demand, partially offset by lower realized prices. Revenue outside the U.S. increased 42 percent primarily driven by increased volume, partially offset by the unfavorable impact of foreign exchange rates and, to a lesser extent, lower realized prices.

Revenue of Humalog, an injectable human insulin analog for the treatment of diabetes, decreased 7 percent in the U.S., primarily driven by lower realized prices and decreased demand. Revenue outside the U.S. decreased 5 percent, primarily driven by the unfavorable impact of foreign exchange rates. Included in the revenue of Humalog in the U.S. is our own insulin lispro authorized generic, which was launched in the second quarter of 2019 in order to lower out-of-pocket costs for patients. A competitor launched a similar version of insulin lispro in certain European markets in 2017 and in the U.S. in the second quarter of 2018. While it is difficult to estimate the severity of the impact of similar insulin lispro products entering the market, we do not expect and have not experienced a rapid severe decline in revenue. However, due to the impact of competition and due to pricing pressure in the U.S. and some international markets, we expect some price decline and loss of market share to continue over time.

Revenue of Alimta, a treatment for various cancers, increased 8 percent in the U.S., driven by increased demand, partially offset by lower realized prices. Revenue outside the U.S. decreased 11 percent, driven by lower realized prices, and to a lesser extent, the unfavorable impact of foreign exchange rates and lower volume resulting from the entry of generic pemetrexed in Germany. 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 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 15 percent in the U.S., primarily driven by decreased demand. Revenue outside the U.S. decreased 7 percent, driven by decreased volume and, to a lesser extent, the unfavorable impact of foreign exchange rates and lower realized prices. We expect further volume decline as a result of competitive dynamics in the U.S. and the entry of generic and biosimilar competition following the loss of patent exclusivity in the third quarter of 2019 in the U.S., Japan, and major European markets. See "Executive Overview - Other Matters - Patent Matters" for more information.

Revenue of Taltz, a treatment for moderate-to-severe plaque psoriasis, active psoriatic arthritis, and ankylosing spondylitis, increased 38 percent in the U.S., primarily driven by increased demand, partially offset by lower realized prices. Revenue outside the U.S. increased 76 percent, driven by increased volume from recent launches, partially offset by the unfavorable impact of foreign exchange rates.

Revenue of Humulin, an injectable human insulin for the treatment of diabetes, decreased 3 percent in the U.S., driven by lower realized prices, partially offset by increased volume. Revenue outside the U.S. decreased 3 percent, primarily driven by the unfavorable impact of foreign exchange rates, partially offset by increased volume and, to a lesser extent, higher realized prices.

Revenue of Basaglar, a long-acting human insulin analog for the treatment of diabetes, increased 41 percent in the U.S., driven by higher realized prices and increased demand. Revenue outside the U.S. increased 32 percent driven by increased volume, partially offset by the unfavorable impact of foreign exchange rates and, to a lesser extent, lower realized prices.

Revenue of Jardiance, a treatment for type 2 diabetes and to reduce the risk of cardiovascular death in adult patients with type 2 diabetes and established cardiovascular disease, increased 41 percent in the U.S., driven by increased demand. Revenue outside the U.S. increased 47 percent, primarily driven by increased volume, partially offset by the unfavorable impact of foreign exchange rates.

Revenue of Cyramza, a treatment for various cancers, increased 15 percent in the U.S., driven by increased demand and, to a lesser extent, higher realized prices. Revenue outside the U.S. increased 11 percent, primarily due to increased volume, partially offset by the unfavorable impact of foreign exchange rates and lower realized prices.

Revenue of Cialis, a treatment for erectile dysfunction and benign prostatic hyperplasia, decreased 79 percent in the U.S., driven by decreased demand due to generic competition. Revenue outside the U.S. decreased 9 percent, driven by the unfavorable impact of foreign exchange rates, lower volume due to the loss of exclusivity in Europe and, to a lesser extent, lower realized prices. We lost our compound patent protection for Cialis in major European markets in November 2017 and U.S. exclusivity ended in late September 2018. We have faced and remain exposed to generic competition following the loss of exclusivity, which has eroded revenue and is likely to continue to rapidly and severely erode revenue from current levels. See "Results of Operations - Executive Overview - Other Matters - Patent Matters" for more information.

Gross Margin, Costs, and Expenses

Gross margin as a percent of total revenue was 78.8 percent in 2019, an increase of 0.6 percentage points compared with 2018, primarily due to the favorable impact of foreign exchange rates on international inventories sold and lower intangibles amortization expense, partially offset by unfavorable product mix, the impact of lower realized prices on revenue, and charges resulting from the product withdrawal of Lartruvo.

Research and development expenses increased 11 percent to $5.60 billion in 2019 driven by higher late-stage development expenses.

Marketing, selling, and administrative expenses increased 4 percent to $6.21 billion in 2019 primarily due to increased marketing expenses for recently launched products, partially offset by lower expenses for late life-cycle products.

We recognized acquired IPR&D charges of $239.6 million in 2019 resulting from business development transactions with AC Immune, Centrexion, ImmuNext, and Avidity. In 2018, we recognized acquired IPR&D charges of $1.98 billion primarily related to the acquisition of ARMO and the collaboration with Dicerna.

We recognized asset impairment, restructuring, and other special charges of $575.6 million in 2019. The charges were primarily associated with the accelerated vesting of Loxo employee equity awards as part of the closing of the acquisition of Loxo, and, to a lesser extent, the charges associated with the decision to close and sell a research and development facility located in the U.K. In 2018, we recognized $266.9 million of asset impairment, restructuring, and other special charges 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.

Other—net, (income) expense was income of $291.6 million in 2019 compared to income of $145.6 million in 2018 primarily driven by higher net gains on investment securities and the gain on the sale of the company's antibiotics business in China, partially offset by the charge related to the repurchase of debt and higher net interest expense.

Our effective tax rate was 11.9 percent in 2019, compared with 14.4 percent in 2018. The higher effective tax rate in 2018 was primarily due to non-deductible acquired IPR&D charges.

Operating Results—2018

Financial Results

The following table summarizes our key operating results:

	Year Ended December 31,		Percent Change
	2018	2017	
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)	3,232.0	(204.1)	NM
Earnings (loss) per share from continuing operations	3.05	(0.08)	NM
Earnings (loss) per share	3.13	(0.19)	NM

NM - not meaningful

Revenue increased in 2018 driven by increased volume and, to a lesser extent, the favorable impact of foreign exchange rates, partially offset by lower realized prices. The increases in net income and EPS in 2018 were driven by lower income taxes, higher gross margin, and lower asset impairment, restructuring, and other special charges, partially offset by higher acquired IPR&D charges.

Certain items affect the comparisons of our 2018 and 2017 results. The 2018 highlighted items are summarized in the "Results of Operations - Executive Overview" section. The 2017 highlighted items are summarized as follows:

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 U.S. voluntary early retirement program.

Income Taxes (Note 14 to the consolidated financial statements)

- We recognized a provisional tax expense of $1.91 billion due to the Tax Cuts and Jobs Act (2017 Tax Act).

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 in 2018 compared with 2017:

	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 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 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.

Revenue of Alimta 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.

Revenue of Cialis 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.

Revenue of Forteo 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.

Revenue of Humulin 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 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 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 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 treatment for 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.

FINANCIAL CONDITION

Cash and cash equivalents decreased to $2.34 billion as of December 31, 2019, compared with $7.32 billion at December 31, 2018. Net cash provided by operating activities was $4.84 billion in 2019, compared with $5.52 billion in 2018. Net cash provided by operating activities in 2019 included approximately $360 million of cash paid to settle the accelerated vesting of Loxo employee equity awards (see Note 5 to the consolidated financial statements). Net cash provided by operating activities in 2018 included approximately $500 million of net cash provided by operating activities related to our discontinued operations (See Note 19 to the consolidated financial statements). 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, 2019 and 2018.

In addition to our cash and cash equivalents, we held total investments of $2.06 billion and $2.09 billion as of December 31, 2019 and 2018, respectively. See Note 7 to the consolidated financial statements for additional details.

In February 2019, we completed our acquisition of Loxo for $235 per share or approximately $6.9 billion, which was funded through a mixture of cash and debt. See Note 3 to the consolidated financial statements for additional information.

As of December 31, 2019, total debt was $15.32 billion, an increase of $5.02 billion compared with $10.30 billion at December 31, 2018. The increase primarily related to the net proceeds of $4.45 billion from the issuance of senior notes in February 2019. The proceeds from these notes were used to repay commercial paper that was issued in connection with the acquisition of Loxo and for general corporate purposes. See Note 11 to the consolidated financial statements for additional details.

As of December 31, 2019, we had a total of $5.21 billion of unused committed bank credit facilities, $5.00 billion of which is available to support our commercial paper program. See Note 11 to the consolidated financial statements for additional details. We believe that amounts accessible through existing commercial paper markets should be adequate to fund any short-term borrowing needs.

For the 134th consecutive year, we distributed dividends to our shareholders. Dividends of $2.58 per share and $2.25 per share were paid in 2019 and 2018, respectively. In the fourth quarter of 2019, effective for the dividend to be paid in the first quarter of 2020, the quarterly dividend was increased to $0.74 per share, resulting in an indicated annual rate for 2020 of $2.96 per share.

Capital expenditures of $1.03 billion during 2019, compared to $1.21 billion in 2018.

In 2019, we repurchased $4.40 billion of shares under our $8.00 billion share repurchase program authorized in June 2018. As of December 31, 2019, we had $1.50 billion remaining under this program. See Note 13 to the consolidated financial statements for additional details.

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 January 2020, we announced an agreement to acquire Dermira, Inc. for $18.75 per share, or approximately $1.1 billion. The acquisition will be funded through cash on hand and the issuance of commercial paper. 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.

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 this risk management program 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, 2019 and 2018, 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, 2019 and 2018, 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, 2019 and 2018, 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 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 our 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 were as follows as of December 31, 2019:

	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]	$ 20,934.9	$ 382.2	$ 2,173.8	$ 1,381.3	$ 16,997.6
Finance lease obligations	19.0	7.0	8.8	3.2	—
Operating lease liabilities	720.4	138.1	193.3	116.3	272.7
Purchase obligations[2]	15,897.1	15,452.8	239.6	204.7	—
2017 Tax Act Toll Tax[3]	2,630.0	225.3	507.4	1,109.9	787.4
Other long-term liabilities reflected on our balance sheet[4]	1,800.1	—	421.2	193.8	1,185.1
Total	$ 42,001.5	$ 16,205.4	$ 3,544.1	$ 3,009.2	$ 19,242.8

[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, 2019, 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, 2019. 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 $1.20 billion, because we cannot reasonably estimate the timing of future cash outflows associated with those liabilities.

The contractual obligations table is as of December 31, 2019. 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. For product sales to customers, provisions for returns, rebate and discounts are established in the same period the related product sales are recognized. To determine the appropriate transaction price for our product sales at the time we recognize a sale to a direct customer, we 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 largest of our sales rebate and discount amounts are rebates associated with sales covered by managed care, Medicare, Medicaid, and chargeback contracts in the U.S. In determining the appropriate accrual amount, we consider our historical rebate

payments for these programs by product as a percentage of our historical sales as well as any significant changes in sales trends (e.g., patent expiries and product launches), an evaluation of the current contracts for these programs, the percentage of our products that are sold via these programs, and our product pricing.

Refer to Note 2 to the consolidated financial statements for further information on revenue recognition and sales return, rebate, and discount accruals.

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.

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, 2019, a 5 percent change in our global sales return, rebate, and discount liability would have led to an approximate $270 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, 2019 and 2018.

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)	2019	2018
Sales return, rebate, and discount liabilities, beginning of year	**$ 4,670.9**	$ 4,134.0
Reduction of net sales[(1)]	**15,490.2**	13,424.9
Cash payments	**(15,525.6)**	(12,888.0)
Sales return, rebate, and discount liabilities, end of year	**$ 4,635.5**	$ 4,670.9

[(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 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.

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 estimates and assumptions that are deemed reasonable by management. Significant estimates and assumptions include, but are not limited to, probability of technical success, revenue growth and discount rate. 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.

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, or more frequently if impairment indicators are present, by first assessing qualitative factors to determine whether it is more likely than not that the fair value of the intangible asset is less than its carrying amount. If we conclude it is more likely than not that the fair value is less than the carrying amount, a quantitative test that compares the fair value of the intangible asset to its carrying value 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 15 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.

Annually, we determine the fair value of the plan assets in our defined benefit pension and retiree health benefit plans. Approximately 40 percent of our plan assets are in hedge funds and private equity-like investment funds (collectively, alternative assets). We value these alternative investments using significant unobservable inputs or using the net asset value reported by the counterparty, adjusted as necessary. Inputs include underlying net asset values, discounted cash flows valuations, comparable market valuations, and adjustments for currency, credit, liquidity and other risks.

Financial Statement Impact

If the 2019 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 $29.6 million. If the 2019 expected return on plan assets for U.S. plans were to change by a quarter percentage point, income before income taxes would change by $26.5 million. If our assumption regarding the 2019 expected age of future retirees for U.S. plans were adjusted by one year, our income before income taxes would be affected by $45.9 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, 2019.

Adjustments to the fair value of plan assets are not recognized in pension and retiree health benefit expense in the year that the adjustments occur. Such changes are deferred, along with other actuarial gains and losses, and are amortized into expense over the expected remaining service life of employees.

Income Taxes

Background and Uncertainties

We prepare and file tax returns based upon our interpretation of tax laws and regulations and record estimates based upon these 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. 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 changes to existing tax law, the issuance of regulations 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.

Financial Statement Impact

As of December 31, 2019, a 5 percent change in the amount of uncertain tax positions and the valuation allowance would result in a change in net income of $76.5 million and $30.8 million, respectively.

LEGAL AND REGULATORY MATTERS

Information relating to certain legal proceedings can be found in Note 16 to the consolidated financial statements and is incorporated here by reference.

FINANCIAL EXPECTATIONS FOR 2020

For the full year of 2020, we expect EPS to be in the range of $6.18 to $6.28, which includes the anticipated impact of the Dermira acquisition. We anticipate that total revenue will be between $23.7 billion and $24.2 billion. Revenue growth is expected to be driven by volume from Trulicity, Taltz, Basaglar, Jardiance, Verzenio, Cyramza, Olumiant, Emgality, Baqsimi, and the launch of Reyvow. Revenue growth is expected to be partially offset by lower revenue for products that have lost patent exclusivity, including the expected entry of generic competition for Forteo in the U.S. Revenue growth is also expected to be partially offset by a low-single digit net price decline in the U.S. driven primarily by rebates and legislated increases to Medicare Part D cost sharing, patient affordability programs, and net price declines in China, Japan and Europe.

We anticipate that gross margin as a percent of revenue will be approximately 79 percent in 2020. Research and development expenses are expected to be in the range of $5.6 billion to $5.9 billion. Marketing, selling, and administrative expenses are expected to be in the range of $6.2 billion to $6.4 billion. Other—net, (income) expense is expected to be expense in the range of $100 million to $250 million.

The 2020 effective tax rate is expected to be approximately 15 percent.

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	2019	2018	2017
Revenue	**$ 22,319.5**	$ 21,493.3	$ 19,973.8
Costs, expenses, and other:			
Cost of sales	**4,721.2**	4,681.7	4,447.7
Research and development	**5,595.0**	5,051.2	5,096.2
Marketing, selling, and administrative	**6,213.8**	5,975.1	5,982.4
Acquired in-process research and development (Note 3)	**239.6**	1,983.9	1,112.6
Asset impairment, restructuring, and other special charges (Note 5)	**575.6**	266.9	1,331.6
Other—net, (income) expense (Note 18)	**(291.6)**	(145.6)	(301.5)
	17,053.6	17,813.2	17,669.0
Income before income taxes	**5,265.9**	3,680.1	2,304.8
Income taxes (Note 14)	**628.0**	529.5	2,391.2
Net income (loss) from continuing operations	**4,637.9**	3,150.6	(86.4)
Net income (loss) from discontinued operations (Note 19)	**3,680.5**	81.4	(117.7)
Net income (loss)	**$ 8,318.4**	$ 3,232.0	$ (204.1)
Earnings (loss) per share:			
Earnings (loss) from continuing operations - basic	**4.98**	3.07	(0.08)
Earnings (loss) from discontinued operations - basic	**3.95**	0.07	(0.11)
Earnings (loss) per share - basic	**$ 8.93**	$ 3.14	$ (0.19)
Earnings (loss) from continuing operations - diluted	**4.96**	3.05	(0.08)
Earnings (loss) from discontinued operations - diluted	**3.93**	0.08	(0.11)
Earnings (loss) per share - diluted	**$ 8.89**	$ 3.13	$ (0.19)
Shares used in calculation of earnings (loss) per share:			
Basic	**931,059**	1,027,721	1,052,023
Diluted	**935,684**	1,033,667	1,052,023

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	2019	2018	2017
Net income (loss)	**$ 8,318.4**	$ 3,232.0	$ (204.1)
Other comprehensive income (loss) from continuing operations:			
Change in foreign currency translation gains (losses)	**(89.9)**	(429.6)	362.9
Change in net unrealized gains (losses) on securities	**34.4**	(8.8)	(181.3)
Change in defined benefit pension and retiree health benefit plans (Note 15)	**(970.0)**	544.0	(566.8)
Change in effective portion of cash flow hedges	**34.3**	(6.0)	27.8
Other comprehensive income (loss) from continuing operations before income taxes	**(991.2)**	99.6	(357.4)
Benefit (provision) for income taxes related to other comprehensive income (loss) from continuing operations	**151.0**	(30.3)	402.7
Other comprehensive income (loss) from continuing operations, net of tax (Note 17)	**(840.2)**	69.3	45.3
Other comprehensive income (loss) from discontinued operations, net of tax (Note 17)	**56.8**	14.3	129.2
Other comprehensive income (loss), net of tax (Note 17)	**(783.4)**	83.6	174.5
Comprehensive income (loss)	**$ 7,535.0**	$ 3,315.6	$ (29.6)

See notes to consolidated financial statements.

Consolidated Balance Sheets

ELI LILLY AND COMPANY AND SUBSIDIARIES (Dollars in millions, shares in thousands) December 31	2019	2018
Assets		
Current Assets		
Cash and cash equivalents (Note 7)	**$ 2,337.5**	$ 7,320.7
Short-term investments (Note 7)	**101.0**	88.2
Accounts receivable, net of allowances of **$22.4 (2019)** and $24.1 (2018)	**4,547.3**	4,593.9
Other receivables	**994.2**	1,182.9
Inventories (Note 6)	**3,190.7**	3,098.1
Prepaid expenses and other	**2,538.9**	2,036.7
Current assets of discontinued operations (Note 19)	**—**	2,229.1
Total current assets	**13,709.6**	20,549.6
Investments (Note 7)	**1,962.4**	2,005.4
Goodwill (Note 8)	**3,679.4**	1,366.6
Other intangibles, net (Note 8)	**6,618.0**	1,068.0
Deferred tax assets (Note 14)	**2,572.6**	2,613.7
Property and equipment, net (Note 9)	**7,872.9**	7,996.1
Operating lease assets (Note 10)	**532.1**	—
Other noncurrent assets	**2,339.1**	1,824.9
Noncurrent assets of discontinued operations (Note 19)	**—**	6,484.1
Total assets	**$ 39,286.1**	$ 43,908.4
Liabilities and Equity		
Current Liabilities		
Short-term borrowings and current maturities of long-term debt (Note 11)	**$ 1,499.3**	$ 1,102.2
Accounts payable	**1,405.3**	1,207.1
Employee compensation	**915.5**	955.6
Sales rebates and discounts	**4,933.6**	4,849.5
Dividends payable	**671.5**	650.8
Income taxes payable (Note 14)	**160.6**	393.4
Other current liabilities	**2,189.4**	2,036.7
Current liabilities of discontinued operations (Note 19)	**—**	692.8
Total current liabilities	**11,775.2**	11,888.1
Other Liabilities		
Long-term debt (Note 11)	**13,817.9**	9,196.4
Noncurrent operating lease liabilities (Note 10)	**486.7**	—
Accrued retirement benefits (Note 15)	**3,698.2**	2,802.2
Long-term income taxes payable (Note 14)	**3,607.2**	3,700.0
Other noncurrent liabilities	**1,014.3**	1,357.6
Deferred tax liabilities (Note 14)	**2,187.5**	1,312.7
Noncurrent liabilities of discontinued operations (Note 19)	**—**	2,742.3
Total other liabilities	**24,811.8**	21,111.2
Commitments and Contingencies (Note 16)		
Eli Lilly and Company Shareholders' Equity (Notes 12 and 13)		
Common stock—no par value Authorized shares: 3,200,000 Issued shares: **958,056 (2019)** and 1,057,639 (2018)	**598.8**	661.0
Additional paid-in capital	**6,685.3**	6,583.6

Retained earnings	**4,920.4**	11,395.9
Employee benefit trust	**(3,013.2)**	(3,013.2)
Accumulated other comprehensive loss (Note 17)	**(6,523.6)**	(5,729.2)
Cost of common stock in treasury	**(60.8)**	(69.4)
Total Eli Lilly and Company shareholders' equity	**2,606.9**	9,828.7
Noncontrolling interests	**92.2**	1,080.4
Total equity	**2,699.1**	10,909.1
Total liabilities and equity	**$ 39,286.1**	$ 43,908.4

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								
	Common Stock		Additional Paid-in Capital	Retained Earnings	Employee Benefit Trust	Accumulated Other Comprehensive Loss	Common Stock in Treasury		Noncontrolling Interest
	Shares	Amount					Shares	Amount	
Balance at January 1, 2017	1,101,586	$ 688.5	$ 5,640.6	$ 16,046.3	$ (3,013.2)	$ (5,274.0)	711	$ (80.5)	$ 72.8
Net income (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 1)				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 1)				763.8		(105.2)			
Sale of Elanco Stock (Note 19)			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
Net income				**8,318.4**					**37.7**
Other comprehensive income (loss), net of tax						**(794.4)**			**11.0**
Cash dividends declared per share: $2.68				**(2,430.5)**					
Retirement of treasury shares	**(102,640)**	**(64.1)**		**(12,363.4)**			**(102,640)**	**12,427.5**	
Purchase of treasury shares							**37,639**	**(4,400.0)**	
Issuance of stock under employee stock plans, net	**3,057**	**1.9**	**(210.7)**				**(74)**	**8.6**	
Stock-based compensation			**312.4**						
Acquisition of common stock in exchange offer							**65,001**	**(8,027.5)**	
Deconsolidation of Elanco									**(1,028.9)**
Other									**(8.0)**

Balance at December 31, 2019	**958,056**	**$ 598.8**	**$ 6,685.3**	**$ 4,920.4**	**$ (3,013.2)**	**$ (6,523.6)**	**530**	**$ (60.8)**	**$ 92.2**

See notes to consolidated financial statements.

Consolidated Statements of Cash Flows

ELI LILLY AND COMPANY AND SUBSIDIARIES (Dollars in millions)	Year Ended December 31 2019	2018	2017
Cash Flows from Operating Activities			
Net income (loss)	**$ 8,318.4**	$ 3,232.0	$ (204.1)
Adjustments to Reconcile Net Income (Loss) to Cash Flows from Operating Activities:			
Gain related to disposition of Elanco (Note 19)	**(3,680.5)**	—	—
Gain on sale of antibiotic business in China (Note 3)	**(309.8)**	—	—
Depreciation and amortization	**1,232.6**	1,609.0	1,567.3
Change in deferred income taxes	**62.4**	326.8	(787.9)
Stock-based compensation expense	**312.4**	279.5	281.3
Acquired in-process research and development (Note 3)	**239.6**	1,983.9	1,112.6
Other non-cash operating activities, net	**348.7**	472.0	441.5
Other changes in operating assets and liabilities, net of acquisitions and divestitures:			
Receivables—(increase) decrease	**(127.2)**	(996.7)	(357.0)
Inventories—(increase) decrease	**(258.7)**	7.8	(253.9)
Other assets—(increase) decrease	**(602.3)**	(980.0)	(590.1)
Income taxes payable—increase (decrease)	**(221.3)**	(125.3)	3,489.6
Accounts payable and other liabilities—increase (decrease)	**(477.7)**	(284.5)	916.3
Net Cash Provided by Operating Activities	**4,836.6**	5,524.5	5,615.6
Cash Flows from Investing Activities			
Purchases of property and equipment	**(1,033.9)**	(1,210.6)	(1,076.8)
Proceeds from sales and maturities of short-term investments	**136.6**	2,552.5	4,852.5
Purchases of short-term investments	**(42.7)**	(112.2)	(3,389.7)
Proceeds from sales of noncurrent investments	**609.8**	3,509.5	2,586.0
Purchases of noncurrent investments	**(247.5)**	(837.9)	(4,611.6)
Purchases of in-process research and development	**(319.6)**	(1,807.6)	(1,086.8)
Cash paid for acquisitions, net of cash acquired (Note 3 and 19)	**(6,917.7)**	—	(882.1)
Cash distributed to Elanco upon disposition	**(374.0)**	—	—
Cash received for sale of antibiotic business in China	**354.8**	—	—
Other investing activities, net	**(248.7)**	(187.7)	(175.1)
Net Cash Provided by (Used for) Investing Activities	**(8,082.9)**	1,906.0	(3,783.6)
Cash Flows from Financing Activities			
Dividends paid	**(2,409.8)**	(2,311.8)	(2,192.1)
Net change in short-term borrowings	**995.4**	(2,197.9)	1,397.5
Proceeds from issuance of long-term debt	**6,556.4**	2,477.7	2,232.0
Repayments of long-term debt	**(2,866.4)**	(1,009.1)	(630.6)
Purchases of common stock	**(4,400.0)**	(4,150.7)	(299.8)
Net proceeds from Elanco initial public offering (Note 19)	**—**	1,659.7	—
Other financing activities, net	**(200.1)**	(372.8)	(364.4)
Net Cash Provided by (Used for) Financing Activities	**(2,324.5)**	(5,904.9)	142.6
Effect of exchange rate changes on cash and cash equivalents	**(89.9)**	(63.6)	(20.5)
Net increase (decrease) in cash and cash equivalents	**(5,660.7)**	1,462.0	1,954.1
	7,998.2	6,536.2	4,582.1

Cash and cash equivalents at beginning of year (includes $677.5 (2019), $324.4 (2018), and $258.8 (2017) of discontinued operations)			
Cash and Cash Equivalents at End of Year (includes $677.5 (2018) and $324.4 (2017) of discontinued operations)	**$ 2,337.5**	$ 7,998.2	$ 6,536.2

See notes to consolidated financial statements.

Notes to Consolidated Financial Statements

ELI LILLY AND COMPANY AND SUBSIDIARIES
(Tables present dollars in millions, except per-share data)

Note 1: Summary of Significant Accounting Policies and Implementation of New Financial Accounting Standards

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.

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.

On March 11, 2019, we completed the disposition of our remaining 80.2 percent ownership of Elanco Animal Health Incorporated (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.

Research and Development Expenses and Acquired In-Process Research and Development (IPR&D)

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 IPR&D expense includes the initial costs of externally developed IPR&D projects, acquired directly in a transaction other than a business combination, that do not have an alternative future use.

Earnings Per Share (EPS)

We calculate basic 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 United States (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).

Advertising Expenses

Costs associated with advertising are expensed as incurred and are included in marketing, selling, and administrative expenses. Advertising expenses, comprised primarily of television, radio, print media, and Internet advertising, totaled approximately $1.1 billion, $900 million, and $700 million in 2019, 2018, and 2017, respectively, which was less than 5 percent of revenue each year.

Other Significant Accounting Policies

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

Implementation of New Financial Accounting Standards

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

Effective January 1, 2018, we adopted Accounting Standards Update 2014-09, *Revenue from Contracts with Customers,* and other related updates. This standard 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. We applied this standard 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. We applied this standard through a cumulative effect adjustment to retained earnings as of the beginning of the year of adoption. Upon adoption, the cumulative effect of applying this standard resulted in an increase of approximately $5 million to retained earnings as of January 1, 2018. Revenue presented for periods prior to 2018 was accounted for under previous standards and has not been adjusted. Revenue and net income for 2018 did not differ materially from amounts that would have resulted from application of the previous standards.

Effective January 1, 2018, we adopted Accounting Standards Update 2016-01 (ASU 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). We applied the new standard through a cumulative effect adjustment to retained earnings as of the beginning of the 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 the year of adoption.

Effective January 1, 2018, we adopted 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. We adopted this standard using a modified retrospective approach. Upon adoption, the cumulative effect of applying this 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 as of January 1, 2018. Adoption of this standard did not result in a material change in net income in the year of adoption.

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 14). 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.

Note 2: Revenue

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

	2019	2018	2017
Net product revenue	**$ 20,377.3**	$ 19,866.4	$ 18,776.5
Collaboration and other revenue[(1)]	**1,942.2**	1,626.9	1,197.3
Revenue	**$ 22,319.5**	$ 21,493.3	$ 19,973.8

[(1)] Collaboration and other revenue associated with prior period transfers of intellectual property was $301.5 million, $303.2 million, and $144.9 million during the years ended 2019, 2018, and 2017, respectively.

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

Most of our products are sold to wholesalers that serve pharmacies, physicians and other health care professionals, and hospitals. For the years ended December 31, 2019, 2018, and 2017, our three largest wholesalers each accounted for between 14 percent and 21 percent of consolidated total revenue. Further, they each accounted for between 19 percent and 25 percent of accounts receivable as of December 31, 2019 and 2018.

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

Sales Rebates and Discounts - Background and Uncertainties

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

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

Sales Returns - Background and Uncertainties

- When product sales occur, to determine the appropriate transaction price for our sales, we estimate a reserve for future product returns related to those sales using an expected value approach. This estimate is based on several factors, including: historical return rates, expiration date by product (on average, approximately 24 months after the initial sale of a product to our customer), and estimated levels of inventory in the wholesale and retail channels, as well as any other specifically-identified anticipated returns due to known factors such as the loss of patent exclusivity, product recalls and discontinuances, or a changing competitive environment. We maintain a returns policy that allows U.S. 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 for our most significant U.S. sales returns, rebates, and discounts liability balances for products shipped in previous periods were approximately 2 percent and 1 percent of U.S revenue during 2019 and 2018, respectively.

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

The following table summarizes contract liability balances:

	2019	2018
Contract liabilities	**$ 264.6**	$ 294.9

The contract liabilities balances disclosed above as of December 31, 2019 and 2018 were primarily related to the remaining license period of symbolic intellectual property and obligations to supply product for a defined period of time.

During the years ended December 31, 2019 and 2018, revenue recognized from contract liabilities as of the beginning of the year 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.

Disaggregation of Revenue

The following table summarizes revenue by product:

	U.S.[1]			Outside U.S.		
	2019	**2018**	**2017**	**2019**	**2018**	**2017**
Revenue—to unaffiliated customers:						
Endocrinology:						
Trulicity®	**$ 3,155.2**	$ 2,515.8	$ 1,609.8	**$ 972.7**	$ 683.3	$ 419.9
Humalog® [2]	**1,669.7**	1,787.8	1,717.8	**1,151.0**	1,208.7	1,147.4
Forteo®	**645.5**	757.9	965.2	**759.1**	817.7	783.8
Humulin®	**879.7**	910.2	884.6	**410.4**	421.2	450.7
Basaglar®	**876.2**	622.8	311.1	**236.3**	178.5	121.0
Jardiance [3]	**565.9**	400.2	290.4	**378.3**	258.1	157.0
Trajenta [4]	**224.8**	224.2	213.2	**365.8**	350.5	324.7
Other Endocrinology	**293.7**	292.7	380.9	**230.1**	272.5	307.7
Total Endocrinology	**8,310.7**	7,511.6	6,373.0	**4,503.7**	4,190.5	3,712.2
Oncology:						
Alimta®	**1,219.5**	1,131.0	1,034.3	**896.4**	1,001.9	1,028.2
Cyramza®	**335.3**	291.5	278.8	**589.9**	529.9	479.6
Verzenio®	**454.8**	248.5	21.0	**124.9**	6.6	—
Erbitux®	**487.9**	531.6	541.7	**55.4**	103.8	104.2
Other Oncology	**111.0**	200.6	174.6	**339.3**	215.1	149.6
Total Oncology	**2,608.5**	2,403.2	2,050.4	**2,005.9**	1,857.3	1,761.6
Immunology:						
Taltz®	**1,016.8**	738.7	486.0	**349.6**	198.7	73.2
Olumiant®	**42.2**	6.7	—	**384.7**	195.9	45.8
Total Immunology	**1,059.0**	745.4	486.0	**734.3**	394.6	119.0
Neuroscience:						
Cymbalta®	**49.6**	54.3	114.9	**675.8**	653.7	642.2
Zyprexa®	**41.0**	36.2	75.5	**377.6**	435.1	505.7
Strattera®	**30.8**	89.7	284.9	**211.7**	361.1	333.3
Emgality®	**154.9**	4.9	—	**7.7**	—	—
Other Neuroscience	**80.2**	92.3	115.7	**93.6**	93.4	98.9
Total Neuroscience	**356.5**	277.4	591.0	**1,366.4**	1,543.3	1,580.1
Other:						
Cialis ®	**231.7**	1,129.2	1,358.6	**658.8**	722.7	964.5
Other	**156.2**	325.1	555.4	**327.7**	393.0	422.0
Total Other	**387.9**	1,454.3	1,914.0	**986.5**	1,115.7	1,386.5
Revenue	**$ 12,722.6**	$ 12,391.9	$ 11,414.4	**$ 9,596.8**	$ 9,101.4	$ 8,559.4

Numbers may not add due to rounding.

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

(2) Humalog revenue includes insulin lispro.

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

(4) Trajenta revenue includes Jentadueto®.

