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, 2022

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
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
0.500% Notes due 2033	LLY33	New York Stock Exchange
6.77% Notes due 2036	LLY36	New York Stock Exchange
1.625% Notes due 2043	LLY43	New York Stock Exchange
1.700% Notes due 2049	LLY49A	New York Stock Exchange
1.125% Notes due 2051	LLY51	New York Stock Exchange
1.375% Notes due 2061	LLY61	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 ☐

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

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

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

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

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to § 240.10D-1(b). ☐

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 $274,342,000,000.

Number of shares of common stock outstanding as of February 17, 2023: 950,296,118

Portions of the Registrant's Proxy Statement for the 2023 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, 2022

Table of Contents

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 significant costs and uncertainties in the pharmaceutical research and development process, including with respect to the timing and process of obtaining regulatory approvals;
- the impact and outcome of acquisitions and business development transactions and related integration costs;
- the expiration of intellectual property protection for certain of our products and competition from generic and/or biosimilar products;
- our ability to protect and enforce patents and other intellectual property;
- changes in patent law or regulations related to data package exclusivity;
- competitive developments affecting current products and our pipeline;
- market uptake of recently launched products;
- information technology system inadequacies, breaches, or operating failures;
- unauthorized access, disclosure, misappropriation, or compromise of confidential information or other data stored in our information technology systems, networks, and facilities, or those of third parties with whom we share our data;
- the impact of global macroeconomic conditions, trade disruptions, disputes, unrest, war, regional dependencies, or other costs, uncertainties and risks related to engaging in business globally;
- unexpected safety or efficacy concerns associated with our products;
- litigation, investigations, or other similar proceedings involving past, current, or future products or commercial activities as we are largely self-insured;
- issues with product supply and regulatory approvals stemming from manufacturing difficulties, disruptions, or shortages, including as a result of unpredictability and variability in demand, labor shortages, third-party performance, quality, or regulatory actions related to our facilities;
- dependence on certain products for a significant percentage of our total revenue and an increasingly consolidated supply chain;
- reliance on third-party relationships and outsourcing arrangements;
- the impact of public health outbreaks, epidemics, or pandemics, such as the COVID-19 pandemic;
- regulatory changes or other developments;
- regulatory actions regarding operations and 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;

- changes in accounting and reporting standards promulgated by the Financial Accounting Standards Board and the Securities and Exchange Commission (SEC);
- regulatory compliance problems or government investigations; and
- actual or perceived deviation from environmental-, social-, or governance-related requirements or expectations.

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

All forward-looking statements speak only as of the date of this Annual Report and are expressly qualified in their entirety by the risk factors and cautionary statements included in this Annual Report. Except as is required by law, we expressly disclaim any obligation to publicly release any revisions to forward-looking statements to reflect events after the date of this Annual Report.

Part I

Item 1. Business

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

Our purpose is to unite caring with discovery to create medicines that make life better for people around the world. Most of the products that 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 medicines.

We manufacture and distribute our products through facilities in the United States (U.S.), including Puerto Rico, and 7 other countries. Our products are sold in approximately 110 countries.

Products

Our products include:

Diabetes products, including:

- *Basaglar*®, in collaboration with Boehringer Ingelheim, a long-acting human insulin analog for the treatment of diabetes.
- *Humalog*®, *Humalog Mix 75/25, Humalog U-100, Humalog U-200, Humalog Mix 50/50*, *insulin lispro, insulin lispro protamine*, and *insulin lispro mix 75/25,* human insulin analogs for the treatment of diabetes.
- *Humulin*®, *Humulin 70/30, Humulin N, Humulin R,* and *Humulin U-500*, human insulins of recombinant DNA origin for the treatment of diabetes.
- *Jardiance*®, in collaboration with Boehringer Ingelheim, for the treatment of type 2 diabetes; to reduce the risk of cardiovascular death in adult patients with type 2 diabetes and established cardiovascular disease; and to reduce the risk of cardiovascular death and hospitalizations for heart failure in adults.
- *Mounjaro*®, a glucose-dependent insulinotropic polypeptide and glucagon-like peptide-1 receptor agonist, for the treatment of adults with type 2 diabetes in combination with diet and exercise to improve glycemic control.
- *Trulicity*®, for the treatment of type 2 diabetes in adults and pediatric patients 10 years of age and older, and to reduce the risk of major adverse cardiovascular events in adult patients with type 2 diabetes and established cardiovascular disease or multiple cardiovascular risk factors.

Oncology products, including:

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

- *Jaypirca*™, for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) after at least two lines of systemic therapy, including a BTK inhibitor.
- *Retevmo*®, for the treatment of metastatic NSCLC with a rearranged during transfection (RET) gene fusion in adult patients; for the treatment of advanced metastatic medullary thyroid cancer with a RET mutation who require systemic therapy in adult and pediatric patients; for the treatment of advanced or metastatic thyroid cancer with a RET gene fusion in adult and pediatric patients who require systemic therapy and are radioactive iodine-refractory; and for the treatment of adult patients with locally advanced or metastatic solid tumors with a RET gene fusion that have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options.
- *Tyvyt*®, in collaboration with Innovent Biologics, Inc., for the treatment of relapsed or refractory classic Hodgkin's lymphoma; for the first-line treatment of non-squamous NSCLC in combination with Alimta and another agent; for the first-line treatment of squamous NSCLC in combination with two other agents; for the first-line treatment of hepatocellular carcinoma in combination with another agent; for the first-line treatment of esophageal squamous cell carcinoma in combination with certain other agents; and for the first-line treatment of gastric cancer in combination with two other agents, each in China.
- *Verzenio*®, for use as monotherapy or in combination with endocrine therapy for the treatment of HR+, HER2- metastatic breast cancer and in combination with endocrine therapy for treatment of HR+, HER2-, node positive, early breast cancer at high risk of recurrence and a Ki-67 score at least 20 percent, as determined by a U.S. Food and Drug Administration (FDA) approved test.

Immunology products, including:

- *Olumiant*®, in collaboration with Incyte Corporation, for the treatment of adults with moderately-to-severely active rheumatoid arthritis, moderate to severe atopic dermatitis, and severe alopecia areata, and for the treatment of hospitalized adults with COVID-19 who require supplemental oxygen, mechanical ventilation, or extracorporeal membrane oxygenation.
- *Taltz*®, for the treatment of adults and pediatric patients aged 6 years or older with moderate-to-severe plaque psoriasis, adults with active psoriatic arthritis, adults with ankylosing spondylitis, and adults with active non-radiographic axial spondyloarthritis.

Neuroscience products, including:

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

Other products and therapies , including:

- *Bamlanivimab* and *etesevimab*, administered together, for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients from birth to 12 years old with positive results of direct SARS-CoV-2 viral testing and who are at high risk for progression to severe COVID-19, including hospitalization or death (Emergency Use Authorization (EUA) granted in 2021). In May 2022, the FDA announced that bamlanivimab and etesevimab are not currently authorized for emergency use for any U.S. region.
- *Bebtelovimab*, for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older and weighing at least 40 kilograms) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options approved or authorized by the FDA are not accessible or clinically appropriate (EUA granted in 2022). In November 2022, the FDA announced that bebtelovimab is not currently authorized for emergency use for any U.S. region.
- *Cialis*®, for the treatment of erectile dysfunction and benign prostatic hyperplasia.
- *Forteo*®, for the treatment of osteoporosis in postmenopausal women and men at high risk for fracture and for glucocorticoid-induced osteoporosis in men and postmenopausal women.

Marketing and Distribution

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

U.S.

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

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

In the U.S., most of our products are distributed through wholesalers that serve pharmacies, physicians and other healthcare professionals, and hospitals. In 2022, 2021, and 2020, three wholesale distributors in the U.S.—McKesson Corporation, AmerisourceBergen Corporation, and Cardinal Health, Inc.—each accounted for a significant percentage of our consolidated revenue. No other customer accounted for more than 10 percent of our consolidated revenue in any of these years. For additional information, see Item 8, "Financial Statements and Supplementary Data—Note 2: Revenue."

Outside the U.S.

The products we market and distribution of our products vary from country to country. Outside the U.S., we promote our products to healthcare providers through sales representatives and other channels. In most countries in which we operate, we maintain our own sales organizations, but in some countries we market our products through third parties, some of which we have engaged through distribution and promotion arrangements.

Marketing Collaborations

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

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

Competition

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

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

Generic Pharmaceuticals

One of the biggest competitive challenges we face is from generic pharmaceuticals. In the U.S., Europe, Japan, and other jurisdictions, 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 for our branded products 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 result in the loss of a significant portion of the product's revenue in a very short period of time. Moreover, governments in some countries leverage generic entrants to drive price concessions through the utilization of volume-based procurement bidding and other measures.

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 certain countries outside the U.S., intellectual property protection is weak, and we must compete with generic or counterfeit versions of our products relatively shortly after launch.

Biosimilars

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

Globally, most governments have developed abbreviated regulatory pathways to approve biosimilars as follow-ons to innovator-developed biologics, including the Biologics Price Competition and Innovation Act of 2009 (the BPCIA) in the U.S. A number of biosimilars have been licensed under the BPCIA, as well as in Europe and Japan. The patent and regulatory exclusivity for the existing innovator biologic generally must expire in a given market before biosimilars may enter that market. In addition, the extent to which a biosimilar, once approved, will be substituted for the innovator biologic in a way that is similar to traditional generic substitution for non-biologic products is not yet entirely clear, and will depend on a number of regulatory and marketplace factors that are still developing. In the U.S., currently only a biosimilar product that is determined to be "interchangeable" by the FDA will be considered substitutable for the original biologic product without the intervention of the healthcare provider who prescribed the original biologic product. The FDA requirements for interchangeability are evolving but the FDA has issued several "interchangeable" designations for biosimilar products, including for competitive insulin products, and is expected to continue doing so in the future.

Regulatory interpretation of important aspects of the laws regulating biosimilars continues to evolve and, therefore, the impact of these laws on our business remains subject to substantial uncertainty. Biosimilars may present both competitive challenges and opportunities. While competitors have developed biosimilars that compete with our products, we have developed, and may continue to develop, our own biosimilars.

U.S. Private Sector Dynamics

In the U.S. private sector, consolidation and integration among healthcare organizations significantly affects the competitive marketplace for pharmaceuticals. Health plans, managed care organizations, pharmacy benefit managers, wholesalers, and other supply chain stakeholders have been consolidating into fewer, larger entities, thus enhancing their market power 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 discounts or rebates in exchange for formulary inclusion and placement.

Formulary placement can lead to reduced usage of a drug for the relevant patient population due to coverage restrictions, such as prior authorizations and formulary exclusions, or due to reimbursement limitations that result in higher consumer out-of-pocket cost, such as non-preferred co-pay tiers, increased co-insurance levels, and higher deductibles. Consequently, pharmaceutical companies face increased pressure in negotiations, and compete fiercely for formulary placement, not only on the basis of product attributes such as efficacy, safety profile, or patient ease of use, but also by providing rebates or other concessions. As payers and pharmaceutical companies continue to negotiate formulary placement and rebates, value-based agreements, where rebates may be based on achievement (or not) of specified outcomes, are another tool that has become increasingly prevalent. Cost is an increasingly important factor in formulary decisions, particularly in treatment areas in which the payer has taken the position that multiple branded products are therapeutically comparable. These pressures have negatively affected, and could 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 and uses. 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) for our products, particularly those in major markets such as the U.S., major European countries, and Japan. These patents may be issued based upon the filing of international patent applications, usually filed under the Patent Cooperation Treaty (PCT). Patent applications covering compounds are generally filed during the discovery phase of the drug discovery process, which is described in the "Research and Development" section below. In general, national patents in each relevant country are available for a period of 20 years from the filing date of the PCT application, which is often years prior to the launch of a commercial product. Further patent term adjustments and restorations may extend the original patent term:

- Patent term adjustment is a statutory right available to all U.S. patent applicants to provide relief in the event that a patent grant is delayed during examination by the U.S. 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 compensate 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 determined by a formula that cannot be calculated until product approval due to the uncertainty of the duration of clinical trials and the time it takes the FDA to review an application. There is a five-year cap on any restoration, and no patent's expiration date may be extended beyond 14 years from FDA approval. Some countries outside the U.S. similarly offer forms of patent term restoration for patents claiming inventions subject to a local review by a regulatory agency. For example, Supplementary Protection Certificates are available to extend the life of a European patent up to an additional five years (subject to a 15-year cap from European Medicines Agency (EMA) approval). Also, in Japan, South Korea, Australia, and other jurisdictions, 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, often leading to a severe and rapid decline in revenues for the product. However, in some cases the innovator company may retain exclusivity despite approval of the generic, biosimilar, or other follow-on versions of a new medicine beyond the expiration of the compound patent through manufacturing trade secrets, later-expiring patents on manufacturing processes, methods of use or formulations, or data protection that may be available under pharmaceutical regulatory laws. Changes to the laws and regulations governing these protections could result in earlier loss of effective market exclusivity. The primary forms of data protection are as follows:

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

Outside the major markets, the adequacy and effectiveness of intellectual property protection for pharmaceuticals varies widely, and in a number of these markets we are unable to patent our products or to enforce the patents that we receive for our products. Under the Trade-Related Aspects of Intellectual Property (TRIPs) Agreement 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 TRIPs 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 the TRIPs Agreement.

Our Intellectual Property Portfolio

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

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

- 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).
- Jaypirca is protected by a compound patent (2037) and by data protection (2028).
- Mounjaro is protected by a compound patent (2036) and by data protection (2027).
- Olumiant is protected by a compound patent (2032).
- Retevmo is protected by a compound patent (2037) and by data protection (2025).
- Reyvow® is protected by a compound patent (2030).
- Taltz is protected by a compound patent (2030) and by biologics data protection (2028).
- Trulicity is protected by a compound patent (2027) and by biologics data protection (2027).
- Verzenio is protected by a compound patent (2031).

