
**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)	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

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

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.

<input checked="" type="checkbox"/> Large accelerated filer	Accelerated filer <input type="checkbox"/>
<input type="checkbox"/> Non-accelerated filer	Smaller reporting company <input type="checkbox"/>
	Emerging growth company <input type="checkbox"/>

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 iodine-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®, Syngard®[®], Trijard®[®] XR, and Basagli.

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 backup 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:

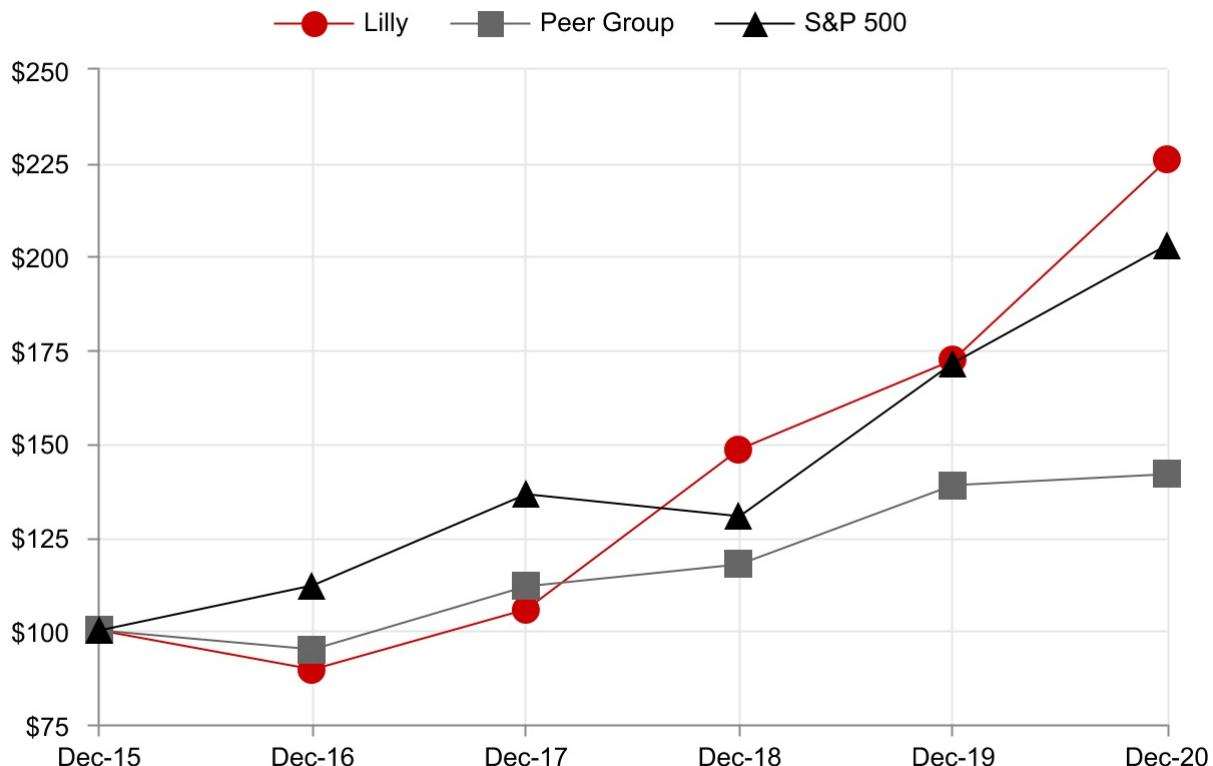
Period	Total Number of Shares Purchased (in thousands)	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs (in thousands)	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs (dollars in millions)
October 2020	—	\$ —	—	\$ 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/TGFα 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 the fourth quarter of 2020.
SSTR4 Agonist	Chronic pain	Phase II	Phase II trials initiated in the fourth quarter of 2020.
Zagotenemab	Alzheimer's disease	Phase II	Phase II trial is ongoing.
Oncology			
Selpercatinib (Retevmo®)	Thyroid cancer	Launched	Granted accelerated approval ⁽⁴⁾ by the FDA based on Phase II data and launched in the U.S. in the second quarter of 2020. Submitted in Japan in the fourth quarter of 2020. Granted conditional marketing authorisation ⁽⁴⁾ in Europe in February 2021. Phase III trials are ongoing.
	Lung cancer		
LOXO-305	Hematological cancers	Phase II	Phase II trial initiated in the second quarter of 2020. Presented positive data at the American Society of Hematology Annual Meeting in the fourth quarter of 2020.