The following table summarizes revenue by geographical area:

	2019	2018	2017
Revenue—to unaffiliated customers[1]:			
U.S.	**$ 12,722.6**	$ 12,391.9	$ 11,414.4
Europe	**3,765.0**	3,663.1	3,390.6
Japan	**2,547.6**	2,407.4	2,339.5
Other foreign countries	**3,284.3**	3,030.9	2,829.3
Revenue	**$ 22,319.5**	$ 21,493.3	$ 19,973.8

Numbers may not add due to rounding.

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

Note 3: Acquisitions and Divestiture

In February 2019, we completed the acquisition of Loxo Oncology, Inc. (Loxo). This transaction, as further discussed in this note below in Acquisition of a Business, was accounted for as a business combination under the acquisition method of accounting. Under this method, the assets acquired and liabilities assumed were recorded at their respective fair values as of the acquisition date in our consolidated financial statements. The determination of estimated fair value required management to make significant estimates and assumptions. The excess of the purchase price over the fair value of the acquired net assets, where applicable, has been recorded as goodwill. The results of operations of Loxo have been included in our consolidated financial statements from the date of acquisition.

We acquired assets in development in 2019, 2018, and 2017, 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, 2019, 2018, and 2017, we recorded acquired IPR&D charges of $239.6 million, $1.98 billion, and $1.11 billion, respectively.

Acquisition of a Business

Loxo Acquisition

Overview of Transaction

In February 2019, we acquired all shares of Loxo for a purchase price of $6.92 billion, net of cash acquired. The accelerated vesting of Loxo employee equity awards was recognized as transaction expense included in asset impairment, restructuring, and other special charges during the year ended December 31, 2019 (see Note 5).

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

Assets Acquired and Liabilities Assumed

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

Estimated Fair Value at February 15, 2019		
Acquired IPR&D[1]	$	4,670.0
Finite-lived intangibles[2]		980.0
Deferred income taxes		(1,032.8)
Other assets and liabilities - net		(26.4)
Total identifiable net assets		4,590.8
Goodwill[3]		2,326.9
Total consideration transferred - net of cash acquired	$	6,917.7

[1] $4.60 billion of the acquired IPR&D relates to selpercatinib (LOXO-292).

[2] Contract-based intangibles (primarily related to Vitrakvi) which are being amortized to cost of sales on a straight-line basis over their estimated useful lives, were expected to have a weighted average useful life of approximately 12 years from the acquisition date.

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

Our consolidated statement of operations for the year ended December 31, 2019 includes Loxo revenues of $136.7 million, primarily due to regulatory approval and sales milestones received. We are unable to provide the results of operations for the year ended December 31, 2019 attributable to Loxo as those operations were substantially integrated into our legacy business.

Pro forma information has not been included because this acquisition did not have a material impact on our results of operations for the years ended December 31, 2019 and 2018.

Asset Acquisitions

The following table and narrative summarize our asset acquisitions during 2019, 2018, and 2017.

Counterparty	Compound(s),Therapy, or Asset	Acquisition Month	Phase of Development[1]	Acquired IPR&D Expense
AC Immune SA	Tau aggregation inhibitor small molecules for the potential treatment of Alzheimer's disease and other neurodegenerative diseases	January 2019 & September 2019[2]	Pre-clinical	$ 127.1
ImmuNext, Inc.	Novel immunometabolism target	March 2019	Pre-clinical	40.0
Avidity Biosciences, Inc.	Potential new medicines in immunology and other select indications	April 2019	Pre-clinical	25.0
Centrexion Therapeutics Corporation	CNTX-0290, a novel, small molecule somatostatin receptor type 4 agonist	July 2019	Phase I	47.5
Sigilon Therapeutics	Encapsulated cell therapies for the potential treatment of type 1 diabetes	April 2018	Pre-clinical	66.9
AurKa Pharma, Inc.	AK-01, an Aurora kinase A inhibitor	June 2018	Phase I	81.8
ARMO BioSciences, Inc. (ARMO)	Cancer therapy - pegilodecakin	June 2018	Phase III	1,475.8
Anima Biotech	Translation inhibitors for selected neuroscience targets	July 2018	Pre-clinical	30.0
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[3]	28.1
Dicerna Pharmaceuticals, Inc.	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

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

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

[3] This research and development collaboration agreement has been terminated, to be effective March 2020.

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

Divestiture

In October 2019, we completed a transaction in which we sold the rights in China for two legacy antibiotic medicines, as well as a manufacturing facility in Suzhou, China to Eddingpharm, a China-based specialty pharmaceutical company. In connection with the sale, we received net cash proceeds of $354.8 million from Eddingpharm in 2019, with an additional payment of $40.3 million due to us in 2020. We accounted for the transaction as the sale of a business. We recorded a gain of $309.8 million in Other—net, (income) expense upon closing the transaction in 2019.

Subsequent Event - Dermira, Inc. (Dermira) Acquisition

On January 10, 2020, we announced an agreement to acquire Dermira for a purchase price of $18.75 per share, or approximately $1.1 billion. The acquisition will expand our immunology pipeline with the addition of lebrikizumab, a novel, investigational, monoclonal antibody designed to bind IL-13 with high affinity that is being evaluated in a Phase III clinical development program for the treatment of moderate-to-severe atopic dermatitis. Lebrikizumab was granted Fast Track designation from the U.S. Food and Drug Administration (FDA). 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. The acquisition will also expand our portfolio of marketed dermatology medicines with the addition of Qbrexza® (glycopyrronium) cloth, a medicated cloth approved by the FDA for the topical treatment of primary axillary hyperhidrosis (uncontrolled excessive underarm sweating). The transaction is not subject to any financing condition and is expected to close by the end of the first quarter of 2020, subject to customary closing conditions, including receipt of required regulatory approvals and the tender of a majority of the outstanding shares of Dermira's common stock.

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 from or payments to the collaboration partner. See Note 2 for amounts of collaboration and other revenue recognized from these types of arrangements.

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

Boehringer Ingelheim Diabetes Collaboration

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

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

Product Family	Milestones (Deferred) Capitalized[1]
Trajenta[2]	$ 446.4
Jardiance[3]	289.0
Basaglar	(250.0)

[1] In connection with the regulatory approvals of Basaglar in the U.S., Europe, and Japan, milestone payments received were recorded as contract liabilities and are being amortized through the term of the collaboration (2029) to collaboration and other revenue. In connection with the regulatory approvals of Trajenta and Jardiance, milestone payments made were capitalized as intangible assets and are being amortized to cost of sales through the term of the collaboration. This represents the cumulative amounts that have been (deferred) or capitalized from the start of this collaboration through the end of the reporting period.

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

[3] The collaboration agreement with Boehringer Ingelheim for Jardiance ends upon expiration of the compound patent and any supplementary protection certificates or extensions thereto.

Through December 31, 2019, in the most significant markets, we and Boehringer Ingelheim shared equally the ongoing development costs, commercialization costs, and agreed upon gross margin for any product resulting from the collaboration. We recorded our portion of the gross margin associated with Boehringer Ingelheim's products as collaboration and other revenue. We recorded 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 recorded our portion of the development and commercialization costs as research and development expense and marketing, selling, and administrative expense, respectively. Each company was entitled to potential performance payments depending on the sales of the molecules it contributes to the collaboration. These performance payments may have resulted 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 have been reduced by any performance payments we make related to these products. Similarly, performance payments we may have received related to Basaglar effectively reduced Boehringer Ingelheim's share of the gross margin, which reduced our cost of sales.

Effective January 1, 2020, we and Boehringer Ingelheim modernized the alliance. In the most significant markets, we and Boehringer Ingelheim share equally the ongoing development costs and commercialization costs for the Jardiance product family. We receive a royalty on net sales of Boehringer Ingelheim's products in the most significant markets and recognize the royalty as collaboration and other revenue. We pay to Boehringer Ingelheim a royalty on net sales for Basaglar in the U.S. We record our sales of Basaglar to third parties as net product revenue with the royalty payments made to Boehringer Ingelheim recorded as cost of sales. For the Jardiance product family, we record our portion of the development and commercialization costs as research and development expense and marketing, selling, and administrative expense, respectively. Boehringer Ingelheim is entitled to potential performance payments depending on the net sales of the Jardiance product family; therefore, our reported revenue for Jardiance may be reduced by any potential performance payments we make related to this product. Beginning January 1, 2021, the royalty received by us related to the Jardiance product family may also be increased or decreased depending on whether net sales for this product family exceed or fall below certain thresholds.

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

	2019	2018	2017
Basaglar	**$ 1,112.6**	$ 801.2	$ 432.1
Jardiance	**944.2**	658.3	447.5
Trajenta	**590.6**	574.7	537.9

Olumiant

We have a worldwide license and collaboration agreement with Incyte Corporation (Incyte), which provides us the development and commercialization rights to its Janus tyrosine kinase (JAK) inhibitor compound, now known as Olumiant, and certain follow-on compounds, for the treatment of inflammatory and autoimmune diseases. Incyte has the right to receive tiered, double-digit royalty payments on future global sales with rates ranging up to 20 percent. The agreement calls for payments by us to Incyte associated with certain development, success-based regulatory, and sales-based milestones.

The following table summarizes our significant milestones achieved:

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

As of December 31, 2019, Incyte is eligible to receive up to $130.0 million of additional payments from us contingent upon certain development and success-based regulatory milestones. Incyte is also eligible to receive up to $150.0 million of potential sales-based milestones.

The agreement provided Incyte with options to co-develop the compound subject to the collaboration on an indication-by-indication basis by funding 30 percent of the associated development costs from the initiation of a Phase IIb trial through regulatory approval in exchange for increased tiered royalties ranging up to percentages in the high twenties. Incyte previously exercised its option to co-develop Olumiant in rheumatoid arthritis, atopic dermatitis, alopecia areata, and SLE; however, it opted-out of co-development of all indications as of January 1, 2019. As a result, we will solely fund all further development and pay a lower royalty rate to Incyte on sales.

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

	2019	2018	2017
Olumiant	**$ 426.9**	$ 202.5	$ 45.8

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, 2019, Pfizer is eligible to receive up to $350.0 million in success-based regulatory milestones and up to $1.23 billion in a series of sales-based milestones, contingent upon the commercial success of tanezumab.

Note 5: 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:

	2019	2018	2017
Severance	**$ 77.8**	$ 127.8	$ 601.0
Pension and post-retirement medical charges associated with U.S. voluntary early retirement program (see Note 15)	**—**	—	446.7
Asset impairment and other special charges	**497.8**	139.1	283.9
Total asset impairment, restructuring, and other special charges	**$ 575.6**	$ 266.9	$ 1,331.6

Severance costs recognized during the years ended December 31, 2019, 2018 and 2017 were incurred as a result of actions taken to reduce our cost structure. Severance costs recognized in 2017 were primarily 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 2017 and 2018 have been paid. Substantially all of the severance costs incurred during the year ended December 31, 2019 are expected to be paid in the next 12 months.

Asset impairment and other special charges recognized during the year ended December 31, 2019 consisted of $400.7 million related to the acquisition of Loxo, substantially all of which is associated with the accelerated vesting of Loxo employee equity awards. In addition, we incurred an asset impairment charge related to our decision to close and sell a research and development facility located in the United Kingdom (U.K). The facility was written down to its estimated fair value, which was based primarily on recent sales of similar assets.

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. 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:

	2019	2018
Finished products	**$ 647.3**	$ 577.8
Work in process	**2,067.6**	2,057.8
Raw materials and supplies	**424.6**	426.1
Total (approximates replacement cost)	**3,139.5**	3,061.7
Increase to LIFO cost	**51.2**	36.4
Inventories	**$ 3,190.7**	$ 3,098.1

Inventories valued under the LIFO method comprised $1.20 billion and $1.37 billion of total inventories at December 31, 2019 and 2018, 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 and observable price changes on a regular basis.

Our derivative activities are initiated within the guidelines of documented corporate risk-management policies and are intended to offset losses and gains on the assets, liabilities, and transactions being hedged. Management reviews the correlation and effectiveness of our derivatives on a quarterly basis.

For derivative instruments that are designated and qualify as fair value hedges, the derivative instrument is marked to market with gains and losses recognized currently in income to offset the respective losses and gains recognized on the underlying exposure. For derivative instruments that are designated and qualify as cash flow hedges, gains and losses are reported as a component of accumulated other comprehensive loss and reclassified into earnings in the same period the hedged transaction affects earnings. For derivative and non-derivative instruments that are designated and qualify as net investment hedges, the foreign currency translation gains or losses due to spot rate fluctuations are reported as a component of accumulated other comprehensive loss. Derivative contracts that are not designated as hedging instruments are recorded at fair value with the gain or loss recognized in earnings during the period of change.

We may enter into foreign currency forward or option contracts to reduce the effect of fluctuating currency exchange rates (principally the euro, British pound, and the Japanese yen). Foreign currency derivatives used for hedging are put in place using the same or like currencies and duration as the underlying exposures. Forward and option contracts are principally used to manage exposures arising from subsidiary trade and loan payables and receivables denominated in foreign currencies. These contracts are recorded at fair value with the gain or loss recognized in other–net, (income) expense. We may enter into foreign currency forward and option contracts and currency swaps as fair value hedges of firm commitments. Forward contracts generally have maturities not exceeding 12 months. At December 31, 2019, we had outstanding foreign currency forward commitments to purchase 447.9 million U.S. dollars and sell 402.9 million euro; commitments to purchase 1.81 billion euro and sell 2.02 billion U.S. dollars; commitments to purchase 308.3 million U.S. dollars and sell 33.49 billion Japanese yen, commitments to purchase 101.4 million Swiss francs and sell 103.5 million U.S. dollars, and commitments to purchase 236.2 million British pounds and sell 310.9 million U.S. dollars which all settled 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 $5.49 billion and $3.40 billion as of December 31, 2019 and 2018, respectively, of which $4.10 billion and $2.65 billion have been designated as, and are effective as, economic hedges of net investments in certain of our euro-denominated foreign operations as of December 31, 2019 and 2018, respectively. At December 31, 2019, we had outstanding cross currency swaps with notional amounts of $1.45 billion swapping U.S. dollars to euro, $1.00 billion swapping swiss francs to U.S. dollars, and $396.0 million swapping U.S. dollars to British pounds, which have settlement dates ranging through 2028. Our cross-currency interest rate swaps, for which a majority convert a portion of our U.S. dollar-denominated floating rate debt to foreign-denominated floating rate debt, have also been designated as, and are effective as, economic hedges of net investments.

In the normal course of business, our operations are exposed to fluctuations in interest rates which can vary the costs of financing, investing, and operating. We seek to address a portion of these risks through a controlled program of risk management that includes the use of derivative financial instruments. The objective of controlling these risks is to limit the impact of fluctuations in interest rates on earnings. Our primary interest-rate risk exposure results from changes in short-term U.S. dollar interest rates. In an effort to manage interest-rate exposures, we strive to achieve an acceptable balance between fixed- and floating-rate debt and investment positions and may enter into interest rate swaps or collars to help maintain that balance.

Interest rate swaps or collars that convert our fixed-rate debt to a floating rate are designated as fair value hedges of the underlying instruments. Interest rate swaps or collars that convert floating-rate debt to a fixed rate are designated as cash flow hedges. Interest expense on the debt is adjusted to include the payments made or received under the swap agreements. Cash proceeds from or payments to counterparties resulting from the termination of interest rate swaps are classified as operating activities in our consolidated statements of cash flows. At December 31, 2019, substantially all of our total long-term debt is at a fixed rate. We have converted approximately 11 percent of our long-term fixed-rate notes to floating rates through the use of interest rate swaps.

We also may enter into forward-starting interest rate swaps, which we designate as cash flow hedges, as part of any anticipated future debt issuances in order to reduce the risk of cash flow volatility from future changes in interest rates. The change in fair value of these instruments is recorded as part of other comprehensive income (loss), and upon completion of a debt issuance and termination of the swap, is amortized to interest expense over the life of the underlying debt. As of December 31, 2019, the total

notional amounts of forward-starting interest rate contracts in designated cash flow hedging instruments were $1.00 billion, which have settlement dates ranging between 2023 and 2025.

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:

	2019	2018	2017
Fair value hedges:			
Effect from hedged fixed-rate debt	**$ 112.1**	$ (40.9)	$ (14.1)
Effect from interest rate contracts	**(112.1)**	40.9	14.1
Cash flow hedges:			
Effective portion of losses on interest rate contracts reclassified from accumulated other comprehensive loss	**15.9**	14.8	14.8
Cross-currency interest rate swaps	**(17.1)**	—	—
Net losses on foreign currency exchange contracts not designated as hedging instruments	**61.9**	100.0	97.9
Total	**$ 60.7**	$ 114.8	$ 112.7

During the years ended December 31, 2019 and 2018, the amortization of losses related to the portion of our risk management hedging instruments, fair value hedges, and cash flow hedges that was excluded from the assessment of effectiveness was not material.

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

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

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

	2019	2018	2017
Net investment hedges:			
Foreign currency-denominated notes	**$ 40.1**	$ 110.4	$ (361.5)
Cross-currency interest rate swaps	**47.4**	96.8	(126.6)
Foreign currency exchange contracts	**—**	5.7	—
Cash flow hedges:			
Forward-starting interest rate swaps	**31.6**	—	13.0
Cross-currency interest rate swaps	**(8.3)**	—	—

In 2020, we expect to reclassify $16.3 million of net losses on cash flow hedges from accumulated other comprehensive loss to other–net, (income) expense. During the year ended December 31, 2019 and 2018, the amounts excluded from the assessment of hedge effectiveness recognized in other comprehensive income (loss) were not material.

Fair Value of Financial Instruments

The following tables summarize certain fair value information at 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, 2019						
Cash equivalents	**$ 1,025.4**	**$ 1,025.4**	**$ 1,025.4**	**$ —**	**$ —**	**$ 1,025.4**
Short-term investments:						
U.S. government and agency securities	**$ 7.2**	**$ 7.2**	**$ 7.2**	**$ —**	**$ —**	**$ 7.2**
Corporate debt securities	**81.4**	**81.1**	**—**	**81.4**	**—**	**81.4**
Asset-backed securities	**2.6**	**2.6**	**—**	**2.6**	**—**	**2.6**
Other securities	**9.8**	**9.8**	**—**	**—**	**9.8**	**9.8**
Short-term investments	**$ 101.0**					
Noncurrent investments:						
U.S. government and agency securities	**$ 77.2**	**$ 76.3**	**$ 77.2**	**$ —**	**$ —**	**$ 77.2**
Corporate debt securities	**271.1**	**267.8**	**—**	**271.1**	**—**	**271.1**
Mortgage-backed securities	**101.1**	**99.6**	**—**	**101.1**	**—**	**101.1**
Asset-backed securities	**30.0**	**29.6**	**—**	**30.0**	**—**	**30.0**
Other securities	**60.0**	**27.4**	**—**	**—**	**60.0**	**60.0**
Marketable equity securities	**718.6**	**254.4**	**718.6**	**—**	**—**	**718.6**
Equity investments without readily determinable fair values[2]	**405.0**					
Equity method investments[2]	**299.4**					
Noncurrent investments	**$ 1,962.4**					
December 31, 2018						
Cash equivalents	$ 5,727.1	$ 5,727.1	$ 5,727.1	$ —	$ —	$ 5,727.1
Short-term investments:						
U.S. government and agency securities	$ 16.9	$ 17.1	$ 16.9	$ —	$ —	$ 16.9
Corporate debt securities	62.2	62.6	—	62.2	—	62.2
Asset-backed securities	7.6	7.7	—	7.6	—	7.6
Other securities	1.5	1.5	—	1.5	—	1.5
Short-term investments	$ 88.2					
Noncurrent investments:						
U.S. government and agency securities	$ 149.1	$ 153.6	$ 149.1	$ —	$ —	$ 149.1
Corporate debt securities	568.0	587.8	—	568.0	—	568.0
Mortgage-backed securities	111.4	114.5	—	111.4	—	111.4

Asset-backed securities	27.7	27.9	—	27.7	—	27.7
Other securities	87.8	29.7	—	—	87.8	87.8
Marketable equity securities	357.5	238.3	357.5	—	—	357.5
Equity investments without readily determinable fair values[2]	414.7					
Equity method investments[2]	289.2					
Noncurrent investments	$ 2,005.4					

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

[2] Fair value disclosures are not applicable for equity method investments and investments accounted for under the measurement alternative for equity investments.

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, 2019	**$ (1,494.2)**	**$ —**	**$ (1,491.6)**	**$ —**	**$ (1,491.6)**
December 31, 2018	(498.9)	—	(497.6)	—	(497.6)
Long-term debt, including current portion					
December 31, 2019	**$ (13,823.0)**	**$ —**	**$ (15,150.0)**	**$ —**	**$ (15,150.0)**
December 31, 2018	(9,799.7)	—	(9,989.4)	—	(9,989.4)

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, 2019					
Risk-management instruments					
Interest rate contracts designated as fair value hedges:					
Other noncurrent assets	**$ 72.0**	**$ —**	**$ 72.0**	**$ —**	**$ 72.0**
Interest rate contracts designated as cash flow hedges:					
Other noncurrent assets	**43.3**	**—**	**43.3**	**—**	**43.3**
Cross-currency interest rate contracts designated as net investment hedges:					
Other noncurrent assets	**45.1**	**—**	**45.1**	**—**	**45.1**
Other current liabilities	**(21.4)**	**—**	**(21.4)**	**—**	**(21.4)**
Other noncurrent liabilities	**(5.7)**	**—**	**(5.7)**	**—**	**(5.7)**
Cross-currency interest rate contracts designated as cash flow hedges:					
Other noncurrent assets	**3.0**		**3.0**		**3.0**
Other noncurrent liabilities	**(20.1)**	**—**	**(20.1)**	**—**	**(20.1)**
Foreign exchange contracts not designated as hedging instruments:					
Other receivables	**18.4**	**—**	**18.4**	**—**	**18.4**
Other current liabilities	**(11.9)**	**—**	**(11.9)**	**—**	**(11.9)**
December 31, 2018					
Risk-management instruments					
Interest rate contracts designated as fair value hedges:					
Other noncurrent assets	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
Other noncurrent assets	8.2	—	8.2	—	8.2
Other current liabilities	(9.2)	—	(9.2)	—	(9.2)
Cross-currency interest rate contracts not designated as hedging instruments:					
Other noncurrent liabilities	(25.8)	—	(25.8)	—	(25.8)
Foreign exchange contracts not designated as hedging instruments:					
Other receivables	11.3	—	11.3	—	11.3
Other current liabilities	(16.3)	—	(16.3)	—	(16.3)

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

We determine our Level 1 and Level 2 fair value measurements based on a market approach using quoted market values, significant other observable inputs for identical or comparable assets or liabilities, or discounted cash flow analyses. Level 3 fair value measurements for other investment securities are determined using unobservable inputs, including the investments' cost adjusted for impairments and price

changes from orderly transactions. The fair values of equity method investments and investments measured under the measurement alternative for equity investments that do not have readily determinable fair values are not readily available.

The table below summarizes the contractual maturities of our investments in debt securities measured at fair value as of December 31, 2019:

	Maturities by Period				
	Total	Less Than 1 Year	1-5 Years	6-10 Years	More Than 10 Years
Fair value of debt securities	$ 570.6	$ 91.2	$ 276.5	$ 80.4	$ 122.5

The net unrealized gains (losses) recognized in our consolidated statements of operations for equity securities were $395.3 million and $(20.1) million for the years ended December 31, 2019 and 2018, respectively.

We adjust our equity investments without readily determinable fair values based upon changes in the equity instruments' values resulting from observable price changes in orderly transactions for an identical or similar investment of the same issuer. Downward adjustments resulting from an impairment are recorded based upon impairment considerations, including the financial condition and near term prospects of the issuer, general market conditions, and industry specific factors. Adjustments recorded for the years ended December 31, 2019 and 2018 were not material.

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

	2019	2018
Unrealized gross gains	**$ 10.3**	$ 0.8
Unrealized gross losses	**4.0**	29.0
Fair value of securities in an unrealized gain position	**429.5**	84.3
Fair value of securities in an unrealized loss position	**141.1**	858.6

We periodically assess our investment in available-for-sale securities for other-than-temporary impairment losses. Other-than-temporary impairment losses were not material in 2019, and there were no other-than-temporary impairment losses in 2018 or 2017.

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

As of December 31, 2019, the available-for-sale securities in an unrealized loss position include primarily fixed-rate debt securities of varying maturities, which are sensitive to changes in the yield curve and other market conditions. Approximately 56 percent of the fixed-rate debt securities in a loss position are investment-grade debt securities. As of December 31, 2019, we do not intend to sell, and it is not more likely than not that we will be required to sell, the securities in a loss position before the market values recover or the underlying cash flows have been received, and there is no indication of default on interest or principal payments for any of our debt securities.

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

	2019	2018	2017
Proceeds from sales	**$ 655.5**	$ 5,668.0	$ 5,769.3
Realized gross gains on sales	**40.0**	11.8	176.0
Realized gross losses on sales	**7.9**	51.3	5.8

Realized gains and losses on sales of available-for-sale investments are computed based upon specific identification of the initial cost adjusted for any other-than-temporary declines in fair value that were recorded in earnings.

Accounts Receivable Factoring Arrangements

We have entered into accounts receivable factoring agreements with financial institutions to sell certain of our non-U.S. accounts receivable. These transactions are accounted for as sales and result in a reduction in accounts receivable because the agreements transfer effective control over and risk related to the receivables to the buyers. Our factoring agreements do not allow for recourse in the event of uncollectibility, and we do not retain any interest in the underlying accounts receivable once sold. We derecognized $678.8 million and $696.2 million of accounts receivable as of December 31, 2019 and 2018, respectively, under these factoring arrangements. The costs of factoring such accounts receivable on our consolidated results of operations for the years ended December 31, 2019, 2018, and 2017 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, or more frequently if impairment indicators are present, by first assessing qualitative factors to determine whether it is more likely than not that the fair value is less than its carrying amount. If we conclude it is more likely than not that the fair value is less than the carrying amount, a quantitative test that compares the fair value to its carrying value is performed to determine the amount of any impairment. The change in goodwill during 2019 was primarily related to our acquisition of Loxo. See Note 3 for further discussion.

No impairments occurred with respect to the carrying value of goodwill for the years ended December 31, 2019, 2018, and 2017.

Other Intangibles

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

	2019			2018		
Description	Carrying Amount, Gross	Accumulated Amortization	Carrying Amount, Net	Carrying Amount, Gross	Accumulated Amortization	Carrying Amount, Net
Finite-lived intangible assets:						
Marketed products	**$ 3,150.2**	**$ (1,244.6)**	**$ 1,905.6**	$ 2,077.2	$ (1,069.0)	$ 1,008.2
Other	**94.2**	**(51.8)**	**42.4**	89.5	(29.7)	59.8
Total finite-lived intangible assets	**3,244.4**	**(1,296.4)**	**1,948.0**	2,166.7	(1,098.7)	1,068.0
Indefinite-lived intangible assets:						
Acquired IPR&D	**4,670.0**	**—**	**4,670.0**	—	—	—
Other intangibles	**$ 7,914.4**	**$ (1,296.4)**	**$ 6,618.0**	$ 2,166.7	$ (1,098.7)	$ 1,068.0

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.

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, analyst expectations, 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 3 for further discussion of intangible assets acquired in recent business combinations and Note 4 for additional discussion of recent capitalized milestone payments. The increases in marketed products and acquired IPR&D intangible assets in 2019 were primarily related to our acquisition of Loxo.

Other indefinite-lived intangible assets are reviewed for impairment at least annually, or more frequently if impairment indicators are present, by first assessing qualitative factors to determine whether it is more likely than not that the fair value of the asset is less than its carrying amount. If we conclude it is more likely than not that the fair value is less than the carrying amount, a quantitative test that compares the fair value of the intangible asset to its carrying value is performed to determine the amount of any impairment. 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.

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, 2019, 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:

	2019	2018	2017
Amortization expense	**$ 225.8**	$ 361.3	$ 462.2

The estimated amortization expense for each of the next five years associated with our finite-lived intangible assets as of December 31, 2019 is as follows:

	2020	2021	2022	2023	2024
Estimated amortization expense	$ 234.3	$ 235.2	$ 227.3	$ 215.6	$ 165.7

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:

	2019	2018
Land	**$ 169.5**	$ 165.5
Buildings	**7,067.3**	7,116.6
Equipment	**7,913.3**	7,792.3
Construction in progress	**1,884.4**	1,588.6
	17,034.5	16,663.0
Less accumulated depreciation	**(9,161.6)**	(8,666.9)
Property and equipment, net	**$ 7,872.9**	$ 7,996.1

Depreciation expense related to property and equipment was as follows:

	2019	2018	2017
Depreciation expense	**$ 814.7**	$ 797.1	$ 681.7

Capitalized interest costs were not material for the years ended December 31, 2019, 2018, and 2017.

The following table summarizes long-lived assets by geographical area:

	2019	2018
Long-lived assets[(1)]:		
U.S. and Puerto Rico	**$ 5,595.4**	$ 5,425.0
Ireland	**1,454.8**	1,351.3
Other foreign countries	**1,758.3**	1,769.9
Long-lived assets	**$ 8,808.5**	$ 8,546.2

(1) Long-lived assets consist of property and equipment, net, operating lease assets, and certain other noncurrent assets.

Note 10: Leases

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

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

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

Lease expense for operating lease assets, which is recognized on a straight-line basis over the lease term, was $172.8 million during the year ended December 31, 2019. Variable lease payments, which represent non-lease components such as maintenance, insurance and taxes, and which vary due to changes in facts or circumstances occurring after the commencement date other than the passage of time, are expensed in the period in which the payment obligation is incurred and were not material during the year ended December 31, 2019. Short-term lease expense was not material during the year ended December 31, 2019.

Supplemental balance sheet information related to operating leases as of December 31, 2019 was as follows:

Weighted-average remaining lease term	8 years
Weighted-average discount rate	3.6 %

Supplemental cash flow information related to operating leases during the year ended December 31, 2019 was as follows:

Operating cash flows from operating leases	$	153.6
Right-of-use assets obtained in exchange for new operating lease liabilities		81.2

The annual minimum lease payments of our operating lease liabilities as of December 31, 2019 were as follows:

Year 1	$	138.1
Year 2		111.0
Year 3		82.3
Year 4		60.6
Year 5		55.7
After Year 5		272.7
Total lease payments		720.4
Less imputed interest		112.0
Total	$	608.4

Rental expense for all leases, including contingent rentals (not material), was $175.7 million and $177.4 million for the years ended December 31, 2018 and 2017, respectively.

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

Note 11: Borrowings

Debt at December 31 consisted of the following:

	2019	2018
Short-term commercial paper borrowings	**$ 1,494.2**	$ 498.9
0.15 to 7.13 percent long-term notes (due 2022-2059)	**13,638.5**	9,640.8
Other long-term debt	**12.9**	10.1
Unamortized debt issuance costs	**(73.6)**	(28.4)
Fair value adjustment on hedged long-term notes	**245.2**	177.2
Total debt	**15,317.2**	10,298.6
Less current portion	**(1,499.3)**	(1,102.2)
Long-term debt	**$ 13,817.9**	$ 9,196.4

The weighted-average effective borrowing rate on outstanding commercial paper at December 31, 2019 was 1.65 percent.

At December 31, 2019, we had a total of $5.21 billion of unused committed bank credit facilities, which consisted primarily of a $3.00 billion credit facility that expires in December 2024 and a $2.00 billion 364-day facility that expires in December 2020, 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 committed bank credit facilities, the outstanding balances as of as December 31, 2019 and December 31, 2018 were not material. 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 February 2019, we issued $1.15 billion of 3.38 percent fixed-rate notes due in March 2029, $850.0 million of 3.88 percent fixed-rate notes due in March 2039, $1.50 billion of 3.95 percent fixed-rate notes due in March 2049, and $1.00 billion of 4.15 percent fixed-rate notes due in March 2059, with interest to be paid semi-annually. We used the net proceeds of $4.45 billion from the offering to repay commercial paper that was issued in connection with the acquisition of Loxo and for general corporate purposes.

In November 2019, we issued euro-denominated notes consisting of €600.0 million of 0.625 percent fixed-notes due November 2031 and €1.00 billion of 1.70 percent fixed-rate notes due in November 2049 with interest to be paid annually. We paid $2.27 billion, comprised of $1.75 billion of net cash proceeds from the offering and proceeds from commercial paper, to purchase and redeem certain higher interest rate U.S. dollar denominated notes with an aggregate principal amount of $2.00 billion and a net carrying value of $2.01 billion, resulting in a debt extinguishment loss of $252.5 million. This loss was included in other-net, (income) expense in our consolidated statement of operations during the year ended December 31, 2019.

In November 2019, we issued Japanese Yen-denominated notes consisting of ¥22.92 billion of 0.42 percent fixed-rate notes due in November 2029, ¥9.28 billion of 0.56 percent fixed-rate notes due in November 2034, and ¥7.64 billion of 0.97 percent fixed-rate notes due in November 2049, with interest to be paid semi-annually. We used the net cash proceeds from the offering of $356.6 million for general corporate purposes, including to repay outstanding commercial paper.

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

	2020	2021	2022	2023	2024
Maturities on long-term debt	$ 7.0	$ 5.9	$ 1,424.7	$ 1.9	$ 619.6

We have converted approximately 11 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, 2019 and 2018, including the effects of interest rate swaps for hedged debt obligations, were 2.88 percent and 3.13 percent, respectively.