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

- Baqsimi® is protected by data protection in Japan (2026).
- Cyramza is protected by a compound patent (2028) and by data protection (2024) in major European countries, and by a compound patent (2026) and by data protection (2023) in Japan.
- Emgality is protected by a compound patent (2033) and by data protection (2028) in major European countries, and by a compound patent (2035) and by data protection (2029) in Japan.
- Jardiance is protected by a compound patent in major European countries (2029) and Japan (2030).
- Mounjaro is protected by a compound patent in major European countries (2037) and Japan (2040).
- Olumiant is protected by a compound patent (2032) and by data protection (2027) in major European countries, and by a compound patent (2033) and by data protection (2025) in Japan.
- Retevmo is protected by a compound patent (2037) and by data protection (2031) in major European countries, and by a compound patent (2038) and by data protection (2029) in Japan.
- Reyvow is protected by data protection (2032) in major European countries, and a compound patent (2028) and by data protection (2032) in Japan.
- Taltz is protected by a compound patent (2031) and data protection (2027) in major European countries and a compound patent (2030) and data protection (2024) in Japan.
- Trulicity is protected by a compound patent (2029) and by data protection (2024) in major European countries and by a compound patent (2029) and by data protection (2023) in Japan.
- Verzenio is protected by a compound patent (2033) and data protection (2028) in major European countries and by a compound patent (2034) and data protection (2026) in Japan.

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

- Donanemab has been submitted for regulatory review in the U.S. for the treatment of early Alzheimer's disease. In January 2023, the FDA issued a complete response letter for our accelerated approval submission. Phase III trials are ongoing.
- Lebrikizumab has been submitted for regulatory review in the U.S. and Europe for the treatment of atopic dermatitis.
- Mirikizumab has been submitted for regulatory review in the U.S., Europe, and Japan for the treatment of ulcerative colitis.

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) that we consider in the aggregate to be important to our operations. Trademark protection varies throughout the world, with protection continuing in some countries as long as the mark is used, and in other countries as long as it is registered. Registrations are normally for fixed but renewable terms. Trademark protection typically extends beyond the patent and data protection for a product.

Patent Licenses and Collaborations

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

Patent Challenges

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

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

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

Under the BPCIA, the FDA cannot approve an application for a biosimilar product until data protection expires, 12 years after initial marketing approval of the innovator biologic, and an application may not be submitted until four years following the date the innovator biologic was first approved. However, the BPCIA does provide a mechanism for a prospective biosimilar 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 by courts. Courts have held that biosimilar applicants are not required to engage in the BPCIA patent litigation scheme and patent holders retain the right to bring suit under normal patent law procedures if a biosimilar applicant attempts to commercialize a product prior to patent expiration. Further, in the U.S., the increased likelihood of generic and biosimilar challenges to innovators' intellectual property has increased the risk of loss of innovators' market exclusivity. See also "—Competition—Biosimilars." In addition, there is a procedure in U.S. patent law, known as inter partes review (IPR), which allows any member of the public to file a petition with the USPTO seeking the review of any issued U.S. patent for validity. IPRs are conducted before Administrative Patent Judges in the USPTO using a lower standard of proof than used in federal district court. In addition, the challenged patents are not accorded the presumption of validity as they are in federal district court. Generic drug companies and even some investment firms have engaged in the IPR process in attempts to invalidate our patents. The use of IPR proceedings after the institution of litigation pursuant to the BPCIA or Hatch-Waxman Act is currently a topic of debate among legislators. We have also observed, and may continue to observe, changes at the Patent Trial and Appeal Board (PTAB), including with respect to the PTAB's policy to discretionarily deny an otherwise meritorious petition for IPR in light of a concurrent district court proceeding. See Item 1A, "Risk Factors—Risks Related to Our Business—Our long-term success depends on intellectual property protection; if our intellectual property rights are invalidated, circumvented, or weakened, our business will be adversely affected."

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

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

Government Regulation of Our Operations

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

Regulation of Products

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

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 also strictly regulates marketing, labeling, advertising, and promotion of products that are placed on the market. Pharmaceutical products may be promoted only for 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.

Outside the U.S., our products and operations are subject to similar regulatory requirements, notably by the EMA in Europe, the Ministry of Health, Labor and Welfare in Japan, and the National Medical Products Administration in China. Specific regulatory requirements vary from country to country. Regulatory and compliance requirements, as well as approval processes outside the U.S., may differ from those in the U.S. and may involve additional costs, uncertainties, and risks.

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

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

Emergency Use Authorizations

The Secretary of Health and Human Services may issue an EUA to authorize unapproved medical products, or unapproved uses of approved medical products, to be manufactured, marketed, and sold in the context of an actual or potential emergency that has been designated by the government. 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 vary and 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 FDA granted EUAs for bamlanivimab and etesevimab administered together, certain COVID-19-related uses of baricitinib, and bebtelovimab, and similar actions have been taken by other regulators in certain jurisdictions outside the U.S. However, the FDA has revised, and may in the future further revise, these EUAs in response to the changing conditions of the COVID-19 pandemic, such as the prevalence of variants against which our antibodies have varying degrees of efficacy. In May and November 2022, respectively, the FDA announced that bamlanivimab and etesevimab are, and bebtelovimab is, not currently authorized for emergency use for any U.S. region.

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. State, federal, and foreign governments, agencies, and other regulatory bodies are active in their oversight, enforcement activities, and coordination with respect to pharmaceutical companies, which has resulted in intensified scrutiny, litigation costs, corporate criminal sanctions, and substantial civil settlements in the pharmaceutical industry.

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, our business is heavily regulated and therefore involves significant interaction with officials outside the U.S. 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 healthcare 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 in any given period.

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

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

U.S.

There continues to be considerable public and government scrutiny of pharmaceutical pricing. In addition, U.S. government actions 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.

In August 2022, the U.S. government enacted the Inflation Reduction Act of 2022 (IRA). Among other measures, the IRA will require the U.S. Department of Health and Human Services to effectively set prices for certain single-source drugs and biologics reimbursed under Medicare Part B and Part D. Generally, these government prices apply nine (medicines approved under an NDA) or thirteen (medicines approved under a Biologics License Application) years following initial FDA approval and will be capped at a statutory ceiling price that is likely to represent a significant discount from average prices to wholesalers and direct purchasers. It is too soon to tell how the U.S. government will set these prices as the law specifies a ceiling price, but not a minimum or floor price. One or more of our significant products may be selected, which would have the effect of accelerating revenue erosion prior to patent expiry. The effect of reducing prices and reimbursement for certain of our products would significantly impact our business and consolidated results of operations. The establishment of payment limits or other restrictions by drug affordability review boards and other state level actors would similarly impact us.

Other IRA provisions provide for rebate obligations on drug manufacturers that increase prices of Medicare Part B and Part D medicines at a rate greater than the rate of inflation and Part D benefit redesign that includes replacing the Part D coverage gap discount program with a new manufacturer discounting program. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties, which could be significant.

The IRA takes effect progressively starting in 2023, with the first government-set prices effective in 2026. The IRA may meaningfully influence our business strategies and those of our competitors. In particular, the nine-year timeline to set prices for medicines approved under an NDA may reduce the attractiveness of investment in small molecule innovation. The implications to us of a competitor’s product being selected for price setting are also uncertain. Provisions of the IRA may be subject to legal challenges or other reformation, and the full impact of the IRA on our business and the pharmaceutical industry remains uncertain.

Heightened governmental scrutiny over the manner in which drug manufacturers price their marketed products has also resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. Restrictive or unfavorable pricing, coverage, or reimbursement determinations for our medicines or product candidates by governments, regulatory agencies, courts, or private payers could also adversely impact our business and financial results. For example, in April 2022, the Centers for Medicare & Medicaid Services issued the Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer’s Disease national coverage determination (the Alzheimer's Monoclonal Antibody NCD) limiting coverage of FDA-approved monoclonal antibodies that target amyloid for the treatment of Alzheimer's disease for people with Medicare only if they are enrolled in qualifying clinical trials. In its current form, the Alzheimer’s Monoclonal Antibody NCD would result in significantly reduced coverage for, and negatively impact, our product candidate donanemab, and may negatively impact our business and financial results. Additional policies, regulations, legislation, or enforcement, including those proposed or pursued by the U.S. Congress, the current U.S. presidential administration, and regulatory authorities worldwide, could intensify these efforts and adversely impact our business and consolidated results of operations.

In the U.S., we are required to provide rebates to the federal government and 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 above the consumer price index over time) and discounts to private entities who treat patients in certain types of healthcare facilities intended to serve low-income and uninsured patients (known as 340B covered entities). 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). Beginning in October 2024, under the IRA the 70 percent discount will be replaced by a 10 percent discount for all Medicare Part D beneficiaries that have met their deductible and incurred out of pocket drug costs below a $2,000 threshold and a 20 percent discount for beneficiaries that have incurred out of pocket drug costs above the $2,000 threshold.

Rebates are also negotiated in the private sector. We pay rebates to private payers that provide prescription drug benefits to seniors covered by Medicare and to private payers that provide prescription drug benefits to their customers. These rebates are affected by the introduction of competitive products and generics in the same class. Our approach to the rebates we offer to private payers that provide prescription drug benefits to seniors covered by Medicare may be impacted by the 2020 regulatory amendments to the anti-kickback statute's discount safe harbor, which have currently been stayed until at least January 1, 2032.

For a discussion of risks related to how we price our products, see Item 1A, "Risk Factors—Risks Related to Our Business—We face litigation and investigations related to our products, how we price our products, and how we commercialize our products; we could face large numbers of claims in the future, which could adversely affect our business, and we are self-insured for such matters."

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, conduct and publish comparative effectiveness and cost/benefit analyses on medicines, the impact of which are uncertain.

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. In October 2022, the German Parliament passed cost cutting reforms and these reforms were followed by activation of a clawback mechanism in France and implementation of increased mandatory rebates in the United Kingdom. These changes may be followed in 2023 by biopharmaceutical-focused austerity measures in more countries in Europe and in other markets. Reforms, including those that may stem from periods of economic downturn or uncertainty, or as a result of high inflation, emergence or escalation of, and responses to, war or unrest (including the Russia-Ukraine war), or government budgeting priorities (including as exacerbated by the COVID-19 pandemic), may continue to result in added pressure on pricing and reimbursement for our products.

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—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 2022, we employed approximately 9,000 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 obesity & diabetes, immunology, neuroscience, and oncology. At the outset of the COVID-19 pandemic, 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 also invest in external research and technologies that we believe complement and strengthen our own efforts. These investments can take many forms, including, among others, licensing arrangements, co-development agreements, co-promotion arrangements, joint ventures, acquisitions, and equity investments.

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

Phases of New Drug Development

- **Discovery Phase**

  In the discovery phase, scientists identify, design, and synthesize promising candidates by analyzing their effect on biological targets thought to play a role in disease. Targets are often unproven and only candidates that have the desired effect on the target and meet other design criteria move to the next phase of development, which includes the initiation of studies in animals to support regulatory and safety requirements for clinical research in humans. The discovery phase can take years and the probability of any one candidate becoming a medicine is extremely low.

- **Early Development Phase**

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

- **Late Development Phase**

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

- **Submission Phase**

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

We believe our investments in research, both internally and in collaboration with others, have resulted in a robust pipeline of potential new medicines and new treatment indications in all stages of development. We have a number of new medicine candidates in clinical development or under regulatory review, and we have a larger number of projects in the discovery phase. See Item 7, "Management's Discussion and Analysis—Executive Overview—Late-Stage Pipeline," for more information on our late-stage 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 can be implemented, in the event one of these suppliers becomes unable to provide the materials or product. However, various developments have led, and may in the future lead, to interruption or shortages in supply until we establish new sources, implement alternative processes, bring new manufacturing facilities online, or pause or discontinue product sales in one or more markets.

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

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

However, pharmaceutical production processes are complex, highly regulated, and vary widely from product to product. Shifting or adding manufacturing capacity can be a very lengthy process requiring significant capital expenditures, process modifications, and regulatory approvals. Accordingly, developments such as unplanned plant shutdowns, manufacturing or quality assurance difficulties at one of our facilities or contracted facilities, failure or refusal of a supplier or contract manufacturer to supply contracted quantities, increases in demand on a supplier, or difficulties in predicting or variability in demand for our products and those of our competitors have led, and may in the future lead, to interruption or higher costs in the supply of certain products, product shortages, or pauses or discontinuations of product sales in one or more markets. Further, global transportation and logistics challenges, cost inflation, and tight labor markets, have caused, and in the future may cause, delays in and/or increased costs related to distribution of our medicines, the construction or acquisition of manufacturing capacity, procurement activity, and supplier or contract manufacturer arrangements. For more information on the additional risks we face in connection with any difficulties, disruptions, and shortages in the manufacturing, distribution, and sale of our products, see Item 1A, "Risk Factors—Risks Related to Our Business—Manufacturing, quality, or supply chain difficulties, disruptions, or shortages could lead to product supply problems."