⁽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:

Product	Year Ended December 31,			2019		Percent Change
	2020	U.S.	Outside U.S.	Total	Total	
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)	
Erbilitux®	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 glargin 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			
<i>Current Assets</i>			
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			
<i>Current Liabilities</i>			
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	
<i>Other Liabilities</i>			
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	
<i>Commitments and Contingencies (Note 16)</i>			
<i>Eli Lilly and Company Shareholders' Equity (Notes 12 and 13)</i>			
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						Noncontrolling Interest		
	Common Stock		Additional Paid-in Capital	Retained Earnings	Employee Benefit Trust	Accumulated Other Comprehensive Loss	Common Stock in Treasury		
	Shares	Amount					Shares	Amount	
Balance at January 1, 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.

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 treatment 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 Basagliar in the U.S. We record our sales of Basagliar 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 Basagliar and collaboration and other revenue recognized with respect to the Jardiance and Trajenta families of products:

	2020	2019	2018
Basagliar	\$ 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				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, 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			Fair Value
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
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			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, 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					\$	128.1
	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			2019		
	Carrying Amount, Gross	Accumulated Amortization	Carrying Amount, Net	Carrying Amount, Gross	Accumulated Amortization	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	<hr/> 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	<u>605.8</u>	<u>595.7</u>
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	<u>\$ 1,036.2</u>	<u>\$ 628.0</u>	<u>\$ 529.5</u>

⁽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	<u>\$ 2,551.9</u>	<u>\$ 2,108.6</u>	<u>\$ 2,034.6</u>

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				
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:

(Percents)	Defined Benefit Pension Plans			Retiree Health Benefit Plans		
	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:

Asset Class	Total	Fair Value Measurements Using			Investments Valued at Net Asset Value ⁽¹⁾		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)			
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:

Asset Class	Total	Fair Value Measurements Using				Investments Valued at Net Asset Value ⁽¹⁾		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)				
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 Inquiries

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):

(Amounts presented net of taxes)	Continuing Operations					Discontinued Operations	Accumulated Other Comprehensive Loss
	Foreign Currency Translation Gains (Losses)	Unrealized Net Gains (Losses) on Securities	Defined Benefit Pension and Retiree Health Benefit Plans	Effective Portion of Cash Flow Hedges			
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:

Details about Accumulated Other Comprehensive Loss Components	Year Ended December 31,			Affected Line Item in the Consolidated Statements of Operations
	2020	2019	2018	
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
Chairman, President, and Chief Executive Officer

Anat Ashkenazi
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:

<u>Exhibit</u>		<u>Location</u>
<u>2.1</u>	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
<u>3.1</u>	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
<u>3.2</u>	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
<u>4.1</u>	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
<u>4.2</u>	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
<u>4.3</u>	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
<u>4.4</u>	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
<u>4.5</u>	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
<u>4.6</u>	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
<u>4.7</u>	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
<u>10.1</u>	Amended and Restated 2002 Lilly Stock Plan	Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2018
<u>10.2</u>	Form of Performance Award under the 2002 Lilly Stock Plan	Attached
<u>10.3</u>	Form of Performance Award under the 2002 Lilly Stock Plan (with non-compete)	Attached
<u>10.4</u>	Form of Performance Award under the 2002 Lilly Stock Plan (non-executive officer)	Attached
<u>10.5</u>	Form of Shareholder Value Award under the 2002 Lilly Stock Plan	Attached

<u>10.6</u>	Form of Shareholder Value Award under the 2002 Lilly Stock Plan (with non-compete)	Attached
<u>10.7</u>	Form of Shareholder Value Award under the 2002 Lilly Stock Plan (non-executive officer)	Attached
<u>10.8</u>	Form of Relative Value Award under the 2002 Lilly Stock Plan	Attached
<u>10.9</u>	Form of Relative Value Award under the 2002 Lilly Stock Plan (with non-compete)	Attached
<u>10.10</u>	Form of Restricted Stock Unit Award under the 2002 Lilly Stock Plan	Attached
<u>10.11</u>	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
<u>10.12</u>	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
<u>10.13</u>	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
<u>10.14</u>	The Eli Lilly and Company Bonus Plan, as amended	Attached
<u>10.15</u>	2007 Change in Control Severance Pay Plan for Select Employees, as amended	Attached
<u>21</u>	List of Subsidiaries	Attached
<u>23</u>	Consent of Independent Registered Public Accounting Firm	Attached
<u>31.1</u>	Rule 13a-14(a) Certification of David A. Ricks, Chairman, President, and Chief Executive Officer	Attached
<u>31.2</u>	Rule 13a-14(a) Certification of Anat Ashkenazi, Senior Vice President and Chief Financial Officer	Attached
<u>32</u>	Section 1350 Certification	Attached
<u>101</u>	Interactive Data File	Attached
<u>104</u>	Cover Page Interactive Data File (formatted in 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 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.

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