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

	2019	2018	2017
Cash payments for interest on borrowings	**$ 305.5**	$ 223.8	$ 192.7

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 12: 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:

	2019	2018	2017
Stock-based compensation expense	**$ 306.8**	$ 253.5	$ 256.3
Tax benefit	**64.4**	53.2	64.1

At December 31, 2019, stock-based compensation awards may be granted under the 2002 Lilly Stock Plan for not more than 54.6 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, 2019, 2018, and 2017 were $112.09, $71.63, and $73.54, 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 1.2 million shares, 0.9 million shares, and 1.3 million shares were issued during the years ended December 31, 2019, 2018, and 2017, respectively. Approximately 1.1 million shares are expected to be issued in 2020. As of December 31, 2019, the total remaining unrecognized compensation cost related to nonvested PAs was $63.2 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, 2019, 2018, and 2017 were $95.01, $48.51, and $66.25, respectively, determined using the following assumptions:

(Percents)	2019	2018	2017
Expected dividend yield	**2.50 %**	2.50 %	2.50 %
Risk-free interest rate	**2.46**	2.31	1.38
Volatility	**21.00**	22.26	22.91

Pursuant to this program, approximately 1.0 million shares, 0.7 million shares, and 1.1 million shares were issued during the years ended December 31, 2019, 2018, and 2017, respectively. Approximately 0.8

million shares are expected to be issued in 2020. As of December 31, 2019, the total remaining unrecognized compensation cost related to nonvested SVAs was $56.1 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, 2019, 2018, and 2017 were $108.43, $70.95, and $72.47, respectively. The number of shares ultimately issued for the RSU program remains constant with the exception of forfeitures. Pursuant to this program, 1.5 million, 1.3 million, and 1.4 million shares were granted and approximately 0.8 million, 1.0 million, and 0.9 million shares were issued during the years ended December 31, 2019, 2018, and 2017, respectively. Approximately 0.7 million shares are expected to be issued in 2020. As of December 31, 2019, the total remaining unrecognized compensation cost related to nonvested RSUs was $134.9 million, which will be amortized over the weighted-average remaining requisite service period of 27 months.

Note 13: Shareholders' Equity

During 2019, 2018, and 2017, we repurchased $4.40 billion, $4.15 billion and $359.8 million, respectively, of shares associated with our share repurchase programs. As of December 31, 2019, we had $1.50 billion remaining under our $8.00 billion share repurchase program that our board authorized in June 2018.

We have 5.0 million authorized shares of preferred stock. As of December 31, 2019 and 2018, 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, 2019 and 2018, 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, 2019 and 2018, 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, 2019, 2018, and 2017.

Note 14: Income Taxes

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 and a global intangible low-taxed income (GILTI) provision, the new U.S. minimum tax on the earnings of our foreign subsidiaries. In 2017, we recognized a provisional amount of $1.91 billion, which was included as a component of income tax expense from continuing operations. This amount represented approximately $3.6 billion attributable to the Toll Tax, partially offset by the changes in deferred taxes resulting from the transition to a U.S. territorial system, including the re-measurement of deferred taxes. In 2018, we recorded $313.3 million of income tax benefit, mainly attributable to measurement period adjustments to the Toll Tax and GILTI.

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. Deferred taxes related to GILTI are also recognized for the future tax effects of temporary differences.

We recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position, based on its technical merits, will be sustained upon examination by the taxing authority. 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:

	2019	2018	2017
Current:			
Federal[1]	**$ 280.2**	$ 169.6	$ 3,181.0
Foreign	**299.8**	106.8	47.5
State	**(14.4)**	4.7	(5.4)
Total current tax expense	**565.6**	281.1	3,223.1
Deferred:			
Federal[2]	**141.3**	(3.7)	(601.2)
Foreign	**(24.1)**	248.7	(230.9)
State	**(54.8)**	3.4	0.2
Total deferred tax (benefit) expense	**62.4**	248.4	(831.9)
Income taxes	**$ 628.0**	$ 529.5	$ 2,391.2

[1] The 2019 current tax expense includes $153.1 million of tax benefit from utilization of net operating loss carryforwards. The 2018 and 2017 current tax expense includes $201.5 million and $3.25 billion of tax expense, respectively, related to effects of the 2017 Tax Act.

[2] The 2018 and 2017 deferred tax benefit includes $26.2 million and $1.33 billion of tax benefit, respectively, related to the effects of the 2017 Tax Act.

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

	2019	2018
Deferred tax assets:		
Purchases of intangible assets	**$ 2,512.4**	$ 2,627.7
Compensation and benefits	**934.3**	781.6
Tax credit carryforwards and carrybacks	**455.8**	359.4
Tax loss carryforwards and carrybacks	**318.8**	248.2
Sales rebates and discounts	**197.3**	45.5
Operating lease liabilities	**140.6**	—
Product return reserves	**98.1**	95.3
Other comprehensive loss on hedging transactions	**59.6**	68.9
Debt	**53.9**	40.3
Other	**835.7**	646.3
Total gross deferred tax assets	**5,606.5**	4,913.2
Valuation allowances	**(616.5)**	(574.8)
Total deferred tax assets	**4,990.0**	4,338.4
Deferred tax liabilities:		
Earnings of foreign subsidiaries	**(1,776.4)**	(1,745.3)
Intangibles	**(1,298.0)**	(86.9)
Inventories	**(686.4)**	(681.3)
Prepaid employee benefits	**(305.9)**	(240.1)
Property and equipment	**(274.1)**	(260.9)
Financial instruments	**(139.4)**	(22.8)
Operating lease assets	**(124.7)**	—
Total deferred tax liabilities	**(4,604.9)**	(3,037.3)
Deferred tax assets - net	**$ 385.1**	$ 1,301.1

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, 2019, based on filed tax returns we have tax credit carryforwards and carrybacks of $799.2 million available to reduce future income taxes; $149.3 million, if unused, will expire by 2026, and $55.6 million, if unused, will expire between 2032 and 2038. The remaining portion of the tax credit carryforwards is

related to federal tax credits of $86.6 million, international tax credits of $114.7 million, and state tax credits of $393.0 million, all of which are substantially reserved.

At December 31, 2019, based on filed tax returns we had net operating losses and other carryforwards for international and U.S. federal income tax purposes of $949.7 million: $181.4 million will expire by 2024; $345.4 million will expire between 2025 and 2039; and $422.9 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 $116.1 million and other state carryforwards of $3.6 million are fully reserved as of December 31, 2019.

Domestic and Puerto Rican companies contributed approximately 44 percent, 15 percent, and 16 percent for the years ended December 31, 2019, 2018, and 2017, 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, 2019, we had 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 U.S. federal, state, and foreign income taxes, net of refunds, were as follows:

	2019	2018	2017
Cash payments of income taxes	**$ 1,180.5**	$ 1,076.7	$ 221.5

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:

	2019	2018	2017
Income tax at the U.S. federal statutory tax rate	**$ 1,105.8**	$ 772.8	$ 806.7
Add (deduct):			
International operations, including Puerto Rico	**(242.0)**	(627.1)	(480.8)
General business credits	**(108.8)**	(87.4)	(66.8)
Non-deductible acquired IPR&D[1]	**—**	309.9	300.1
2017 Tax Act	**—**	175.3	1,914.0
Other	**(127.0)**	(14.0)	(82.0)
Income taxes	**$ 628.0**	$ 529.5	$ 2,391.2

[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:

	2019	2018	2017
Beginning balance at January 1	**$ 2,034.6**	$ 1,000.8	$ 843.3
Additions based on tax positions related to the current year	**187.2**	798.2	133.8
Additions for tax positions of prior years	**425.3**	410.9	93.8
Reductions for tax positions of prior years	**(100.3)**	(115.4)	(59.3)
Settlements	**(260.5)**	(33.2)	(2.4)

Lapses of statutes of limitation	**(161.5)**	(20.5)	(19.3)
Changes related to the impact of foreign currency translation	**(16.2)**	(6.2)	10.9
Ending balance at December 31	**$ 2,108.6**	$ 2,034.6	$ 1,000.8

The total amount of unrecognized tax benefits that, if recognized, would affect our effective tax rate was $1.53 billion and $1.48 billion at December 31, 2019 and 2018, 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 2011.

The U.S. examination of tax years 2013-2015 began in 2016, and certain matters were effectively settled during the second quarter of 2019. As a result, our gross uncertain tax positions were reduced by approximately $200 million, we made a cash payment of approximately $125 million, and our consolidated results were benefited by an immaterial reduction in tax expense. During the fourth quarter of 2019, certain matters for tax year 2015 were effectively settled upon conclusion of the Internal Revenue Service's (IRS) examination which resulted in an immaterial reduction in tax expense and gross uncertain tax positions. Also in the fourth quarter of 2019, the IRS began its examination of tax years 2016-2018.

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:

	2019	2018	2017
Income tax (benefit) expense	**$ (26.4)**	$ 25.1	$ 22.8

At December 31, 2019 and 2018, our accruals for the payment of interest and penalties totaled $150.8 million and $183.9 million, respectively.

Note 15: 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	
	2019	2018	2019	2018
Change in benefit obligation:				
Benefit obligation at beginning of year	**$ 13,427.1**	$ 14,839.7	**$ 1,540.0**	$ 1,718.7
Service cost	**250.4**	292.7	**36.3**	41.5
Interest cost	**486.0**	458.5	**58.0**	57.3
Actuarial (gain) loss	**2,631.7**	(1,386.5)	**54.3**	(176.9)
Benefits paid	**(584.2)**	(579.4)	**(87.3)**	(82.8)
Plan amendments	**—**	17.6	**—**	(14.1)
Curtailment (gain) loss	**(16.8)**	(43.9)	**(0.5)**	2.5
Foreign currency exchange rate changes and other adjustments	**56.8**	(171.6)	**0.6**	(6.2)
Benefit obligation at end of year	**16,251.0**	13,427.1	**1,601.4**	1,540.0
Change in plan assets:				
Fair value of plan assets at beginning of year	**10,932.6**	11,713.0	**2,398.1**	2,372.4
Actual return on plan assets	**2,012.0**	(360.1)	**444.1**	32.6
Employer contribution	**429.9**	319.0	**13.2**	75.9
Benefits paid	**(584.2)**	(579.4)	**(87.3)**	(82.8)
Foreign currency exchange rate changes and other adjustments	**67.7**	(159.9)	**0.1**	—
Fair value of plan assets at end of year	**12,858.0**	10,932.6	**2,768.2**	2,398.1
Funded status	**(3,393.0)**	(2,494.5)	**1,166.8**	858.1
Unrecognized net actuarial (gain) loss	**6,177.6**	5,011.3	**(111.6)**	140.6
Unrecognized prior service (benefit) cost	**17.4**	25.0	**(236.4)**	(299.9)
Net amount recognized	**$ 2,802.0**	$ 2,541.8	**$ 818.8**	$ 698.8
Amounts recognized in the consolidated balance sheet consisted of:				
Other noncurrent assets	**$ 163.3**	$ 193.7	**$ 1,381.3**	$ 1,043.6
Other current liabilities	**(65.3)**	(64.2)	**(7.3)**	(7.3)
Accrued retirement benefits	**(3,491.0)**	(2,624.0)	**(207.2)**	(178.2)
Accumulated other comprehensive (income) loss before income taxes	**6,195.0**	5,036.3	**(348.0)**	(159.3)
Net amount recognized	**$ 2,802.0**	$ 2,541.8	**$ 818.8**	$ 698.8

The unrecognized net actuarial loss (gain) and unrecognized prior service cost (benefit) have not yet been recognized in net periodic pension costs and were included in accumulated other comprehensive loss at December 31, 2019.

Market variables associated with the remeasurement, specifically a decrease in the discount rate partially offset by higher return on plan assets, were the primary drivers for the $2.89 billion increase in the benefit obligation in 2019.

In July 2018, we announced that we would amend our defined benefit pension and retiree health benefit plans to freeze or reduce benefits for certain employees effective January 1, 2019. We remeasured the

impacted pension and retiree health plans' benefit obligations as of July 31, 2018, which resulted in a net curtailment gain of $28.0 million, 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, of 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.

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

	Defined Benefit Pension Plans			Retiree Health Benefit Plans		
(Percents)	2019	2018	2017	2019	2018	2017
Discount rate for benefit obligation	**3.0%**	4.0%	3.4%	**3.3%**	4.4%	3.7%
Discount rate for net benefit costs	**4.0**	3.4	3.9	**4.4**	3.7	4.3
Rate of compensation increase for benefit obligation	**3.3**	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	**6.0**	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:

	2020	2021	2022	2023	2024	2025-2029
Defined benefit pension plans	$ 614.5	$ 621.8	$ 641.0	$ 652.3	$ 682.4	$ 3,712.1
Retiree health benefit plans	93.7	93.8	92.9	91.7	94.3	469.8

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

	2019	2018
Projected benefit obligation	**$ 14,039.7**	$ 11,584.2
Fair value of plan assets	**10,483.4**	8,895.6

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	
	2019	2018	2019	2018
Accumulated benefit obligation	**$ 13,063.7**	$ 10,837.8	**$ 214.4**	$ 189.4
Fair value of plan assets	**10,483.4**	8,895.6	**—**	—

The total accumulated benefit obligation for our defined benefit pension plans was $15.17 billion and $12.57 billion at December 31, 2019 and 2018, respectively.

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

	Defined Benefit Pension Plans			Retiree Health Benefit Plans		
	2019	2018	2017	2019	2018	2017
Components of net periodic (benefit) cost:						
Service cost	**$ 250.4**	$ 292.7	$ 320.8	**$ 36.3**	$ 41.5	$ 46.4
Interest cost	**486.0**	458.5	411.6	**58.0**	57.3	52.9
Expected return on plan assets	**(839.6)**	(842.1)	(773.6)	**(144.3)**	(177.9)	(160.7)
Amortization of prior service (benefit) cost	**6.1**	4.6	5.6	**(62.9)**	(79.5)	(90.0)
Recognized actuarial loss	**284.9**	332.5	286.8	**1.9**	6.1	18.4
Curtailment (gain) loss	**2.2**	1.3	93.5	**—**	(29.3)	65.5
Special termination benefit	**—**	—	317.2	**—**	—	37.5
Net periodic (benefit) cost	**$ 190.0**	$ 247.5	$ 661.9	**$ (111.0)**	$ (181.8)	$ (30.0)

The following represents the amounts recognized in other comprehensive income (loss) for the years ended December 31, 2019, 2018, and 2017:

	Defined Benefit Pension Plans			Retiree Health Benefit Plans		
	2019	2018	2017	2019	2018	2017
Actuarial gain (loss) arising during period	**$ (1,461.0)**	$ 182.8	$ (898.1)	**$ 246.1**	$ 37.5	$ 261.3
Plan amendments during period	**—**	(17.6)	—	**—**	14.1	—
Curtailment gain (loss)	**19.0**	45.2	3.2	**—**	(31.8)	(39.7)
Amortization of prior service (benefit) cost included in net income	**6.1**	4.6	5.6	**(62.9)**	(79.5)	(90.0)
Amortization of net actuarial loss included in net income	**284.9**	332.5	286.8	**1.9**	6.1	18.4
Foreign currency exchange rate changes and other	**(7.7)**	47.1	(108.8)	**3.6**	(0.1)	(3.3)
Total other comprehensive income (loss) during period	**$ (1,158.7)**	$ 594.6	$ (711.3)	**$ 188.7**	$ (53.7)	$ 146.7

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 $145.2 million, $132.6 million, and $147.0 million for the years ended December 31, 2019, 2018, and 2017, 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, 2019, 2018, and 2017 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 in fund-of-funds structures and directly into hedge funds. 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, special situations, private debt, and private real estate investments. 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 equity-like 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 public 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 a portion of the real estate holdings, 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, 2019 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.	$ 794.2	$ 532.5	$ —	$ —	$ 261.7
International	2,439.2	1,046.8	—	—	1,392.4
Fixed income:					
Developed markets	3,661.4	4.8	2,658.9	—	997.7
Developed markets - repurchase agreements	(1,659.1)	—	(1,659.1)	—	—
Emerging markets	648.0	18.5	277.4	4.1	348.0
Private alternative investments:					
Hedge funds	2,897.9	—	—	—	2,897.9
Equity-like funds	2,279.3	—	—	16.8	2,262.5
Real estate	570.3	166.2	—	—	404.1
Other	1,226.8	62.9	222.6	6.6	934.7
Total	$ 12,858.0	$ 1,831.7	$ 1,499.8	$ 27.5	$ 9,499.0
Retiree Health Benefit Plans					
Public equity securities:					
U.S.	$ 76.5	$ 52.1	$ —	$ —	$ 24.4
International	152.6	60.8	—	—	91.8
Fixed income:					
Developed markets	82.7	—	56.3	—	26.4
Emerging markets	58.5	—	27.0	0.4	31.1
Private alternative investments:					
Hedge funds	250.8	—	—	—	250.8
Equity-like funds	187.4	—	—	1.6	185.8
Cash value of trust owned insurance contract	1,832.2	—	1,832.2	—	—
Real estate	31.3	16.2	—	—	15.1
Other	96.2	11.4	7.9	0.7	76.2
Total	$ 2,768.2	$ 140.5	$ 1,923.4	$ 2.7	$ 701.6

[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, 2019. The activity in the Level 3 investments during the year ended December 31, 2019 was not material.

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:

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.	$ 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.

In 2020, we expect to contribute approximately $40 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 16: 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.

Patent Litigation

Alimta Patent Litigation and Administrative Proceedings

A number of manufacturers are seeking approvals in the U.S., a number of countries in Europe, and Japan to market generic forms of Alimta prior to the expiration of our vitamin regimen patents, alleging that those patents are invalid, not infringed, or both. We believe our Alimta vitamin regimen patents are valid and enforceable against these generic manufacturers. However, it is not possible to determine the ultimate outcome of the proceedings, and accordingly, we can provide no assurance that we will prevail. An unfavorable outcome in the U.S. could have a material adverse impact on our future consolidated results of operations, liquidity, and financial position. We expect that a loss of exclusivity for Alimta in any of the below jurisdictions would result in a rapid and severe decline in future revenue for the product in the relevant market.

U.S. Patent Litigation and Administrative Proceedings

We filed a lawsuit in the U.S. District Court for the District of Delaware against Eagle Pharmaceuticals, Inc. (Eagle) in response to its application to market a product using an alternative form of pemetrexed (the active ingredient in Alimta). In December 2019, we and Eagle reached an agreement to settle all pending litigation, allowing Eagle a limited initial entry into the market with its product starting February 2022 (up to an approximate three-week supply) and subsequent unlimited entry starting April 2022. Alimta is protected by a vitamin regimen patent (2021) plus pediatric exclusivity through May 2022.

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 method of use patent under the doctrine of equivalents. The district court also ruled that the use of Hospira's proposed product would literally infringe our method of use patent. In August 2019, the U.S. Court of Appeals for the Federal Circuit affirmed the district court's ruling that the use of Dr. Reddy's and Hospira's proposed products would infringe our patent under the doctrine of equivalents but reversed the finding of literal infringement with respect to Hospira's product. In November 2019, the court denied Dr. Reddy and Hospira's petition for rehearing of the court's doctrine of equivalents ruling. Dr. Reddy and Hospira have petitioned the U.S. Supreme Court to review the case.

We have lawsuits pending alleging infringement against Actavis LLC (Actavis) and Apotex Inc. (Apotex) in response to their applications to market products using alternative forms of pemetrexed. In December 2019, the U.S. District Court for the Southern District of Indiana granted our motion for summary judgment of infringement under the doctrine of equivalents and denied Apotex's motion. Apotex has appealed. The

lawsuit against Actavis has been stayed, pending the conclusion of the Dr. Reddy and Hospira appeals (described above).

European Patent Litigation

Legal proceedings are ongoing in various national courts throughout Europe. We are aware that several companies have received approval to market generic versions of pemetrexed in major European markets (including generics currently on the market at risk in France, Germany, and the Netherlands) and that additional generic competitors may choose to launch at risk. We will continue to seek to remove any generic

pemetrexed products launched at risk in European markets and seek damages with respect to such launches, and defend our patents against validity challenges.

Japanese Administrative Proceedings

Three separate sets of demands for invalidation of our two Japanese vitamin regimen patents, involving several companies, have been filed with the Japanese Patent Office (JPO). The JPO rejected a demand for invalidation by Sawai Pharmaceutical Co., Ltd., which was affirmed on appeal in 2017. In July 2018, the JPO issued written decisions dismissing demands brought by Nipro Corporation (Nipro) for invalidation of our two Japanese vitamin regimen patents. In November 2019, the IP High Court in Tokyo affirmed the dismissal of Nipro's demand for invalidation. The JPO scheduled a hearing in March 2020 concerning the demands brought by Hospira. 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.

Jardiance Patent Litigation

Boehringer Ingelheim, our partner in marketing and development of Jardiance, initiated U.S. patent litigation in the U.S. District Court of Delaware involving Jardiance, Glyxambi, and Synjardy in accordance with the procedures set out in the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act). Several companies submitted Abbreviated New Drug Applications seeking approval to market generic versions of Jardiance prior to the expiration of the relevant patents, alleging certain patents, including in some allegations the compound patent, are invalid or would not be infringed. Trial is scheduled in April 2021.

Taltz Patent Litigation

We have been named as a defendant in litigation filed by Genentech, Inc. in the U.S. District Court for the Southern District of California seeking a ruling that Genentech's patent would be infringed by our continued sales of Taltz. Separately, the U.S. Patent and Trademark Office (USPTO) has granted our request to initiate a post grant review (PGR) to examine the validity of Genentech's patent asserted against us in the litigation. We expect USPTO's decision on the merits in the fourth quarter of 2020. The litigation in the U.S. District Court for the Southern District of California has been stayed pending the outcome of the PGR. We have also been named as defendant in litigation filed by Genentech in Germany asserting infringement of a related Genentech patent and seeking a similar ruling of patent infringement by sales of Taltz in Germany. We expect a trial to assess Genentech's infringement claims could take place in late 2020 or early 2021. We have ongoing litigation in the U.K. in which Genentech has asserted similar claims regarding Genentech's corresponding U.K. patent. We believe all of these lawsuits are without merit and we are vigorously defending against them.

Emgality Patent Litigation

We have been named as a defendant in litigation filed by Teva Pharmaceuticals International GMBH and Teva Pharmaceuticals USA, Inc. (collectively, Teva) in the U.S. District Court for the District of Massachusetts seeking a ruling that various claims in nine different Teva patents would be infringed by our launch and continued sales of Emgality for the prevention of migraine in adults. We believe this lawsuit is without merit and are defending against it vigorously. Separately, the USPTO granted our request to initiate an *inter partes review* (IPR) to reexamine the validity of the nine Teva patents asserted against us in the litigation. In February 2020, the USPTO ruled in our favor and found that all claims asserted against us in six of Teva's nine patents were invalid. We expect the USPTO to issue a decision on the remaining three Teva patents in the second quarter of 2020. The litigation in the U.S. District Court for the District of Massachusetts has been stayed pending the outcome of the USPTO's decision on all nine of Teva's patents.

Product Liability Litigation

Cymbalta Product Liability Litigation

We were named as a defendant in a purported class-action lawsuit in the U.S. District Court for the Central District of California (now called *Strafford et al. v. Eli Lilly and Company*) involving Cymbalta. The plaintiffs, purporting to represent a class of persons who purchased and/or paid for Cymbalta, asserted claims under the consumer protection statutes of California, Massachusetts, Missouri, and New York, and sought declaratory, injunctive, and monetary relief for various alleged economic injuries arising from their purchases.

After the district court denied the plaintiffs' motions for class certification, plaintiffs voluntarily dismissed their claims. The plaintiffs subsequently appealed to the U.S. Court of Appeals for the Ninth Circuit. In November 2017, the U.S. Court of Appeals for the Ninth Circuit dismissed the appeal for lack of jurisdiction. In July 2018, the U.S. District Court for the Central District of California denied the plaintiffs' motion to reopen the case. The plaintiffs appealed this denial to the U.S. Court of Appeals for the Ninth Circuit and in January 2020, the Ninth Circuit affirmed the district court's decision. The plaintiffs have filed a petition for rehearing before the Ninth Circuit.

Other Matters

Brazil Litigation – Cosmopolis Facility

Labor Attorney Litigation

Our subsidiary in Brazil, Eli Lilly do Brasil Limitada (Lilly Brasil), is named in a lawsuit brought by the Labor Attorney for the 15th Region in the Labor Court of Paulinia, State of Sao Paulo, Brazil, alleging possible harm to employees and former employees caused by exposure to heavy metals at a former Lilly Brasil manufacturing facility in Cosmopolis, Brazil, operated by the company between 1977 and 2003. In May 2014, the labor court judge ruled against Lilly Brasil, ordering it to undertake several actions of unspecified financial impact, including paying lifetime health coverage for the employees and contractors who worked at the Cosmopolis facility more than six months during the affected years and their children born during and after this period. We appealed this decision. In July 2018, the appeals court affirmed the labor court's ruling with the total financial impact of the ruling estimated to be approximately 500 million Brazilian real (approximately $125 million as of December 31, 2019). The appeals court restricted the broad health coverage awarded by the labor court to health problems that claimants could show arose from exposure to the alleged contamination. In August 2019, Lilly Brasil filed an appeal to the superior labor court. In September 2019, the appeals court stayed a number of elements of its prior decision, including the obligation to provide health coverage for contractors, their children, and children of employees who worked at the Cosmopolis facility, pending the determination of Lilly Brasil's appeal to the superior labor court.

In June 2019, the Labor Attorney filed an application in the labor court for enforcement of the healthcare coverage granted by the appeals court in its July 2018 ruling and requested restrictions on Lilly Brasil's assets in Brazil. In July 2019, the labor court issued a ruling requiring either a freeze of Lilly Brasil's immovable property or, alternatively, a security deposit of 500 million Brazilian real (approximately $125 million as of December 31, 2019). Lilly Brasil filed a writ of mandamus challenging this ruling, but the court has stayed its decision on this writ and instead directed the parties to attend conciliation hearings, a process which is ongoing. The labor court also stayed the Labor Attorney's application to enforce the previous healthcare coverage ruling until after the appeals court ruled on the various motions pending before it. If the conciliation hearings are unsuccessful, once concluded, we intend to file a motion to strike the Labor Attorney's application to enforce the previous healthcare coverage given the appeals court's stay in September 2019 of a number of elements of its prior decision described above.

Individual Former Employee Litigation

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

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

Pricing Litigation, Investigations, and Inquiries

Litigation

We, along with Sanofi and Novo Nordisk, are named as defendants in a consolidated purported class action lawsuit, *In re. Insulin Pricing Litigation*, in the U.S. District Court of New Jersey relating to insulin pricing. Plaintiffs seek damages under various state consumer protection laws and the Federal Racketeer Influenced and Corrupt Organization Act (federal RICO Act). Separately, we, along with Sanofi and Novo Nordisk, are named as defendants in *MSP Recovery Claims, Series, LLC et al. v. Sanofi Aventis U.S. LLC et al.*, in the same court, seeking damages under various state consumer protection laws, common law fraud, unjust enrichment, and the federal RICO Act. Also, in the same court, we, along with Sanofi and Novo Nordisk, had been named as defendants in a purported class action lawsuit, *Prof'l Drug Co., Inc. & FWK Holdings, LLC v. Novo Nordisk Inc. et al.,* seeking damages under the federal and New Jersey RICO Acts. Plaintiffs in that matter voluntarily dismissed their lawsuit in January 2020.

The Minnesota Attorney General's Office filed a complaint against us, Sanofi, and Novo Nordisk, State of Minnesota v. Sanofi-Aventis U.S. LLC et al., in the U.S. District Court of New Jersey, alleging unjust enrichment, and violations of various Minnesota state consumer protection laws and the federal RICO Act. Additionally, the Kentucky Attorney General's Office filed a complaint against us, Sanofi, and Novo Nordisk, Commonwealth of Kentucky v. Novo Nordisk, Inc. et al., in Kentucky state court, alleging violations of the Kentucky consumer protection law, false advertising, and unjust enrichment. Harris County in Texas filed a complaint against us, Sanofi, Novo Nordisk, Express Scripts, CVS, Optum, and Aetna, *County of Harris Texas v. Eli Lilly & Co., et al.*, in federal court in the Southern District of Texas, alleging violations of the federal RICO Act and RICO conspiracy, federal and state anti-trust law, and the state deceptive trade practices-consumer protection act. Harris County also alleges common law claims such as, fraud, unjust enrichment, and civil conspiracy. This lawsuit relates to our insulins as well as Trulicity.

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

Investigations, Subpoenas, and Inquiries

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

Product Liability Insurance

Because of the nature of pharmaceutical products, it is possible that we could become subject to large numbers of additional product liability and related claims in the future. Due to a very restrictive market for product liability insurance, we are self-insured for product liability losses for all our currently and previously marketed products.

Note 17: Other Comprehensive Income (Loss)

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

(Amounts presented net of taxes)	Continuing Operations					
	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, 2017 [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 1)	(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
Balance at December 31, 2018[4]	(1,569.7)	(22.1)	(3,852.7)	(238.9)	(56.8)	(5,740.2)
Other comprehensive income (loss) before reclassifications	**(46.2)**	**28.9**	**(967.6)**	**14.5**	**(27.2)**	**(997.6)**
Net amount reclassified from accumulated other	**(62.1)**	**(1.9)**	**181.7**	**12.5**	**84.0**	**214.2**

comprehensive loss						
Net other comprehensive income (loss)	**(108.3)**	**27.0**	**(785.9)**	**27.0**	**56.8**	**(783.4)**
Ending balance at December 31, 2019	**$ (1,678.0)**	**$ 4.9**	**$ (4,638.6)**	**$ (211.9)**	**$ —**	**$ (6,523.6)**

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

(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 1 for further details regarding the reclassification due to the adoption of ASU 2016-01.

(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)	2019	2018	2017
Foreign currency translation gains/losses	**$ (18.4)**	$ 51.6	$ 170.8
Unrealized net gains/losses on securities	**(7.4)**	2.1	55.0
Defined benefit pension and retiree health benefit plans	**184.1**	(85.3)	186.6
Effective portion of cash flow hedges	**(7.3)**	1.3	(9.7)
Benefit/(provision) for income taxes allocated to other comprehensive income (loss) items	**$ 151.0**	$ (30.3)	$ 402.7

Except for the tax effects of foreign currency translation gains and losses related to our foreign currency-denominated notes, cross-currency interest rate swaps, and other foreign currency exchange contracts designated as net investment hedges (see Note 7), income taxes were not provided for foreign currency translation. Generally, the assets and liabilities of foreign operations are translated into U.S. dollars using the current exchange rate. For those operations, changes in exchange rates generally do not affect cash flows; therefore, resulting translation adjustments are made in shareholders' equity rather than in the consolidated statements of operations.

Reclassifications out of accumulated other comprehensive loss were as follows:

Details about Accumulated Other Comprehensive Loss Components	Year Ended December 31, 2019	2018	2017	Affected Line Item in the Consolidated Statements of Operations
Amortization of retirement benefit items:				
Prior service benefits, net	**$ (56.8)**	$ (74.9)	$ (84.4)	Other—net, (income) expense
Actuarial losses	**286.8**	338.6	305.2	Other—net, (income) expense
Total before tax	**230.0**	263.7	220.8	
Tax benefit	**(48.3)**	(55.8)	(68.9)	Income taxes
Net of tax	**181.7**	207.9	151.9	
Unrealized gains/losses on available-for-sale securities:				
Realized gains, net	**(2.4)**	(39.5)	(170.2)	Other—net, (income) expense
Tax expense	**0.5**	8.3	59.6	Income taxes
Net of tax	**(1.9)**	(31.2)	(110.6)	
Other, net of tax	**(49.6)**	11.7	17.7	Other—net, (income) expense
Reclassifications from continuing operations (net of tax)	**130.2**	188.4	59.0	
Reclassifications from discontinued operations (net of tax)	**84.0**	2.1	1.5	Net income (loss) from discontinued operations
Total reclassifications for the period, net of tax	**$ 214.2**	$ 190.5	$ 60.5	

Note 18: Other–Net, (Income) Expense

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

	2019	2018	2017
Interest expense	**$ 400.6**	$ 242.5	$ 225.0
Interest income	**(80.4)**	(159.3)	(166.4)
Debt extinguishment loss (Note 11)	**252.5**	—	—
Gain on sale of antibiotic business in China (Note 3)	**(309.8)**	—	—
Retirement benefit	**(209.9)**	(240.5)	(249.0)
Other (income) expense	**(344.6)**	11.7	(111.1)
Other–net, (income) expense	**$ (291.6)**	$ (145.6)	$ (301.5)

For the years ended December 31, 2019 and 2017, other income was primarily related to net gains on investments (Note 7).

Note 19: Discontinued Operations

On September 24, 2018, Elanco completed its initial public offering (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.

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 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. 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.

Through March 11, 2019, we continued to consolidate Elanco, as we retained control over Elanco. We completed the disposition of our remaining 80.2 percent ownership of Elanco common stock through a tax-free exchange offer that closed on on March 11, 2019 (the disposition date). The earnings attributable to the divested, noncontrolling interest for the period from the IPO until disposition were not material.

As a result of the disposition, 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 financial statements for all periods presented.

The following table sets summarizes revenue and net income (loss) from discontinued operations:

	2019	2018	2017
Revenue from discontinued operations	**$ 580.0**	$ 3,062.4	$ 2,897.5
Net income (loss) from discontinued operations	**3,680.5**	81.4	(117.7)

The following table presents the major classes of assets and liabilities from discontinued operations at December 31, 2018:

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

The gain related to the disposition of Elanco in the consolidated statement of cash flows includes the operating results of Elanco through the disposition date, which were not material. Net cash flows of our discontinued operations for operating and investing activities for the year ended December 31, 2019 were not material. Net cash provided by operating activities related to our discontinued operations was approximately $500 million and $300 million for the years ended December 31, 2018 and 2017, respectively. Net cash used by investing activities related to our discontinued operations was approximately $130 million and $960 million for the years ended December 31, 2018 and 2017, 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 the disposition date. This agreement is not material and does not confer upon us the ability to influence the operating and/or financial policies of Elanco subsequent to the disposition date.