In addition, cost inflation, the strain on global transportation, logistics, and labor markets (including as exacerbated by the COVID-19 pandemic and the emergence or escalation of, and responses to, war or unrest, including the Russia-Ukraine war), global economic downturns or uncertainty, and an increase in overall demand in our industry for certain products and materials have had, and may continue to have, a number of impacts on our business, including increased costs and disruptions in the supply of our medicines. For more information, see Item 1A, "Risk Factors—Risks Related to Our Business—Public health outbreaks, epidemics, or pandemics, such as the COVID-19 pandemic, have adversely impacted and may in the future adversely impact our business and operations." and Item 7, "Management's Discussion and Analysis—Executive Overview—Other Matters—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 requires 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 1, 2023 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 Ricks	55	Chair, President, and Chief Executive Officer (CEO) (since 2017). Previously, Mr. Ricks held various leadership roles with Lilly, including senior vice president and president, Lilly Bio-Medicines. Mr. Ricks has 26 years of service with Lilly.
Anat Ashkenazi	50	Executive 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 21 years of service with Lilly.
Eric Dozier	56	Executive Vice President, Human Resources and Diversity (since 2022). Previously, Mr. Dozier held various leadership roles with Lilly, including senior vice president, chief commercial officer for Loxo@Lilly, and vice president, global ethics and compliance officer. Mr. Dozier has 25 years of service with Lilly.
Anat Hakim	53	Executive 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 three years of service with Lilly.
Edgardo Hernandez	48	Executive Vice President and President, Manufacturing Operations (since 2021). Previously, Mr. Hernandez held various leadership roles with Lilly, including senior vice president, global parenteral drug product, delivery devices and regional manufacturing, and vice president, Fegersheim operations. Mr. Hernandez has 18 years of service with Lilly.
Patrik Jonsson	56	Executive Vice President and President, Lilly Immunology, Lilly USA, and Chief Customer Officer (since 2021). Previously, Mr. Jonsson held various leadership roles with Lilly, including senior vice president and president, Lilly USA, and chief customer officer, senior vice president and president, Lilly Bio-Medicines and president and general manager, Lilly Japan. Mr. Jonsson has 32 years of service with Lilly.
Michael Mason	56	Executive 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 33 years of service with Lilly.
Johna Norton	56	Executive 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 32 years of service with Lilly.
Leigh Ann Pusey	60	Executive 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 five years of service with Lilly.
Diogo Rau	48	Executive Vice President and Chief Information and Digital Officer (since 2021). Prior to joining Lilly, Mr. Rau was senior director of information systems and technology for retail and online stores of Apple Inc. from 2011 to 2021. Prior to his tenure at Apple, he served as a partner at McKinsey & Company. Mr. Rau has two years of service with Lilly.
Daniel Skovronsky, M.D., Ph.D.	49	Executive Vice President, Chief Scientific and Medical Officer, and President, Lilly Research Laboratories (since 2021). Previously, Dr. Skovronsky held various leadership roles with Lilly, including senior vice president, chief scientific officer, and president, Lilly Research Laboratories, and senior vice president, clinical and product development. Dr. Skovronsky has 12 years of service with Lilly.
Jacob Van Naarden	38	Executive Vice President, CEO, Loxo@Lilly, and President, Lilly Oncology (since 2021). Previously, Mr. Van Naarden served as Chief Executive Officer-Loxo Oncology at Lilly, and Chief Operating Officer-Loxo Oncology at Lilly. Mr. Van Naarden joined Lilly in 2019 when the company acquired Loxo Oncology, Inc., where he was the chief operating officer. In previous roles, Mr. Van Naarden worked in various biotechnology investing, operating, and advisory capacities, including positions with HealthCor Management, Aisling Capital, and Goldman Sachs. Mr. Van Naarden has four years of service with Lilly.
Alonzo Weems	52	Executive Vice President, Enterprise Risk Management, and Chief Ethics and Compliance Officer (since 2021). Previously, Mr. Weems held various leadership roles with Lilly, including vice president and deputy general counsel for corporate legal functions, general counsel for Lilly USA, and general counsel for biomedicines and diabetes. Mr. Weems has 25 years of service with Lilly.
Anne White	54	Executive Vice President and President, Lilly Neuroscience (since 2021). Previously, Ms. White held various leadership roles with Lilly, including senior vice president and president, Lilly Oncology, vice president of Portfolio Management, Chorus, and Next Generation Research and Development. Ms. White has 27 years of service with Lilly.
Ilya Yuffa	48	Executive Vice President and President, Lilly International (since 2021). Previously, Mr. Yuffa held various leadership roles with Lilly, including senior vice president and president, Lilly Bio-Medicines, vice president of U.S. Diabetes, general manager of Italy Hub, and vice president, global ethics and compliance officer since 2014. Mr. Yuffa has 26 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 medicines. We believe that fostering a positive culture that values the contributions of our talented colleagues helps drive our success.

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

We regularly conduct anonymous employee surveys to seek feedback from our workforce on a variety of topics. These results are reviewed and analyzed by our leaders to identify opportunities to adjust our policies and benefits to improve our employees' experience. 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 2022, we employed approximately 39,000 people, including approximately 21,000 employees outside the U.S. Our employees include approximately 9,000 people engaged in research and development activities.

Strategy and Oversight

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

Diversity, Equity, and Inclusion

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

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

In 2020, as part of our DEI and community initiatives, Lilly and the Lilly Foundation launched the Racial Justice Commitment, with Lilly pledging 25,000 volunteer hours and the Lilly Foundation committing $25 million over five years to help decrease the burden of racial injustice and its effects on communities of color. The Racial Justice Commitment aims to drive change across five areas: internal people development, health equity, social impact, diversity partners, and family sustaining jobs, through the use of financial and people resources. From 2020 through 2022, we have made progress in these efforts, including nearly tripling our spending with Black-owned businesses, committing over $98 million in minority-led venture capital firms, serving over 30,000 volunteer hours to advance racial justice initiatives, and expanding our Skills First Program at Lilly for individuals without four-year college degrees.

Since 2017, we have committed to increasing women, Black/African American, Latinx, and Asian representation in leadership roles, and we actively monitor our progress. From the end of 2018 through the end of 2022, we increased the percentage of women in management globally from 42 percent to 49 percent. For minority group members (MGM) in the U.S. over the same period, we increased management representation from 19 percent to 25 percent. Across all levels of our workforce, from the end of 2018 through the end of 2022, we have seen increased representation for MGMs in the U.S. and women globally. Our focus on DEI is also evident at our executive committee and board of directors. Five of 15 current members (approximately 33 percent) of our executive committee (which includes our CEO) are women and three are MGMs. In addition, as of the filing of this report, the company's 13-member board of directors includes five women and six members who are MGMs.

Our efforts in DEI and workplace benefits have garnered numerous recognitions, including, in 2022, Top 50 Companies for Diversity by DiversityInc., Top Companies for Board of Directors by DiversityInc., Top Companies for Supplier Diversity by DiversityInc., Top Companies for ESG by DiversityInc., America's Best Employers for Women by Forbes, Perfect Score on the Human Rights Campaign Foundation Corporate Equality Index, World's Most Ethical Companies by Ethisphere, Perfect Score on Disability Equity Index Best Places to Work by Disability:IN, Pharmaceutical Innovation Index, Zero Project Award for Access Lilly, and Top Companies for Executive Women, Best Companies for Multicultural Women, Best Companies for Dads, 70 percent and Higher Inclusion Index by Seramount.

Employee Development

We believe attracting and retaining the best, diverse 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.

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

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 in addition to our in-person programs. Many training courses are designed to improve accessibility for people with disabilities and other unique needs. Across Lilly, we are continuously working to design learning experiences to be more inclusive and effective. In addition, we have implemented development tools and resources for all employees, improved our talent programs and processes to provide broader access to information, and increased transparency regarding career development and advancement at Lilly.

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

We have continued our efforts to create an inclusive workplace with the goal of ensuring that all employees feel safe to speak up and share their ideas at work. Our Make it Safe to Thrive education and awareness program is designed to help employees and leaders understand how individual psychological safety can be created and enhanced and includes live and online training. In late 2022, we introduced a new version of Make it Safe to Thrive for leaders that continues to focus on psychological safety and creating an inclusive environment. Leaders are provided the opportunity to work through challenging conversations and situations currently being navigated in the workplace.

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

Employee Health and Safety

We strive to foster a healthy, vibrant work environment, which includes keeping our employees safe. We seek to create a companywide culture where best-in-class safety practices are consistently followed. To do this, we assess and continuously attempt to improve our companywide safety performance to promote the well-being of employees and to help safeguard communities where we operate. As the COVID-19 pandemic has evolved, we have continued to take various measures (as necessary) to protect and support the health and safety of our employees globally. We believe a holistic approach and dedication to safety helps us be our best as we deliver on our company purpose to improve lives around the world.

Information Available on Our Website

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

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

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

In addition, the "Governance" section 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**.

We routinely post important information for investors in the “Investors” section of our website, **www.lilly.com**. We may use our website as a means of disclosing material, non-public information and for complying with our disclosure obligations under Regulation FD. Accordingly, investors should monitor the “Investors” section of our website, in addition to following our press releases, filings with the SEC, public conference calls, presentations, and webcasts. We may also use social media channels to communicate with investors and the public about our business, products and other matters, and those communications could be deemed to be material information. The information contained on, or that may be accessed through, our website or social media channels, is not incorporated by reference into, and is not a part of, this Annual Report on Form 10-K.

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

- **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 lose intellectual property protection or are displaced by competing products or therapies.**

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

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

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

  We must maintain a continuous flow of successful new products and successful new indications or line 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 become subject to pricing controls, lose intellectual property exclusivity, or are displaced by competing products or therapies. Failure to do so in the short-term or long-term would have a material adverse effect on our business, results of operations, cash flows, and financial position.

  We engage in various forms of business development activities to enhance our product pipeline, including licensing arrangements, co-development agreements, co-promotion arrangements, joint ventures, acquisitions, and equity investments. There are substantial risks associated with identifying successful business development targets and consummating related transactions. Increased focus on business combinations in our industry, including by the Federal Trade Commission and competition authorities in Europe and other jurisdictions, and heightened competition for attractive targets has and could continue to delay, jeopardize or increase the costs of our business development activities. In addition, failures or difficulties in integrating or retaining new personnel or the operations of the businesses, products, or assets we acquire (including related technology, commercial operations, compliance programs, information security, manufacturing, distribution, and general business operations and procedures) may affect our ability to realize the expected benefits of business development transactions and may result in our incurrence of substantial asset impairment or restructuring charges. We also may fail to generate the expected revenue and pipeline enhancement from business development activities due to developments outside our control, including unsuccessful clinical trials, issues related to the quality, integrity, or broad applicability of data, regulatory impediments, and commercialization challenges. Accordingly, business

development transactions may not be completed in a timely manner (if at all), may not result in successful development outcomes or successful commercialization of any product, and may give rise to legal proceedings or regulatory scrutiny.

See Item 1, "Business—Research and Development—Phases of New Drug Development" and Item 7, "Management's Discussion and Analysis—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; the loss of effective intellectual property protection for certain of our products has resulted, and in the future is likely to continue to result, in rapid and severe declines in revenues for those products.**

  In the ordinary course of their lifecycles, our products lose significant patent protection and/or data protection in the U.S., as well as in key jurisdictions outside the U.S., after a specified period of time. Some products also lose patent protection as a result of successful third-party challenges. We have faced, and remain exposed to, generic competition following the expiration or loss of such intellectual property protection. For example, following the expiration of patent exclusivity for Alimta in Europe and Japan in June 2021, we have faced generic competition that has rapidly and severely eroded revenue from prior levels, and we expect such competition will continue to erode revenue from current levels in these markets. In addition, as a result of the entry of multiple generics in the U.S. following the expiration of patent and pediatric exclusivity for Alimta in in the first half of 2022, we began facing, and expect to continue to face, generic competition that has rapidly and severely eroded revenue from prior levels, and we expect will continue to erode revenue from current levels.

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

  There is no assurance that the patents we are seeking will be granted or that the patents we hold will be found valid and enforceable if challenged. Moreover, patents relating to particular products, uses, formulations, or processes do not preclude other manufacturers from employing alternative processes or marketing alternative products or formulations that compete with our patented products. In addition, competitors or other third parties may assert claims that our activities infringe patents or other intellectual property rights held by them, or allege a third-party right of ownership in our existing intellectual property. See Item 7, "Management's Discussion and Analysis—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 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 and indications 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, regulations, and enforcement practices could reduce protections for our innovative products and indications. For example, potential reforms to pharmaceutical legislation in the European Union may threaten the predictability and length of certain pharmaceutical intellectual property incentives. Changes proposed by the USPTO to limit the number of, and differences between, patents obtained could also affect the scope of patent protection for our products in the U.S. Also in the U.S., in addition to the process for challenging patents set forth in the BPCIA, which applies to biologic products, the Hatch-Waxman Act provides generic companies substantial incentives to seek to invalidate our patents covering pharmaceutical products. As a result, we expect that our U.S. patents on major pharmaceutical products, including biologics, will continue to be routinely challenged in litigation

and may not be upheld. In addition, a separate IPR process currently allows competitors to seek invalidation of patents at the USPTO without the protections of the BPCIA or Hatch-Waxman Act. The use of IPR proceedings after the institution of litigation pursuant to the BPCIA or Hatch-Waxman Act is currently a topic of debate among legislators and the future ability of our competitors to use IPR proceedings as an alternative to Hatch-Waxman Act or BPCIA litigation procedures to challenge our patents remains uncertain. Recently, the USPTO issued an interim procedure regarding the use of discretionary denials of IPR proceedings when there is parallel district court litigation. However, it is not clear how this interim procedure could affect the ability of our competitors to institute IPR proceedings after institution of litigation. If our patents are challenged through this expedited review process, even if we prevail in demonstrating the validity of our patent, our win provides limited precedential value at the PTAB and no precedential value in federal district court, meaning the same patent can be challenged by other competitors. We face many generic manufacturer challenges to our patents outside the U.S. as well. The entry of generic competitors typically results in rapid and severe declines in revenues. In addition, competitors or other third parties may claim that our activities infringe patents or other intellectual property rights held by them. If successful, such claims could result in our being unable to market a product in a particular territory or being required to pay significant damages for past infringement or royalties on future sales. In addition, intellectual property protection in certain jurisdictions outside the U.S. is weak and we face additional risks to our intellectual property rights, including competition with generic or counterfeit versions of our products relatively shortly after launch. See Item 1, "Business—Patents, Trademarks, and Other Intellectual Property Rights," and Item 8, "Financial Statements and Supplementary Data—Note 16: Contingencies," for more details.

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

  We compete with a large number of multinational pharmaceutical companies, biotechnology companies, and generic pharmaceutical companies and, in many cases, our products compete against the leading products of one or more of our competitors. To compete successfully, we must continue to deliver to the market innovative, cost-effective products that meet important medical needs. Our product revenues can be adversely affected by the introduction by competitors of branded products that are perceived as superior by the marketplace, by generic or biosimilar versions of our branded products, and by generic or biosimilar versions of other products in the same therapeutic class as our branded products. Our revenues can also be adversely affected by treatment innovations, including new modalities, 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, health authority guidelines and legislative actions could make it less burdensome for competitor products to enter the market and further incentivize uptake of biosimilars. In the U.S., the FDA has issued several "interchangeability" designations for biosimilar products, and is expected to continue doing so in the future. These designations could – subject to state law requirements – enable pharmacies to substitute biosimilars for innovator biological products. Given the importance of biologic products to our clinical-stage pipeline, such regulation could have a material adverse effect on our business. See Item 1, "Business—Competition" and "Business—Research and Development," for more details.

  In addition, we rely on our ability to attract, engage, and retain highly qualified and skilled personnel in order to compete effectively. To continue to commercialize our products, and advance the research, development, and commercialization of additional modalities, indications, and product candidates, we have expanded, and will likely need to further expand, our workforce, including in the areas of manufacturing, clinical trials management, regulatory affairs, and sales and marketing, both in and outside the U.S. We continue to face intense competition for qualified individuals from numerous multinational pharmaceutical companies, biotechnology companies, academic and other research institutions, as well as employers near our manufacturing and other facilities, which has and may continue to increase our labor costs. Our ability to attract and retain talent in our increasingly competitive environment may be further complicated by evolving employment trends, including as related to increased preferences for remote or flexible work arrangements; public health outbreaks, epidemics, or pandemics, such as the COVID-19 pandemic; political, social, civil, or cultural unrest; emergence or escalation of, and responses to, war and unrest; or the threat of or perceived potential for any of the foregoing events. Our failure to compete effectively for talent could negatively affect sales of our current and any future

approved products, and could result in material financial, legal, commercial, or reputational harm to our business.

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

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

  IT systems are vulnerable to system inadequacies, operating failures, service interruptions or failures, security breaches, malicious intrusions, or cyber-attacks from a variety of sources, which may remain undetected for significant periods of time. Such vulnerabilities, inadequacies, or failures are in many cases more acute for IT systems associated with recently acquired businesses, and we may be unable to address such vulnerabilities, inadequacies, or failures immediately after acquiring a business. As a result, our newly acquired businesses could be more vulnerable to potential interruptions, breaches, intrusions, or attacks.

  Cyber-attacks are growing in their frequency, sophistication, and intensity, and are becoming increasingly difficult to detect, mitigate, or prevent. Cyber-attacks come in many forms, including the deployment of harmful malware, exploitation of vulnerabilities (including those of third-party software or systems), denial-of-service attacks, the use of social engineering, and other means to compromise the confidentiality, integrity, and availability of our IT systems, confidential information, and other data. Breaches resulting in the compromise, disruption, degradation, manipulation, loss, theft, destruction, or unauthorized disclosure or use of confidential information, or the unauthorized access to, disruption of, or interference with our IT systems, products and services, can occur in a variety of ways, including negligent or wrongful conduct by employees or others with permitted access to our systems and information, or wrongful conduct by hackers, competitors, certain governments or nation-states, or other current or former company personnel. Our third-party partners, including third-party providers of data hosting or cloud services, as well as suppliers, distributors, alliances, and other third parties with whom we may share data, face similar risks, which could affect us directly or indirectly. Unassociated third parties present further risks, including by propagating misinformation related to our products, business, and industry. The healthcare industry has been and continues to be a target for cyber-attacks, and the number of threats has increased over time. Numerous federal agencies that monitor and regulate internet and cyber-crime have issued guidance, alerts and directives warning of software vulnerabilities that require immediate patching, malicious actors targeting healthcare-related systems and nation-state sponsored hacking designed to steal valuable information.

  The failure, inadequacy, or breach of our IT systems or business processes, the compromise, disruption, degradation, manipulation, loss, theft, destruction, or unauthorized access to, disclosure or use of, confidential information, or the unauthorized access to, disruption of, or interference with our products and services that rely on IT systems or business processes, could impair our ability to secure and maintain intellectual property rights; result in a product manufacturing interruption or failure, or in the interruption or failure of products or services that rely on IT systems or business processes; damage our operations, customer relationships, or reputation; undermine integration activities or otherwise delay the launch of acquired products; result in unfavorable clinical trial results by virtue of incorrect or unreliable data; and/or cause us to lose trade secrets or other competitive advantages. Unauthorized disclosure of personally identifiable information could expose us to significant sanctions for violations of data privacy laws and

regulations around the world and could damage public trust in our company. In addition, IT system security in jurisdictions outside the U.S. is weaker and may result in additional costs, uncertainties, and risks.

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

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

  Economic slowdowns could lead to decreased utilization of our products, affecting our sales. Declining tax revenues and increased government spending on other programs attributable to economic downturns increase the pressure on governments to reduce healthcare spending, leading to increased control of drug prices or lower utilization. Additionally, some customers, including governments or other entities reliant upon government funding, may be unable to pay for our products fully or 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 significant economic downturns could limit our ability to access capital markets.

  In addition, significant portions of our business are conducted in Europe (including the United Kingdom), Asia (including China), and other international geographies. Trade and other global disputes and interruptions in international relationships, including related to tariffs, trade protection measures, import or export licensing requirements, the imposition of trade sanctions or similar restrictions by the U.S. or other governments, unrest or war, as well as public health outbreaks, epidemics, or pandemics, such as the COVID-19 pandemic, affect our ability to do business. For example, tensions between the U.S. and China have led to a series of tariffs and sanctions being imposed by the U.S. on imports from China mainland, as well as other business restrictions. As a further example, the financial impact of higher energy prices, defense spending, and inflation due, in part, to the Russia-Ukraine war and resulting geopolitical and economic disruptions, particularly following the COVID-19 pandemic, has further exacerbated financial pressures on governments with single-payer or government funded healthcare systems, leading to increased impetus for increases in rebates, clawbacks, and other reforms to reimbursement systems, particularly in Europe. These and similar events have adversely affected, and may continue to adversely affect, us, our business partners, and our customers. For more details, see Item 1, "Business—Regulations and Private Payer Actions Affecting Pharmaceutical Pricing, Reimbursement, and Access."

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

  Pharmaceutical products receive regulatory approval based on data obtained in controlled clinical trials of limited duration. After approval, the products are used for longer periods of time by much larger numbers of patients. Accordingly, we and others (including regulatory agencies and private payers) collect extensive information on the efficacy and safety of our marketed products by continuously monitoring the use of our products in the marketplace. In addition, we or others may conduct post-marketing clinical studies on efficacy and safety of our marketed products. New safety or efficacy data from both market surveillance and post-marketing clinical studies may result in product label changes or other measures that could reduce the product's market acceptance and result in declining sales. Serious safety or efficacy issues that arise after product approval have, and could in the future, result in voluntary or mandatory product recalls or withdrawals from the market. Safety issues have, and could in the future, result in costly product liability claims.

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

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

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

  Pharmaceutical manufacturing is complex and highly regulated. Manufacturing or quality assurance difficulties at our facilities or those of our contractors and suppliers, the failure or refusal of a supplier or contract manufacturer to supply contracted quantities, or increases in demand on a supplier could result in delays and disruptions in the manufacturing, distribution, and sale of our products and/or product shortages, leading to lost revenue. In select cases, supply constraints may also lead to pauses, discontinuations or other product availability issues in one or more markets, which could have a material adverse effect on our consolidated results of operations and cash flows. Further, cost inflation and global transportation and logistics challenges, as well as tight labor markets, have caused, and in the future may cause, delays in, and/or increase costs related to, distribution of our medicines, the construction or other acquisition of manufacturing capacity, procurement activity, and supplier or contract manufacturer arrangements. Such difficulties, disruptions, or challenges could result from quality, oversight, or regulatory compliance problems; natural disasters (including increased instances of natural disasters or other events that may be due to climate change), public health outbreaks, epidemics, or pandemics (such as the COVID-19 pandemic); periods of global economic downturn or uncertainty; emergence or escalation of, and responses to, war or unrest (including the Russia-Ukraine war); equipment, mechanical, data, or IT system vulnerabilities, such as system inadequacies, inadequate controls or procedures, operating failures, service interruptions or failures, security breaches, malicious intrusions, or cyber-attacks from a variety of sources; labor shortages; contractual disputes with our suppliers and contract manufacturers; or inability to obtain single-source or other raw or intermediate materials. Regional dependencies may in some cases accentuate risks related to manufacturing and supply. For example, we, and the pharmaceutical industry generally, depend on China-based partners for integral chemical synthesis, reagents, starting materials, and ingredients.

  Difficulties in predicting or variability in demand for our products and those of our competitors and the very long lead times necessary for the expansion and regulatory qualification of pharmaceutical manufacturing capacity have resulted, and in the future may result, in difficulty meeting demand for, or disruptions, shortages, and higher costs in the supply of, our products. For example, we have experienced challenges in meeting demand for our incretin products, partially due to the limited availability of competitor therapies. Despite our ongoing efforts to meet significant expected demand by obtaining additional internal and contracted manufacturing capacity, there can be no assurances that such capacity increases will be realized as expected. Delays or challenges in operationalizing additional manufacturing capacity would limit our ability to capitalize on expected demand. Conversely, unexpected contingencies that limit demand for our incretin products would undermine our ability to realize the full benefit of significant capital expenditures that we have incurred, and expect to continue to incur, to augment manufacturing capacity and may also subject us to contractual payment obligations. The foregoing risks and uncertainties could negatively impact our consolidated results of operations and reputation. See Item 1, "Business—Raw Materials and Product Supply," and Item 7, "Management's Discussion and Analysis—Financial Condition and Liquidity" for more details.

- **We derive a significant percentage of our total revenue from relatively few products and sell our products through increasingly consolidated supply chain stakeholders, which may subject us to, or exacerbate, various risks.**

  We derived direct product and/or alliance revenues of more than $1 billion for each of Trulicity, Verzenio, Taltz, Jardiance (including Glyxambi, Synjardy, and Trijardy XR), Humalog (including Insulin Lispro), our COVID-19 antibodies, and Humulin that collectively accounted for 69 percent of our total revenues in 2022. In particular, Trulicity accounted for 26 percent of our total revenues in 2022 and we expect GLP-1s, including Mounjaro, which we launched in 2022, to represent a significant and growing portion of our business. Loss of patent protection, changes in prescription rates, material product liability litigation, unexpected side effects or safety concerns, significant changes in demand, regulatory proceedings, negative publicity affecting doctor or patient confidence, pressure from existing or new competitive products, changes in labeling, pricing, and access pressures, or supply shortages or disruptions for these products or any of our other major products could materially impact our results of operations.

  In addition, in the U.S., most of our products are distributed through wholesalers and if one of these significant wholesalers should encounter financial or other difficulties, it might decrease the amount of business the wholesaler does with us or we might be unable to timely collect the amounts that the wholesaler owes us, which could negatively impact our results of operations. See Item 1, “Business—Marketing and Distribution,” for more details.

  Moreover, the negotiating power of health plans, managed care organizations, pharmacy benefit managers, and other supply chain stakeholders has increased due to consolidation, regulatory, and other market impacts, and they, along with governments, increasingly employ formularies to control costs and encourage utilization of certain drugs, including through the use of formulary inclusion, or favorable formulary placement. Such stakeholders have also increasingly imposed utilization management tools favoring the use of generic products. As these practices expand, including due to potential further consolidation of U.S. private third-party payers, we may face difficulty in obtaining or maintaining timely or adequate pricing or formulary placement of our products. We expect that consolidation of supply chain stakeholders will continue to increase competitive and pricing pressures on pharmaceutical manufacturers. For additional information on pricing and reimbursement for our pharmaceutical products, see "U.S. Private Sector Dynamics" and "Regulations and Private Payer Actions Affecting Pharmaceutical Pricing, Reimbursement, and Access—U.S."

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

  We rely on third parties, including suppliers, distributors, alliances, and collaborations with other pharmaceutical and biotechnology companies, and third-party service providers, for selected aspects of product and clinical development, manufacturing, commercialization, hosting of, and support for, IT systems, product distribution, and certain financial transactional processes. As examples, we outsource the day-to-day management and oversight of some of our clinical trials to contract research organizations and the distribution of our products through logistics providers. Outsourcing involves many risks, including the risk that the third parties may not perform to our standards or legal requirements, including applicable requirements for diversity in clinical trials; 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 IT system vulnerabilities, breaches, cyber-attacks, or inadequate controls or procedures; may be unable to satisfy their commitments to us in which case we may not be able to achieve acceptable alternative sourcing; or may fail to perform at all. The foregoing risks may be heightened in jurisdictions outside the U.S., where we may have fewer alternative providers as well as face additional costs, uncertainties, and risks. Failure of 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.

- **Public health outbreaks, epidemics, or pandemics, such as the COVID-19 pandemic, have adversely impacted and may in the future adversely impact our business and operations.**

  Actual or threatened public health outbreaks, epidemics, or pandemics, such as the COVID-19 pandemic, have adversely impacted and may in the future adversely impact our business and operations. The

COVID-19 pandemic has adversely impacted and may continue to adversely impact our business and operations across markets to varying and fluctuating degrees, including as a result of:

- Cost inflation and strain on global transportation, manufacturing, and labor markets, which have negatively impacted development, manufacturing, supply, distribution, and sales of our medicines, including through increased costs to provide, and in some cases disruptions in supply or shortages of, our medicines.
- Fewer in-person interactions among patients and healthcare providers and our employees with healthcare professionals in certain markets.
- Pricing pressures, rebates, clawbacks, and other changes in reimbursement policies and programs resulting, in part, from the financial strain of the COVID-19 pandemic on government-funded healthcare systems around the world.
- Risks related to our COVID-19 therapies, including heightened regulatory scrutiny of our manufacturing practices, quality assurance, and similar regulations; restrictions on administration that limit widespread and timely access to our therapies, and risks related to handling, return, and/or refund of product after delivery by us; concerns related to expedited authorization of restricted distribution of products with less than typical safety and efficacy data; and fluctuations in, or elimination of, demand for our COVID-19 therapies, including based on the availability of superior or competitive therapies, preventative measures such as vaccines and antiviral medicines, mutations of the virus impacting effectiveness, revocations or restrictions on EUAs, reaching endemic status in different jurisdictions, reduced government and payer funding for COVID-19 therapies, the unpredictable nature of pandemics, and other developments.

These and other risks related to the COVID-19 pandemic and other actual or threatened public health outbreaks, epidemics, or pandemics could affect other aspects of our business or intensify other risks inherent in our business. The degree to which the COVID-19 pandemic could continue to affect us and other actual or threatened public health outbreaks, epidemics, or pandemics could affect us, will depend on developments that are highly uncertain and beyond our knowledge or control, including the duration and severity of the public health threat, the actions taken to reduce its transmission, the introduction and spread of new variants, the degree and extent of government restrictions on economic activity, government spending, and access to healthcare, and the speed with which, and extent to which, economic and operating conditions recover. Should the COVID-19 pandemic, or any other actual or threatened public health outbreak, epidemic, or pandemic, as well as any associated or resulting cost of inflation, supply chain disruption, labor market impact, recession, depression, or other negative contingency, continue for a prolonged period, these risks could be exacerbated, causing further impact on our business and operations.

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 results of operations, reputation or business.**

  Public and private payers continue to take aggressive steps to control their expenditures for pharmaceuticals by placing restrictions on pricing and reimbursement for, and patient access to, our medicines. These pressures have negatively affected, and could continue to negatively affect, our consolidated results of operations. Governments and private payers worldwide have intensified their scrutiny of, and actions intended to address, pricing, reimbursement, and access to pharmaceutical products. Additional policies, regulations, legislation, or enforcement, including as a result of the regulatory priorities of the current U.S. presidential administration and regulatory authorities worldwide, could adversely impact our business and consolidated results of operations. In particular, if one or more of our significant products are selected under the IRA, the resulting price reduction and reimbursement could negatively impact our business and consolidated results of operations. For more details, see Item 1, "Business—Regulations and Private Payer Actions Affecting Pharmaceutical Pricing, Reimbursement, and Access."