Note 20: Selected Quarterly Data (unaudited)

2019	Fourth	Third	Second	First
Revenue	$ 6,114.0	$ 5,476.6	$ 5,636.7	$ 5,092.2
Cost of sales	1,282.6	1,175.0	1,124.9	1,138.7
Operating expenses[1]	3,279.5	2,793.2	2,988.5	2,747.6
Acquired IPR&D	—	77.7	25.0	136.9
Asset impairment, restructuring, and other special charges[2]	151.7	—	—	423.9
Income before income taxes	1,663.1	1,405.8	1,465.9	731.1
Income taxes	167.4	151.9	138.7	170.0
Net income from continuing operations	1,495.7	1,253.9	1,327.2	561.1
Net Income from discontinued operations	—	—	—	3,680.5
Net income	1,495.7	1,253.9	1,327.2	4,241.6
EPS from continuing operations - basic	1.64	1.37	1.44	0.57
EPS from discontinued operations - basic	—	—	—	3.76
EPS—basic	1.64	1.37	1.44	4.33
EPS from continuing operations - diluted	1.64	1.37	1.44	0.57
EPS from discontinued operations - diluted	—	—	—	3.74
EPS—diluted	1.64	1.37	1.44	4.31
Dividends paid per share	0.6450	0.6450	0.6450	0.6450

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 IPR&D[3]	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[4]	(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) per share from continuing operations - basic	1.11	1.07	(0.22)	1.11
Earnings (loss) per share 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) per share from continuing operations - diluted	1.10	1.07	(0.22)	1.11
Earnings (loss) per share 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

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

[2] Asset impairment, restructuring, and other special charges in the first quarter of 2019 were primarily associated with the accelerated vesting of Loxo employee equity awards as a result of the closing of the acquisition of Loxo. See Note 5 for further discussion.

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

[4] Income taxes in the fourth quarter of 2018 were a tax benefit primarily due to adjustments associated with U.S. tax reform. See Note 14 for further discussion.

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

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 our annual report on Form 10-K. Ernst & Young reports directly to the audit committee of the board of directors.

Our audit committee includes five 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. 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 are subject to 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, 2019. 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, 2019. 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, 2020

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, 2019 and 2018, 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, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, 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, 2019, 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, 2020 expressed an unqualified opinion thereon.

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

As discussed in Note 1 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.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Medicaid, Managed Care, and Medicare sales rebate accruals

Description of the Matter

As described in Note 1 to the consolidated financial statements under the caption "Revenue Recognition," the Company establishes provisions for sales rebate and discounts in the same period as the related sales occur. At December 31, 2019 the Company had $4,933.6 million in sales rebate and discount accruals. A large portion of these accruals are rebates associated with sales in the United States for which payment for purchase of the product is covered by Medicaid, Managed Care, and Medicare.

Auditing the Medicaid, Managed Care, and Medicare sales rebate and discount liabilities is challenging because of the subjectivity of certain assumptions required to estimate the rebate liabilities. In calculating the appropriate accrual amount, the Company considers historical Medicaid, Managed Care, and Medicare rebate payments by product as a percentage of their historical sales as well as any significant changes in sales trends, the lag in payment timing, an evaluation of the current Medicaid and Medicare laws and interpretations, the percentage of products that are sold via Medicaid, Managed Care, and Medicare, and product pricing. For Medicaid, there is significant complexity associated with calculating the legislated Medicaid rebates. Management utilizes employees with legislative experience and knowledge in developing assumptions used to calculate Medicaid rebates. Similarly, for Managed Care and Medicare, given variability in prescription drug costs, continued historical year over year increases in enrollees and variability in prescription data, historical rebate information may not be predictive for management to estimate the rebate accrual and thus, management supplements its historical data analysis with qualitative adjustments based upon current utilization.

How We Addressed the Matter in Our Audit

We tested the Company's controls addressing the identified risks of material misstatement related to the valuation of the sales rebate and discount liabilities. This included testing controls over management's review of the significant assumptions used to calculate the Medicaid, Managed Care, and Medicare rebate liabilities, including the significant assumptions discussed above. This testing also included management's control to compare actual activity to forecasted activity and controls to ensure the data used to evaluate the significant assumptions was complete and accurate.

Our audit procedures included, among others, evaluating for reasonableness the significant assumptions in light of economic trends, product profiles, and other regulatory factors. Our testing involved assessing the historical accuracy of management's estimates by comparing actual activity to previous estimates and performing analytical procedures, based on internal and external data sources, to evaluate the completeness of the reserves. Additionally, our procedures included reviewing a sample of contracts, testing a sample of rebate payments and testing the underlying data used in management's evaluation. For Medicaid, we involved our professional with an understanding of the statutory reimbursement requirements to assess the consistency of the Company's calculation methodologies with the applicable government regulations and policy. For Medicare we evaluated the reasonableness of assumptions made by management in estimating the Medicare coverage gap liability.

Retirement Benefits - Valuation of Alternative Investments

Description of the Matter

As described in Note 15 to the consolidated financial statements under the caption "Benefit Plan Investments," the Company's benefit plan investment policies are set with specific consideration of return and risk requirements in relationship to the respective liabilities. At December 31, 2019 the Company had $15,626.2 million in plan assets related to the defined benefit pension plans and retiree health benefit plans. Approximately 40% of the total pension and retiree assets are in hedge funds and private equity-like investment funds ("alternative investments"). These alternative investments are valued using significant unobservable inputs or are

valued at net asset value (NAV) reported by the counterparty, adjusted as necessary.

Auditing the fair value of these alternative investments is challenging because of the higher estimation uncertainty of the inputs to the fair value calculations, including the underlying net asset values (“NAVs”), discounted cash flow valuations, comparable market valuations, and adjustments for currency, credit, liquidity and other risks. Additionally, certain information regarding the fair value of these alternative investments is based on unaudited information available to management at the time of valuation.

How We Addressed the Matter in Our Audit

We tested the Company's controls addressing the risks of material misstatement relating to valuation of alternative investments. This included testing management's review controls over alternative investment valuation, which included a comparison of returns to benchmarks and in-person or telephonic meetings with investment firms to discuss valuation policies and procedures.

Our audit procedures included, among others, comparing fund returns to selected relevant benchmarks and understanding variations, obtaining the latest audited financial statements and comparing to the Company's estimated fair values and reconciling any differences. We also inquired of management about changes to the investment portfolio and/or related investment strategies and considerations. We assessed the historical accuracy of management's estimates by comparing actual activity to previous estimates. We evaluated for contrary evidence by confirming the fair value of the investments and ownership interest directly with the trustees and a sample of managers at year end.

Valuation of intangible assets related to the Loxo Oncology (Loxo) Acquisition

Description of the Matter

As described in Note 3 to the consolidated financial statements, in February 2019, the Company completed its acquisition of Loxo Oncology, Inc. (Loxo) for a purchase price of $6.92 billion, net of cash acquired. As a result of the acquisition, the Company acquired a pipeline of investigational medicines, including LOXO-292, an oral RET inhibitor that has been granted Breakthrough Therapy designation by the U.S. Food and Drug Administration. LOXO-292 was accounted for as an indefinite-lived in-process research and development (IPR&D) asset and valued at $4.60 billion.

Auditing the valuation of the LOXO-292 IPR&D asset was complex because of the significant estimation uncertainty in determining the fair value of the asset. The fair value determination is based on a discounted cash flow model using certain assumptions for which there is high subjectivity, such as revenue growth, probability of technical success and discount rate. These significant assumptions are forward-looking and could be affected by future economic and market conditions. Further, the estimated fair value of the IPR&D asset was sensitive to changes in these assumptions.

How We Addressed the Matter in Our Audit

We tested the Company's controls addressing the identified risks of material misstatement related to the valuation of the IPR&D asset. For example, we tested controls over management's review of the significant assumptions used to calculate the valuation of the intangible assets acquired including forecasts of future cash flows and review of the valuation model.

Our audit procedures included, among others, obtaining an understanding of management's approach to developing the probability of technical success and evaluating the reasonableness by comparing to analyst expectations, historical results of similar products in development and industry trends, to the extent applicable. We also evaluated the reasonableness of the projected revenue growth used within the valuation against analyst expectations, industry trends, market trends, other market information and identified contrary evidence. We involved our valuation specialist to evaluate the discounted cash flow model used by the Company and to test the discount rate utilized in the Company's valuation. Lastly, we evaluated the appropriateness of the Company's related disclosures.

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

Indianapolis, Indiana

February 19, 2020

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, 2019, 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, 2019, 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, 2019 and 2018, 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, 2019, and the related notes and our report dated February 19, 2020 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.

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Indianapolis, Indiana

February 19, 2020

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

Under applicable Securities and Exchange Commission (SEC) regulations, management of a reporting company, with the participation of the principal executive officer and principal financial officer, must periodically evaluate the company's "disclosure controls and procedures," which are defined generally as controls and other procedures designed to ensure that information required to be disclosed by the reporting company in its periodic reports filed with the SEC (such as this Form 10-K) is recorded, processed, summarized, and reported on a timely basis.

Our management, with the participation of David A. Ricks, president and chief executive officer, and Joshua L. Smiley, senior vice president and chief financial officer, evaluated our disclosure controls and procedures as of December 31, 2019, and concluded that they were effective.

Internal Control over Financial Reporting

Mr. Ricks and Mr. Smiley provided a report on behalf of management on our internal control over financial reporting, in which management concluded that the company's internal control over financial reporting is effective at December 31, 2019. In addition, Ernst & Young LLP, the company's independent registered public accounting firm, provided an attestation report on the company's internal control over financial reporting as of December 31, 2019. You can find the full text of management's report and Ernst & Young's attestation report in Item 8.

Changes in Internal Controls

During the fourth quarter of 2019, there were no changes in our internal control over financial reporting that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

Part III

Item 10. Directors, Executive Officers, and Corporate Governance

Directors and Executive Officers

Information relating to our Board of Directors is found in our Definitive Proxy Statement to be dated on or about March 20, 2020 (the Proxy Statement) under “Board of Directors” and is incorporated in this report by reference.

Information relating to our executive officers is found at Item 1, "Business - Executive Officers of the Company.”

Code of Ethics

Information relating to our code of ethics is found in our Proxy Statement under “Code of Ethics” and is incorporated in this report by reference.

Corporate Governance

Information about the procedures by which shareholders can recommend nominees to our board of directors is found in our Proxy Statement under “Director Qualifications and Nomination Process” and is incorporated in this report by reference.

The board has appointed an audit committee consisting entirely of independent directors in accordance with applicable SEC and New York Stock Exchange rules for audit committees. Information about our audit committee is found in our Proxy Statement under “Audit Committee” and is incorporated in this report by reference.

Section 16(a) Reporting Compliance

Information about our compliance with Section 16(a) is found in our Proxy Statement under “Other Matters - Delinquent Section 16(a) Reports” and is incorporated in this report by reference.

Item 11. Executive Compensation

Information on director compensation, executive compensation, and compensation committee matters can be found in the Proxy Statement under “Director Compensation,” "Committees of the Board of Directors - Compensation Committee," "Compensation Discussion and Analysis," and “Executive Compensation.” That information is incorporated in this report by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

Security Ownership of Certain Beneficial Owners and Management

Information relating to ownership of the company's common stock by management and by persons known by the company to be the beneficial owners of more than five percent of the outstanding shares of common stock is found in the Proxy Statement under "Ownership of Company Stock." That information is incorporated in this report by reference.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table presents information as of December 31, 2019, regarding our compensation plans under
which shares of Lilly common stock have been authorized for issuance.

Plan category	(a) Number of securities to be issued upon exercise of outstanding options, warrants, and rights [1]	(b) Weighted-average exercise price of outstanding options, warrants, and rights	(c) Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders	—	$ —	54,639,336
Equity compensation plan not approved by security holders	—	—	—
Total	—	—	54,639,336

[1] 6,711,231 shares are underlying outstanding equity awards other than options.

Item 13. Certain Relationships and Related Transactions, and Director Independence

Related Person Transactions

Information relating to the board's policies and procedures for approval of related person transactions can be found in the Proxy Statement under "Highlights of the Company's Corporate Governance - Conflicts of Interest and Transactions with Related Persons." That information is incorporated in this report by reference.

Director Independence

Information relating to director independence can be found in the Proxy Statement under "Director Independence" and is incorporated in this report by reference.

Item 14. Principal Accountant Fees and Services

Information related to the fees and services of our principal independent accountants, Ernst & Young LLP, can be found in the Proxy Statement under "Item 3. Proposal to Ratify the Appointment of Principal Independent Auditor - Audit Committee Report - Services Performed by the Independent Auditor" and "Independent Auditor Fees." That information is incorporated in this report by reference.

Item 15. Exhibits and Financial Statement Schedules

(a)1. Financial Statements

The following consolidated financial statements of the company and its subsidiaries are found at Item 8:

- Consolidated Statements of Operations—Years Ended December 31, 2019, 2018, and 2017
- Consolidated Statements of Comprehensive Income (Loss)—Years Ended December 31, 2019, 2018, and 2017
- Consolidated Balance Sheets—December 31, 2019 and 2018
- Consolidated Statements of Shareholders' Equity—Years Ended December 31, 2019, 2018, and 2017
- Consolidated Statements of Cash Flows—Years Ended December 31, 2019, 2018, and 2017
- Notes to Consolidated Financial Statements

(a)2. Financial Statement Schedules

The consolidated financial statement schedules of the company and its subsidiaries have been omitted because they are not required, are inapplicable, or are adequately explained in the financial statements.

Financial statements of interests of 50 percent or less, which are accounted for by the equity method, have been omitted because they do not, considered in the aggregate as a single subsidiary, constitute a significant subsidiary.

(a)3. Exhibits

2.1	Agreement and Plan of Merger, dated January 5, 2019, among Eli Lilly and Company, Bowfin Acquisition Corporation and Loxo Oncology, Inc.
3.1	Amended Articles of Incorporation
3.2	Bylaws, as amended
4.1	Indenture with respect to Debt Securities dated as of February 1, 1991, between Eli Lilly and Company and Deutsche Bank Trust Company Americas, as successor trustee to Citibank, N.A., Trustee
4.2	Agreement dated September 13, 2007 appointing Deutsche Bank Trust Company Americas as Successor Trustee under the Indenture listed above
4.3	Description of Common Stock
4.4	Description of the Company's 1.000% EUR Notes due 2022, 1.625% EUR Notes due 2026, and 2.125% EUR Notes due 2030
4.5	Description of the Company's 6.77% Notes due 2036
4.6	Description of the Company's 7 1/8% Notes due 2025
4.7	Description of the Company's 0.625% EUR Notes due 2031 and 1.700% EUR Notes due 2049
10.1	Amended and Restated 2002 Lilly Stock Plan[(1)]
10.2	Form of Performance Award under the 2002 Lilly Stock Plan[(1)]
10.3	Form of Shareholder Value Award under the 2002 Lilly Stock Plan[(1)]
10.4	Form of Relative Value Award under the 2002 Lilly Stock Plan[(1)]
10.5	Restricted Stock Unit Award to Michael Harrington under the 2002 Lilly Stock Plan[(1)]
10.6	The Lilly Deferred Compensation Plan, as amended[(1)]
10.7	The Lilly Directors' Deferral Plan, as amended[(1)]
10.8	The Eli Lilly and Company Bonus Plan, as amended[(1)]
10.9	The Eli Lilly and Company Executive Officer Incentive Plan[(1)]
10.10	2007 Change in Control Severance Pay Plan for Select Employees, as amended[(1)]
21	List of Subsidiaries
23	Consent of Independent Registered Public Accounting Firm
31.1	Rule 13a-14(a) Certification of David A. Ricks, Chairman, President, and Chief Executive Officer
31.2	Rule 13a-14(a) Certification of Joshua L. Smiley, Senior Vice President and Chief Financial Officer
32	Section 1350 Certification
101	Interactive Data File
104	Cover Page Interactive Data File (formatted Inline XBRL and contained in Exhibit 101)

[(1)] Indicates management contract or compensatory plan.

Item 16. Form 10-K Summary

Not applicable.

Index to Exhibits

The following documents are filed as part of this report:

Exhibit		Location
2.1	Agreement and Plan of Merger, dated January 5, 2019, among Eli Lilly and Company, Bowfin Acquisition Corporation and Loxo Oncology, Inc.	Incorporated by reference to Exhibit 2.1 to the Current Report on Form 8-K filed by Loxo Oncology on January 7, 2019
3.1	Amended Articles of Incorporation	Incorporated by reference to Exhibit 3.1 to the Company's Report on Form 10-K for the year ended December 31, 2013
3.2	Bylaws, as amended	Bylaws, as amended, are incorporated by reference to Exhibit 99.1 to the Company's Report on Form 8-K dated on December, 20, 2019
4.1	Indenture with respect to Debt Securities dated as of February 1, 1991, between Eli Lilly and Company and Deutsche Bank Trust Company Americas, as successor trustee to Citibank, N.A., Trustee	Incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-3, Registration No. 333-186979
4.2	Agreement dated September 13, 2007 appointing Deutsche Bank Trust Company Americas as Successor Trustee under the Indenture listed above	Incorporated by reference to Exhibit 4.2 to the Company's Report on Form 10-K for the year ended December 31, 2008
4.3	Description of the Company's Common Stock	Attached
4.4	Description of the Company's 1.000% EUR Notes due 2022, 1.625% EUR Notes due 2026, and 2.125% EUR Notes due 2030	Attached
4.5	Description of the Company's 6.77% Notes due 2036	Attached
4.6	Description of the Company's 7 1/8% Notes due 2025	Attached
4.7	Description of the Company's 0.625% EUR Notes due 2031 and 1.700% EUR Notes due 2049	Attached
10.1	Amended and Restated 2002 Lilly Stock Plan	Incorporated by reference to Exhibit 10.1 to the Company's Report on Form 10-Q for the quarter ended June 30, 2018
10.2	Form of Performance Award under the 2002 Lilly Stock Plan	Attached
10.3	Form of Shareholder Value Award under the 2002 Lilly Stock Plan	Attached
10.4	Form of Relative Value Award under the 2002 Lilly Stock Plan	Attached
10.5	Restricted Stock Unit Award to Michael Harrington under the 2002 Lilly Stock Plan	Attached
10.6	The Lilly Deferred Compensation Plan, as amended	Incorporated by reference to Exhibit 10.5 to the Company's Report on Form 10-K for the year ended December 31, 2013

10.7	The Lilly Directors' Deferral Plan, as amended	Incorporated by reference to Exhibit 10 to the Company's Report on Form 10-Q for the quarter ended June 30, 2017
10.8	The Eli Lilly and Company Bonus Plan, as amended	Incorporated by reference to Exhibit 10.7 to the Company's Report on Form 10-K for the year ended December 31, 2013

10.9	The Eli Lilly and Company Executive Officer Incentive Plan	Incorporated by reference to Appendix B to the Company's proxy statement on Schedule 14A filed March 7, 2011
10.10	2007 Change in Control Severance Pay Plan for Select Employees, as amended	Incorporated by reference to Exhibit 10 to the Company's Report on Form 10-Q for the quarter ended September 30, 2010
21	List of Subsidiaries	Attached
23	Consent of Registered Independent Public Accounting Firm	Attached
31.1	Rule 13a-14(a) Certification of David A. Ricks, Chairman, President, and Chief Executive Officer	Attached
31.2	Rule 13a-14(a) Certification of Joshua L. Smiley, Senior Vice President and Chief Financial Officer	Attached
32	Section 1350 Certification	Attached
101	Interactive Data File	Attached
104	Cover Page Interactive Data File (formatted Inline XBRL and contained in Exhibit 101)	Attached

Signatures

Pursuant to the requirements of Section 13 or 15(d) 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

By /s/ David A. Ricks

David A. Ricks

Chairman, President, and Chief Executive Officer

February 19, 2020

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below on February 19, 2020 by the following persons on behalf of the Registrant and in the capacities indicated.

Signature	Title
/s/ David A. Ricks DAVID A. RICKS	Chairman, President, and Chief Executive Officer (principal executive officer)
/s/ Joshua L. Smiley JOSHUA L. SMILEY	Senior Vice President and Chief Financial Officer (principal financial officer)
/s/ Donald A. Zakrowski DONALD A. ZAKROWSKI	Vice President, Finance and Chief Accounting Officer (principal accounting officer)
/s/ Ralph Alvarez RALPH ALVAREZ	Director
/s/ Katherine Baicker, Ph.D. KATHERINE BAICKER, Ph.D.	Director
/s/ Carolyn R. Bertozzi, Ph.D. CAROLYN R. BERTOZZI, Ph.D.	Director
/s/ Michael L. Eskew MICHAEL L. ESKEW	Director
/s/ J. Erik Fyrwald J. ERIK FYRWALD	Director
/s/ Jamere Jackson JAMERE JACKSON	Director
/s/ William G. Kaelin, Jr., M.D. WILLIAM G. KAELIN, JR., M.D.	Director
/s/ Juan R. Luciano JUAN R. LUCIANO	Director
/s/ Marschall S. Runge, M.D., Ph.D. MARSCHALL S. RUNGE, M.D., Ph.D.	Director
/s/ Kathi P. Seifert KATHI P. SEIFERT	Director
/s/ Jackson P. Tai JACKSON P. TAI	Director
/s/ Karen Walker KAREN WALKER	Director

Trademarks Used In This Report

Trademarks or service marks owned by Eli Lilly and Company or its affiliates, when first used in this report, appear with an initial capital and are followed by the symbol ® or ™, as applicable. In subsequent uses of the marks in the report, the symbols may be omitted.

Actos® is a trademark of Takeda Pharmaceutical Company Limited.

Byetta® is a trademark of Amylin Pharmaceuticals, Inc.

Glyxambi®, Jardiance®, Jentadueto®, Synjardy®, Trajenta®, and Trijardy® are trademarks of Boehringer Ingelheim GmbH.

Posilac® is a trademark of Union Agener and Elanco US Inc.

Qbrexza® is a trademark of Dermira, Inc.

Viagra® is a trademark of Pfizer Inc.

United States
Securities and Exchange Commission
Washington, D.C. 20549

Form 10-K

Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
for the fiscal year ended December 31, 2018

Commission file number 001-06351

Eli Lilly and Company

An Indiana corporation — I.R.S. employer identification no. 35-0470950

Lilly Corporate Center, Indianapolis, Indiana 46285

(317) 276-2000

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

Title of Each Class	Name of Each Exchange On Which Registered
Common Stock (no par value)	New York Stock Exchange
1.00% Notes Due June 2, 2022	New York Stock Exchange
7.13% Notes Due June 1, 2025	New York Stock Exchange
1.63% Notes Due June 2, 2026	New York Stock Exchange
2.13% Notes Due June 3, 2030	New York Stock Exchange
6.77% Notes Due January 1, 2036	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Exchange Act: None

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 under the Securities Act. Yes ☑ No ☐

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act. Yes ☐ No ☑

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

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the Registrant was required to submit and post such files).
Yes ☑ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant's knowledge, in the definitive proxy statement incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☑

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 under the Exchange Act. (Check one):

Large accelerated filer ☒	Accelerated filer ☐
Non-accelerated filer ☐	Smaller reporting company ☐
	Emerging growth company ☐

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

Indicate by check mark whether the Registrant is a shell company as defined in Rule 12b-2 under the Exchange Act: Yes ☐ No ☑

Aggregate market value of the common equity held by non-affiliates computed by reference to the price at which the common equity was last sold as of the last business day of the Registrant's most recently completed second fiscal quarter (Common Stock): approximately $78,196,000,000

Number of shares of common stock outstanding as of February 13, 2019: 1,035,418,562 Portions of the Registrant's Proxy Statement to be filed on or about March 22, 2019 have been incorporated by reference into Part III of this report.

Eli Lilly and Company

Form 10-K
For the Year Ended December 31, 2018

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Forward-Looking Statements

This Annual Report on Form 10-K includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934 (Exchange Act), and the Private Securities Litigation Reform Act of 1995. Forward-looking statements include all statements that do not relate solely to historical or current facts, and can generally be identified by the use of words such as “may,” “believe,” “will,” “expect,” “project,” “estimate,” “intend,” “anticipate,” “plan,” “continue,” or similar expressions.

In particular, information appearing under “Business,” “Risk Factors,” and “Management's Discussion and Analysis of Financial Condition and Results of Operations” includes forward-looking statements. Forward-looking statements inherently involve many risks and uncertainties that could cause actual results to differ materially from those projected in these statements. Where, in any forward-looking statement, we express an expectation or belief as to future results or events, it is based on management's current plans and expectations, expressed in good faith and believed to have a reasonable basis. However, we can give no assurance that any such expectation or belief will result or will be achieved or accomplished. The following include some but not all of the factors that could cause actual results or events to differ materially from those anticipated:

- uncertainties in the pharmaceutical research and development process, including with respect to the timing of anticipated regulatory approvals and launches of new products;
- market uptake of recently launched products;
- competitive developments affecting current products and our pipeline;
- the expiration of intellectual property protection for certain of our products;
- our ability to protect and enforce patents and other intellectual property;
- the impact of actions of governmental and private payers affecting pricing of, reimbursement for, and access to pharmaceuticals;
- regulatory compliance problems or government investigations;
- regulatory actions regarding currently marketed products;
- unexpected safety or efficacy concerns associated with our products;
- issues with product supply stemming from manufacturing difficulties or disruptions;
- regulatory changes or other developments;
- changes in patent law or regulations related to data-package exclusivity;
- litigation involving past, current, or future products as we are largely self-insured;
- unauthorized disclosure, misappropriation, or compromise of trade secrets or other confidential data stored in our information systems, networks, and facilities, or those of third parties with whom we share our data;
- changes in tax law, including the impact of tax reform legislation enacted in December 2017 and related guidance;
- changes in foreign currency exchange rates, interest rates, and inflation;
- asset impairments and restructuring charges;
- changes in accounting standards promulgated by the Financial Accounting Standards Board and the Securities and Exchange Commission;

- acquisitions and business development transactions and related integration costs;
- information technology system inadequacies or operating failures;
- reliance on third-party relationships and outsourcing arrangements;
- the impact of global macroeconomic conditions; and
- uncertainties and risks related to timing and potential value to both Elanco and Lilly of the planned separation of the Elanco animal health business, including business, industry, and market risks, as well as risks involving the anticipated tax-free nature of the separation.

Investors should not place undue reliance on forward-looking statements. You should carefully read the factors described in the “Risk Factors” section of this Annual Report on Form 10-K for a description of certain risks that could, among other things, cause our actual results to differ from these forward-looking statements.

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

Part I

Item 1. Business

Eli Lilly and Company (the “company” or “registrant” or "Lilly") was incorporated in 1901 in Indiana to succeed to the drug manufacturing business founded in Indianapolis, Indiana, in 1876 by Colonel Eli Lilly. We discover, develop, manufacture, and market products in two business segments—human pharmaceutical products and animal health products.

The mission of our human pharmaceutical business is to make medicines that help people live longer, healthier, more active lives. Our vision is to make a significant contribution to humanity by improving global health in the 21st century. Most of the products we sell today were discovered or developed by our own scientists, and our success depends to a great extent on our ability to continue to discover or acquire, develop, and bring to market innovative new medicines.

Our animal health business, Elanco Animal Health Incorporated (Elanco), develops, manufactures, and markets products for both food animals and companion animals. Elanco food animal products help the food industry produce an abundant supply of safe, nutritious, and affordable food. Elanco companion animal products help pets live longer, healthier, happier lives.

In September 2018 Elanco completed an initial public offering of its common stock, which trades on the New York Stock Exchange under the symbol "ELAN." In February 2019, Elanco filed a registration statement to launch an exchange offer in which shareholders can exchange shares of Lilly common stock for Elanco common stock. For more information on the exchange offer, see Item 7, “Management’s Discussion and Analysis - Results of Operations - Executive Overview - Other Matters - Elanco Animal Health.”

We manufacture and distribute our products through facilities in the United States (U.S.), Puerto Rico, and 13 other countries. Our products are sold in approximately 125 countries.

Human Pharmaceutical Products

Our human pharmaceutical products include:

Cardiovascular products, including:

- *Cialis*®*,* for the treatment of erectile dysfunction and benign prostatic hyperplasia
- *Effient*®, for the reduction of thrombotic cardiovascular events (including stent thrombosis) in patients with acute coronary syndrome who are managed with an artery-opening procedure known as percutaneous coronary intervention, including patients undergoing angioplasty, atherectomy, or stent placement

Endocrinology products, including:

- *Basaglar*® (insulin glargine injection), a long-acting human insulin analog for the treatment of diabetes (launched in Japan and Europe under the trade name Abasaglar™)
- *Evista*®*,* for the prevention and treatment of osteoporosis in postmenopausal women and for the reduction of the risk of invasive breast cancer in postmenopausal women with osteoporosis and postmenopausal women at high risk for invasive breast cancer
- *Forteo*®*,* for the treatment of osteoporosis in postmenopausal women and men at high risk for fracture and for glucocorticoid-induced osteoporosis in men and postmenopausal women
- *Glyxambi*®, a combination tablet of linagliptin (Trajenta®) and empagliflozin (Jardiance®) for the treatment of type 2 diabetes
-

Humalog®, *Humalog Mix 75/25, Humalog U-100, Humalog U-200* and *Humalog Mix 50/50*, insulin analogs for the treatment of diabetes

- *Humatrope*®*,* for the treatment of human growth hormone deficiency and certain pediatric growth conditions

- *Humulin*®*, Humulin 70/30, Humulin N, Humulin R, and Humulin U-500,* human insulins of recombinant DNA origin for the treatment of diabetes

- *Jardiance*, for the treatment of type 2 diabetes and to reduce the risk of cardiovascular death in adult patients with type 2 diabetes and established cardiovascular disease

- *Jentadueto® and Jentadueto XR,* a combination of linagliptin and metformin hydrochloride for use in the treatment of type 2 diabetes

- *Synjardy® and Synjardy XR*, a combination tablet of empagliflozin and metformin hydrochloride for the treatment of type 2 diabetes

- *Trajenta,* for the treatment of type 2 diabetes

- *Trulicity®*, for the treatment of type 2 diabetes

Immunology products, including:

- *Olumiant®,* for the treatment of adults with moderately-to-severely active rheumatoid arthritis (approved in the European Union (EU) and Japan in 2017, and in the U.S. in 2018)

- *Taltz®*, for the treatment of moderate-to-severe plaque psoriasis (approved in the U.S. and EU in 2016) and active psoriatic arthritis (approved in Japan in 2016, in the U.S. in 2017, and in the EU in 2018)

Neuroscience products, including:

- *Amyvid®*, a radioactive diagnostic agent for positron emission tomography (PET) imaging of beta-amyloid neuritic plaques in the brains of adult patients with cognitive impairment who are being evaluated for Alzheimer's disease and other causes of cognitive decline

- *Cymbalta®*, for the treatment of major depressive disorder, diabetic peripheral neuropathic pain, generalized anxiety disorder, fibromyalgia, and chronic musculoskeletal pain due to chronic low back pain or chronic pain due to osteoarthritis

- *Emgality®*, a once-monthly subcutaneously injected calcitonin gene-related peptide (CGRP) antibody for the treatment of migraine prevention (approved in the U.S. and EU in 2018).

- *Prozac®,* for the treatment of major depressive disorder, obsessive-compulsive disorder, bulimia nervosa, and panic disorder

- *Strattera®,* for the treatment of attention-deficit hyperactivity disorder

- *Zyprexa®,* for the treatment of schizophrenia, acute mixed or manic episodes associated with bipolar I disorder, and bipolar maintenance

Oncology products, including:

- *Alimta®,* for the first-line treatment, in combination with another agent, of advanced non-small cell lung cancer (NSCLC) for patients with non-squamous cell histology; for the second-line treatment of advanced non-squamous NSCLC; as monotherapy for the maintenance treatment of advanced non-squamous NSCLC in patients whose disease has not progressed immediately following chemotherapy treatment; and in combination with another agent, for the treatment of malignant pleural mesothelioma

- *Cyramza®,* for the treatment of various cancers, with approvals as follows:

    - as a single agent and in combination with another agent as a second-line treatment of advanced or metastatic gastric cancer

- in combination with another agent as a second-line treatment of metastatic NSCLC
- as a second-line treatment of metastatic colorectal cancer

- *Erbitux®,* indicated both as a single agent and in combination with another chemotherapy agent for the treatment of certain types of colorectal cancers; and as a single agent, in combination with chemotherapy, or in combination with radiation therapy for the treatment of certain types of head and neck cancers

- *Gemzar®,* for the treatment of pancreatic cancer; in combination with other agents, for the treatment of metastatic breast cancer, NSCLC, and advanced or recurrent ovarian cancer; and in the EU for the treatment of bladder cancer

- *Lartruvo®*, approved in the U.S., and conditionally approved in the EU, in 2016 for use in combination with another agent for the treatment of soft tissue carcinoma. Following a negative result in a recent

clinical trial, we are suspending promotion of Lartruvo and are working with global regulators to determine the appropriate next steps.