  Further, restrictive or unfavorable pricing, coverage, or reimbursement determinations for our medicines or product candidates by governments, regulatory agencies, courts, or private payers, such as the Alzheimer's Monoclonal Antibody NCD, may adversely impact our business and financial results. We

continue to experience additional pricing pressures, rebates, clawbacks, and other changes in reimbursement policies and programs resulting from the financial strain of the COVID-19 pandemic, periods of global economic downturn or uncertainty, and the emergence or escalation of, and responses to, war or unrest (including the Russia-Ukraine war).

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

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

  As a global company, we face foreign currency risk exposure from fluctuating currency exchange rates, interest rate risk from our exposure to floating and variable interest rates, and inflation risk from existing and expected rates of inflation in the U.S. and other jurisdictions, each of which impacts our results of operations. In recent periods, significant fluctuations in currency rates and inflation have had a significant negative impact on our results of operations. We are a net receiver of foreign currencies and our results of operations may continue to be adversely impacted if the U.S. dollar remains strong compared to foreign currencies. Further, in the event of an extreme devaluation of local currency in a particular market in which we operate, the price of our products could become unsustainable in the relevant market. Inflationary pressures in recent periods have also negatively impacted us and may continue to negatively impact us in various ways, including cost inflation, higher labor costs, and other higher expenses, with some of these higher expenses due in part to policy actions intended to curb inflation. See Item 7, "Management's Discussion and Analysis—Financial Condition and Liquidity" and Item 8, "Financial Statements and Supplementary Data—Note 1: Summary of Significant Accounting Policies and Implementation of New Financial Accounting Standards," for more details.

- **We are subject to evolving and complex tax laws, which may result in additional liabilities and affect our results of operations.**

  We are subject to income taxes in the U.S. and numerous other jurisdictions, and in the course of our business, we make judgments about the expected tax treatment of various transactions and events. Changes in tax laws, regulations, administrative practices, principles, and interpretations, as well as events that differ from our expectations, have affected and may adversely affect our effective tax rates, cash flows, and/or results of operations. Significant uncertainty currently exists regarding tax proposals introduced by the current U.S. administration and Congress, including modifications to certain aspects of the Tax Cuts and Jobs Act of 2017, such as the potential repeal or deferral of the provision requiring capitalization of research and development expenses. In addition, tax authorities in the U.S. and other jurisdictions in which we do business routinely examine our tax returns and are intensifying their scrutiny and examinations of profit allocations among jurisdictions, which could unfavorably impact our results of operations. Further, actions taken with respect to tax-related matters by associations such as the Organisation for Economic Co-operation and Development and the European Commission could influence tax laws in countries in which we operate. Modifications to key elements of the current U.S. or international tax framework could have a significant impact on our effective tax rate, results of operations, and cash flows. See Item 7, "Management's Discussion and Analysis—Executive Overview—Other Matters—Tax Matters" and Item 8, "Financial Statements and Supplementary Data—Note 14: Income Taxes," for more details.

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

  The marketing, promotional, and pricing practices of pharmaceutical manufacturers, as well as the manner in which manufacturers interact with purchasers, prescribers, and patients, are subject to extensive scrutiny and regulation. Many companies, including us, are and have been subject to investigations and claims related to these practices asserted by federal, state, and foreign governmental authorities, private payers, and consumers. These investigations and claims have resulted in substantial expense and other significant consequences to us. We are, and could in the future become, subject to such investigations and claims, the outcomes of which include criminal charges and fines, penalties, or other monetary or non-monetary remedies, including exclusion from U.S. federal and other healthcare programs. Such investigations and claims have intensified and may continue to intensify as a result of the regulatory priorities of each particular U.S. presidential administration and other regulatory authorities worldwide. In addition, regulatory issues concerning compliance with cGMP, quality assurance, evolving standards, and increased scrutiny around excipients and potential impurities such as nitrosamines, and

similar regulations and standards (and comparable foreign regulations and standards) 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 new product approvals or line extensions or supplemental approvals of current products pending resolution of the issues, and reputational harm, any of which would adversely affect our business. Regulatory compliance and processes in jurisdictions outside the U.S. may also be less predictable and result in additional costs, uncertainties, and risks. See Item 1, "Business—Government Regulation of Our Operations," for more details.

Furthermore, there is an increased focus by foreign, federal, state, and local regulatory and legislative bodies regarding environmental policies relating to climate change, regulating greenhouse gas emissions, carbon taxes, emissions trading schemes, sustainable manufacturing, human rights and equity matters, and disclosure regarding the foregoing, many of which may be ambiguous, inconsistent, dynamic or conflicting. We expect to experience increased restrictions and compliance costs, legal costs, and expenses related to such new or changing legal or regulatory requirements. Moreover, compliance with any such legal or regulatory requirements would require us to devote substantial time and attention to these matters. In addition, we may still be subject to penalties or potential litigation if such laws and regulations are interpreted or applied in a manner inconsistent with our practices.

Additionally, we are subject to increased negative attention from the media, stockholders, activists, and other stakeholders on climate change, social, and sustainability matters. The perception that we have failed to act in a socially responsible manner, whether or not valid, results in adverse publicity that can negatively affect our business and reputation, as well as result in increased scrutiny from legislators and regulatory authorities. Moreover, from time to time we establish and publicly announce goals and commitments, including to reduce our impact on the environment. Our ability to achieve any stated environmental, social or governance goal, target or objective is subject to numerous factors and conditions, many of which are outside our control. Examples of such factors include evolving regulatory requirements affecting sustainability standards or disclosures or imposing different requirements, the availability of requisite financing, and the availability of suppliers that can meet our sustainability and other goals. If we fail to achieve, are perceived to have failed or been delayed in achieving, or improperly report our progress toward achieving these goals and commitments, it could negatively affect our reputation or investor confidence, and expose us to enforcement actions and litigation.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our principal domestic and international executive offices are located in Indianapolis. At December 31, 2022, we owned nine production, distribution, and corporate administrative sites in the United States (U.S.), including Puerto Rico. These facilities contain an aggregate of approximately 8.1 million square feet of floor area dedicated to production, distribution, and administration. Major production sites include Indianapolis, Indiana; Carolina, Puerto Rico; and Branchburg, New Jersey. In 2023, we expect production to commence at an additional approximately 0.4 million square foot facility in Durham, North Carolina, with other production facilities and expansions of production facilities expected to come online in future periods.

We own production and distribution sites in seven countries outside the U.S., containing an aggregate of approximately 4.6 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 4.5 million square feet of floor area, primarily consisting of owned facilities located in Indianapolis and smaller leased sites primarily in San Diego, California; San Francisco, California; and New York, New York. Outside the U.S., we own a small research and development facility in Spain and lease a small site in Singapore.

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

Item 3. Legal Proceedings

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

Item 4. Mine Safety Disclosures

Not applicable.

Part II

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

Information relating to the principal market for our common stock, dividends, 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 17, 2023, there were approximately 19,868 holders of record of our common stock based on information provided by EQ Shareowner Services, our transfer agent. Our common stock is listed under the ticker symbol LLY on the New York Stock Exchange (NYSE).

The following table summarizes the activity related to repurchases of our equity securities during the fourth quarter ended December 31, 2022:

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 2022	—	$ —	—	$ 3,250.0
November 2022	—	—	—	3,250.0
December 2022	—	—	—	3,250.0
Total	—	—	—	

During the three months ended December 31, 2022, we did not repurchase any shares under our $5.00 billion share repurchase program authorized in May 2021.

PERFORMANCE GRAPH

The following graph compares the return on Lilly stock with that of the Standard & Poor's (S&P) 500 Stock Index and our peer group for the years 2018 through 2022. The graph assumes that, on the last business day of 2017, 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 2017 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-17	$ 100.00	$ 100.00	$ 100.00
Dec-18	140.45	104.95	95.62
Dec-19	163.13	124.15	125.72
Dec-20	213.80	126.98	148.85
Dec-21	355.08	152.56	191.58
Dec-22	476.65	167.09	156.88

[1] We constructed the peer group as the industry index for this graph. It is comprised of the following companies in the pharmaceutical and biotechnology industries: AbbVie Inc.; Amgen Inc.; AstraZeneca PLC; Biogen Inc.; Bristol-Myers Squibb Company; Gilead Sciences Inc.; GlaxoSmithKline plc; Johnson & Johnson; Merck & Co., Inc.; Novartis AG; Novo Nordisk A/S; Pfizer Inc.; Roche Holding AG; Sanofi S.A.; and Takeda Pharmaceutical Company Limited. The peer group used for performance benchmarking aligns with the peer group used for executive compensation purposes for 2022.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Results of Operations and Financial Condition

(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 our company's results of operations and financial position. This discussion and analysis should be read in conjunction with Item 8, "Financial Statements and Supplementary Data." Certain statements in this Item 7 constitute forward-looking statements. Various risks and uncertainties, including those discussed in "Forward-Looking Statements" and Item 1A, "Risk Factors," may cause our actual results, financial position, and cash generated from operations to differ materially from these forward-looking statements.

EXECUTIVE OVERVIEW

This section provides an overview of our financial results, late-stage pipeline developments, and other matters affecting our company and the pharmaceutical industry.

Financial Results

The following table summarizes our key operating results:

	Year Ended December 31		
	2022	**2021**	**Percent Change**
Revenue	**$ 28,541.4**	$ 28,318.4	1
Gross margin	**21,911.6**	21,005.6	4
Gross margin as a percent of revenue	**76.8 %**	74.2 %	
Research and development	**$ 7,190.8**	$ 6,930.7	4
Marketing, selling, and administrative	**6,440.4**	6,431.6	—
Acquired in-process research and development (IPR&D) and development milestones	**908.5**	970.1	(6)
Asset impairment, restructuring, and other special charges	**244.6**	316.1	(23)
Other—net, (income) expense	**320.9**	201.6	59
Net income	**6,244.8**	5,581.7	12
Earnings per share - diluted	**6.90**	6.12	13

Revenue increased in 2022 driven by increased volume, largely offset by lower realized prices and the unfavorable impact of foreign exchange rates. Research and development expenses increased in 2022, driven primarily by higher development expenses for late-stage assets, partially offset by lower development expenses for COVID-19 antibodies and the favorable impact of foreign exchange rates. Marketing, selling, and administrative expenses in 2022 remained relatively flat compared to 2021 as increased costs associated with launches of new products and indications were offset by the favorable impact of foreign exchange rates.

The following highlighted items affect comparisons of our 2022 and 2021 financial results:

2022

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

- We recognized $908.5 million of acquired IPR&D and development milestones that included the buy-out of substantially all future obligations that were contingent upon the occurrence of certain events linked to the success of our mutant-selective PI3kα inhibitor and a purchase of a Priority Review Voucher.

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

- We recognized charges of $244.6 million primarily related to an intangible asset impairment for GBA1 Gene Therapy (PR001) due to changes in estimated launch timing.

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

- We recognized $410.7 million of net investment losses on equity securities.

2021

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

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

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

- We recognized $970.1 million of acquired IPR&D and development milestones that included charges resulting from business development transactions with Foghorn Therapeutics Inc. (Foghorn), Rigel Pharmaceuticals, Inc. (Rigel), and Precision Biosciences, Inc. (Precision).

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

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

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

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

Late-Stage Pipeline

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

The following certain new molecular entities (NMEs) are currently in Phase II or Phase III clinical trials or have been submitted for regulatory review or have received regulatory approval in the U.S., Europe, or Japan. The following table reflects the status of certain NMEs, including certain other developments, up to the time of the filing of this Annual Report on Form 10-K:

Compound	Indication	Status	Developments
Diabetes			
Basal Insulin-Fc	Type 1 and 2 diabetes	Phase III	Phase III trials initiated in 2022 and 2023.
ANGPTL3 siRNA	Cardiovascular disease	Phase II	Phase II trial initiated in 2022.
LP(a) Inhibitor	Cardiovascular disease	Phase II	Phase II trial initiated in 2022.
LP(a) siRNA	Cardiovascular disease	Phase II	Phase II trial initiated in 2022.
Orforglipron	Obesity	Phase II	Phase II trials were recently completed.
	Type 2 diabetes		
Retatrutide	Obesity	Phase II	Phase II trials were recently completed.
	Type 2 diabetes		
Immunology			
Lebrikizumab[(1)]	Atopic dermatitis	Submitted	Submitted in the U.S. and Europe in 2022. Phase III trials are ongoing.
Mirikizumab	Ulcerative colitis	Submitted	Submitted in the U.S., Europe, and Japan in 2022.
	Crohn's Disease	Phase III	Phase III trials are ongoing.
BTLA MAB Agonist	Systemic lupus erythematosus	Phase II	Phase II trial initiated in 2022.
CXCR1/2 Ligands Monoclonal Antibody	Hidradenitis suppurativa	Phase II	Phase II trial is ongoing.
Peresolimab	Rheumatoid arthritis	Phase II	Phase II trial is ongoing.
Rezpegaldesleukin	Systemic lupus erythematosus	Phase II	Phase II trial is ongoing.

Compound	Indication	Status	Developments
Neuroscience			
Donanemab	Early Alzheimer's disease	Complete Response Letter	Granted U.S. Food and Drug Administration (FDA) Breakthrough Therapy designation[2]. Submitted in the U.S. in 2022 under the accelerated approval pathway. In January 2023, the FDA issued a complete response letter for the accelerated approval submission. Phase III trials are ongoing.
	Preclinical Alzheimer's disease	Phase III	Phase III trial is ongoing.
Remternetug	Early Alzheimer's disease	Phase III	Phase III trial initiated in 2022.
Solanezumab	Preclinical Alzheimer's disease	Phase III	Phase III trial is ongoing.
GBA1 Gene Therapy (PR001)	Parkinson's disease	Phase II	Granted FDA Fast Track designation[3]. Phase II trial is ongoing.
GRN Gene Therapy (PR006)	Frontotemporal dementia	Phase II	Granted FDA Fast Track designation[3]. Phase II trial is ongoing.
O-GlcNAcase Inh	Alzheimer's disease	Phase II	Phase II trial is ongoing.
P2X7 Inhibitor	Pain	Phase II	Phase II trials initiated in 2022.
SSTR4 Agonist	Pain	Phase II	Phase II trials are ongoing.
TRPA1 Antagonist	Pain	Phase II	Phase II trials are ongoing.
Oncology			
Pirtobrutinib (Jaypirca™)	Mantle cell lymphoma	Approved[4]	FDA granted accelerated approval[4] in the U.S. in January 2023. Phase III trial is ongoing.
	Chronic lymphocytic leukemia	Phase III	Phase III trials are ongoing.
	B-cell malignancies	Phase II	Phase II trial is ongoing.
Selpercatinib (Retevmo®)	Lung cancer	Approved[4]	Phase III trials are ongoing.
	Thyroid cancer	Approved[4]	Phase III trial is ongoing.
Imlunestrant	Adjuvant Breast Cancer	Phase III	Phase III trial initiated in 2022.
	ER+HER2- metastatic breast cancer	Phase III	Phase III trial is ongoing.

[1] In collaboration with Almirall, S.A. in Europe.
[2] Breakthrough Therapy designation is designed to expedite the development and review of potential medicines that are intended to treat a serious condition where preliminary clinical evidence indicates that the treatment may demonstrate substantial improvement over available therapy on a clinically significant endpoint.
[3] Fast Track designation is designed to facilitate the development and expedite the review of medicines to treat serious conditions and fill an unmet medical need.
[4] Continued approval may be contingent on verification and description of clinical benefit in confirmatory Phase III trials.

Our pipeline also contains several new indication line extension (NILEX) products. The following certain NILEX products for use in the indication described are currently in Phase II or Phase III clinical trials or have been submitted for regulatory review or have received regulatory approval in the U.S., Europe, or Japan. The following table reflects the status of certain NILEX products, including certain other developments, up to the time of the filing of this Annual Report on Form 10-K:

Compound	Indication	Status	Developments
Diabetes			
Empagliflozin (Jardiance®)[1]	Chronic kidney disease	Submitted	Granted FDA Fast Track designation[2]. Submitted in the U.S. and Europe in January 2023.
Tirzepatide (Mounjaro®)	Obesity	Submission initiated	Granted FDA Fast Track designation[2] in 2022. Initiated a rolling submission in the U.S. in 2022. Phase III trials are ongoing.
	Heart failure with preserved ejection fraction	Phase III	Phase III trials are ongoing.
	Obstructive sleep apnea	Phase III	Phase III trial initiated in 2022. Granted FDA Fast Track designation[2] in 2022.
	Nonalcoholic steatohepatitis	Phase II	Phase II trial is ongoing.
Oncology			
Abemaciclib (Verzenio®)	Prostate cancer	Phase III	Phase III trials are ongoing.

[1] In collaboration with Boehringer Ingelheim.
[2] Fast Track designation is designed to facilitate the development and expedite the review of medicines to treat serious conditions and fill an unmet medical need.

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, the application of pricing controls, limited scope of approved uses, label changes, changes in the relevant treatment standards or the availability of new or better competitive products, difficulty or excessive costs to manufacture, or infringement of the patents or intellectual property rights of others. Regulatory agencies establish high hurdles for the efficacy and safety of new products and indications. Delays, uncertainties, unpredictabilities, and inconsistencies in drug approval processes across markets and agencies can result in delays in product launches and lost market opportunity. In addition, it can be very difficult to predict revenue growth rates of or variability in demand for new products and indications.

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

Other Matters

Patent Matters

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

Following the expiration of patent exclusivity for Alimta® in Europe and Japan in June 2021, we have faced generic competition that has rapidly and severely eroded revenue from prior levels, and we expect such competition will continue to erode revenues from current levels in these markets. In addition, as a result of the entry of multiple generics in the U.S. following the expiration of patent and pediatric exclusivity in the first half of 2022, we began facing, and expect to continue to face, generic competition that has rapidly and severely eroded revenue from prior levels, and we expect will continue to erode revenue from current levels. This decline in revenue will continue to impact period-over-period financial results comparisons, particularly during the first half of 2023. See Note 16 to the consolidated financial statements for a description of legal proceedings currently pending regarding certain of our patents.

Our compound patents for Humalog® (insulin lispro) have expired in the U.S. and major international markets, and we have also introduced lower-priced versions of Humalog as part of our insulin access and affordability solutions. A competitor has a similar version of insulin lispro in the U.S. and in certain European markets. Due to the impact of competition and pricing pressure in the U.S. and certain international markets, we expect that lower revenue for Humalog due to realized price decline will continue over time.

Trends Affecting Pharmaceutical Pricing, Reimbursement, and Access

Reforms, including those that may stem from periods of economic downturn or uncertainty, or as a result of high inflation, emergence or escalation of, and responses to, war or unrest (including the Russia-Ukraine war), or government budgeting priorities (including as exacerbated by the COVID-19 pandemic), may continue to result in added pressure on pricing and reimbursement for our products.

Global concern over access to and affordability of pharmaceutical products continues to drive regulatory and legislative debate and action, as well as worldwide cost containment efforts by governmental authorities. Such measures include the use of mandated discounts, price reporting requirements, mandated reference prices, restrictive formularies, changes to available intellectual property protections, as well as other efforts. In August 2022, the U.S. government enacted the Inflation Reduction Act of 2022 (IRA). Among other measures, the IRA will require the U.S. Department of Health and Human Services to effectively set prices for certain single-source drugs and biologics reimbursed under Medicare Part B and Part D. Generally, these government prices apply nine (medicines approved under a New Drug Application) or thirteen (medicines approved under a Biologics License Application) years following initial FDA approval and will be capped at a statutory ceiling price that is likely to represent a significant discount from average prices to wholesalers and direct purchasers. It is too soon to tell how the U.S. government will set these prices as the law specifies a ceiling price, but not a minimum or floor price. One or more of our significant products may be selected, which would have the effect of accelerating revenue erosion prior to patent expiry. The effect of reducing prices and reimbursement for certain of our products would significantly impact our business and consolidated results of operations. The establishment of payment limits or other restrictions by drug affordability review boards and other state level actors would similarly impact us.

Other IRA provisions provide for rebate obligations on drug manufacturers that increase prices of Medicare Part B and Part D medicines at a rate greater than the rate of inflation and Part D benefit redesign that includes replacing the Part D coverage gap discount program with a new manufacturer discounting program. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties, which could be significant.

The IRA takes effect progressively starting in 2023, with the first government-set prices effective in 2026. The IRA may meaningfully influence our business strategies and those of our competitors. In particular, the nine-year timeline to set prices for medicines approved under a new drug application may reduce the attractiveness of investment in small molecule innovation. The implications to us of a competitor's product being selected for price setting are also uncertain. Provisions of the IRA may be subject to legal challenges or other reformation, and the full impact of the IRA on our business and the pharmaceutical industry remains uncertain.

Additional policies, regulations, legislation, or enforcement, including those proposed and/or pursued by the U.S. Congress, the current U.S. presidential administration, and regulatory authorities worldwide, could adversely impact our business and consolidated results of operations.

Consolidation and integration of private payors and pharmacy benefit managers in the U.S. has also significantly impacted the market for pharmaceuticals by increasing payor leverage in negotiating manufacturer price or rebate concessions and pharmacy reimbursement rates. Furthermore, restrictive or unfavorable pricing, coverage, or reimbursement determinations for our medicines or product candidates by governments, regulatory agencies, courts, or private payers, such as the Centers for Medicare & Medicaid Services' national coverage determination for monoclonal antibodies for the treatment of Alzheimer's Disease, may adversely impact our business and consolidated results of operations. We expect that these actions may intensify and could particularly affect certain products, such as insulin, as governments manage and emerge from the COVID-19 pandemic, which could adversely affect our business. In addition, we are engaged in litigation and investigations related to our 340B program and access to insulin that, if resolved adversely to us, could negatively impact our business and consolidated results of operations. It is not currently possible to predict the overall potential adverse impact to us or the general pharmaceutical industry of continued cost containment efforts worldwide.

In addition, regulatory issues concerning compliance with current Good Manufacturing Practices, quality assurance, evolving standards, and increased scrutiny around excipients and potential impurities such as nitrosamines, and similar regulations and standards (and comparable foreign regulations and standards) 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 new product approvals or line extensions or supplemental approvals of current products pending resolution of the issues, and reputational harm, any of which would adversely affect our business. Moreover, increased focus on business combinations across industries and jurisdictions can lead to impediments to the completion of business combinations.

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

Product Supply

We have faced challenges, and expect to continue to face challenges, meeting strong demand for our incretin products, including due to the limited and fluctuating availability of competitor therapies. In the U.S., given very strong uptake of Mounjaro following its launch in the U.S. for type 2 diabetes in the second quarter of 2022, and as demand for Trulicity® has remained strong, we have experienced intermittent delays in fulfilling certain U.S. orders for these products. Outside the U.S., we have implemented certain actions to minimize the impact on existing Trulicity patients, but we expect to continue to experience intermittent disruptions in our supply of Trulicity in international markets.

We anticipate tight supplies of our incretin products will persist until additional manufacturing capacity is operationalized. We expect additional internal and contracted manufacturing capacity will become fully operational around the world in the next several years, with significant expansion in 2023, as part of our ongoing efforts to meet the significant demand for our incretin medicines.

Tax Matters

We are subject to income taxes and various other taxes in the U.S. and in many foreign jurisdictions; therefore, changes in both domestic and international tax laws or regulations have affected and may affect our effective tax rate, results of operations, and cash flows. In 2017, the U.S. enacted the Tax Cuts and Jobs Act (the 2017 Tax Act), which contained a provision that requires capitalization and amortization of research and development expenses for tax purposes starting in 2022. Previously, these expenses could be deducted in the year incurred. The implementation of this provision increased our cash payments of income taxes by approximately $1.20 billion in 2022. While the implementation of this provision will continue to increase our cash payments of income taxes, the increase will moderately decrease from 2022 levels over the five-year amortization period.

The U.S. and countries around the world are actively proposing and enacting tax law changes. Further, actions taken with respect to tax-related matters by associations such as the Organisation for Economic Co-operation and Development and the European Commission could influence tax laws in countries in which we operate. Tax authorities in the U.S. and other jurisdictions in which we do business routinely examine our tax returns and are intensifying their scrutiny and examinations of profit allocations among jurisdictions. Changes to existing U.S. and foreign tax laws and increased scrutiny by tax authorities in the U.S. and other jurisdictions could adversely impact our future consolidated results of operations and cash flows.

Foreign Currency Exchange Rates and Other Impacts

As a global company, we face foreign currency risk exposure from fluctuating currency exchange rates, primarily the U.S. dollar against the euro, Japanese yen, and Chinese yuan. While we seek to manage a portion of these exposures through hedging and other risk management techniques, significant fluctuations in currency rates can have a material impact, either positive or negative, on our consolidated results of operations in any given period. During the year ended December 31, 2022, revenue was unfavorably impacted by 3 percent due to foreign exchange rates. While there is uncertainty in the future movements in foreign exchange rates, fluctuations in these rates have, and we currently expect in the near-term future will, adversely impact our consolidated results of operations and cash flows.

In addition, cost inflation, the strain on global transportation, logistics, and labor markets (including as exacerbated by the COVID-19 pandemic and the emergence or escalation of, and responses to, war or unrest, including the Russia-Ukraine war), global economic downturns or uncertainty, and an increase in overall demand in our industry for certain products and materials have had, and may continue to have, a number of impacts on our business, including increased costs and disruptions in the supply of our medicines.

Acquisitions

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

See Note 3 to the consolidated financial statements for further discussion regarding our recent acquisitions.

COVID-19 Pandemic

As the COVID-19 pandemic evolves, we remain focused on protecting the health, safety, and well-being of our employees; supporting the medical system and our communities; and affordability of and access to our medicines. At the outset of the COVID-19 pandemic, we also focused on researching, developing, and supplying COVID-19 therapies, although we do not currently expect significant further revenue attributable to treatments for COVID-19.

The COVID-19 pandemic has adversely impacted and may continue to adversely impact our business and operations across markets to varying and fluctuating degrees, including as a result of cost inflation and strain on the global transportation, manufacturing, and labor markets, fewer in-person interactions among patients and healthcare providers and our employees with healthcare professionals in certain markets, pricing pressures, rebates, clawbacks, and other changes in reimbursement policies resulting from the financial strain of the COVID-19 pandemic on government-funded healthcare systems, and risks related to our COVID-19 therapies. The degree to which the COVID-19 pandemic could continue to affect us will depend on developments that are highly uncertain and beyond our knowledge or control. For additional information, see Item 1A, "Risk Factors—Risk Related to Our Business—Public health outbreaks, epidemics, or pandemics, such as the COVID-19 pandemic, have adversely impacted and may in the future adversely impact our business and operations."

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

RESULTS OF OPERATIONS

Operating Results—2022

Revenue

The following table summarizes our revenue activity by region:

	Year Ended December 31,		
	2022	2021	Percent Change
U.S.	**$ 18,190.0**	$ 16,811.0	8
Outside U.S.	**10,351.3**	11,507.4	(10)
Revenue	**$ 28,541.4**	$ 28,318.4	1

Numbers may not add due to rounding.

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

	2022 vs. 2021		
	U.S.	Outside U.S.	Consolidated
Volume	11 %	9 %	10 %
Price	(3)%	(10) %	(6) %
Foreign exchange rates	— %	(8) %	(3) %
Percent change	8 %	(10) %	1 %

Numbers may not add due to rounding.

In the U.S. the increase in volume in 2022 was primarily driven by Trulicity, Verzenio, Jardiance, Mounjaro, and Taltz ®, partially offset by decreased volume for Alimta, following the entry of multiple generics in the first half of 2022. In the U.S. the decrease in realized prices was primarily driven by Humalog, due to a list price reduction of insulin lispro injection and unfavorable segment mix, and Trulicity and Basaglar®, due to unfavorable segment mix and higher contracted rebates. In addition, the decrease in realized prices of Humalog was partially offset by changes to estimates for rebates and discounts in 2021.

Outside the U.S. the increase in volume in 2022 was primarily driven by Verzenio, Trulicity, Jardiance, Tyvyt ®, and Taltz, partially offset by a decrease in volume due to generic competition for Alimta and Cymbalta® and decreased utilization of COVID-19 antibodies. The decrease in realized prices outside the U.S. was primarily driven by the impact of government pricing in China from National Reimbursement Drug List (NRDL) formulary for certain products, particularly Tyvyt and Verzenio, and volume-based procurement (VBP) for Humalog.