- *Portrazza*®, approved in the U.S. for use in combination with other agents as a first-line treatment of metastatic squamous NSCLC, and approved in the EU for use in combination with other agents as a first-line treatment for epidermal growth factor receptor expressing squamous NSCLC

- *Verzenio*®*,* approved in 2017 in the U.S. for use as a single agent and in combination with endocrine therapy for the treatment of a certain type of metastatic breast cancer

Animal Health Products

Our products for food animals include:

- *Clynav*™, a vaccine to control pancreas disease in salmon
- *Coban*®*, Maxiban*®*,* and *Monteban*®*,* anticoccidial agents for use in poultry
- *Denagard*®*,* an antibiotic for the control and treatment of respiratory and enteric diseases in swine and poultry
- *Imvixa*™, to prevent and control infestation caused by sea lice in salmon
- *Optaflexx*® and *Paylean*®*,* leanness and performance enhancers for cattle and swine, respectively
- *Rumensin*®*,* a cattle feed additive that improves feed efficiency and growth and also controls and prevents coccidiosis
- *Tylan*®*,* an antibiotic used to control certain diseases in cattle, swine, and poultry

Our products for companion animals include:

- *Comfortis*®, a chewable tablet that kills fleas and prevents flea infestations on dogs
- *Credelio*®, a monthly chewable tablet for dogs that kills fleas, treats flea infestations, and treats and controls tick infestations
- Feline, canine, and rabies vaccines including: *Duramune*® and *Ultra Duramune*®, *Duramune Lyme*®, *Bronchi-Shield*®, *Fel-O-Vax*®*, ULTRA*™ *Fel-O-Vax*®, and *Fel-O-Guard*®*,* and *Rabvac*®
- *Galliprant*®, an anti-inflammatory tablet that targets the key receptor associated with canine osteoarthritis pain
- *Interceptor*® *Plus,* a monthly chewable tablet that prevents heartworm disease and treats and controls adult hookworm, roundworm, whipworm, and tapeworm in dogs
- *Osurnia*®*,* to treat otitis externa in dogs caused by certain strains of bacteria and yeast
- *Trifexis*®*,* a monthly chewable tablet for dogs that kills fleas, prevents flea infestations, prevents heartworm disease, and controls intestinal parasite infections

Marketing

We sell most of our products worldwide. We adapt our marketing methods and product emphasis in various countries to meet local customer needs.

Human Pharmaceuticals—U.S.

In the U.S., most of our pharmaceutical products are distributed through wholesalers that serve pharmacies, physicians and other health care professionals, and hospitals. In 2018, 2017, and 2016, three wholesale distributors in the U.S. - McKesson Corporation, AmerisourceBergen Corporation, and Cardinal Health, Inc. - each accounted for between 11 percent and 18 percent of our consolidated total revenue. No other distributor accounted for more than 10 percent of our consolidated total revenue in any of those years.

We promote our major human pharmaceutical products in the U.S. through sales representatives who call upon physicians and other health care professionals. We also promote to healthcare providers in medical journals and on-line health care channels, distribute literature and samples of certain products to physicians, and exhibit at medical meetings. In addition, we advertise certain products directly to consumers in the U.S., and we maintain websites with information about our major products. We supplement our employee sales force with contract sales organizations to leverage our own resources.

We maintain special business groups to service wholesalers, pharmacy benefit managers, managed care organizations, group purchasing organizations, government and long-term care institutions, hospitals, and certain retail pharmacies. We enter into arrangements with these organizations providing for discounts or rebates on our products.

Human Pharmaceuticals—Outside the U.S.

Outside the U.S, we promote our human pharmaceutical products to healthcare providers primarily through sales representatives and on-line health care channels. While the products marketed vary from country to country, endocrinology products constitute the largest single group in consolidated revenue. Distribution patterns vary from country to country. In most countries in which we operate, we maintain our own sales organizations, but in some smaller countries we market our products through independent distributors.

Human Pharmaceutical Marketing Collaborations

Certain of our human pharmaceutical products are marketed in arrangements with other pharmaceutical companies, including the following:

- We and Boehringer Ingelheim have a diabetes alliance under which we jointly develop and commercialize Trajenta, Jentadueto, Jardiance, Glyxambi, Synjardy, and Basaglar in major markets.

- Outside the U.S. and Canada, Erbitux is commercialized by Merck KGaA.

- We and Daiichi Sankyo Co., Ltd. (Daiichi Sankyo) co-promote Effient in the U.S., Brazil, Mexico, and certain other countries. Effective January 2016, Daiichi Sankyo has been exclusively promoting Effient in major European markets; however, the economic results for these countries continue to be shared. We retain sole marketing rights in Canada, Australia, Russia, and certain other countries. Daiichi Sankyo retains sole marketing rights in Japan and certain other countries.

For additional information, see Item 8, "Financial Statements and Supplementary Data - Note 4, Collaborations and Other Arrangements."

Animal Health Products

Our Elanco animal health business unit employs field salespeople throughout the U.S. and has an extensive sales force outside the U.S. Elanco sells its products primarily to wholesale distributors, and promotes its products primarily to producers and veterinarians for food animal products and to veterinarians for companion animal products. Elanco also advertises certain companion animal products directly to pet owners in markets where it is consistent with allowable promotional practices.

Competition

Our human pharmaceutical products compete globally with products of many other companies in highly competitive markets. Our animal health products compete globally with products of animal health care companies as well as pharmaceutical, chemical, and other companies that operate animal health businesses.

Important competitive factors for both human pharmaceutical and animal health products include effectiveness, safety, and ease of use; price and demonstrated cost-effectiveness; marketing effectiveness; and research and development of new products, processes, and uses. Most new products that we introduce must compete with other branded or generic products already on the market or products that are later developed by competitors. If competitors introduce new products or delivery systems with therapeutic or cost advantages, our products can be subject to decreased sales, progressive price reductions, or both.

We believe our long-term competitive success depends upon discovering and developing (either alone or in collaboration with others) or acquiring innovative, cost-effective human pharmaceutical and animal health products that provide improved outcomes and deliver value to payers, and continuously improving

the productivity of our operations in a highly competitive environment. There can be no assurance that our efforts will result in commercially successful products, and it is possible that our products will be, or become, uncompetitive from time to time as a result of products developed by our competitors.

Generic Pharmaceuticals

One of the biggest competitive challenges we face is from generic pharmaceuticals. In the U.S. and the EU, the regulatory approval process for human pharmaceuticals (other than biological products (biologics)) exempts generics from costly and time-consuming clinical trials to demonstrate their safety and efficacy, allowing generic manufacturers to rely on the safety and efficacy of the innovator product. Therefore, generic manufacturers

generally invest far less than we do in research and development and can price their products much lower than our branded products. Accordingly, when a branded non-biologic human pharmaceutical loses its market exclusivity, it normally faces intense price competition from generic forms of the product. Public and private payers typically encourage the use of generics as alternatives to brand-name drugs in their healthcare programs. Laws in the U.S. generally allow, and in many cases require, pharmacists to substitute generic drugs that have been rated under government procedures to be essentially equivalent to a brand-name drug. Where substitution is mandatory, it must be made unless the prescribing physician expressly forbids it. In many countries outside the U.S., intellectual property protection is weak, and we must compete with generic or counterfeit versions of our products. Many of our animal health products also compete with generics.

Biosimilars

Several of our current products, including Cyramza, Erbitux, Trulicity, Taltz, and Emgality and many of the new molecular entities (NMEs) in our research pipeline are biologics. Competition for Lilly's biologics may be affected by the approval of follow-on biologics, also known as biosimilars. A biosimilar is a subsequent version of an approved innovator biologic that, due to its functional and structural similarity to the innovator biologic, is approved based on an abbreviated data package that relies in part on the full testing required of the innovator biologic. Globally, most governments have developed regulatory pathways to approve biosimilars as alternatives to innovator-developed biologics, but the patent and regulatory exclusivity for the existing innovator biologic must expire in a given market before biosimilars may enter that market. The extent to which a biosimilar, once approved, will be substituted for the innovator biologic in a way that is similar to traditional generic substitution for non-biologic products, is not yet entirely clear, and will depend on a number of regulatory and marketplace factors that are still developing.

Biosimilars may present both competitive challenges and opportunities. For example, a competitor company has developed a version of insulin lispro which competes with our product Humalog. On the other hand, with our partner Boehringer Ingelheim, we developed Basaglar, a new insulin glargine product, which has the same amino acid sequence as the product currently marketed by a competitor and has launched as a follow-on biologic in the U.S., and as a biosimilar in the EU and Japan.

U.S. Private Sector Dynamics

In the U.S. private sector, consolidation and integration among healthcare providers is also a major factor in the competitive marketplace for human pharmaceuticals. Health plans and pharmacy benefit managers have been consolidating into fewer, larger entities, thus enhancing their purchasing strength and importance. For example, in 2018 CVS Health, a large pharmacy benefit manager and pharmacy chain, acquired Aetna, a large national insurer, and Cigna Corporation acquired Express Scripts in a similar transaction.

Payers typically maintain formularies which specify coverage (the conditions under which drugs are included on a plan's formulary) and reimbursement (the associated out-of-pocket cost to the consumer). Formulary placement can lead to reduced usage of a drug for the relevant patient population due to coverage restrictions, such as prior authorizations and formulary exclusions, or due to reimbursement limitations which result in higher consumer out-of-pocket cost, such as non-preferred co-pay tiers, increased co-insurance levels, and higher deductibles. Consequently, pharmaceutical companies compete for formulary placement not only on the basis of product attributes such as efficacy, safety profile, or patient ease of use, but also by providing rebates. Value-based agreements, where pricing is based on achievement, or not, of specified outcomes, 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 our future consolidated results of operations.

Patents, Trademarks, and Other Intellectual Property Rights

Overview

Intellectual property protection is critical to our ability to successfully commercialize our life sciences innovations and invest in the search for new medicines. We own, have applied for, or are licensed under, a large number of patents in the U.S. and many other countries relating to products, product uses, formulations, and manufacturing processes. In addition, as discussed below, for some products we have

additional effective intellectual property protection in the form of data protection under pharmaceutical regulatory laws.

The patent protection anticipated to be of most relevance to human pharmaceuticals is provided by national patents claiming the active ingredient (the compound patent), particularly those in major markets such as the

U.S., various European countries, and Japan. These patents may be issued based upon the filing of international patent applications, usually filed under the Patent Cooperation Treaty (PCT). Patent applications covering the compounds are generally filed during the Discovery Research Phase of the drug discovery process, which is described in the “Research and Development” section below. In general, national patents in each relevant country are available for a period of 20 years from the filing date of the PCT application, which is often years prior to the launch of a commercial product. Further patent term adjustments and restorations may extend the original patent term:

- Patent term adjustment is a statutory right available to all U.S. patent applicants to provide relief in the event that a patent grant is delayed during examination by the United States Patent and Trademark Office (USPTO).

- Patent term restoration is a statutory right provided to U.S. patent holders that claim inventions subject to review by the U.S. Food and Drug Administration (FDA). To make up for a portion of the time invested in clinical trials and the FDA review process, a single patent for a human pharmaceutical product may be eligible for patent term restoration. Patent term restoration is limited by a formula and cannot be calculated until product approval due to uncertainty about the duration of clinical trials and the time it takes the FDA to review an application. There is a five-year cap on any restoration, and no patent may be extended for more than 14 years beyond FDA approval. Some countries outside the U.S. also offer forms of patent term restoration. For example, Supplementary Protection Certificates are sometimes available to extend the life of a European patent up to an additional five years. Similarly, in Japan, South Korea, and Australia, patent terms can be extended up to five years, depending on the length of regulatory review and other factors.

Loss of effective patent protection for human pharmaceuticals typically results in the loss of effective market exclusivity for the product, which often results in severe and rapid decline in revenues for the product. However, in some cases the innovator company may be protected from approval of generic or other follow-on versions of a new medicine beyond the expiration of the compound patent through manufacturing trade secrets, later-expiring patents on manufacturing processes, methods of use or formulations, or data protection that may be available under pharmaceutical regulatory laws. The primary forms of data protection are as follows:

- Regulatory authorities in major markets generally grant data package protection for a period of years following new drug approvals in recognition of the substantial investment required to complete clinical trials. Data package protection prohibits other manufacturers from submitting regulatory applications for marketing approval based on the innovator company’s regulatory submission data for the drug. The base period of data package protection depends on the country. For example, the period is generally five years in the U.S. (12 years for new biologics as described below), effectively 10 years in the EU, and eight years in Japan. The period begins on the date of product approval and runs concurrently with the patent term for any relevant patent.

- Under the Biologics Price Competition and Innovation Act of 2009 (the BPCI Act), the FDA has the authority to approve biosimilars. A competitor seeking approval of a biosimilar must file an application to show its molecule is highly similar to an approved innovator biologic and include a certain amount of safety and efficacy data that the FDA will determine on a case-by-case basis. Under the data protection provisions of this law, the FDA cannot approve a biosimilar application until 12 years after initial marketing approval of the innovator biologic, subject to certain conditions.

- In the U.S., the FDA has the authority to grant additional data protection for approved drugs where the sponsor conducts specified testing in pediatric or adolescent populations within a specified time period. If granted, this “pediatric exclusivity” provides an additional six months of exclusivity, which is added to the term of data protection as well as to the term of any relevant patents, to the extent these protections have not already expired. While the term of the pediatric exclusivity attaches to the term of any relevant patent, pediatric exclusivity is a regulatory exclusivity, a bar to generic approval, not a patent right.

- Under the U.S. orphan drug law, a specific use of a drug or biologic can receive "orphan" designation if it is intended to treat a disease or condition affecting fewer than 200,000 people in the U.S., or affecting more than 200,000 people but not reasonably expected to recover its development and marketing costs through U.S. sales. Among other benefits, orphan designation entitles the particular use of the drug to seven years of market exclusivity, meaning that the FDA cannot (with limited exceptions) approve another marketing application for the same drug for the same indication until expiration of the seven-year period. Unlike pediatric exclusivity, the orphan exclusivity period is independent of and runs in parallel with any applicable patents.

Outside the major markets, the adequacy and effectiveness of intellectual property protection for human pharmaceuticals varies widely, and in a number of these markets we are unable to patent our products or to enforce the patents we receive for our products. Under the Trade-Related Aspects of Intellectual Property Agreement (TRIPs) administered by the World Trade Organization, more than 140 countries have agreed to provide non-discriminatory protection for most pharmaceutical inventions and to assure that adequate and effective rights are available to patent owners. Implementation of this agreement differs between developed and developing countries, with many developing countries limiting protection for biopharmaceutical products under their interpretation of “flexibilities” allowed under the agreement. Thus, certain types of patents, such as those on new uses of compounds or new forms of molecules, are not available in many developing countries. Further, many developing countries, and some developed countries, do not provide effective data package protection even though it is specified in TRIPs.

Certain of our Elanco animal health products are covered by patents or other forms of intellectual property protection. Historically, upon loss of effective market exclusivity for our animal health products, we have not generally experienced the rapid and severe declines in revenues that are common in the human pharmaceutical segment.

Our Intellectual Property Portfolio

We consider intellectual property protection for certain products, processes, uses, and formulations—particularly with respect to those products discussed below—to be important to our operations. For many of our products, in addition to the compound patent, we hold other patents on manufacturing processes, formulations, or uses that may extend exclusivity beyond the expiration of the compound patent.

The most relevant U.S. patent protection or data protection for our top-selling or recently launched patent-protected marketed products is as follows:

- Alimta is protected by a vitamin regimen patent (2021) plus pediatric exclusivity (2022).
- Cyramza is protected by a compound patent and biologics data package protection (2026).
- Emgality is protected by a compound patent (2033).
- Forteo is protected by use patents (August 2019).
- Jardiance, and the related combination products Glyxambi and Synjardy, are protected by a compound patent (2025, not including possible patent extension).
- Lartruvo is protected by a compound patent (2027, not including possible patent extension) and by biologics data package protection (2028). Following a negative result in a recent clinical trial, we are suspending promotion of Lartruvo and are working with global regulators to determine the appropriate next steps.
- Olumiant, is protected by a compound patent (2030, not including possible patent extension).
- Portrazza is protected by a compound patent (2025, not including possible patent extension), and by biologics data package protection (2027).
- Taltz is protected by a compound patent (2026, not including possible patent extension) and by biologic data package protection (2028).
- Trajenta and Jentadueto are protected by a compound patent (2023, not including possible patent extension).
- Trulicity is protected by a compound patent (2024, not including possible patent extension) and by biologics data package protection (2026).
- Verzenio is protected by a compound patent (2029, not including possible patent extension).

Outside the U.S., important patent protection or data protection includes:

- Alimta in major European countries (vitamin regimen patent 2021) and Japan (patents covering use to treat cancer concomitantly with vitamins 2021).
- Cymbalta in Japan (data package protection January 2020).
- Forteo in Japan (patents covering its formulation and its use August 2019).

- Lartruvo in major European countries (compound patent and data package protection 2026, not including possible patent extension). Following a negative result in a recent clinical trial, we are suspending promotion of Lartruvo and are working with global regulators to determine the appropriate next steps.

- Olumiant in major European countries (compound patent 2029, not including possible patent extension) and Japan (compound patent 2033).

- Taltz in major European countries (data package protection 2026; compound patent 2031).

Nasal glucagon has been submitted for regulatory review in the U.S. and is protected by delivery device patents (latest expiring 2034), with data protection (3.5 years) expected upon approval. In Europe, nasal glucagon is protected by delivery device patents (latest expiring 2034), with data protection (6 years) expected upon approval.

Lasmiditan has been submitted for regulatory review in the U.S. and is protected by a compound patent (2025, not including possible patent extension).

Worldwide, we sell all of our major products under trademarks for names and unique product appearance, which we consider in the aggregate to be important to our operations. Trademark protection varies throughout the world, with protection continuing in some countries as long as the mark is used, and in other countries as long as it is registered. Registrations are normally for fixed but renewable terms. Trademark protection often extends beyond the patent and data protection for a product.

Patent Licenses

Most of our major products are not subject to significant license agreements. For information on our license and collaboration agreement with Incyte Corporation related to Olumiant, see Item 8, "Financial Statements and Supplementary Data - Note 4, Collaborations."

Patent Challenges

In the U.S., the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, authorizes the FDA to approve generic versions of innovative human pharmaceuticals (other than biologics) without completion of safety and efficacy studies, i.e., a complete New Drug Application (NDA) by filing an Abbreviated New Drug Application (ANDA). In an ANDA, the generic manufacturer must demonstrate only “bioequivalence” between the generic version and the NDA-approved drug—not safety and efficacy. Establishing bioequivalence is generally straightforward and inexpensive for the generic company.

Absent a patent challenge, the FDA cannot approve an ANDA until after certain of the innovator’s patents expire. However, after the innovator has marketed its product for four years, a generic manufacturer may file an ANDA alleging that one or more of the patents listed in the innovator’s NDA are invalid or not infringed. This allegation is commonly known as a “Paragraph IV certification.” The innovator must then file suit against the generic manufacturer to protect its patents. The FDA is then prohibited from approving the generic company’s application for a 30-month period (which can be shortened or extended by the trial court judge hearing the patent challenge). If one or more of the NDA-listed patents are challenged, the first filer(s) of a Paragraph IV certification may be entitled to a 180-day period of market exclusivity over all other generic manufacturers.

Generic manufacturers use Paragraph IV certifications extensively to challenge patents on innovative human pharmaceuticals. In addition, generic companies have shown willingness to launch “at risk,” i.e., after receiving ANDA approval but before final resolution of their patent challenge. We are currently in litigation with numerous generic manufacturers in Hatch-Waxman litigation involving Alimta, among other products. For more information on Hatch-Waxman litigation involving the company, see Item 8, “Financial Statements and Supplementary Data - Note 15, Contingencies” and Item 3, "Legal Proceedings."

Under the BPCI Act, the FDA cannot approve a biosimilar application until data protection expires, 12 years after initial marketing approval of the innovator biologic. However, the BPCI Act does provide a mechanism for a competitor to challenge the validity of an innovator’s patents as early as four years after initial marketing approval of the innovator biologic. The patent litigation scheme under the BPCI Act is complex, and interpretation of the BPCI Act is currently the subject of ongoing litigation. Specifically, courts

have now held that biosimilar applicants are not required to engage in the BPCI Act litigation scheme. Patent holders still have the right to bring suit under normal patent law procedures if a biosimilar applicant attempts to commercialize a product prior to patent expiration.

In addition, there is a procedure in U.S. patent law known as inter partes review (IPR), which allows any member of the public to file a petition with the USPTO seeking the review of any issued U.S. patent. IPRs are conducted before Administrative Patent Judges in the USPTO using a lower standard of proof than used in federal district court. In addition, the challenged patents are not accorded the presumption of validity as they are in federal district court. We are now seeing instances where generic drug companies and some investment firms are attempting to invalidate our patents by filing IPR challenges in the USPTO. For more information, see Item 8, “Financial Statements and Supplementary Data - Note 15, Contingencies.”

Outside the U.S., the legal doctrines and processes by which pharmaceutical patents can be challenged vary widely. In recent years, we have experienced an increase in patent challenges from generic manufacturers in many countries outside the U.S., and we expect this trend to continue. For more information on administrative challenges and litigation involving our Alimta patents in Europe and Japan, see Item 8, “Financial Statements and Supplementary Data - Note 15, Contingencies.”

Government Regulation of Our Operations

Our operations are regulated extensively by numerous national, state, and local agencies. The lengthy process of laboratory and clinical testing, data analysis, manufacturing development, and regulatory review necessary for governmental approvals is extremely costly and can significantly delay product introductions. Promotion, marketing, manufacturing, and distribution of human pharmaceutical and animal health products are extensively regulated in all major markets. We conduct extensive post-marketing surveillance of the safety of the products we sell. In addition, our operations are subject to complex federal, state, local, and foreign laws and regulations concerning the environment, occupational health and safety, and privacy. Animal health product regulations address the administration of the product in or on the animal, and in the case of food animal products, the impact on humans who consume the food as well as the impact on the environment at the production site. Compliance with the laws and regulations affecting the manufacture and sale of current products and the discovery, development, and introduction of new products will continue to require substantial effort, expense, and capital investment.

Of particular importance to our business is the FDA in the U.S. Pursuant to the Federal Food, Drug, and Cosmetic Act, the FDA has jurisdiction over all of our human pharmaceutical products and devices and certain animal health products in the U.S. and administers requirements covering the testing, safety, effectiveness, manufacturing, quality control, distribution, labeling, marketing, advertising, dissemination of information, and post-marketing surveillance of those products.

The FDA extensively regulates all aspects of manufacturing quality for human pharmaceuticals under its current Good Manufacturing Practices (cGMP) regulations. Outside the U.S., our products and operations are subject to similar regulatory requirements, notably by the European Medicines Agency in the EU and the Ministry of Health, Labor and Welfare in Japan. Specific regulatory requirements vary from country to country. We make substantial investments of capital and operating expenses to implement comprehensive, company-wide quality systems in our manufacturing, product development, and process development operations in an effort to ensure sustained compliance with cGMP and similar regulations. However, in the event we fail to adhere to these requirements in the future, we could be subject to interruptions in production, fines and penalties, and delays in new product approvals. Certain of our products are manufactured by third parties, and their failure to comply with these regulations could adversely affect us through failure to supply product to us or delays in new product approvals.

The U.S. Department of Agriculture and the U.S. Environmental Protection Agency also regulate some animal health products.

The marketing, promotional, and pricing practices of human pharmaceutical manufacturers, as well as the manner in which manufacturers interact with purchasers, prescribers, and patients, are subject to various other U.S. federal and state laws, including the federal anti-kickback statute and the False Claims Act and state laws governing kickbacks, false claims, unfair trade practices, and consumer protection. These laws are administered by, among others, the Department of Justice (DOJ), the Office of Inspector General of the Department of Health and Human Services, the Federal Trade Commission, the Office of Personnel Management, and state attorneys general. Over the past several years, state and federal governments have increased their oversight, enforcement activities, and intra-agency coordination with respect to pharmaceutical companies. Several claims brought by these agencies against us and other companies

under these and other laws have resulted in corporate criminal sanctions and very substantial civil settlements.

The U.S. Foreign Corrupt Practices Act of 1977 (FCPA) prohibits certain individuals and entities, including U.S. publicly traded companies, from promising, offering, or giving anything of value to foreign officials with the corrupt intent of influencing the foreign official for the purpose of helping the company obtain or retain business or gain any improper advantage. The FCPA also imposes specific recordkeeping and internal controls requirements on U.S. publicly traded companies. As noted above, outside the U.S., our business is heavily regulated and therefore involves significant interaction with foreign officials. Additionally, in many countries outside the U.S., the health care providers who prescribe human pharmaceuticals are employed by the government and the purchasers of human pharmaceuticals are government entities; therefore, our interactions with these prescribers and purchasers are subject to regulation under the FCPA.

In addition to the U.S. application and enforcement of the FCPA, the various jurisdictions in which we operate and supply our products have laws and regulations aimed at preventing and penalizing corrupt and anticompetitive behavior. In recent years, several jurisdictions, including China, Brazil, and the United Kingdom (U.K.), have enhanced their laws and regulations in this area, increased their enforcement activities, and/or increased the level of cross-border coordination and information sharing.

We are and could in the future become subject to administrative and legal proceedings and actions, which could include claims for civil penalties (including treble damages under the False Claims Act), criminal sanctions, and administrative remedies, including exclusion from U.S. federal and other health care programs. It is possible that an adverse outcome in future actions could have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

Regulations and Private Payer Actions Affecting Human Pharmaceutical Pricing, Reimbursement, and Access

In the U.S., we are required to provide rebates to the federal government and respective state governments on their purchases of our human pharmaceuticals under state Medicaid and Medicaid Managed Care programs (minimum of 23.1 percent plus adjustments for price increases over time) and rebates to private payers who cover patients in certain types of health care facilities that serve low-income and uninsured patients (known as 340B facilities). No rebates are required at this time in the Medicare Part B (physician and hospital outpatient) program where reimbursement is set on an "average selling price plus 4.3 percent" formula. Additionally, an annual fee is imposed on pharmaceutical manufacturers and importers that sell branded prescription drugs to specified government programs. Beginning in 2019,the Bipartisan Budget Act requires manufacturers of brand-name drugs, biologics, and biosimilars to provide a discount of 70 percent of the cost of branded prescription drugs for Medicare Part D participants who are in the “doughnut hole” (the coverage gap in Medicare prescription drug coverage), up from the previous 50-percent discount. 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.

Rebates are also negotiated in the private sector. We give rebates to private payers who provide prescription drug benefits to seniors covered by Medicare and to private payers who provide prescription drug benefits to their customers. These rebates are affected by the introduction of competitive products and generics in the same class.

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 other proposals 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. At the state level in the U.S., California, Nevada, and several other states have enacted legislation related to prescription drug pricing transparency. It is unclear the effect this legislation will have on our business.

In most international markets, we operate in an environment of government-mandated cost-containment programs, which may include price controls, international reference pricing (to other countries’ prices),

discounts and rebates, therapeutic reference pricing (to other, often generic, pharmaceutical choices), restrictions on physician prescription levels, and mandatory generic substitution.

Globally, public and private payers are increasingly restricting access to human pharmaceuticals based on assessments of comparative effectiveness and value, including through the establishment of formal health technology assessment processes. In addition, third party organizations, including professional associations, academic institutions, and non-profit entities associated with payers, are conducting and publishing comparative effectiveness and cost/benefit analyses on medicines, the impact of which are uncertain at this time.

We cannot predict the extent to which our business may be affected by these or other potential future legislative, regulatory, or payer developments. However, in general we expect that state, federal, and international legislative and regulatory developments could have further negative effects on pricing and reimbursement for our human pharmaceutical products.

Research and Development

Our commitment to research and development dates back more than 140 years. We invest heavily in research and development because we believe it is critical to our long-term competitiveness. At the end of 2018, we employed approximately 8,500 people in human pharmaceutical and animal health research and development activities, including a substantial number of physicians, scientists holding graduate or postgraduate degrees, and highly skilled technical personnel.

Our internal human pharmaceutical research focuses primarily on the areas of oncology, diabetes, neurodegeneration, immunology, and pain. We believe that we have a strong biotechnology research program, with more than half of our clinical-stage pipeline currently consisting of biologics. In addition to discovering and developing NMEs, we seek to expand the value of existing products through new uses, formulations, and therapeutic approaches that provide additional value to patients.

To supplement our internal efforts, we collaborate with others, including academic institutions and research-based pharmaceutical and biotechnology companies. We use the services of physicians, hospitals, medical schools, and other research organizations worldwide to conduct clinical trials to establish the safety and effectiveness of our human pharmaceutical products. We actively invest in external research and technologies that we believe complement and strengthen our own efforts. These investments can take many forms, including licensing arrangements, co-development and co-marketing agreements, co-promotion arrangements, joint ventures, and acquisitions.

Our Elanco animal health innovation strategy is focused on identifying and developing promising technologies and potential products from internal and external sources to meet unmet veterinary, food producer, and pet owner needs. Our animal health scientists also leverage discoveries from our human health laboratories to develop products to enhance the health and well-being of farm animals and pets.

Human pharmaceutical development is time-consuming, expensive, and risky. On average, only one out of many thousands of molecules discovered by researchers ultimately becomes an approved medicine. The process from discovery to regulatory approval can take over a decade. Drug candidates can fail at any stage of the process, and even late-stage drug candidates sometimes fail to receive regulatory approval or achieve commercial success. The rate of innovation cycles leading to medical improvements over initial inventions is accelerating, which has increased the risk that we opt not to develop a late-stage asset or that new products fail to achieve commercial success due to technical obsolescence - displacement by follow-on competitor products - before the period of exclusivity has ended. After approval and launch of a product, we expend considerable resources on post-marketing surveillance and additional clinical studies to collect data and understand the benefits and potential risks of medicines as they are used as therapeutics. The following describes in more detail the research and development process for human pharmaceutical products:

Phases of New Drug Development

- **Discovery Phase**

  The earliest phase of new drug research and development, the discovery phase, can take many years. Scientists identify, design, and synthesize promising molecules, screening tens of thousands of molecules for their effect on biological targets that appear to play an important role in one or more diseases. Targets can be part of the body, such as a protein, receptor, or gene; or foreign, such as a virus or bacteria. Some targets have been proven to affect disease processes, but often the target is unproven and may later prove to be irrelevant to the disease or to yield insufficient clinical benefit.

Molecules that have the desired effect on the target and meet other design criteria become candidate molecules and move to the next phase of development. The probability of any one candidate molecule becoming a commercial product is extremely low.

- **Early Development Phase**

  The early development phase involves refining candidate molecules, understanding how to manufacture them efficiently, and completing initial testing for safety and efficacy. Safety testing is done first in laboratory tests and animals as necessary, to identify toxicity and other potential safety issues that would preclude use in humans. In general, the first human tests (often referred to as Phase I) are conducted in small groups of healthy volunteers or patients to assess safety and find the potential dosing range. After a safe dose range has been established, the drug is typically administered to small populations of patients (Phase II) to look for initial signs of efficacy in treating the targeted disease, or biomarkers of the disease, and to continue to assess safety. In parallel, scientists work to identify safe, effective, and economical manufacturing processes. Long-term animal studies continue to test for potential safety issues. Of the molecules that enter the early development phase, approximately 10 percent move on to the product phase. The early development phase can take several years to complete.

- **Product Phase**

  Product phase (Phase III) molecules have met initial safety requirements and, typically, shown initial evidence of efficacy. As a result, these molecules generally have a higher likelihood of success. The molecules are tested in much larger patient populations to demonstrate efficacy to a predetermined level of statistical significance and to continue to develop the safety profile. These trials are generally global in nature and are designed to generate the data necessary to submit the molecule to regulatory agencies for marketing approval. The potential new drug is generally compared with existing competitive therapies, placebo, or both. The resulting data is compiled and may be submitted to regulatory agencies around the world. Phase III testing varies by disease state, but can often last from three to four years.

- **Submission Phase**

  Once a molecule is submitted to regulatory agencies, the time to final marketing approval can vary from several months to several years, depending on variables such as the disease state, the strength and complexity of the data presented, the novelty of the target or compound, and the time required for the agency(ies) to evaluate the submission. There is no guarantee that a potential medicine will receive marketing approval, or that decisions on marketing approvals or indications will be consistent across geographic areas.

We believe our investments in research, both internally and in collaboration with others, have been rewarded by the large number of new molecules and new indications for existing molecules that we have in all stages of development. We currently have approximately 45 drug candidates across all stages of human testing and a larger number of projects in preclinical development. Among our new investigational molecules currently in the product phase of development or awaiting regulatory approval or launch are potential therapies for various cancers; Alzheimer’s disease; pain; migraine; diabetes; severe hypoglycemia; and autoimmune diseases, including rheumatoid arthritis, systemic lupus erythematosus, psoriasis, atopic dermatitis, and ulcerative colitis. We are studying many other drug candidates in the earlier stages of development in our chosen priority areas. We are also developing new uses, formulations, or delivery methods for many of these molecules as well as several currently marketed products. See Item 7, "Management's Discussion and Analysis - Results of Operations - Executive Overview - Late-Stage Pipeline," for more information on certain of our product candidates.

Raw Materials and Product Supply

Most of the principal materials we use in our manufacturing operations are available from more than one source. However, we obtain certain raw or intermediate materials primarily from only one source. We generally seek to maintain sufficient inventory to supply the market until an alternative source of supply could be implemented, in the event one of these suppliers was unable to provide the materials or product. However, in the event of an extended failure of a supplier, it is possible that we could experience an interruption in supply until we established new sources or, in some cases, implemented alternative processes.

The majority of our revenue comes from products produced in our own facilities. Our principal active ingredient manufacturing occurs at sites we own in the U.S., Ireland, and Puerto Rico. Finishing operations, including formulation, filling, assembling, delivery device manufacturing, and packaging, take place at a number of sites throughout the world. We utilize third parties for certain active ingredient manufacturing and finishing operations.

We manage our supply chain (including our own facilities, contracted arrangements, and inventory) in a way that is intended to allow us to meet all expected product demand while maintaining flexibility to reallocate manufacturing capacity to improve efficiency and respond to changes in supply and demand. To maintain a stable supply of our products, we use a variety of techniques including comprehensive quality systems, inventory management, and back-up sites.

However, human pharmaceutical and animal health production processes are complex, highly regulated, and vary widely from product to product. Shifting or adding manufacturing capacity can be a very lengthy process requiring significant capital expenditures, process modifications, and regulatory approvals. Accordingly, if we were to experience extended plant shutdowns at one of our own facilities, extended failure of a contract supplier, or extraordinary unplanned increases in demand, we could experience an interruption in supply of certain products or product shortages until production could be resumed or expanded.

Quality Assurance

Our success depends in great measure upon customer confidence in the quality of our products and in the integrity of the data that support their safety and effectiveness. Product quality arises from a total commitment to quality in all parts of our operations, including research and development, purchasing, facilities planning, manufacturing, distribution, and dissemination of information about our medicines.

Quality of production processes involves strict control of ingredients, equipment, facilities, manufacturing methods, packaging materials, and labeling. We perform tests at various stages of production processes and on the final product in an effort to assure that the product meets all regulatory requirements and Lilly internal standards. These tests may involve chemical and physical chemical analyses, microbiological testing, testing in animals, or a combination thereof. Additional assurance of quality is provided by corporate quality-assurance groups that audit and monitor all aspects of quality related to human pharmaceutical and animal health manufacturing procedures and systems in company operations and at third-party suppliers.

Executive Officers of the Company

The following table sets forth certain information regarding our executive officers. Except as otherwise noted, all executive officers have been employed by the company in management or executive positions during the last five years.

The term of office for each executive officer expires on the date of the annual meeting of the Board of Directors, to be held on May 6, 2019, or on the date his or her successor is chosen and qualified. No director or executive officer has a “family relationship” with any other director or executive officer of the company, as that term is defined for purposes of this disclosure requirement. There is no understanding between any executive officer or director and any other person pursuant to which the executive officer was selected.

Name	Age	Offices and Business Experience
David A. Ricks	51	President, Chief Executive Officer, director (since January 2017) and board chair (since June 2017)
Melissa S. Barnes	50	Senior Vice President, Enterprise Risk Management and Chief Ethics and Compliance Officer (since January 2013)
Enrique A. Conterno	52	Senior Vice President and President, Lilly Diabetes (since November 2009) and President, Lilly USA (since February 2017)
Stephen F. Fry	53	Senior Vice President, Human Resources and Diversity (since February 2011)
Michael J. Harrington	56	Senior Vice President and General Counsel (since January 2013)
Johna L. Norton	52	Senior Vice President, Global Quality (since April 2017)
Myles O'Neill	60	Senior Vice President and President, Manufacturing Operations (since January 2018)
Leigh Ann Pusey	56	Senior Vice President, Corporate Affairs and Communications (since June 2017). Prior to joining Lilly, Ms. Pusey served as president and CEO of the American Insurance Association.
Aarti Shah, Ph.D.	54	Senior Vice President and Chief Information and Digital Officer (since January 2018)
Christi Shaw	52	Senior Vice President and President, Lilly Bio-Medicines (since April 2017). Prior to returning to Lilly, Ms. Shaw served as U.S. country head and president of Novartis Pharmaceutical Corporation from 2014 to 2016, and as North American region head of Novartis Oncology from 2010 to 2014.

Daniel Skovronsky, M.D., Ph.D.	45	Senior Vice President and Chief Scientific Officer (since June 2018)
Joshua L. Smiley	49	Senior Vice President and Chief Financial Officer (since January 2018)
Alfonso Zulueta	56	Senior Vice President and President, Lilly International (since February 2017)
Anne E. White	50	Senior Vice President and President, Lilly Oncology (since September 2018)

Employees

At the end of 2018, we employed approximately 38,680 people, including approximately 21,975 employees outside the U.S. A substantial number of our employees have long records of continuous service.

Information Available on Our Website

Our company website is **https://www.lilly.com.** None of the information accessible on or through our website is incorporated into this Form 10-K. We make available through the website, free of charge, our company filings with the Securities and Exchange Commission (SEC) as soon as reasonably practicable after we electronically file them with, or furnish them to, the SEC. These include our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements, registration statements, and any amendments to those documents. The company website link to our SEC filings is **https://investor.lilly.com/financial-information/sec-filings.**

In addition, the Corporate Governance portion of our website includes our corporate governance guidelines, board and committee information (including committee charters), and our articles of incorporation and by-laws. The link to our corporate governance information is **https://www.lilly.com/about/corporate-governance/Pages/corporate-governance.aspx.**

We will provide paper copies of our SEC filings free of charge upon request to the company's secretary at the address listed on the front of this Form 10-K.

Item 1A. Risk Factors

In addition to the other information contained in this Form 10-K, the following risk factors should be considered carefully in evaluating our company. It is possible that our business, financial condition, liquidity, or results of operations could be materially adversely affected by any of these risks. Certain of these risks could also adversely affect the company's reputation.

- **Pharmaceutical research and development is very costly and highly uncertain; we may not succeed in developing or acquiring commercially successful products sufficient in number or value to replace revenues of products that have lost or will soon lose intellectual property protection or are displaced by competing products or therapies.**

  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 cannot state with certainty when or whether our products now under development will be approved or launched; whether, if initially granted, such approval will be maintained; whether we will be able to develop, license, or otherwise acquire additional product candidates or products; or whether our products, once launched, will be commercially successful. We must maintain a continuous flow of successful new products and successful new indications or brand extensions for existing products sufficient both to cover our substantial research and development costs and to replace revenues that are lost as profitable products lose intellectual property exclusivity or are displaced by competing products or therapies. Failure to do so in the short-term or long-term would have a material adverse

effect on our business, results of operations, cash flows, financial position, and prospects. See Item 7, “Management’s Discussion and Analysis - Results of Operations - Executive Overview - Late-Stage Pipeline,” for more details.

- **We depend on products with intellectual property protection for most of our revenues, cash flows, and earnings; we have lost or will lose effective intellectual property protection for many of those products in the next several years, which has resulted and is likely to continue to result in rapid and severe declines in revenues.**

A number of our top-selling human pharmaceutical products have recently lost, or will lose in the next several years, significant patent protection and/or data protection in the U.S. as well as key countries outside the U.S., as illustrated in the tables below:

Product	U.S. Revenues (2018) ($ in millions)	Percent of Worldwide Revenues (2018)	Patent / Data Protection - U.S.
Alimta	1,131.0	5%	Vitamin regimen patent plus pediatric exclusivity will expire in 2022
Cialis	1,129.2	5%	Compound patent plus pediatric exclusivity expired in May 2018 and unit dose patent expired in September 2018
Forteo	757.9	3%	Formulation and related process patents expired in December 2018 and use patents will expire in August 2019

Product	Revenues Outside U.S. (2018) ($ in millions)	Percent of Worldwide Revenues (2018)	Patent / Data Protection - Major Europe / Japan
Alimta	$ 1,001.9	4%	Major European countries: vitamin regimen patent will expire in 2021 Japan: use patents to treat cancer concomitantly with vitamins will expire in 2021
Forteo	817.7	3%	Japan: data package protection expired in July 2018; formulation and use patents will expire in August 2019
Cymbalta	653.7	3%	Japan: data package protection will expire in January 2020

Certain other significant products no longer have effective exclusivity through patent protection or data protection. For non-biologic products, loss of exclusivity (whether by expiration or as a consequence of litigation) typically results in the entry of one or more generic competitors, leading to a rapid and severe decline in revenues, especially in the U.S. Historically, outside the U.S. the market penetration of generics following loss of exclusivity has not been as rapid or pervasive as in the U.S.; however, generic market penetration is increasing in many markets outside the U.S., including Japan, Europe, and many countries in the emerging markets. For biologics (such as Humalog, Humulin, Erbitux, Cyramza, Trulicity, Taltz, and Emgality), loss of exclusivity may or may not result in the near-term entry of competitor versions (i.e., biosimilars) due to development timelines, manufacturing challenges, and/or uncertainties in the regulatory pathways for approval of the competitor versions.

There is no assurance that the patents we are seeking will be granted or that the patents we hold will be found valid and enforceable if challenged. Moreover, patents relating to particular products, uses, formulations, or processes do not preclude other manufacturers from employing alternative processes or marketing alternative products or formulations that compete with our patented products. In addition, competitors or other third parties may assert claims that our activities infringe patents or other intellectual property rights held by them, or allege a third-party right of ownership in our existing intellectual property. See Item 7, “Management’s Discussion and Analysis - Results of Operations - Executive Overview - Other Matters - Patent Matters,” and Item 1, "Business - Patents, Trademarks, and Other Intellectual Property Rights," for more details.

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Our long-term success depends on intellectual property protection; if our intellectual property rights are invalidated, circumvented, or weakened, our business will be adversely affected.

Our long-term success depends on our ability to continually discover or acquire, develop, and commercialize innovative new pharmaceutical products. Without strong intellectual property protection, we would be unable to generate the returns necessary to support the enormous investments in research and development and capital as well as other expenditures required to bring new drugs to the market.

Intellectual property protection varies throughout the world and is subject to change over time. In the U.S., in addition to the process for challenging patents which applies to our biologic products, the Hatch-Waxman Act provides generic companies powerful incentives to seek to invalidate our other human pharmaceutical patents. As a result, we expect that our U.S. patents on major pharmaceutical products will continue to be routinely challenged in litigation and administrative proceedings, and may not be upheld. In addition, a separate IPR process allows competitors to request review of issued patents by the USPTO without the protections of the Hatch-Waxman Act. Our patents may be invalidated via this review process. Although such a decision can be appealed to the courts, in certain circumstances a loss in such a proceeding could result in a competitor entering the market, while a win provides no precedential value - the same patent can still be challenged by other competitors. We face many generic manufacturer challenges to our patents outside the U.S. as well. The entry of generic competitors typically results in rapid and severe declines in revenues. In addition, competitors or other third parties may claim that our activities infringe patents or other intellectual property rights held by them. If successful, such claims could result in our being unable to market a product in a particular territory or being required to pay significant damages for past infringement or royalties on future sales. See Item 1, “Business - Patents, Trademarks, and Other Intellectual Property Rights,” Item 3, "Legal Proceedings," and Item 8, "Financial Statements and Supplementary Data - Note 15, Contingencies," for more details.

- **Our human pharmaceutical business is subject to increasing government price controls and other public and private restrictions on pricing, reimbursement, and access for our drugs, which could have a material adverse effect on our reputation or business.**

  Public and private payers are taking increasingly aggressive steps to control their expenditures for human pharmaceuticals by placing restrictions on pricing and reimbursement for, and patient access to, our medications. These pressures could continue to negatively affect our future revenues and net income.

  We expect pricing, reimbursement, and access pressures from both governments and private payers inside and outside the U.S. to become more severe. For more details, see Item 1, “Business - Regulations and Private Payer Actions Affecting Human Pharmaceutical Pricing, Reimbursement, and Access,” and Item 7, “Management’s Discussion and Analysis - Results of Operations - Executive Overview - Other Matters - Trends Affecting Pharmaceutical Pricing, Reimbursement, and Access.”

- **We face intense competition from multinational pharmaceutical companies, biotechnology companies, and lower-cost generic and biosimilar manufacturers, and such competition could have a material adverse effect on our business.**

  We compete with a large number of multinational pharmaceutical companies, biotechnology companies, and generic pharmaceutical companies. To compete successfully, we must continue to deliver to the market innovative, cost-effective products that meet important medical needs. Our product revenues can be adversely affected by the introduction by competitors of branded products that are perceived as superior by the marketplace, by generic or biosimilar versions of our branded products, and by generic or biosimilar versions of other products in the same therapeutic class as our branded products. Our revenues can also be adversely affected by treatment innovations that eliminate or minimize the need for treatment with our drugs. See Item 1, “Business - Competition” and "Business - Research and Development," for more details.

- **Changes in foreign currency rates or devaluation of a foreign currency can materially affect our revenue, cost of sales, and operating expenses.**

  As a global company with substantial operations outside the U.S., we face foreign currency risk exposure from fluctuating currency exchange rates. While we seek to manage a portion of these exposures through hedging and other risk management techniques, significant fluctuations in currency rates can have a material impact, either positive or negative, on our revenue, cost of sales, and operating expenses. In the event of an extreme devaluation of local currency, the price of our products could become unsustainable in the relevant market. See Item 7, “Management’s Discussion and Analysis - Financial Condition” for more details.

- **Unanticipated changes in our tax rates or exposure to additional tax liabilities could increase our income taxes and decrease our net income.**

  We are subject to income taxes in the U.S. and numerous foreign jurisdictions. Changes in the relevant tax laws, regulations, administrative practices, principles, and interpretations could adversely affect our future effective tax rates. The U.S. enacted tax reform legislation significantly revising the U.S. tax law, effective January 2018, and a number of other countries are actively considering or enacting tax changes. Modifications to key elements of the U.S. or international tax framework could have a material adverse effect on our consolidated operating results and cash flows. See Item 7, “Management’s Discussion and Analysis - Results of Operations - Executive Overview - Other Matters” and Item 8, "Financial Statements and Supplementary Data - Note 13, Income Taxes," for more details.

- **Failure, inadequacy, or breach of our information technology systems, infrastructure, and business information or violations of data protection laws could result in material harm to our business and reputation.**

  A great deal of confidential information owned by both us and our business partners is stored in our information systems, networks, and facilities or those of third parties. This includes valuable trade secrets and intellectual property, clinical trial information, corporate strategic plans, marketing plans, customer information, and personally identifiable information, such as employee and patient information (collectively, “confidential information”). We also rely to a large extent on the efficient and uninterrupted operation of complex information technology systems, infrastructure, and hardware (together “IT systems”), some of which are within the company’s control and some of which are within the control of third parties, to accumulate, process, store, and transmit large amounts of confidential information and other data. Maintaining the confidentiality, integrity and availability of our IT systems and confidential information is vital to our business.

  IT systems are vulnerable to system inadequacies, operating failures, service interruptions or failures, security breaches, malicious intrusions, or cyber-attacks from a variety of sources. Cyber-attacks are growing in their frequency, sophistication, and intensity, and are becoming increasingly difficult to detect, mitigate, or prevent. Cyber-attacks come in many forms, including the deployment of harmful malware, exploitation of vulnerabilities, denial-of-service attacks, the use of social engineering, and other means to compromise the confidentiality, integrity and availability of our IT systems, confidential information, and other data. Breaches resulting in the compromise, loss, theft, destruction, or unauthorized disclosure or use of confidential information, or the unauthorized access to, disruption of, or interference with our products and services, can occur in a variety of ways, including but not limited to, negligent or wrongful conduct by employees or others with permitted access to our systems and information, or wrongful conduct by hackers, competitors, certain governments, or other current or former company personnel. Our third party partners face similar risks.

  The failure or inadequacy of our IT systems, the compromise, loss, theft, destruction, or unauthorized disclosure or use of confidential information, or the unauthorized access to, disruption of, or interference with our products and services that rely on IT systems, could impair our ability to secure and maintain intellectual property rights; result in a product manufacturing interruption or failure, or in the interruption or failure of products or services that rely on IT systems; damage our operations, customer relationships, or reputation; or cause us to lose trade secrets or other competitive advantages. Unauthorized disclosure of personally identifiable information could expose us to significant sanctions for violations of data privacy laws and regulations around the world and could damage public trust in our company.

  To date, system inadequacies, operating failures, unauthorized access, service interruptions or failures, security breaches, malicious intrusions, cyber-attacks, and the compromise, loss, theft, destruction, or unauthorized disclosure or use of confidential information have not had a material impact on our consolidated results of operations. We have implemented measures to protect, detect, respond to, and minimize or prevent these risks; however, these measures may not be successful. If they are not successful, any of these events could result in material financial, legal, business, or reputational harm to our business .

- **Significant economic downturns or international trade disruptions or disputes could adversely affect our business and operating results.**

  While human pharmaceuticals and companion animal health products have not generally been sensitive to overall economic cycles, prolonged economic slowdowns could lead to decreased utilization of our products, affecting our sales volume. Our food animal business may be affected by depressed prices for our customers' end products. Declining tax revenues attributable to economic downturns increase the pressure on governments to reduce human health care spending, leading to increasing government efforts to control drug prices and utilization. Additionally, some customers, including governments or other entities reliant upon government funding, may be unable to pay in a timely manner for our products. Also, if our customers, suppliers, or collaboration partners experience financial difficulties, we could experience slower customer collections, greater bad debt expense, and performance defaults by suppliers or collaboration partners. Similarly, in the event of a significant economic downturn, we could have difficulty accessing credit markets.

  Significant portions of our business are conducted in Europe, including the U.K.; Asia; and other international geographies. Interruptions in international relationships such as the current negotiations between U.K. and the EU on the U.K.'s exit from the EU ("Brexit"), and trade disputes such as the current trade negotiations between the U.S. and China, could result in changes to regulations governing our products and our intellectual property, or otherwise affect our ability to do business. While we do not expect either circumstance to materially affect our business in a direct manner, these and similar events could adversely affect us, or our business partners or customers.

- **Pharmaceutical products can develop unexpected safety or efficacy concerns, which could have a material adverse effect on revenues and income.**

  Human pharmaceutical products receive regulatory approval based on data obtained in controlled clinical trials of limited duration. After approval, the products are used for longer periods of time by much larger numbers of patients; we and others (including regulatory agencies and private payers) collect extensive information on the efficacy and safety of our marketed products by continuously monitoring the use of our products in the marketplace. In addition, we or others may conduct post-marketing clinical studies on efficacy and safety of our marketed products. New safety or efficacy data from both market surveillance and post-marketing clinical studies may result in product label changes or other measures that could reduce the product's market acceptance and result in declining sales. Serious safety or efficacy issues that arise after product approval could result in voluntary or mandatory product recalls or withdrawals from the market. Safety issues could also result in costly product liability claims.

- **We face many product liability claims and are self-insured; we could face large numbers of claims in the future, which could adversely affect our business.**

  We are subject to a substantial number of product liability claims involving Actos®, Axiron®, Byetta®, Cialis, and Cymbalta among other products. See Item 8, "Financial Statements and Supplementary Data - Note 15, Contingencies," and Item 3, "Legal Proceedings," for more information on our current product liability litigation. Because of the nature of pharmaceutical products, we are and could in the future become subject to large numbers of product liability claims for these or other products in the future, which require substantial expenditures to resolve and, if involving marketed products, could adversely affect sales of the product. Due to a very restrictive market for product liability insurance, we are self-insured for product liability losses for all our currently marketed products.

- **Regulatory compliance problems could be damaging to the company.**

  The marketing, promotional, and pricing practices of human pharmaceutical manufacturers, as well as the manner in which manufacturers interact with purchasers, prescribers, and patients, are subject to extensive regulation. Many companies, including us, have been subject to claims related to these practices asserted by federal, state, and foreign governmental authorities, private payers, and consumers. These claims have resulted in substantial expense and other significant consequences to us. We are and could in the future become subject to such investigations, the outcomes of which

could include criminal charges and fines, penalties, or other monetary or non-monetary remedies, including exclusion from U.S. federal and other health care programs. In addition, regulatory issues concerning compliance with cGMP regulations (and comparable foreign regulations) for pharmaceutical products can lead to product recalls and seizures, fines and penalties, interruption of production leading to product shortages, and delays in the approvals of new products pending resolution of the issues. See Item 1, “Business - Government Regulation of Our Operations,” for more details.

- **Manufacturing difficulties or disruptions could lead to product supply problems.**

  Pharmaceutical and animal health manufacturing is complex and highly regulated. Manufacturing difficulties at our facilities or contracted facilities, or the failure or refusal of a contract manufacturer to supply contracted quantities, could result in product shortages, leading to lost revenue. Such difficulties or disruptions could result from quality or regulatory compliance problems; natural disasters; mechanical or information technology system vulnerabilities, such as system inadequacies, operating failures, service interruptions or failures, security breaches, malicious intrusions, or cyber-attacks from a variety of sources; or inability to obtain sole-source raw or intermediate materials. In addition, given the difficulties in predicting sales of new products and the very long lead times necessary for the expansion and regulatory qualification of pharmaceutical manufacturing capacity, it is possible that we could have difficulty meeting unanticipated demand for new products. See Item 1, “Business - Raw Materials and Product Supply,” for more details.

- **Reliance on third-party relationships and outsourcing arrangements could adversely affect our business.**

  We rely on third parties, including suppliers, distributors, alliances with other pharmaceutical and biotechnology companies, and third-party service providers, for selected aspects of product development, manufacture, commercialization, support for information technology systems, product distribution, and certain financial transactional processes. For example, we outsource the day-to-day management and oversight of our clinical trials to contract research organizations. Outsourcing these functions involves the risk that the third parties may not perform to our standards or legal requirements; may not produce reliable results; may not perform in a timely manner; may not maintain the confidentiality, integrity, and availability of our proprietary information; or may fail to perform at all. Failure of these third parties to meet their contractual, regulatory, confidentiality, or other obligations to us could have a material adverse effect on our business.

- **Our animal health segment faces risks related to increased generic competition, food and animal safety concerns, factors affecting global agricultural markets, and other risks.**

  The animal health segment may be impacted by, among other things, emerging restrictions and bans on the use of antibacterials in food-producing animals; perceived adverse effects on human health linked to the consumption of food derived from animals that utilize our products; increased regulation or decreased governmental support relating to the raising, processing, or consumption of food-producing animals; an outbreak of infectious disease carried by animals; adverse weather conditions and the availability of natural resources; adverse global economic conditions affecting agricultural markets; and failure of our research and development, acquisition, and licensing efforts to generate new products. The failure to manage these risks could have a material adverse effect on our revenues and income.

- **We may not realize the anticipated value or tax treatment for the divestiture of our interest in Elanco.**

  There are uncertainties and risks related to the timing and potential value to Elanco, Lilly, and our and their shareholders of the planned separation of the Elanco animal health business, including business, industry, and market risks, as well as risks involving realizing the anticipated tax-free nature of the separation. Failure to implement the separation effectively could result in a lower value to Lilly and to shareholders.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our principal domestic and international executive offices are located in Indianapolis. At December 31, 2018, we owned 12 production and distribution sites in the U.S. and Puerto Rico. Together with the corporate administrative offices, these facilities contain an aggregate of approximately 10.6 million square feet of floor area dedicated to production, distribution, and administration. Major production sites include Indianapolis and Clinton, Indiana; Carolina, Puerto Rico; Fort Dodge, Iowa; and Branchburg, New Jersey.

We own production and distribution sites in 13 countries outside the U.S. and Puerto Rico, containing an aggregate of approximately 5.9 million square feet of floor area. Major production sites include facilities in Ireland, France, China, the U.K., Spain, and Italy.

In the U.S., our research and development facilities contain an aggregate of approximately 4.2 million square feet of floor area, primarily consisting of owned facilities located in Indianapolis. We also lease smaller sites in San Diego, California and New York City, New York. Outside the U.S., we own smaller research and development facilities in the U.K., Australia, Spain, and lease smaller sites in Singapore.

We believe that none of our properties is subject to any encumbrance, easement, or other restriction that would detract materially from its value or impair its use in the operation of the business. The buildings we own are of varying ages and in good condition.

Item 3. Legal Proceedings

We are a party to various currently pending legal actions, government investigations, and environmental proceedings, and we anticipate that such actions could be brought against us in the future. The most significant of these matters are described below or, as noted, in Item 8, "Financial Statements and Supplementary Data - Note 15, Contingencies." While it is not possible to determine the outcome of the legal actions, investigations, and proceedings brought against us, we believe that, except as otherwise specifically noted in Item 8, "Financial Statements and Supplementary Data - Note 15, Contingencies," the resolution of all such matters will not have a material adverse effect on our consolidated financial position or liquidity, but could be material to our consolidated results of operations in any one accounting period.

Legal Proceedings Described in Note 15 to the Consolidated Financial Statements

See Item 8, "Financial Statements and Supplementary Data - Note 15, Contingencies," for information on various legal proceedings, including but not limited to:

- The patent litigation and administrative proceedings involving Alimta;
- The patent arbitration involving Adocia;
- The product liability litigation involving Cymbalta;
- The employee litigation in Brazil; and
- The insulin and glucagon pricing litigation.

That information is incorporated into this Item by reference.

Other Product Liability Litigation

We are named along with Takeda Chemical Industries, Ltd. and Takeda affiliates (collectively, Takeda) as a defendant in three purported product liability class actions in Canada related to Actos, which we commercialized with Takeda in Canada until 2009, including one in Ontario (*Casseres et al. v. Takeda Pharmaceutical North America, Inc., et al.*), one in Quebec (*Whyte et al. v. Eli Lilly et al.*), and one in Alberta (*Epp v. Takeda Canada et al.*). In general, plaintiffs in these actions alleged that Actos caused or contributed to their bladder cancer. We believe these lawsuits are without merit, and we and Takeda are defending against them vigorously.

We are named as a defendant in approximately 535 Byetta product liability lawsuits in the U.S. involving approximately 795 plaintiffs. Approximately 59 of these lawsuits, covering about 316 plaintiffs, are filed in California state court and coordinated in a Los Angeles Superior Court. Approximately 475 of the lawsuits, covering about 480 plaintiffs, are filed in federal court, the majority of which are coordinated in a multi-district litigation (MDL) in the U.S. District Court for the Southern District of California. Three lawsuits, representing

approximately five plaintiffs, have also been filed in various state courts. Approximately 525 of the lawsuits, involving approximately 760 plaintiffs, contain allegations that Byetta caused or contributed to the plaintiffs' cancer (primarily pancreatic cancer or thyroid cancer); most others allege Byetta caused or contributed to pancreatitis. In addition, two suits involving approximately nine plaintiffs allege that Byetta caused or contributed to renal injuries and one case alleges that Byetta caused or contributed to ampullary cancer. The federal and state trial courts granted summary judgment in favor of us and our co-defendants on the claims alleging pancreatic cancer. The plaintiffs appealed those rulings. In November 2017, the U.S. Court of Appeals for the Ninth Circuit reversed the U.S. District Court's grant of summary judgment based on that court's discovery rulings and remanded the cases for further proceedings. In November 2018, the California Court of Appeal reversed the state court's grant of summary judgment based on that court's discovery rulings and remanded for further proceedings. We are aware of approximately 20 additional claimants who have not yet filed suit. These additional claims allege damages for pancreatic cancer or thyroid cancer. We believe these lawsuits are without merit and are defending against them vigorously.

We are named as a defendant in approximately 500 Axiron product liability lawsuits in the U.S. involving approximately 550 plaintiffs. In about one-third of the cases, other manufacturers of testosterone are named as co-defendants. Nearly all of these lawsuits have been consolidated in a federal MDL in the U.S. District Court for the Northern District of Illinois. A small number of lawsuits have been filed in state courts. The cases generally allege cardiovascular and related injuries. We have reached agreement on a settlement framework that provides for a comprehensive resolution of nearly all of these personal injury claims alleging cardiovascular and related injuries from Axiron treatment. There can be no assurances, however, that a final settlement will be reached. We have also been engaged in litigation with Medical Mutual of Ohio ("MMO") who has filed a class action complaint against multiple manufacturers of testosterone products, including us, in the U.S. District Court for the Northern District of Illinois, on behalf of third-party payers who paid for those products seeking damages under the Federal Racketeer Influenced and Corrupt Organizations Act. MMO's motion for class certification was denied, and in February 2019, the District Court granted summary judgment in favor of defendants, dismissing MMO's lawsuit with prejudice. We continue to believe all of these lawsuits are without merit and are defending against them vigorously.

We are named as a defendant in approximately 295 Cialis product liability lawsuits in the U.S. These cases, many of which were originally filed in various federal courts, contain allegations that Cialis caused or contributed to the plaintiffs' cancer (melanoma). In December 2016, the Judicial Panel on Multidistrict Litigation (JPML) granted the plaintiffs' petition to have filed cases and an unspecified number of future cases coordinated into a federal MDL in the U.S. District Court for the Northern District of California, alongside an existing coordinated proceeding involving Viagra®. The JPML ordered the transfer of the existing cases to the now-renamed MDL *In re: Viagra (Sildenafil Citrate) and Cialis (Tadalafil) Products Liability Litigation*. We believe these lawsuits are without merit and are defending against them vigorously.

Other Patent Litigation

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

We have been named as a defendant in litigation filed by Genentech, Inc. in the U.S. District Court for the Southern District of California seeking a ruling that Genentech's patent would be infringed by our continued sales of Taltz. We believe this lawsuit is without merit and are defending against it vigorously.

We have been named as a defendant in litigation filed by Teva Pharmaceuticals International GMBH and Teva Pharmaceuticals USA, Inc. (collectively, Teva) in the U.S. District Court for the District of Massachusetts seeking a ruling that various patents would be infringed by our launch and continued sales of Emgality for the prevention of migraine in adults. We believe this lawsuit is without merit and are defending against it vigorously.

We have been engaged in U.S. patent litigation involving Forteo brought pursuant to procedures set out in the Hatch-Waxman Act. In January 2018, we reached a settlement agreement with Teva Pharmaceuticals USA, Inc. In April 2018, we filed a patent infringement suit against Apotex, Inc. (Apotex) and Apotex Corp. asserting

our Forteo pen injector device patent and this suit was dismissed in December 2018 by agreement between the parties. We do not expect generic Forteo to enter the market earlier than August 2019.

In Canada, several generic companies previously challenged the validity of our Zyprexa compound patent. In 2012, the Canadian Federal Court of Appeals affirmed the lower court's decision that the patent was invalid for lack of utility. In 2013, our petition for leave to appeal the decision to the Supreme Court of Canada was denied. Two of the generic companies, Apotex and Teva Canada Limited (Teva Canada), pursued claims for damages arising from our enforcement of the patent under Canadian regulations. The Apotex litigation is ongoing and trial is expected in 2020. In 2017, the court issued a ruling that Teva Canada is entitled to damages and the Canadian Federal Court of Appeals affirmed the lower court ruling. In November 2018, the Supreme Court of Canada denied our leave application. We then filed a motion asking the Supreme Court of Canada to reconsider its decision based on conflicting precedent handed down shortly after the denial of our leave application. We expect a decision on our reconsideration motion in the first quarter of 2019.

Other Matters

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

We are named as a defendant in a lawsuit in the U.S. District Court for the Eastern District of Texas seeking damages under the federal anti-kickback statute and state and federal false claims acts for certain patient support programs related to our products Humalog, Humulin, and Forteo. We believe this lawsuit is without merit and are defending against it vigorously.

We have received a civil investigative demand from the U.S. Attorney's Office for the Southern District of New York requesting documents and information relating to our contracts with, services performed by, and payments to pharmacy benefit managers. We are cooperating with this investigation.

The China National Development and Reform Commission is investigating our distributor pricing practices in China in connection with a broader inquiry into pharmaceutical industry pricing. We are cooperating with this investigation.

We, along with another pharmaceutical manufacturer, are named as co-defendants in *United States et al. ex rel. Streck v. Takeda Pharm. Am., Inc., et al.* , which was unsealed in the U.S. District Court for the Northern District of Illinois. The complaint alleges that the defendants should have treated certain credits from distributors as retroactive price increases and included such increases in calculating Average Manufacturer Prices (AMP). This complaint is connected to an inquiry that the U.S. Attorney's Office for the Eastern District of Pennsylvania and the Civil Division of the DOJ began in September 2015 concerning the treatment by various pharmaceutical companies, including us, of certain distribution service agreements with wholesalers when calculating and reporting AMP in connection with the Medicaid drug rebate program. We have since received a civil investigative demand from the Civil Division of the DOJ in connection with that inquiry and this lawsuit, and we are cooperating with that investigation.

Under the Comprehensive Environmental Response, Compensation, and Liability Act, commonly known as "Superfund," we have been designated as one of several potentially responsible parties with respect to the cleanup of fewer than 10 sites. Under Superfund, each responsible party may be jointly and severally liable for the entire amount of the cleanup.

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

Item 4. Mine Safety Disclosures

Not applicable.

Part II

Item 5. Market for the Registrant's Common Equity, Related Stockholder Matters, and Issuer Purchases of Equity Securities

You can find information relating to the principal market for our common stock and related stockholder matters at Item 6, "Selected Financial Data (unaudited)", Item 7, "Management's Discussion and Analysis of Results of Operations and Financial Condition", and Item 8, "Financial Statements and Supplementary Data - Note 19, Selected Quarterly Data (unaudited)." That information is incorporated here by reference.