The following table summarizes our revenue activity in 2022 compared with 2021:

	Year Ended December 31,				
	2022			2021	
Product	U.S.	Outside U.S.	Total	Total	Percent Change
Trulicity	**$ 5,688.8**	**$ 1,750.9**	**$ 7,439.7**	$ 6,471.9	15
Verzenio	**1,653.2**	**830.3**	**2,483.5**	1,349.9	84
Taltz	**1,724.6**	**757.4**	**2,482.0**	2,212.8	12
Jardiance[1]	**1,194.5**	**871.5**	**2,066.0**	1,490.8	39
Humalog[2]	**1,191.9**	**868.7**	**2,060.6**	2,453.0	(16)
COVID-19 antibodies[3]	**2,008.9**	**14.7**	**2,023.5**	2,239.3	(10)
Humulin®	**730.2**	**289.2**	**1,019.4**	1,222.6	(17)
Cyramza®	**351.4**	**620.0**	**971.4**	1,033.0	(6)
Alimta	**543.7**	**384.0**	**927.7**	2,061.4	(55)
Olumiant®[4]	**148.2**	**682.3**	**830.5**	1,115.1	(26)
Basaglar	**470.7**	**289.7**	**760.4**	892.5	(15)
Emgality®	**462.8**	**188.1**	**650.9**	577.2	13
Forteo®	**367.3**	**245.8**	**613.1**	801.9	(24)
Cialis®	**35.2**	**552.1**	**587.3**	718.4	(18)
Erbitux®	**500.1**	**66.4**	**566.5**	548.3	3
Mounjaro	**366.6**	**115.9**	**482.5**	—	NM
Zyprexa®	**30.4**	**306.5**	**336.9**	430.3	(22)
Tyvyt	**—**	**293.3**	**293.3**	418.1	(30)
Cymbalta	**33.7**	**249.6**	**283.3**	581.5	(51)
Other products	**687.8**	**974.9**	**1,662.9**	1,700.4	(2)
Revenue	**$ 18,190.0**	**$ 10,351.3**	**$ 28,541.4**	$ 28,318.4	1

Numbers may not add due to rounding.
NM - Not meaningful
[1] Jardiance revenue includes Glyxambi®, Synjardy®, and Trijardy® XR.
[2] Humalog revenue includes insulin lispro.
[3] COVID-19 antibodies include sales for bamlanivimab administered alone, for bamlanivimab and etesevimab administered together, and for bebtelovimab and were made pursuant to Emergency Use Authorizations (EUAs) or similar regulatory authorizations.
[4] Olumiant revenue includes sales for baricitinib that were made pursuant to EUA or similar regulatory authorizations.

Revenue of Trulicity increased 16 percent in the U.S., driven by increased demand, partially offset by lower realized prices due to unfavorable segment mix and higher contracted rebates. Revenue outside the U.S. increased 12 percent, driven by increased volume, partially offset by the unfavorable impact of foreign exchange rates and, to a lesser extent, lower realized prices. We experienced intermittent delays in fulfilling certain U.S. Trulicity orders during the second half of 2022. Actions to manage strong demand across our incretin portfolio, including measures to minimize existing patient impact in international markets, also affected volume in 2022.

Revenue of Verzenio increased 98 percent in the U.S., primarily driven by increased demand. Revenue outside the U.S. increased 61 percent, driven by increased demand, partially offset by lower realized prices primarily due to the impact of the NRDL formulary in China and the unfavorable impact of foreign exchange rates.

Revenue of Taltz increased 12 percent in the U.S., driven by increased demand, partially offset by lower realized prices. Revenue outside the U.S. increased 13 percent, driven by increased volume, partially offset by the unfavorable impact of foreign exchange rates and lower realized prices.

Revenue of Jardiance increased 48 percent in the U.S., primarily driven by increased demand. Revenue outside the U.S. increased 28 percent, primarily driven by increased demand, partially offset by the unfavorable impact of foreign exchange rates. See Note 4 to the consolidated financial statements for information regarding our collaboration with Boehringer Ingelheim involving Jardiance.

Revenue of Humalog decreased 10 percent in the U.S., primarily driven by lower realized prices due to a list price reduction of insulin lispro injection and unfavorable segment mix, partially offset by changes to estimates for rebates and discounts in 2021. Revenue outside the U.S. decreased 23 percent, primarily driven by lower realized prices due to the impact of VBP in China and the unfavorable impact of foreign exchange rates. Due to the impact of competition and pricing pressure in the U.S. and certain international markets, we expect that lower revenue for Humalog due to realized price decline will continue over time. See "—Executive Overview—Other Matters—Patent Matters" for additional information.

Revenue of COVID-19 antibodies was $2.01 billion in the U.S. during the year ended December 31, 2022, primarily due to bebtelovimab supplied to the U.S. government. COVID-19 antibodies are not currently authorized for emergency use in the U.S. We do not currently expect significant further revenue attributable to the treatment of COVID-19.

Revenue of Alimta decreased 56 percent in the U.S., primarily driven by decreased demand due to the entry of multiple generics in the first half of 2022. Revenue outside the U.S. decreased 54 percent, primarily driven by decreased demand due to generic competition. Following the expiration of patent exclusivity for Alimta in Europe and Japan in June 2021, we have faced generic competition that has rapidly and severely eroded revenue from prior levels, and we expect such competition will continue to erode revenues from current levels in these markets. In addition, as a result of the entry of multiple generics in the U.S. following the expiration of patent and pediatric exclusivity in the first half of 2022, we began facing, and expect to continue to face, generic competition that has rapidly and severely eroded revenue from prior levels, and we expect will continue to erode revenue from current levels. See "—Executive Overview—Other Matters—Patent Matters" for additional information.

Gross Margin, Costs, and Expenses

Gross margin as a percent of revenue was 76.8 percent in 2022, an increase of 2.6 percentage points compared with 2021, primarily driven by a net inventory impairment charge related to our COVID-19 antibodies recognized in 2021 and the unfavorable effect of foreign exchange rates on international inventories sold in 2021. Additionally, in 2022, favorable product mix, including the impact of lower sales of COVID-19 antibodies and Olumiant for the treatment of COVID-19, were offset by lower realized prices and increased expenses due to inflation and logistics costs.

Research and development expenses increased 4 percent to $7.19 billion in 2022, driven primarily by higher development expenses for late-stage assets, partially offset by lower development expenses for COVID-19 antibodies and the favorable impact of foreign exchange rates.

Marketing, selling, and administrative expenses remained relatively flat at $6.44 billion in 2022, as increased costs associated with launches of new products and indications were offset by the favorable impact of foreign exchange rates.

We have undertaken compensatory actions to improve retention and address wage inflation, which will increase compensation costs and impact our consolidated results of operations.

We recognized acquired IPR&D and development milestones of $908.5 million in 2022 that included the buy-out of substantially all future obligations that were contingent upon the occurrence of certain events linked to the success of our mutant-selective PI3kα inhibitor and a purchase of a Priority Review Voucher. We recognized acquired IPR&D and development milestones of $970.1 million in 2021 that included charges resulting from business development transactions with Foghorn, Rigel, and Precision. See Note 3 to the consolidated financial statements for additional information.

We recognized asset impairment, restructuring, and other special charges of $244.6 million in 2022, primarily related to an intangible asset impairment for GBA1 Gene Therapy (PR001) due to changes in estimated launch timing. We recognized asset impairment, restructuring, and other special charges of $316.1 million in 2021, primarily related to an impairment of a contract-based intangible asset from our acquisition of Loxo, an intangible asset impairment resulting from the sale of the rights to Qbrexza, as well as acquisition and integration costs associated with the acquisition of Prevail.

Other—net, (income) expense was expense of $320.9 million in 2022, primarily driven by net investment losses on equity securities. Other—net, (income) expense was expense of $201.6 million in 2021, primarily driven by a debt extinguishment loss of $405.2 million related to the repurchase of debt, partially offset by net investment gains on equity securities.

Our effective tax rate was 8.3 percent in 2022, reflecting the favorable tax impact of the implementation of a provision in the 2017 Tax Act that requires capitalization and amortization of research and development expenses for tax purposes starting in 2022, partially offset by the tax impact of the mix of earnings in higher tax jurisdictions. Our effective tax rate was 9.3 percent in 2021, reflecting the favorable tax impacts of acquired IPR&D and development milestone charges, net investment gains on equity securities, and a net discrete tax benefit.

Operating Results—2021

For a discussion of our results of operations pertaining to 2021 and 2020 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, 2021.

FINANCIAL CONDITION AND LIQUIDITY

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

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

Our management continuously evaluates our liquidity and capital resources, including our access to external capital, to ensure we can adequately and efficiently finance our capital requirements. As of December 31, 2022, our material cash requirements primarily related to purchases of goods and services to produce our products and conduct our operations, capital expenditures, dividends, repayment of outstanding borrowings, milestone and royalty payments, the remaining obligations for the one-time repatriation transition tax (also known as the 'Toll Tax') from the 2017 Tax Act, leases, unfunded commitments to invest in venture capital funds, and retirement benefits (see Notes 11, 4, 14, 10, 7, and 15 to the consolidated financial statements). We anticipate our cash requirements related to ordinary course purchases of goods and services will be consistent with our past levels relative to revenues.

In 2022, we committed to invest over several years more than $2 billion in two new facilities in Lebanon, Indiana to manufacture existing and future products, more than $1 billion in a new facility in Concord, North Carolina to manufacture parenteral (injectable) products and devices, and more than 400 million euro in a new facility in Limerick, Ireland to expand our manufacturing network for biologic active ingredients. In early 2023, we committed to invest an additional $450 million to expand manufacturing capacity at Research Triangle Park facility in Durham, North Carolina for additional parenteral filling, device assembly, and packaging capacity. These investments, and other capital investments that support our operations, will result in higher capital expenditures for the next several years.

The 2017 Tax Act contained a provision that requires us to capitalize and amortize research and development expenses for tax purposes starting in 2022, whereas previously we could fully deduct these expenses in the year incurred. The implementation of this provision increased our cash payments of income taxes by approximately $1.20 billion in 2022. While the implementation of this provision will continue to increase our cash payments of income taxes, the increase will moderately decrease from 2022 levels over the five-year amortization period. See "—Executive Overview—Other Matters—Tax Matters" for additional information.

Cash and cash equivalents decreased to $2.07 billion as of December 31, 2022, compared with $3.82 billion at December 31, 2021. Net cash provided by operating activities was $7.08 billion in 2022, compared with $7.26 billion in 2021. Refer to the consolidated statements of cash flows for additional information on the significant sources and uses of cash for the years ended December 31, 2022 and 2021.

In addition to our cash and cash equivalents, we held total investments of $3.05 billion and $3.30 billion as of December 31, 2022 and 2021, respectively. See Note 7 to the consolidated financial statements for additional information.

In December 2022, we acquired all shares of Akouos, Inc. (Akouos) for a purchase price that included $12.50 per share in cash (or an aggregate of $327.2 million, net of cash acquired) plus one non-tradable contingent value right (CVR) per share. The CVR entitles Akouos shareholders up to an additional $3.00 per share in cash (or an aggregate of approximately $122 million) payable, subject to certain terms and conditions, upon the achievement of certain specified milestones. This acquisition was funded through cash on hand. See Note 3 to the consolidated financial statements for additional information.

As of December 31, 2022, total debt was $16.24 billion, a decrease of $646.1 million compared with $16.88 billion at December 31, 2021. See Note 11 to the consolidated financial statements for additional information.

As of December 31, 2022, we had a total of $7.33 billion of unused committed bank credit facilities, $7.00 billion of which is available to support our commercial paper program. See Note 11 to the consolidated financial statements for additional information. We believe that amounts accessible through existing commercial paper markets should be adequate to fund short-term borrowing needs.

Dividends of $3.92 per share and $3.40 per share were paid in 2022 and 2021, respectively. The quarterly dividend was increased to $1.13 per share effective for the dividend to be paid in the first quarter of 2023, resulting in an indicated annual rate for 2023 of $4.52 per share.

Capital expenditures were $1.85 billion during 2022, compared to $1.31 billion in 2021.

In 2022, we repurchased $1.50 billion of shares under our $5.00 billion share repurchase program authorized in May 2021. As of December 31, 2022, we had $3.25 billion remaining under this program. See Note 13 to the consolidated financial statements for additional information.

See "—Executive Overview—Other Matters—Patent Matters" for information regarding recent 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 healthcare 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 impact the costs of financing, investing, and operating. We seek to address a portion of these risks through a controlled program of risk management that includes the use of derivative financial instruments. The objective of this risk management program is to limit the impact on earnings of fluctuations in interest and currency exchange rates. All derivative activities are for purposes other than trading.

Our primary interest rate risk exposure results from changes in short-term U.S. dollar interest rates. In an effort to manage interest rate exposures, we strive to achieve an acceptable balance between fixed and floating rate debt positions and may enter into interest rate derivatives to help maintain that balance. As of December 31, 2022, substantially all of our total long-term debt carries interest at a fixed rate. We have converted approximately 10 percent of our long-term fixed-rate notes to floating rates through the use of interest rate swaps. Based on our overall interest rate exposure at December 31, 2022 and 2021, 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, 2022 and 2021, respectively, would not have a material impact on earnings, cash flows, or fair values of interest rate risk-sensitive instruments over a one-year period.

Our foreign currency risk exposure results from fluctuating currency exchange rates, primarily the U.S. dollar against the euro, Japanese yen, and Chinese yuan. We face foreign currency exchange exposures when we enter into transactions arising from subsidiary trade and loan payables and receivables denominated in foreign currencies. We also face currency exposure that arises from translating the results of our global operations to the U.S. dollar at exchange rates that have fluctuated from the beginning of the period. We may enter into foreign currency forward or option derivative contracts to reduce the effect of fluctuating currency exchange rates (primarily the euro, the Japanese yen, and Chinese yuan). Our corporate risk-management policy outlines the minimum and maximum hedge coverage of such exposures. Gains and losses on these derivative contracts offset, in part, the impact of currency fluctuations on the existing assets and liabilities. We periodically analyze the fair values of the outstanding foreign currency derivative contracts to determine their sensitivity to changes in foreign exchange rates. A hypothetical 10 percent change in exchange rates (primarily against the U.S. dollar) applied to the fair values of our outstanding foreign currency derivative contracts as of December 31, 2022 and 2021, 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, 2022 and 2021, our carrying values of these investments were $1.16 billion and $1.83 billion, respectively. A hypothetical 20 percent change in fair value of the equity instruments would have impacted other-net, (income) expense by $232.4 million and $365.6 million as of December 31, 2022 and 2021, respectively.

We have no off-balance sheet arrangements that have a material current effect or that are reasonably likely to have a material future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures, or capital resources. We acquire and collaborate on potential products still in development and enter into research and development arrangements with third parties that often require milestone and royalty payments to the third party contingent upon the occurrence of certain future events linked to the success of the asset in development. Milestone payments may be required contingent upon the successful achievement of an important point in the development life cycle of the pharmaceutical product (e.g., approval for marketing by the appropriate regulatory agency or upon the achievement of certain sales levels). If required by the arrangement, we may make royalty payments based upon a percentage of the sales of the product in the event that regulatory approval for marketing is obtained.