The following table summarizes the activity related to repurchases of our equity securities during the fourth quarter ended December 31, 2018:

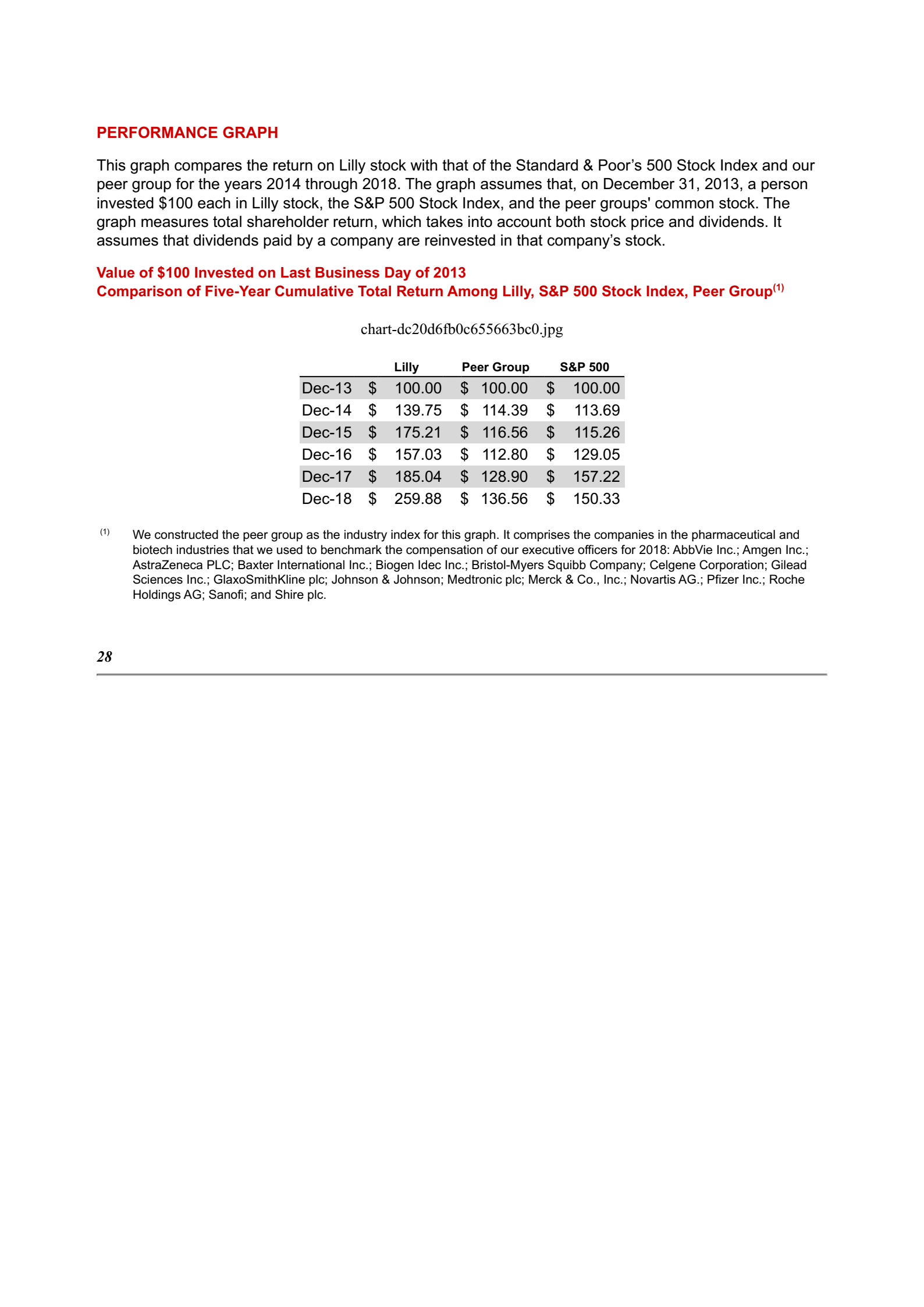
Period	Total Number of Shares Purchased (in thousands)	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs (in thousands)	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs (dollars in millions)
October 2018	8,972.2	$ 111.46	8,972.2	$ 6,000.0
November 2018	895.5	111.65	895.5	5,900.0
December 2018	—	—	—	5,900.0
Total	9,867.7	111.47	9,867.7	

During the three months ended December 31, 2018, we repurchased $1.10 billion of shares under the $8.00 billion share repurchase program authorized in June 2018.

PERFORMANCE GRAPH

This graph compares the return on Lilly stock with that of the Standard & Poor's 500 Stock Index and our peer group for the years 2014 through 2018. The graph assumes that, on December 31, 2013, a person invested $100 each in Lilly stock, the S&P 500 Stock Index, and the peer groups' common stock. The graph measures total shareholder return, which takes into account both stock price and dividends. It assumes that dividends paid by a company are reinvested in that company's stock.

Value of $100 Invested on Last Business Day of 2013
Comparison of Five-Year Cumulative Total Return Among Lilly, S&P 500 Stock Index, Peer Group[(1)]



	Lilly	Peer Group	S&P 500
Dec-13	$ 100.00	$ 100.00	$ 100.00
Dec-14	$ 139.75	$ 114.39	$ 113.69
Dec-15	$ 175.21	$ 116.56	$ 115.26
Dec-16	$ 157.03	$ 112.80	$ 129.05
Dec-17	$ 185.04	$ 128.90	$ 157.22
Dec-18	$ 259.88	$ 136.56	$ 150.33

(1) We constructed the peer group as the industry index for this graph. It comprises the companies in the pharmaceutical and biotech industries that we used to benchmark the compensation of our executive officers for 2018: AbbVie Inc.; Amgen Inc.; AstraZeneca PLC; Baxter International Inc.; Biogen Idec Inc.; Bristol-Myers Squibb Company; Celgene Corporation; Gilead Sciences Inc.; GlaxoSmithKline plc; Johnson & Johnson; Medtronic plc; Merck & Co., Inc.; Novartis AG.; Pfizer Inc.; Roche Holdings AG; Sanofi; and Shire plc.

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	**$ 24,555.7**	$ 22,871.3	$ 21,222.1	$ 19,958.7	$ 19,615.6
Cost of sales	**6,430.0**	6,150.8	5,710.1	5,054.5	4,959.2
Research and development	**5,307.1**	5,357.3	5,310.3	4,816.3	4,760.2
Marketing, selling, and administrative	**6,631.8**	6,680.1	6,528.0	6,548.3	6,643.4
Other[1]	**2,391.1**	2,485.7	299.7	749.6	252.5
Income before income taxes	**3,795.7**	2,197.4	3,374.0	2,790.0	3,000.3
Income taxes[2]	**563.7**	2,401.5	636.4	381.6	609.8
Net income (loss)	**3,232.0**	(204.1)	2,737.6	2,408.4	2,390.5
Net income (loss) as a percent of revenue	**13.2%**	(0.9%)	12.9%	12.1%	12.2%
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	**8,919.5**	8,826.5	8,252.6	8,053.5	7,963.9
Total assets	**43,908.4**	44,981.0	38,805.9	35,568.9	36,307.6
Long-term debt	**11,639.7**	9,940.5	8,367.8	7,972.4	5,332.8
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]	**14.9%**	109.3%	18.9%	13.7%	20.3%
Revenue per employee	**$ 635,000**	$ 563,000	$ 506,000	$ 484,000	$ 501,000
Number of employees	**38,680**	40,655	41,975	41,275	39,135
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 in Item 8 of Part II of this Annual Report on Form 10-K. Certain statements in this Item 7 of Part II of this Annual Report on Form 10-K constitute forward-looking statements. Various risks and uncertainties, including those discussed in "Forward-Looking Statements" and Item 1A, "Risk Factors," may cause our actual results, financial position, and cash generated from operations to differ materially from these forward-looking statements.

Executive Overview

This section provides an overview of our financial results, recent product and late-stage pipeline developments, and other matters affecting our company and the pharmaceutical industry. Earnings per share (EPS) data are presented on a diluted basis.

Financial Results

The following table summarizes our key operating results:

	Year Ended December 31,		Percent Change
	2018	2017	
Revenue	**$ 24,555.7**	$ 22,871.3	7
Gross margin	**18,125.7**	16,720.5	8
Gross margin as a percent of revenue	**73.8 %**	73.1 %	
Operating expense	**$ 11,938.9**	$ 12,037.4	(1)
Acquired in-process research and development	**1,983.9**	1,112.6	78
Asset impairment, restructuring, and other special charges	**482.0**	1,673.6	(71)
Income before income taxes	**3,795.7**	2,197.4	73
Income taxes	**563.7**	2,401.5	(77)
Net income (loss)	**3,232.0**	(204.1)	NM
Earnings (loss) per share	**3.13**	(0.19)	NM

NM - not meaningful

Revenue and gross margin increased in 2018. The decrease in operating expense in 2018 was due to decreases in marketing, selling, and administrative expense and research and development expense. Income before income taxes increased in 2018 as a higher gross margin, lower asset impairment, restructuring, and other special charges and, to a lesser extent, lower operating expense 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 (pretax), or $1.83 per share, 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 $482.0 million (pretax), or $0.41 per share, primarily associated with asset impairments related to the sale of the Posilac® (rbST) brand and the related sale of the Augusta, Georgia manufacturing site, as well as the suspension of commercial activities for Imrestor®. The charges also include expenses associated with the initial public offering (IPO) and separation of the Elanco animal health business, as well as 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, or $0.30 per share, 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 (pretax), or $0.97 per share, 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 $1.67 billion (pretax), or $1.23 per share, 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, or $1.81 per share, 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" 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.

Compound	Indication	U.S.	Europe	Japan	Developments
Immunology					
Mirikizumab	Psoriasis	Phase III			Phase III trials were initiated during the second quarter of 2018.
	Ulcerative colitis	Phase III			Phase III trial was initiated during the second quarter of 2018.
Olumiant	Rheumatoid arthritis	Launched			Granted approval of 2mg dose by FDA and launched in U.S. in second quarter of 2018.
	Atopic dermatitis	Phase III			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 Notes 3 and 10 to the consolidated financial statements for additional details.

We have announced our intent to divest our remaining 293,290,000 shares of Elanco common stock through an exchange offer and on February 8, 2019, Elanco filed a registration statement on Form S-4 with the Securities and Exchange Commission (SEC). In the exchange offer, our shareholders can exchange all, some, or none of their shares of our common stock for shares of Elanco common stock owned by us, subject to the specific terms and conditions of the offer described in Elanco's registration statement. The completion of the exchange offer is subject to certain conditions, including at least 146,645,000 shares of Elanco common stock being distributed in exchange for shares of our common stock validly tendered in the exchange offer, and the receipt of an opinion of counsel that the exchange offer will qualify for tax-free treatment to us and our participating shareholders. However, the conditions of the exchange offer may not be satisfied; we may exchange less than our entire interest in Elanco; or we may decide to waive one or more of these conditions, to the extent legally permissible, and consummate the exchange offer even if all of the conditions are not satisfied. If the exchange offer is not fully subscribed, we intend, from time to time, to complete subsequent exchange offers and/or pro rata spin-off of our remaining interest in Elanco.

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]	**$ 13,875.2**	$ 12,785.1	8
Outside U.S.	**10,680.5**	10,086.3	6
Revenue	**$ 24,555.7**	$ 22,871.3	7

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 %	7 %	8 %
Price	(1)%	(3)%	(1)%
Foreign exchange rates	— %	2 %	1 %
Percent change	8 %	6 %	7 %

Numbers may not add due to rounding.

In the U.S., the revenue increase in 2018 was driven by increased volume for newer pharmaceutical 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 pharmaceutical products, including Trulicity, Basaglar, Forteo, and Taltz.

Outside the U.S., the revenue increase in 2018 was due to increased volume for several newer pharmaceutical 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 pharmaceutical 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 human pharmaceutical products	**1,131.1**	**1,136.2**	**2,267.4**	1,694.3	34
Animal health products	**1,523.0**	**1,619.5**	**3,142.5**	3,085.6	2
Revenue	**$ 13,875.2**	**$ 10,680.5**	**$ 24,555.7**	$ 22,871.3	7

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.

Worldwide animal health revenue increased 2 percent, driven by higher prices, partially offset by lower volume. The overall increase in revenue included increased revenue in the companion animal disease prevention, future protein and health, and companion animal therapeutics product categories, partially offset by decreased revenue of products that are being exited.

Gross Margin, Costs, and Expenses

Gross margin as a percent of total revenue was 73.8 percent in 2018, an increase of 0.7 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 $5.31 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 decreased 1 percent to $6.63 billion in 2018 due to lower expenses related to late life-cycle products, partially offset by increased marketing expenses for newer products.

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 $482.0 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, as well as the suspension of commercial activities for Imrestor. The charges also include expenses associated with the initial public offering and separation of the Elanco animal health business, as well as efforts to reduce our cost structure. In 2017, we recognized $1.67 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, asset impairments related to lower projected revenue for Posilac (rbST), and asset impairments and other special charges related to product rationalizations and site closures resulting from our acquisition and integration of Novartis Animal Health (Novartis AH).

Other—net, (income) expense was income of $74.8 million in 2018 compared to income of $300.5 million in 2017 driven by lower net gains on sales of investments.

During 2018, we recorded income tax expense of $563.7 million while earning $3.80 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 $2.20 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,		Percent Change
	2017	2016	
Revenue	$ 22,871.3	$ 21,222.1	8
Gross margin	16,720.5	15,512.0	8
Gross margin as a percent of revenue	73.1 %	73.1 %	
Operating expense	$ 12,037.4	$ 11,838.3	2
Acquired in-process research and development	1,112.6	30.0	NM
Asset impairment, restructuring, and other special charges	1,673.6	382.5	NM
Income before income taxes	2,197.4	3,374.0	(35)
Income taxes	2,401.5	636.4	NM
Net income (loss)	(204.1)	2,737.6	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 (pretax), or $0.02 per share, 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 $382.5 million (pretax), or $0.29 per share, related to integration and severance costs related to the acquisition of Novartis AH, other global severance costs, and asset impairments primarily related to the closure of an animal health manufacturing facility in Ireland.

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

- We recognized charges of $203.9 million (pretax), or $0.19 per share, 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]	$ 12,785.1	$ 11,506.2	11
Outside U.S.	10,086.3	9,715.9	4
Revenue	$ 22,871.3	$ 21,222.1	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 to the prior year:

	2017 vs. 2016		
	U.S.	Outside U.S.	Consolidated
Volume	6 %	5 %	6 %
Price	5 %	(1 %)	2 %
Foreign exchange rates	— %	— %	— %
Percent change	11 %	4 %	8 %

Numbers may not add due to rounding.

In the U.S., the revenue increase in 2017 was driven by increased volume for newer pharmaceutical products, including Trulicity, Taltz, Basaglar, Lartruvo, and Jardiance, and higher realized prices for several pharmaceutical products, primarily Forteo and Cialis, as well as increased volume for companion animal products from the acquisition of Boehringer Ingelheim Vetmedica, Inc.'s U.S. feline, canine, and rabies vaccine portfolio and other related assets (BIVIVP). 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 and food animal products. 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 pharmaceutical 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 human pharmaceutical products	767.0	927.5	1,694.3	1,564.3	8
Animal health products	1,511.1	1,574.5	3,085.6	3,158.2	(2)
Revenue	$ 12,785.1	$ 10,086.3	$ 22,871.3	$ 21,222.1	8

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.

Worldwide food animal revenue decreased 8 percent, primarily driven by market access and competitive pressure in the U.S. for Posilac (rbST) and Optaflexx®, respectively. Worldwide companion animal revenue increased 10 percent, driven by the inclusion of $216.7 million in revenue from the acquisition of BIVIVP, partially offset by competitive pressure.

Gross Margin, Costs, and Expenses

Gross margin as a percent of total revenue was 73.1 percent in 2017, which remained flat compared with 2016.

Research and development expenses increased 1 percent to $5.36 billion in 2017.

Marketing, selling, and administrative expenses increased 2 percent to $6.68 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 $1.67 billion in 2017. The charges are primarily associated with efforts to reduce our cost structure, including the U.S. voluntary early retirement program, asset impairments related to lower projected revenue for Posilac (rbST), and asset impairments and other special charges related to product rationalizations and site closures resulting from our acquisition and integration of Novartis AH. In 2016, we recognized $382.5 million of asset impairment, restructuring, and other special charges primarily associated with integration and severance costs related to the acquisition of Novartis AH, other global severance costs associated with actions taken to reduce cost structure, and asset impairments primarily related to the closure of an animal health manufacturing facility in Ireland. See Note 5 to the consolidated financial statements for additional information.

Other-net, (income) expense was income of $300.5 million in 2017, compared with income of $112.8 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 $2.40 billion, which included a provisional tax charge of $1.91 billion, despite earning $2.20 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 18.9 percent.

FINANCIAL CONDITION

As of December 31, 2018, cash and cash equivalents were $8.00 billion, an increase of $1.46 billion, compared with $6.54 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 $2.11 billion and $7.18 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 $12.77 billion, a decrease of $876.2 million 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, partially offset by the debt incurred by Elanco as a result of a notes offering and entry into credit facilities totaling $2.48 billion. See Note 10 to the consolidated financial statements for additional details.

Excluding Elanco, at 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.

In September 2018, Elanco entered into a revolving credit agreement providing for a five-year $750.0 million senior unsecured revolving credit facility, which expires in September 2023. See Note 10 to the consolidated financial statements for additional details.

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.

We have separately announced our intent to divest our remaining interest in Elanco through an exchange offer. In the exchange offer, our shareholders can exchange all, some, or none of their shares of our common stock at a discount for shares of Elanco common stock owned by us, subject to the terms and conditions of the offer described in Elanco's registration statement, filed with the SEC on February 8, 2019.

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]	$ 16,605.7	$ 927.7	$ 1,690.5	$ 2,800.2	$ 11,187.3
Capital lease obligations	11.8	4.5	5.9	1.4	—
Operating leases	805.2	155.8	217.0	132.9	299.5
Purchase obligations[2]	17,019.6	16,805.5	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]	1,571.6	—	412.4	190.9	968.3
Total	$ 38,850.4	$ 18,053.3	$ 3,040.1	$ 3,867.9	$ 13,889.1

[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 $1.05 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 $275 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. pharmaceutical 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 $74.5 million and $29.8 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.

The fair value of any contingent consideration liability that results from a business combination is determined using a market approach based on quoted market values, significant other observable inputs for identical or comparable assets or liabilities, or a discounted cash flow analysis. Estimating the fair value of contingent consideration requires the use of significant estimates and judgments, including, but not limited to, revenue and the discount rate.

Financial Statement Impact

As of December 31, 2018, a 5 percent change in the contingent consideration liability would result in a change in income before income taxes of $3.71 million.

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.

FINANCIAL EXPECTATIONS FOR 2019

For the full year of 2019, we expect EPS to be in the range of $4.57 to $4.67, reflecting the anticipated impacts of the Loxo acquisition and the suspension of promotion of Lartruvo. We anticipate that total revenue will be between $25.1 billion and $25.6 billion. Revenue growth is expected to be driven by volume from newer products including Trulicity, Taltz, Basaglar, Jardiance, Verzenio, Cyramza, and Olumiant.

We anticipate that gross margin as a percent of revenue will be approximately 75 percent in 2019. Research and development expenses are expected to be in the range of $5.8 billion to $6.0 billion, reflecting additional expenses associated with the acquisition of Loxo. Marketing, selling, and administrative expenses are expected to be in the range of $6.4 billion to $6.7 billion. Other—net, (income) expense is expected to be expense in the range of $175 million to $325 million, reflecting additional interest expense associated with the acquisition of Loxo.

The 2019 tax rate is expected to be approximately 16.5 percent.

The individual elements of the 2019 financial guidance outlined above include consolidated financial expectations for both our human pharmaceutical business and Elanco.

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	**$ 24,555.7**	$ 22,871.3	$ 21,222.1
Costs, expenses, and other:			
Cost of sales	**6,430.0**	6,150.8	5,710.1
Research and development	**5,307.1**	5,357.3	5,310.3
Marketing, selling, and administrative	**6,631.8**	6,680.1	6,528.0
Acquired in-process research and development (Notes 3)	**1,983.9**	1,112.6	30.0
Asset impairment, restructuring, and other special charges (Note 5)	**482.0**	1,673.6	382.5
Other—net, (income) expense (Note 17)	**(74.8)**	(300.5)	(112.8)
	20,760.0	20,673.9	17,848.1
Income before income taxes	**3,795.7**	2,197.4	3,374.0
Income taxes (Note 13)	**563.7**	2,401.5	636.4
Net income (loss)	**$ 3,232.0**	$ (204.1)	$ 2,737.6
Earnings (loss) per share:			
Basic	**$ 3.14**	$ (0.19)	$ 2.59
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):			
Change in foreign currency translation gains (losses)	**(440.7)**	501.9	(436.4)
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)	**569.4**	(576.6)	(512.8)
Change in effective portion of cash flow hedges	**(6.0)**	27.8	11.7
Other comprehensive income (loss) before income taxes	**113.9**	(228.2)	(634.5)
Benefit (provision) for income taxes related to other comprehensive income (loss) items	**(30.3)**	402.7	(10.6)
Other comprehensive income (loss) (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)		**$ 7,998.2**	$ 6,536.2
Short-term investments (Note 7)		**88.2**	1,497.9
Accounts receivable, net of allowances of **$32.5 (2018)** and $38.7 (2017)		**5,246.5**	4,546.3
Other receivables		**958.4**	715.9
Inventories (Note 6)		**4,111.8**	4,458.3
Prepaid expenses and other		**2,146.5**	1,447.5
Total current assets		**20,549.6**	19,202.1
Other Assets			
Investments (Note 7)		**2,020.7**	5,678.8
Goodwill (Note 8)		**4,347.5**	4,370.1
Other intangibles, net (Note 8)		**3,521.0**	4,029.2
Deferred tax assets (Note 13)		**2,657.7**	1,166.4
Sundry		**1,892.4**	1,707.9
Total other assets		**14,439.3**	16,952.4
Property and equipment, net (Note 9)		**8,919.5**	8,826.5
Total assets		**$ 43,908.4**	$ 44,981.0
Liabilities and Equity			
Current Liabilities			
Short-term borrowings and current maturities of long-term debt (Note 10)		**$ 1,131.2**	$ 3,706.6
Accounts payable		**1,412.3**	1,410.7
Employee compensation		**1,054.5**	997.9
Sales rebates and discounts		**5,021.9**	4,465.1
Dividends payable		**650.8**	590.6
Income taxes payable (Note 13)		**404.0**	532.9
Other current liabilities		**2,213.4**	2,832.1
Total current liabilities		**11,888.1**	14,535.9
Other Liabilities			
Long-term debt (Note 10)		**11,639.7**	9,940.5
Accrued retirement benefits (Note 14)		**2,911.3**	3,513.9
Long-term income taxes payable (Note 13)		**3,724.6**	3,776.5
Other noncurrent liabilities		**2,835.6**	1,546.3
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								
	Common Stock		Additional Paid-in Capital	Retained Earnings	Employee Benefit Trust	Accumulated Other Comprehensive Loss	Common Stock in Treasury		Noncontrolling Interest
	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: $2.33				**(2,372.0)**					
Retirement of treasury shares	**(45,882)**	**(28.7)**		**(4,122.0)**			**(45,882)**	**4,150.7**	
Purchase of treasury shares							**45,882**	**(4,150.7)**	
Issuance of stock under employee stock plans, net	**2,849**	**1.8**	**(139.0)**				**(60)**	**6.4**	
Stock-based compensation			**279.5**						
Adoption of new accounting standards (Note 2)				**763.8**		**(105.2)**			
Sale of Elanco Stock (Note 3)			**629.2**			**9.0**			**1,017.2**
Other			**(3.9)**						**(14.2)**
Balance at December 31, 2018	**1,057,639**	**$ 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)		**—**	(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 3)		**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		**6,536.2**	4,582.1	3,666.4
Cash and Cash Equivalents at End of Year		**$ 7,998.2**	$ 6,536.2	$ 4,582.1

See notes to consolidated financial statements.

Notes to Consolidated Financial Statements

ELI LILLY AND COMPANY AND SUBSIDIARIES
(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.

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. In addition, Elanco completed a debt offering and entered into a term loan facility during the third quarter of 2018. See Notes 3 and 10 to the consolidated financial statements for additional information.

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	**$ 22,928.8**	$ 21,671.4	$ 20,388.4
Collaboration and other revenue[(1)]	**1,626.9**	1,199.9	833.7
Revenue	**$ 24,555.7**	$ 22,871.3	$ 21,222.1

[(1)] Collaboration and other revenue associated with prior year transfers of intellectual property was $303.2 million, $145.8 million, and $146.1 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 75 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 pharmaceutical products are sold to wholesalers that serve pharmacies, physicians and other health care professionals, and hospitals. Most of our animal health products are sold to wholesale distributors. We initially invoice our customers at contractual list prices. Contracts with direct and indirect customers may provide for various rebates and discounts that may differ in each contract. As a consequence, to determine the appropriate transaction price for our product sales at the time we recognize a sale to a direct customer, we must estimate any rebates or discounts that ultimately will be due to the direct customer and other customers in the distribution chain under the terms of our contracts. Significant judgments are required in making these estimates.

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

- The largest of our sales rebate and discount amounts are rebates associated with sales covered by managed care, Medicare, Medicaid, and chargeback contracts in the 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. pharmaceutical customers to return product for dating issues within a specified period prior to

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

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

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

Adjustments to Revenue

Adjustments to revenue recognized as a result of changes in estimates for the judgments described above during 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	**$ 299.3**	$ 335.2

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 $248.1 million for the year ended December 31, 2017, while increasing cost of sales by $80.6 million, research and development expenses by $75.5 million, and marketing, selling, and administrative expenses by $92.0 million for the same period. The application of the new standard resulted in reclassification to other income of $197.6 million for the year ended December 31, 2016, while increasing cost of sales by $55.2 million, research and development expenses by $66.4 million, and marketing, selling, and administrative expenses by $76.0 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	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 $650 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

	effect of initially applying the standard recognized at the date of initial application in retained earnings. We plan to use the latter approach.	consolidated statement of operations.

Note 3: Divestiture and Acquisitions

Divestiture

Formation of Elanco and Initial Public Offering

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

In connection with the completion of the IPO, through a series of equity and other transactions, we transferred to Elanco the animal health businesses that form its business going forward. In exchange, Elanco transferred to us, or will transfer to us, consideration of approximately $4.2 billion, which consists primarily of the net proceeds from the IPO, the net proceeds from the debt offering completed by Elanco in August 2018, and the term loan facility entered into by Elanco during the period (see Note 10). The consideration that we receive is intended to be used for debt repayment, dividends, and/or share repurchases. The excess of the net proceeds from the IPO over the net book value of our divested interest was $629.2 million and was recorded in additional paid-in capital. Of our consolidated cash and cash equivalents as of December 31, 2018, approximately $475 million is retained by Elanco for working capital purposes.

We continue to consolidate Elanco, as we retain control over Elanco. The earnings attributable to the divested, noncontrolling interest for the period from the IPO until December 31, 2018 were not material. As of December 31, 2018, the noncontrolling interest of $1.02 billion associated with Elanco is reflected in noncontrolling interests in the consolidated balance sheet.

We have announced our intent to divest our remaining 293,290,000 shares of Elanco common stock through an exchange offer and on February 8, 2019, Elanco filed a registration statement on Form S-4 with the SEC. In the exchange offer, our shareholders can exchange all, some, or none of their shares of our common stock for shares of Elanco common stock owned by us, subject to the specific terms and conditions of the offer described in Elanco's registration statement. The completion of the exchange offer is subject to certain conditions, including at least 146,645,000 shares of Elanco common stock being distributed in exchange for shares of our common stock validly tendered in the exchange offer, and the receipt of an opinion of counsel that the exchange offer will qualify for tax-free treatment to us and our participating shareholders. However, the conditions of the exchange offer may not be satisfied; we may exchange less than our entire interest in Elanco; or we may decide to waive one or more of these conditions, to the extent legally permissible, and consummate the exchange offer even if all of the conditions are not satisfied. If the exchange offer is not fully subscribed, we intend, from time to time, to complete subsequent exchange offers and/or pro rata spin-off of our remaining interest in Elanco.

Acquisitions

During 2017, we completed the acquisition of Boehringer Ingelheim Vetmedica, Inc.'s U.S. feline, canine, and rabies vaccine portfolio and other related assets (BIVIVP). This transaction, as further discussed in this note below in Acquisitions of Businesses was accounted for as a business combination under the acquisition method of accounting. We also had an immaterial acquisition of a business in 2016. Under this method, the assets acquired and liabilities assumed were recorded at their respective fair values as of the acquisition date in our consolidated financial statements. The determination of estimated fair value required management to make significant estimates and assumptions. The excess of the purchase price over the fair value of the acquired net assets, where applicable, has been recorded as goodwill. The results of operations of this acquisition have been included in our consolidated financial statements from the date of acquisition.

In addition to the acquisition of BIVIVP, 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.

Acquisitions of Businesses

Boehringer Ingelheim Vetmedica, Inc. Vaccine Portfolio Acquisition

Overview of Transaction

On January 3, 2017, we acquired BIVIVP in an all-cash transaction for $882.1 million. Under the terms of the agreement, we acquired a manufacturing and research and development site and a U.S. vaccine portfolio including vaccines used for the treatment of bordetella, Lyme disease, rabies, and parvovirus, among others.

Assets Acquired and Liabilities Assumed

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

Estimated Fair Value at January 3, 2017		
Inventories	$	108.6
Marketed products[1]		297.0
Property and equipment		148.2
Other assets and liabilities - net		8.2
Total identifiable net assets		562.0
Goodwill[2]		320.1
Total consideration transferred - net of cash acquired	$	882.1

[1] These intangible assets, which are being amortized to cost of sales on a straight-line basis over their estimated useful lives, were expected to have a weighted average useful life of 10 years.

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

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:			
Human pharmaceutical products	**$ 127.8**	$ 601.0	$ 85.9
Animal health products	**14.8**	96.4	40.8
Total severance	**142.6**	697.4	126.7
Pension and post-retirement medical charges associated with U.S. voluntary early retirement program (see Note 14):			
Human pharmaceutical products	**—**	446.7	—
Animal health products	**—**	67.0	—
Total pension and post-retirement medical charges associated with U.S. voluntary early retirement program	**—**	513.7	—
Asset impairment (gains from facility sales) and other special charges:			
Human pharmaceutical products	**46.0**	81.7	(13.0)
Animal health products	**293.4**	380.8	268.8
Total asset impairment and other special charges	**339.4**	462.5	255.8
Total asset impairment, restructuring, and other special charges	**$ 482.0**	$ 1,673.6	$ 382.5

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 $412.5 million and $284.9 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, as well as the decision to suspend commercialization of Imrestor®, an animal health product. We also incurred expenses associated with the IPO and separation of Elanco.

Asset impairment and other special charges related to animal health products 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. In addition, we incurred approximately $43.4 million of costs associated with the temporary shut down of our Puerto Rico facility following Hurricane Maria. The remaining asset impairment and other special charges recognized in 2017 and 2016 were primarily related to integration costs and asset impairments due to product rationalizations and site closures resulting from our acquisition and integration of Novartis Animal Health, including the closure of a manufacturing facility in Ireland in 2016 (refer to Note 8 for further detail relating to intangible asset impairments).

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	**$ 988.1**	$ 1,211.4
Work in process	**2,628.2**	2,697.7
Raw materials and supplies	**506.5**	488.8
Total (approximates replacement cost)	**4,122.8**	4,397.9
Increase (reduction) to LIFO cost	**(11.0)**	60.4
Inventories	**$ 4,111.8**	$ 4,458.3

Inventories valued under the LIFO method comprised $1.57 billion and $1.56 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 and $350.0 million swapping U.S. dollars to British pounds, which all will settle within 12 months.

In the normal course of business, our operations are exposed to fluctuations in interest rates which can vary the costs of financing, investing, and operating. We 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 20 percent of our long-term fixed-rate notes to floating rates through the use of interest rate swaps.

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

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

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: 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						
Cash equivalents	**$ 5,752.2**	**$ 5,752.2**	**$ 5,752.2**	**$ —**	**$ —**	**$ 5,752.2**
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]	**304.5**					
Noncurrent investments	**$ 2,020.7**					
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
	202.4	204.2	—	202.4	—	202.4

Mortgage-backed securities						
Asset-backed securities	653.9	656.0	—	653.9	—	653.9
Other securities	132.1	66.4	—	—	132.1	132.1
Marketable equity securities	281.3	131.0	281.3	—	—	281.3
Cost and equity method investments[2]	584.8					
Noncurrent investments	$ 5,678.8					

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

[2] Fair value disclosures are not applicable for equity method investments, 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	**$ (12,272.0)**	**$ —**	**$ (12,461.7)**	**$ —**	**$ (12,461.7)**
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)**
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)**
Contingent consideration liabilities:					
Other current liabilities	**(5.1)**	**—**	**—**	**(5.1)**	**(5.1)**
Other noncurrent liabilities	**(69.0)**	**—**	**—**	**(69.0)**	**(69.0)**
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	(208.0)	—	—	(208.0)	(208.0)
Other noncurrent liabilities	(45.2)	—	—	(45.2)	(45.2)

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 $215.9 million and $203.9 million, which primarily 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 by segment at December 31 was as follows:

	2018	2017
Human pharmaceutical products	**$ 1,366.6**	$ 1,366.8
Animal health	**2,980.9**	3,003.3
Total goodwill	**$ 4,347.5**	$ 4,370.1

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. The change in goodwill is the result of disposal of businesses and foreign exchange translation adjustments.

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	**$ 5,270.7**	**$ (1,848.2)**	**$ 3,422.5**	$ 7,682.0	$ (3,851.1)	$ 3,830.9
Other	**142.6**	**(63.7)**	**78.9**	171.2	(70.1)	101.1
Total finite-lived intangible assets	**5,413.3**	**(1,911.9)**	**3,501.4**	7,853.2	(3,921.2)	3,932.0
Indefinite-lived intangible assets:						
Acquired in-process research and development	**19.6**	**—**	**19.6**	97.2	—	97.2
Other intangibles	**$ 5,432.9**	**$ (1,911.9)**	**$ 3,521.0**	$ 7,950.4	$ (3,921.2)	$ 4,029.2

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 are capitalized as other 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 animal health intangible impairment charges of $68.9 million (comprised of a $55.9 million impairment of finite-lived intangible assets and a $13.0 million impairment of indefinite-lived intangible assets) 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 and competitive pressures for certain companion animal products resulting in a reduction of revenue. During 2017, we had animal health intangible impairment charges of $135.5 million (comprised of a $97.5 million impairment of finite-lived intangible assets and a $38.0 million impairment of indefinite-lived intangible assets) which were recorded in asset impairment, restructuring and other special charges on the consolidated statements of operations. These impairments were related to competitive pressures for certain companion animal products resulting in a reduction of revenue, as well as 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 12 years.

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

	2018	2017	2016
Amortization expense	**$ 558.7**	$ 683.4	$ 687.9

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	$ 343.3	$ 342.3	$ 339.6	$ 329.8	$ 318.4

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	**$ 193.1**	$ 192.7
Buildings	**7,683.8**	7,425.6
Equipment	**8,817.4**	8,689.0
Construction in progress	**1,769.7**	1,783.8
	18,464.0	18,091.1
Less accumulated depreciation	**(9,544.5)**	(9,264.6)
Property and equipment, net	**$ 8,919.5**	$ 8,826.5

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	**$ 879.6**	$ 763.1	$ 716.2
Rental expense	**223.2**	224.5	221.0

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

	2019	2020	2021	2022	2023	After 2023
Lease commitments	$ 155.8	$ 128.0	$ 89.0	$ 74.7	$ 58.2	$ 299.5

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)	**11,640.8**	10,756.7
Other long-term debt	**503.1**	13.6
Unamortized debt issuance costs	**(49.1)**	(49.0)
Fair value adjustment on hedged long-term notes	**177.2**	229.0
Total debt	**12,770.9**	13,647.1
Less current portion	**(1,131.2)**	(3,706.6)
Long-term debt	**$ 11,639.7**	$ 9,940.5

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 $6.17 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 August 2018, our subsidiary, Elanco, issued $2.00 billion of senior notes in a private placement. The senior notes are comprised of $500.0 million of 3.91 percent senior notes due in August 2021, $750.0 million of 4.27 percent senior notes due in August 2023, and $750.0 million of 4.90 percent senior notes due in August 2028. Interest is to be paid semi-annually and the interest rate payable on each series of senior notes is subject to adjustment if certain bond rating agencies downgrade, or subsequently upgrade, their ratings on the respective series of senior notes.

The indenture that governs the Elanco senior notes contains covenants, including limitations on the ability of Elanco and certain Elanco subsidiaries to incur liens or engage in sale-leaseback transactions. The indenture also contains restrictions on Elanco's ability to consolidate, merge or sell substantially all of their assets, in addition to other customary terms. Elanco was in compliance with all such covenants under the indentures governing the senior notes as of December 31, 2018.

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

In September 2018, Elanco entered into a revolving credit agreement with a syndicate of banks providing for a five-year $750.0 million senior revolving credit facility (Revolving Facility). The Revolving Facility bears interest at a variable rate plus specified margin as defined in the agreement and is payable quarterly. There were no borrowings outstanding under the Revolving Facility at December 31, 2018. The Revolving Facility is payable in full at the end of the term.

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

The Credit Facilities are subject to various financial and other covenants including restrictions on Elanco's level of borrowings based on their consolidated leverage ratio and their consolidated interest coverage ratio. Elanco was in compliance with all such covenants as of December 31, 2018.

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

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	$ 634.5	$ 33.5	$ 942.3	$ 1,439.0	$ 750.3

We have converted approximately 20 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 3.36 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	**$ 279.5**	$ 281.3	$ 255.3
Tax benefit	**58.7**	70.5	89.4

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 $63.7 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 $55.7 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 $112.2 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 $1.68 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	**$ (54.3)**	$ (100.6)	$ (57.0)
Foreign	**80.0**	38.5	378.9
State	**9.7**	4.0	(125.0)
2017 Tax Act	**201.5**	3,247.5	—
Total current tax expense	**236.9**	3,189.4	196.9
Deferred:			
Federal	**64.0**	801.5	517.0
Foreign	**285.6**	(256.3)	(83.3)
State	**3.4**	0.4	5.8
2017 Tax Act	**(26.2)**	(1,333.5)	—
Total deferred tax (benefit) expense	**326.8**	(787.9)	439.5
Income taxes	**$ 563.7**	$ 2,401.5	$ 636.4

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	**$ 2,655.9**	$ 443.1
Compensation and benefits	**814.2**	1,021.7
Tax credit carryforwards and carrybacks	**365.2**	473.0
Tax loss carryforwards and carrybacks	**271.7**	501.4
Product return reserves	**100.5**	88.4
Other comprehensive loss on hedging transactions	**68.9**	68.9
Debt	**40.3**	53.5
Contingent consideration	**17.7**	41.8
Other	**714.7**	555.8
Total gross deferred tax assets	**5,049.1**	3,247.6
Valuation allowances	**(596.3)**	(709.1)
Total deferred tax assets	**4,452.8**	2,538.5
Deferred tax liabilities:		
Earnings of foreign subsidiaries	**(1,692.3)**	(16.6)
Inventories	**(658.4)**	(654.8)
Property and equipment	**(311.7)**	(282.1)
Prepaid employee benefits	**(240.1)**	(231.5)
Intangibles	**(250.5)**	(314.6)
Financial instruments	**(22.7)**	(41.5)
Total deferred tax liabilities	**(3,175.7)**	(1,541.1)
Deferred tax assets - net	**$ 1,277.1**	$ 997.4

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 $735.4 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 $122.7 million, and state tax credits of $339.4 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 $922.8 million: $102.4 million will expire by 2023; $521.5 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 $106.1 million and other state carryforwards of $2.6 million are fully reserved.

Domestic and Puerto Rican companies contributed approximately 16 percent, 15 percent, and 70 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	**$ 1,101.5**	$ 246.5	$ 700.6

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	**$ 797.1**	$ 769.1	$ 1,180.9
Add (deduct):			
International operations, including Puerto Rico	**(629.7)**	(428.9)	(313.7)
General business credits	**(87.4)**	(66.8)	(58.3)
Non-deductible acquired IPR&D[(1)]	**309.9**	300.1	—
2017 Tax Act	**175.3**	1,914.0	—
Other	**(1.5)**	(86.0)	(172.5)
Income taxes	**$ 563.7**	$ 2,401.5	$ 636.4

[(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	**$ 1,014.5**	$ 853.4	$ 1,066.6
Additions based on tax positions related to the current year	**798.2**	133.8	73.4
Additions for tax positions of prior years	**414.9**	97.5	14.8
Reductions for tax positions of prior years	**(117.1)**	(59.3)	(15.2)
Settlements	**(33.2)**	(2.4)	(171.9)
Lapses of statutes of limitation	**(23.5)**	(19.3)	(110.0)
Changes related to the impact of foreign currency translation	**(6.8)**	10.8	(4.3)
Ending balance at December 31	**$ 2,047.0**	$ 1,014.5	$ 853.4

The total amount of unrecognized tax benefits that, if recognized, would affect our effective tax rate was $1.49 billion and $670.9 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 (benefit) expense	**$ 24.4**	$ 27.4	$ (52.5)

At December 31, 2018 and 2017, our accruals for the payment of interest and penalties totaled $197.2 million and $170.7 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	**$ 15,098.4**	$ 12,455.9	**$ 1,728.5**	$ 1,494.6
Service cost	**304.0**	331.3	**41.5**	46.4
Interest cost	**461.0**	413.4	**57.3**	52.9
Actuarial (gain) loss	**(1,431.2)**	1,580.5	**(182.8)**	40.0
Benefits paid	**(582.1)**	(486.3)	**(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	**(161.9)**	396.0	**(6.2)**	12.0
Benefit obligation at end of year	**13,661.9**	15,098.4	**1,543.9**	1,728.5
Change in plan assets:				
Fair value of plan assets at beginning of year	**11,844.5**	10,179.7	**2,372.4**	1,961.2
Actual return on plan assets	**(370.3)**	1,447.6	**32.6**	462.0
Employer contribution	**324.7**	414.3	**75.9**	9.1
Benefits paid	**(582.1)**	(486.3)	**(82.8)**	(60.1)
Foreign currency exchange rate changes and other adjustments	**(152.6)**	289.2	**—**	0.2
Fair value of plan assets at end of year	**11,064.2**	11,844.5	**2,398.1**	2,372.4
Funded status	**(2,597.7)**	(3,253.9)	**854.2**	643.9
Unrecognized net actuarial loss	**5,011.8**	5,645.5	**140.6**	182.0
Unrecognized prior service (benefit) cost	**25.8**	15.2	**(299.9)**	(395.0)
Net amount recognized	**$ 2,439.9**	$ 2,406.8	**$ 694.9**	$ 430.9
Amounts recognized in the consolidated balance sheet consisted of:				
Sundry	**$ 196.0**	$ 106.8	**$ 1,043.6**	$ 869.0
Other current liabilities	**(64.5)**	(64.8)	**(7.3)**	(7.1)
Accrued retirement benefits	**(2,729.2)**	(3,295.9)	**(182.1)**	(218.0)
Accumulated other comprehensive (income) loss before income taxes	**5,037.6**	5,660.7	**(159.3)**	(213.0)

Net amount recognized	**$ 2,439.9**	$ 2,406.8	**$ 694.9**	$ 430.9

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 Elanco employees effective January 1, 2019. We remeasured the impacted pension and retiree health plans' benefit obligations as of July 31, 2018, which resulted in a net curtailment gain of $28.0 million, 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 $1.62 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 was recorded in asset impairment, restructuring, and other special charges, 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 $2.88 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	**3.9%**	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	**7.3**	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	$ 609.9	$ 613.6	$ 623.6	$ 638.2	$ 647.9	$ 3,560.6
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	**$ 11,813.4**	$ 13,025.0
Fair value of plan assets	**9,019.7**	9,664.3

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	**$ 11,032.1**	$ 11,956.7	**$ 189.4**	$ 225.1
Fair value of plan assets	**9,019.7**	9,639.4	**—**	—

The total accumulated benefit obligation for our defined benefit pension plans was $12.76 billion and $13.90 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	**$ 304.0**	$ 331.3	$ 277.7	**$ 41.5**	$ 46.4	$ 39.1
Interest cost	**461.0**	413.4	420.8	**57.3**	52.9	53.2
Expected return on plan assets	**(848.3)**	(776.0)	(752.1)	**(177.9)**	(160.7)	(150.2)
Amortization of prior service (benefit) cost	**4.8**	5.7	11.8	**(79.5)**	(90.0)	(85.8)
Recognized actuarial loss	**334.4**	288.2	285.6	**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	**$ 257.2**	$ 673.3	$ 243.8	**$ (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	**$ 211.1**	$ (915.1)	$ (725.2)	**$ 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	**4.8**	5.7	11.8	**(79.5)**	(90.0)	(85.8)
Amortization of net actuarial loss included in net income	**334.4**	288.2	285.6	**6.1**	18.4	19.1
Foreign currency exchange rate changes and other	**45.2**	(105.3)	75.6	**(0.1)**	(3.3)	2.5
Total other comprehensive income (loss) during period	**$ 623.1**	$ (723.3)	$ (352.2)	**$ (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 $153.5 million, $169.1 million, and $175.0 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.	$ 619.9	$ 410.1	$ —	$ —	$ 209.8
International	2,117.8	828.8	—	1.8	1,287.2
Fixed income:					
Developed markets	2,963.2	25.0	2,173.3	—	764.9
Developed markets - repurchase agreements	(1,225.5)	—	(1,225.5)	—	—
Emerging markets	571.6	4.1	256.2	6.1	305.2
Private alternative investments:					
Hedge funds	2,801.9	—	—	—	2,801.9
Equity-like funds	1,942.5	—	—	16.8	1,925.7
Real estate	525.8	147.2	—	—	378.6
Other	747.0	213.3	86.1	—	447.6
Total	$ 11,064.2	$ 1,628.5	$ 1,290.1	$ 24.7	$ 8,120.9
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.	$ 466.2	$ 199.6	$ —	$ —	$ 266.6
International	2,934.2	955.1	—	—	1,979.1
Fixed income:					
Developed markets	3,182.9	28.7	2,468.2	—	686.0
Developed markets - repurchase agreements	(1,372.9)	—	(1,372.9)	—	—
Emerging markets	584.7	4.2	252.0	3.1	325.4
Private alternative investments:					
Hedge funds	2,984.6	—	—	—	2,984.6
Equity-like funds	1,639.6	—	—	16.8	1,622.8
Real estate	563.9	338.6	—	—	225.3
Other	861.3	119.2	602.8	2.2	137.1
Total	$ 11,844.5	$ 1,645.4	$ 1,950.1	$ 22.1	$ 8,226.9
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. 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):

(Amounts presented net of taxes)	Foreign Currency Translation Gains (Losses)	Unrealized Net Gains (Losses) on Securities	Defined Benefit Pension and Retiree Health Benefit Plans	Effective Portion of Cash Flow Hedges	Accumulated Other Comprehensive Loss
Beginning balance at January 1, 2016	$ (1,360.2)	$ 10.1	$ (3,012.1)	$ (218.5)	$ (4,580.7)
Other comprehensive income (loss) before reclassifications	(581.6)	206.7	(518.7)	(2.2)	(895.8)
Net amount reclassified from accumulated other comprehensive loss	74.5	7.2	159.2	9.8	250.7
Net other comprehensive income (loss)	(507.1)	213.9	(359.5)	7.6	(645.1)
Balance at December 31, 2016[1]	(1,867.3)	224.0	(3,371.6)	(210.9)	(5,225.8)
Other comprehensive income (loss) before reclassifications	664.6	(15.7)	(543.4)	8.5	114.0
Net amount reclassified from accumulated other comprehensive loss	8.1	(110.6)	153.4	9.6	60.5
Net other comprehensive income (loss)	672.7	(126.3)	(390.0)	18.1	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]	(1,233.4)	113.5	(4,340.7)	(234.3)	(5,694.9)
Reclassification due to adoption of new accounting standard[3]	**—**	**(128.9)**	**—**	**—**	**(128.9)**
Other comprehensive income (loss) before reclassifications	**(389.1)**	**24.5**	**274.0**	**(16.3)**	**(106.9)**
Net amount reclassified from accumulated other comprehensive loss	**—**	**(31.2)**	**210.0**	**11.7**	**190.5**
Net other comprehensive income (loss)	**(389.1)**	**(6.7)**	**484.0**	**(4.6)**	**83.6**
Ending balance at December 31, 2018[4]	**$ (1,622.5)**	**$ (22.1)**	**$ (3,856.7)**	**$ (238.9)**	**$ (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	**$ (74.7)**	$ (84.3)	$ (74.0)	Other—net, (income) expense
Actuarial losses	**340.5**	306.6	304.7	Other—net, (income) expense
Total before tax	**265.8**	222.3	230.7	
Tax benefit	**(55.8)**	(68.9)	(71.5)	Income taxes
Net of tax	**210.0**	153.4	159.2	
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]	**11.7**	17.7	84.3	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	**$ 272.1**	$ 225.0	$ 185.2
Interest income	**(161.3)**	(167.3)	(108.7)
Venezuela charge	**—**	—	203.9
Retirement benefit	**(242.1)**	(248.1)	(197.6)
Other (income) expense	**56.5**	(110.1)	(195.6)
Other–net, (income) expense	**$ (74.8)**	$ (300.5)	$ (112.8)

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 year ended December 31, 2018, other expense was primarily driven by net foreign exchange losses. 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

We have two operating segments—human pharmaceutical products and animal health products. Our operating segments are distinguished by the ultimate end user of the product—humans or animals. Performance is evaluated based on profit or loss from operations before income taxes. The accounting policies of the individual segments are the same as those described throughout the notes to the consolidated financial statements.

Our human pharmaceutical products segment includes the discovery, development, manufacturing, marketing, and sale of human pharmaceutical products worldwide in the following therapeutic areas: endocrinology, oncology, cardiovascular, neuroscience, immunology, and other. 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.

Our animal health segment, operating through our Elanco animal health division, includes the development, manufacturing, marketing, and sales of animal health products worldwide for both food and companion animals. Animal health products include Rumensin®, Maxiban®, Denagard®, Tylan®, and other products for livestock and poultry, as well as Trifexis®, Interceptor®, Comfortis®, and other products for companion animals. The animal health segment for the years ended December 31, 2018 and 2017, included the results of operations from BIVIVP, which was acquired on January 3, 2017 (Note 3).

Most of our pharmaceutical 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 11 percent and 18 percent of consolidated total revenue. Further, they each accounted for between 14 percent and 22 percent of accounts receivable as of December 31, 2018 and 2017. Animal health products are sold primarily to wholesale distributors.

Our chief operating decision maker does not review any asset information by operating segment and, accordingly, we do not report asset information by operating segment.

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**
Segment revenue—to unaffiliated customers:						
Human pharmaceutical products:						
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 human pharmaceutical products	**58.7**	50.9	42.6	**176.6**	190.3	157.8
Total human pharmaceutical products	**12,352.2**	11,274.0	9,941.7	**9,061.0**	8,511.7	8,122.2
Animal health products	**1,523.0**	1,511.1	1,564.5	**1,619.5**	1,574.5	1,593.7
Revenue	**$ 13,875.2**	$ 12,785.1	$ 11,506.2	**$ 10,680.5**	$ 10,086.3	$ 9,715.9

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
Segment profits:			
Human pharmaceutical products	**$ 6,217.8**	$ 5,139.7	$ 4,010.0
Animal health products	**607.3**	561.3	663.7
Total segment profits	**$ 6,825.1**	$ 5,701.0	$ 4,673.7
Reconciliation of total segment profits to consolidated income before taxes:			
Segment profits	**$ 6,825.1**	$ 5,701.0	$ 4,673.7
Other profits (losses):			
Amortization of intangible assets (Note 8)	**(546.0)**	(674.8)	(683.3)
Asset impairment, restructuring, and other special charges (Note 5)	**(482.0)**	(1,673.6)	(382.5)
Venezuela charge (Note 17)	**—**	—	(203.9)
Acquired in-process research and development (Note 3)	**(1,983.9)**	(1,112.6)	(30.0)
Inventory fair value adjustment related to acquisition of BIVIVP (Note 3)	**—**	(42.7)	—
Other, net	**(17.5)**	—	—
Consolidated income before taxes	**$ 3,795.7**	$ 2,197.4	$ 3,374.0

Numbers may not add due to rounding.

Depreciation and software amortization expense included in our segment profits was as follows:

	2018	2017	2016
Human pharmaceutical products	**$ 934.0**	$ 789.8	$ 723.4
Animal health products	**111.3**	102.7	89.9
Total depreciation expense and software amortization included in segment profits	**$ 1,045.3**	$ 892.5	$ 813.3

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

	2018	2017	2016
Geographic Information			
Revenue—to unaffiliated customers[(1)]:			
United States	**$ 13,875.2**	$ 12,785.1	$ 11,506.2
Europe	**4,231.1**	3,943.2	3,768.1
Japan	**2,493.7**	2,419.7	2,330.9
Other foreign countries	**3,955.7**	3,723.3	3,616.9
Revenue	**$ 24,555.7**	$ 22,871.3	$ 21,222.1
Long-lived assets[(2)]:			
United States	**$ 4,946.6**	$ 5,013.4	$ 4,984.6
Europe	**2,708.1**	2,550.1	2,140.7
Japan	**181.9**	155.1	92.4
Other foreign countries	**1,695.5**	1,761.7	1,776.8
Long-lived assets	**$ 9,532.1**	$ 9,480.3	$ 8,994.5

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	$ 6,438.6	$ 6,061.9	$ 6,355.2	$ 5,700.0
Cost of sales	1,593.7	1,562.3	1,702.7	1,571.3
Operating expenses[1]	3,315.3	2,959.9	2,986.8	2,676.9
Acquired in-process research and development[2]	329.4	30.0	1,624.5	—
Asset impairment, restructuring, and other special charges	246.0	83.3	74.4	78.3
Income before income taxes	938.9	1,411.0	4.8	1,441.0
Income taxes[3]	(186.2)	261.5	264.7	223.6
Net income (loss)	1,125.1	1,149.5	(259.9)	1,217.4
Earnings (loss) per share—basic	1.11	1.13	(0.25)	1.16
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	$ 6,160.7	$ 5,658.0	$ 5,824.3	$ 5,228.3
Cost of sales[4]	1,644.9	1,586.3	1,571.7	1,347.9
Operating expenses[1][4]	3,290.4	2,918.5	3,002.5	2,826.0
Acquired in-process research and development[2]	50.0	205.0	—	857.6
Asset impairment, restructuring, and other special charges[5]	1,003.2	406.5	50.0	213.9
Income before income taxes	284.1	591.6	1,260.5	61.2
Income taxes[3]	1,941.0	36.0	252.5	172.0
Net income (loss)	(1,656.9)	555.6	1,008.0	(110.8)
Earnings (loss) per share—basic	(1.58)	0.53	0.96	(0.10)
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.

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 our annual report on Form 10-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.

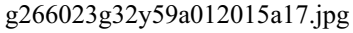
Adoption of Accounting Standards Update ("ASU") No. 2016-16

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

Indianapolis, Indiana

February 19, 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.

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Indianapolis, Indiana

February 19, 2019

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

Under applicable Securities and Exchange Commission (SEC) regulations, management of a reporting company, with the participation of the principal executive officer and principal financial officer, must periodically evaluate the company's "disclosure controls and procedures," which are defined generally as controls and other procedures designed to ensure that information required to be disclosed by the reporting company in its periodic reports filed with the SEC (such as this Form 10-K) is recorded, processed, summarized, and reported on a timely basis.

Our management, with the participation of David A. Ricks, president and chief executive officer, and Joshua L. Smiley, senior vice president and chief financial officer, evaluated our disclosure controls and procedures as of December 31, 2018, and concluded that they were effective.

Internal Control over Financial Reporting

Mr. Ricks and Mr. Smiley provided a report on behalf of management on our internal control over financial reporting, in which management concluded that the company's internal control over financial reporting is effective at December 31, 2018. In addition, Ernst & Young LLP, the company's independent registered public accounting firm, provided an attestation report on the company's internal control over financial reporting as of December 31, 2018. You can find the full text of management's report and Ernst & Young's attestation report in Item 8, and both reports are incorporated by reference in this Item.

Changes in Internal Controls

During the fourth quarter of 2018, there were no changes in our internal control over financial reporting that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

Ellen Marram will retire from our board of directors effective May 6, 2019.

Part III

Item 10. Directors, Executive Officers, and Corporate Governance

Directors and Executive Officers

Information relating to our Board of Directors is found in our Definitive Proxy Statement to be dated on or about March 22, 2019 (the Proxy Statement) under “Board of Directors” and is incorporated in this report by reference.

Information relating to our executive officers is found at Item 1, "Business - Executive Officers of the Company.”

Code of Ethics

Information relating to our code of ethics is found in our Proxy Statement under “Code of Ethics” and is incorporated in this report by reference.

Corporate Governance

Information about the procedures by which shareholders can recommend nominees to our board of directors is found in our Proxy Statement under “Director Qualifications and Nomination Process” and is incorporated in this report by reference.

The board has appointed an audit committee consisting entirely of independent directors in accordance with applicable SEC and New York Stock Exchange rules for audit committees. Information about our audit committee is found in our Proxy Statement under “Audit Committee” and is incorporated in this report by reference.

Section 16(a) Reporting Compliance

Information about our compliance with Section 16(a) is found in our Proxy Statement under “Other Matters - Section 16(a) Beneficial Ownership Reporting Compliance” and is incorporated in this report by reference.

Item 11. Executive Compensation

Information on director compensation, executive compensation, and compensation committee matters can be found in the Proxy Statement under “Director Compensation,” "Committees of the Board of Directors - Compensation Committee," "Compensation Discussion and Analysis," and “Executive Compensation.” That information is incorporated in this report by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

Security Ownership of Certain Beneficial Owners and Management

Information relating to ownership of the company's common stock by management and by persons known by the company to be the beneficial owners of more than five percent of the outstanding shares of common stock is found in the Proxy Statement under "Ownership of Company Stock." That information is incorporated in this report by reference.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table presents information as of December 31, 2018, regarding our compensation plans under
which shares of Lilly common stock have been authorized for issuance.

Plan category	(a) Number of securities to be issued upon exercise of outstanding options, warrants, and rights [1]	(b) Weighted-average exercise price of outstanding options, warrants, and rights	(c) Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders	—	$ —	53,253,739
Equity compensation plan not approved by security holders	—	—	—
Total	—	—	53,253,739

[1] 11,153,234 shares are underlying outstanding equity awards other than options

Item 13. Certain Relationships and Related Transactions, and Director Independence

Related Person Transactions

Information relating to one related person transaction and the board's policies and procedures for approval of related person transactions can be found in the Proxy Statement under "Highlights of the Company's Corporate Governance - Conflicts of Interest and Transactions with Related Persons." That information is incorporated in this report by reference.

Director Independence

Information relating to director independence can be found in the Proxy Statement under "Director Independence" and is incorporated in this report by reference.

Item 14. Principal Accountant Fees and Services

Information related to the fees and services of our principal independent accountants, Ernst & Young LLP, can be found in the Proxy Statement under "Item 3. Proposal to Ratify the Appointment of Principal Independent Auditor - Audit Committee Report - Services Performed by the Independent Auditor" and "Independent Auditor Fees." That information is incorporated in this report by reference.

Item 15. Exhibits and Financial Statement Schedules

(a)1. Financial Statements

The following consolidated financial statements of the company and its subsidiaries are found at Item 8:

- Consolidated Statements of Operations—Years Ended December 31, 2018, 2017, and 2016
- Consolidated Statements of Comprehensive Income—Years Ended December 31, 2018, 2017, and 2016
- Consolidated Balance Sheets—December 31, 2018 and 2017
- Consolidated Statements of Shareholders' Equity—Years Ended December 31, 2018, 2017, and 2016
- Consolidated Statements of Cash Flows—Years Ended December 31, 2018, 2017, and 2016
- Notes to Consolidated Financial Statements

(a)2. Financial Statement Schedules

The consolidated financial statement schedules of the company and its subsidiaries have been omitted because they are not required, are inapplicable, or are adequately explained in the financial statements.

Financial statements of interests of 50 percent or less, which are accounted for by the equity method, have been omitted because they do not, considered in the aggregate as a single subsidiary, constitute a significant subsidiary.

(a)3. Exhibits

2.1	Agreement and Plan of Merger, dated January 5, 2019, among Eli Lilly and Company, Bowfin Acquisition Corporation and Loxo Oncology, Inc.
2.2	Master Separation Agreement, dated September 24, 2018, between Eli Lilly and Company and Elanco Animal Health Incorporated
3.1	Amended Articles of Incorporation
3.2	Bylaws, as amended
4.1	Indenture with respect to Debt Securities dated as of February 1, 1991, between Eli Lilly and Company and Deutsche Bank Trust Company Americas, as successor trustee to Citibank, N.A., Trustee
4.2	Agreement dated September 13, 2007 appointing Deutsche Bank Trust Company Americas as Successor Trustee under the Indenture listed above
10.1	Amended and Restated 2002 Lilly Stock Plan[(1)]
10.2	Form of Performance Award under the 2002 Lilly Stock Plan[(1)]
10.3	Form of Shareholder Value Award under the 2002 Lilly Stock Plan[(1)]
10.4	The Lilly Deferred Compensation Plan, as amended[(1)]
10.5	The Lilly Directors' Deferral Plan, as amended[(1)]
10.6	The Eli Lilly and Company Bonus Plan, as amended[(1)]
10.7	The Eli Lilly and Company Executive Officer Incentive Plan[(1)]
10.8	2007 Change in Control Severance Pay Plan for Select Employees, as amended[(1)]
10.9	Elanco Corporate Bonus[(1)]
10.10	Form of Elanco Stock Plan[(1)]
10.11	Form of 2018 Change in Control Severance Pay Plan for Select Employees[(1)]
10.12	Elanco RSU Awards Agreement[(1)]
10.13	Elanco Nonqualified Stock Option Agreement[(1)]
21	List of Subsidiaries
23	Consent of Independent Registered Public Accounting Firm
31.1	Rule 13a-14(a) Certification of David A. Ricks, President and Chief Executive Officer
31.2	Rule 13a-14(a) Certification of Joshua L. Smiley, Senior Vice President and Chief Financial Officer
32	Section 1350 Certification
101	Interactive Data File

[(1)] Indicates management contract or compensatory plan.

Item 16. Form 10-K Summary

Not applicable.

Index to Exhibits

The following documents are filed as part of this report:

Exhibit		Location
2.1	Agreement and Plan of Merger, dated January 5, 2019, among Eli Lilly and Company, Bowfin Acquisition Corporation and Loxo Oncology, Inc.	Incorporated by reference to Exhibit 2.1 to the Current Report on Form 8-K filed by Loxo Oncology on January 7, 2019
2.2	Master Separation Agreement, dated September 24, 2018, between Eli Lilly and Company and Elanco Animal Health Incorporated	Incorporated by reference to Exhibit 10.1 to Elanco Animal Health Incorporated's Report on Form 8-K dated September 26, 2018
3.1	Amended Articles of Incorporation	Incorporated by reference to Exhibit 3.1 to the Company's Report on Form 10-K for the year ended December 31, 2013 (SEC File No. 001-06351, Film No. 14624999)
3.2	Bylaws, as amended	Bylaws, as amended, are incorporated by reference to Exhibit 99.1 to the Company's Report on Form 8-K dated on December, 17, 2018
4.1	Indenture with respect to Debt Securities dated as of February 1, 1991, between Eli Lilly and Company and Deutsche Bank Trust Company Americas, as successor trustee to Citibank, N.A., Trustee	Incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-3, Registration No. 333-186979
4.2	Agreement dated September 13, 2007 appointing Deutsche Bank Trust Company Americas as Successor Trustee under the Indenture listed above	Incorporated by reference to Exhibit 4.2 to the Company's Report on Form 10-K for the year ended December 31, 2008 (SEC File No. 001-06351, Film No. 09640420)
10.1	Amended and Restated 2002 Lilly Stock Plan	Incorporated by reference to Exhibit 10.1 to the Company's Report on Form 10-Q for the quarter ended June 30, 2018
10.2	Form of Performance Award under the 2002 Lilly Stock Plan	Attached
10.3	Form of Shareholder Value Award under the 2002 Lilly Stock Plan	Attached
10.4	The Lilly Deferred Compensation Plan, as amended	Incorporated by reference to Exhibit 10.5 to the Company's Report on Form 10-K for the year ended December 31, 2013
10.5	The Lilly Directors' Deferral Plan, as amended	Incorporated by reference to Exhibit 10 to the Company's Report on Form 10-Q for the quarter ended June 30, 2017
10.6	The Eli Lilly and Company Bonus Plan, as amended	Incorporated by reference to Exhibit 10.7 to the Company's Report on Form 10-K for the year ended December 31, 2013 (SEC File No. 001-06351, Film No. 14624999)
10.7	The Eli Lilly and Company Executive Officer Incentive Plan	Incorporated by reference to Appendix B to the Company's proxy statement on Schedule 14A filed March 7, 2011 (SEC File No. 001-06351, Film No. 11666753)

Exhibit		Location
10.8	2007 Change in Control Severance Pay Plan for Select Employees, as amended	Incorporated by reference to Exhibit 10 to the Company's Report on Form 10-Q for the quarter ended September 30, 2010 (SEC File No. 001-06351, Film No. 101149876)
10.9	Elanco Corporate Bonus	Incorporated by Reference to Exhibit 10.16 to Elanco Animal Health Incorporated's Report on Form S-1 dated August 2, 2018
10.10	Form of Elanco Stock Plan	Incorporated by Reference to Exhibit 10.17 to Elanco Animal Health Incorporated's Report on Form S-1 dated August 2, 2018
10.11	Form of 2018 Change in Control Severance Pay Plan for Select Employees	Incorporated by Reference to Exhibit 10.20 to Elanco Animal Health Incorporated's Report on Form S-1/A dated August 28, 2018
10.12	Elanco RSU Awards Agreement	Incorporated by Reference to Exhibit 10.21 to Elanco Animal Health Incorporated's Report on Form S-1/A dated August 28, 2018
10.13	Elanco Nonqualified Stock Option Agreement	Incorporated by Reference to Exhibit 10.22 to Elanco Animal Health Incorporated's Report on Form S-1/A dated August 28, 2018
21	List of Subsidiaries	Attached
23	Consent of Registered Independent Public Accounting Firm	Attached
31.1	Rule 13a-14(a) Certification of David A. Ricks, President and Chief Executive Officer	Attached
31.2	Rule 13a-14(a) Certification of Joshua L. Smiley, Senior Vice President and Chief Financial Officer	Attached
32	Section 1350 Certification	Attached
101	Interactive Data File	Attached

Signatures

Pursuant to the requirements of Section 13 or 15(d) 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

By /s/ David A. Ricks

David A. Ricks

Chairman, President and Chief Executive Officer

February 19, 2019

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below on February 19, 2019 by the following persons on behalf of the Registrant and in the capacities indicated.

Signature	Title
/s/ David A. Ricks DAVID A. RICKS	Chairman, President and Chief Executive Officer (principal executive officer)
/s/ Joshua L. Smiley JOSHUA L. SMILEY	Senior Vice President and Chief Financial Officer (principal financial officer)
/s/ Donald A. Zakrowski DONALD A. ZAKROWSKI	Vice President, Finance and Chief Accounting Officer (principal accounting officer)
/s/ Ralph Alvarez RALPH ALVAREZ	Director
/s/ Katherine Baicker, Ph.D. KATHERINE BAICKER, Ph.D.	Director
/s/ Carolyn R. Bertozzi, Ph.D. CAROLYN R. BERTOZZI, Ph.D.	Director
/s/ Michael L. Eskew MICHAEL L. ESKEW	Director
/s/ J. Erik Fyrwald J. ERIK FYRWALD	Director
/s/ Jamere Jackson JAMERE JACKSON	Director
/s/ William G. Kaelin, Jr., M.D. WILLIAM G. KAELIN, JR., M.D.	Director
/s/ Juan R. Luciano JUAN R. LUCIANO	Director
/s/ Ellen R. Marram ELLEN R. MARRAM	Director
/s/ Marschall S. Runge, M.D., Ph.D. MARSCHALL S. RUNGE, M.D., Ph.D.	Director
/s/ Kathi P. Seifert KATHI P. SEIFERT	Director
/s/ Jackson P. Tai JACKSON P. TAI	Director
/s/ Karen Walker KAREN WALKER	Director

Trademarks Used In This Report

Trademarks or service marks owned by Eli Lilly and Company or its affiliates, when first used in this report, appear with an initial capital and are followed by the symbol ® or ™, as applicable. In subsequent uses of the marks in the report, the symbols may be omitted.

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