Individually, these arrangements are generally not material in any one annual reporting period. However, if milestones for multiple products covered by these arrangements were reached in the same reporting period, the aggregate expense or aggregate milestone payments made could be material to our results of operations or cash flows, respectively, in that period. See Note 4 to the consolidated financial statements for additional information. These arrangements often give us the discretion to unilaterally terminate development of the product, which would allow us to avoid making the contingent payments; however, we are unlikely to cease development if the compound successfully achieves milestone objectives. We 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.

As we expand our manufacturing capacity in order to meet existing and expected demand of our incretin products, we have entered, and expect to continue to enter, into various agreements for contract manufacturing and for supply of materials. The executed agreements could, under certain circumstances, require us to pay up to approximately $4.5 billion if we do not purchase specified amounts of goods or services over the durations of the agreements, which generally range from 2 to 8 years.

APPLICATION OF CRITICAL ACCOUNTING ESTIMATES

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

Revenue Recognition and Sales Return, Rebate, and Discount Accruals

Background and Uncertainties

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 include rebates associated with sales covered by managed care, Medicare, Medicaid, and chargeback programs, as well as reductions in revenue related to our patient assistance programs, in the U.S. In determining the appropriate accrual amount, we consider our historical rebate payments for these programs, as well as patient assistance program costs, by product as a percentage of our historical sales as well as any significant changes in sales trends (e.g., patent expiries and product launches), an evaluation of the current contracts for these programs, the percentage of our products that are sold via these programs, and our product pricing.

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

Revenue recognized from collaborations and other arrangements will include our share of profits from the collaboration, as well as royalties, upfront and milestone payments we receive under these types of contracts.

Financial Statement Impact

We believe that our accruals for sales returns, rebates, and discounts are reasonable and appropriate based on current facts and circumstances. Our rebate and discount liabilities are included in sales rebates and discounts on our consolidated balance sheet. Our sales return liability is included in other current liabilities and other noncurrent liabilities on our consolidated balance sheet. As of December 31, 2022, a 5 percent change in our consolidated sales return, rebate, and discount liability would result in a change in revenue of approximately $464 million.

The portion of our consolidated sales return, rebate, and discount liability resulting from sales of our products in the U.S. was approximately 90 percent as of December 31, 2022 and 2021.

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

(Dollars in millions)	2022	2021
Sales return, rebate, and discount liabilities, beginning of year	**$ 6,161.6**	$ 5,400.0
Reduction of net sales[1]	**28,398.4**	20,106.3
Cash payments	**(26,345.9)**	(19,344.7)
Sales return, rebate, and discount liabilities, end of year	**$ 8,214.1**	$ 6,161.6

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

Increase in reduction of net sales in 2022 was primarily driven by our incretin products due to increase in our patient assistance programs and in volume of rebates for managed care, Medicare and Medicaid programs.

Litigation Liabilities and Other Contingencies

Background and Uncertainties

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

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

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

Acquisitions

Background and Uncertainties

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

If the acquired set of activities and assets meets the definition of a business, assets acquired and liabilities assumed are required to be recorded at their respective fair values on our consolidated balance sheet 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 acquired IPR&D and development milestones on our consolidated statement of operations at the acquisition date, and goodwill is not recorded. See Note 3 to the consolidated financial statements for additional information.

The judgments made in determining estimated fair values assigned to assets acquired and liabilities assumed in a business combination, as well as estimated asset lives, can materially affect our consolidated results of operations. The fair values of intangible assets, including acquired IPR&D, are determined using information available near the acquisition date based on estimates and assumptions that are deemed reasonable by management. Significant estimates and assumptions include, but are not limited to, probability of technical success, revenue projections, and discount rate. Depending on the facts and circumstances, we may deem it necessary to engage an independent valuation expert to assist in valuing significant assets and liabilities.

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

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

Financial Statement Impact

As of December 31, 2022, a 5 percent change in the contingent consideration liabilities would result in a change in income before income taxes of $5.5 million.

Impairment of Indefinite-Lived and Long-Lived Assets

Background and Uncertainties

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

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

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

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

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

Retirement Benefits Assumptions

Background and Uncertainties

Defined benefit pension plan and retiree health benefit plan costs include assumptions for the discount rate, expected return on plan assets, and retirement age. These assumptions have a significant effect on the amounts reported. In addition to the analysis below, see Note 15 to the consolidated financial statements for additional information regarding our retirement benefits.

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

Annually, we determine the fair value of the plan assets in our defined benefit pension and retiree health benefit plans. Approximately 50 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 2022 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 $23.8 million. If the 2022 expected return on plan assets for U.S. plans were to change by a quarter percentage point, income before income taxes would change by $33.5 million. If our assumption regarding the 2022 expected age of future retirees for U.S. plans were adjusted by one year, our income before income taxes would be affected by $46.3 million. The U.S. plans, including Puerto Rico, represent approximately 85 percent of each of the total projected benefit obligation and total plan assets at December 31, 2022.

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 file tax returns based upon our interpretation of tax laws and regulations, and we record estimates in our financial statements based upon these interpretations at the applicable tax rates in the jurisdictions in which we operate. Our tax returns are routinely subject to examination by taxing authorities, which could result in future tax, interest, and penalty assessments. Inherent uncertainties also exist in estimates of many tax positions due to the complexity of tax laws. We recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained upon examination by the taxing authorities, based on the technical merits of the position. The tax benefits recognized in the financial statements from such a position are measured based on the largest benefit that has a greater than 50 percent likelihood of being realized upon ultimate resolution. The amount of unrecognized tax benefits is adjusted for changes in facts and circumstances such as changes to existing tax law, the issuance of regulations by taxing authorities, new information obtained during a tax examination, or resolution of a tax examination. We believe our estimates for uncertain tax positions are both appropriate and sufficient to pay assessments that may result from examinations of our tax returns. We recognize both accrued interest and penalties related to unrecognized tax benefits in income tax expense.

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

Financial Statement Impact

As of December 31, 2022, a 5 percent change in the amount of uncertain tax positions and the valuation allowance would result in a change in net income of $85.0 million and $38.8 million, respectively.

LEGAL AND REGULATORY MATTERS

Information relating to certain legal proceedings can be found in Note 16 to the consolidated financial statements and is incorporated here by reference.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

You can find quantitative and qualitative disclosures about market risk (e.g. , interest rate risk) at Item 7, "Management's Discussion and Analysis - Financial Condition and Liquidity." That information is incorporated by reference herein.

Item 8. Financial Statements and Supplementary Data

Consolidated Statements of Operations

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

Year Ended December 31	2022	2021	2020
Revenue (Note 2)	**$ 28,541.4**	$ 28,318.4	$ 24,539.8
Costs, expenses, and other:			
Cost of sales	**6,629.8**	7,312.8	5,483.3
Research and development	**7,190.8**	6,930.7	5,976.3
Marketing, selling, and administrative	**6,440.4**	6,431.6	6,121.2
Acquired in-process research and development and development milestones (Note 3)	**908.5**	970.1	769.8
Asset impairment, restructuring, and other special charges (Note 5)	**244.6**	316.1	131.2
Other—net, (income) expense (Note 18)	**320.9**	201.6	(1,171.9)
	21,735.0	22,162.9	17,309.9
Income before income taxes	**6,806.4**	6,155.5	7,229.9
Income taxes (Note 14)	**561.6**	573.8	1,036.2
Net income	**$ 6,244.8**	$ 5,581.7	$ 6,193.7
Earnings per share:			
Basic	**$ 6.93**	$ 6.15	$ 6.82
Diluted	**$ 6.90**	$ 6.12	$ 6.79
Shares used in calculation of earnings per share:			
Basic	**901,736**	906,963	907,634
Diluted	**904,619**	911,681	912,505

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	2022	2021	2020
Net income	**$ 6,244.8**	$ 5,581.7	$ 6,193.7
Other comprehensive income (loss):			
Change in foreign currency translation gains (losses)	**(248.1)**	13.5	122.1
Change in net unrealized gains (losses) on securities	**(53.2)**	(15.9)	14.2
Change in defined benefit pension and retiree health benefit plans (Note 15)	**616.9**	2,699.4	(157.1)
Change in effective portion of cash flow hedges	**432.9**	151.6	(152.9)
Other comprehensive income (loss) before income taxes	**748.5**	2,848.6	(173.7)
Benefit (provision) for income taxes related to other comprehensive income (loss)	**(250.0)**	(695.3)	200.9
Other comprehensive income, net of tax (Note 17)	**498.5**	2,153.3	27.2
Comprehensive income	**$ 6,743.3**	$ 7,735.0	$ 6,220.9

See notes to consolidated financial statements.

Consolidated Balance Sheets

ELI LILLY AND COMPANY AND SUBSIDIARIES (Dollars in millions, shares in thousands)	December 31	2022	2021
Assets			
Current Assets			
Cash and cash equivalents (Note 7)		**$ 2,067.0**	$ 3,818.5
Short-term investments (Note 7)		**144.8**	90.1
Accounts receivable, net of allowances of **$16.0 (2022)** and $22.5 (2021)		**6,896.0**	6,672.8
Other receivables		**1,662.9**	1,454.4
Inventories (Note 6)		**4,309.7**	3,886.0
Prepaid expenses and other current assets		**2,954.1**	2,530.6
Total current assets		**18,034.5**	18,452.4
Investments (Note 7)		**2,901.8**	3,212.6
Goodwill (Note 8)		**4,073.0**	3,892.0
Other intangibles, net (Note 8)		**7,206.6**	7,691.9
Deferred tax assets (Note 14)		**2,792.9**	2,489.3
Property and equipment, net (Note 9)		**10,144.0**	8,985.1
Other noncurrent assets		**4,337.0**	4,082.7
Total assets		**$ 49,489.8**	$ 48,806.0
Liabilities and Equity			
Current Liabilities			
Short-term borrowings and current maturities of long-term debt (Note 11)		**$ 1,501.1**	$ 1,538.3
Accounts payable		**1,930.6**	1,670.6
Employee compensation		**1,059.8**	958.1
Sales rebates and discounts		**8,784.1**	6,845.8
Dividends payable		**1,017.2**	885.5
Income taxes payable (Note 14)		**475.1**	126.9
Other current liabilities		**2,370.3**	3,027.5
Total current liabilities		**17,138.2**	15,052.7
Other Liabilities			
Long-term debt (Note 11)		**14,737.5**	15,346.4
Accrued retirement benefits (Note 15)		**1,305.1**	1,954.1
Long-term income taxes payable (Note 14)		**3,709.6**	3,920.0
Deferred tax liabilities (Note 14)		**87.3**	1,733.7
Other noncurrent liabilities		**1,736.7**	1,644.3
Total other liabilities		**21,576.2**	24,598.5
Commitments and Contingencies (Note 16)			
Eli Lilly and Company Shareholders' Equity (Notes 12 and 13)			
Common stock—no par value Authorized shares: 3,200,000 Issued shares: **950,632 (2022)** and 954,116 (2021)		**594.1**	596.3
Additional paid-in capital		**6,921.4**	6,833.4
Retained earnings		**10,042.6**	8,958.5
Employee benefit trust		**(3,013.2)**	(3,013.2)
Accumulated other comprehensive loss (Note 17)		**(3,844.6)**	(4,343.1)
Cost of common stock in treasury		**(50.5)**	(52.7)
Total Eli Lilly and Company shareholders' equity		**10,649.8**	8,979.2
Noncontrolling interests		**125.6**	175.6
Total equity		**10,775.4**	9,154.8
Total liabilities and equity		**$ 49,489.8**	$ 48,806.0

See notes to consolidated financial statements.

Consolidated Statements of Shareholders' Equity

ELI LILLY AND COMPANY AND SUBSIDIARIES (Dollars in millions, except per-share data, and shares in thousands)	Equity of Eli Lilly and Company Shareholders								Noncontrolling Interest
	Common Stock		Additional Paid-in Capital	Retained Earnings	Employee Benefit Trust	Accumulated Other Comprehensive Loss	Common Stock in Treasury		
	Shares	Amount					Shares	Amount	
Balance at January 1, 2020	958,056	$ 598.8	$ 6,685.3	$ 4,920.4	$ (3,013.2)	$ (6,523.6)	530	$ (60.8)	$ 92.2
Net income				6,193.7					126.6
Other comprehensive income, net of tax						27.2			
Cash dividends declared per share: $ 3.07				(2,786.2)					
Retirement of treasury shares	(3,627)	(2.3)		(497.7)			(3,627)	500.0	
Purchase of treasury shares							3,627	(500.0)	
Issuance of stock under employee stock plans, net	2,648	1.7	(212.7)				(43)	5.1	
Stock-based compensation			308.1						
Other			(2.2)						(35.2)
Balance at December 31, 2020	957,077	598.2	6,778.5	7,830.2	(3,013.2)	(6,496.4)	487	(55.7)	183.6
Net income				5,581.7					3.4
Other comprehensive income, net of tax						2,153.3			
Cash dividends declared per share: $ 3.53				(3,201.7)					
Retirement of treasury shares	(5,412)	(3.4)		(1,246.6)			(5,412)	1,250.0	
Purchase of treasury shares							5,412	(1,250.0)	
Issuance of stock under employee stock plans, net	2,451	1.5	(287.9)				(24)	3.0	
Stock-based compensation			342.8						
Other				(5.1)					(11.4)
Balance at December 31, 2021	954,116	596.3	6,833.4	8,958.5	(3,013.2)	(4,343.1)	463	(52.7)	175.6
Net income (loss)				**6,244.8**					**(20.9)**
Other comprehensive income, net of tax						**498.5**			
Cash dividends declared per share: $ 4.07				**(3,667.5)**					
Retirement of treasury shares	**(5,607)**	**(3.5)**		**(1,496.5)**			**(5,607)**	**1,500.0**	
Purchase of treasury shares							**5,607**	**(1,500.0)**	
Issuance of stock under employee stock plans, net	**2,123**	**1.3**	**(283.1)**				**(13)**	**2.2**	
Stock-based compensation			**371.1**						
Other				**3.3**					**(29.1)**
Balance at December 31, 2022	**950,632**	**$ 594.1**	**$ 6,921.4**	**$ 10,042.6**	**$ (3,013.2)**	**$ (3,844.6)**	**450**	**$ (50.5)**	**$ 125.6**

See notes to consolidated financial statements.

Consolidated Statements of Cash Flows

ELI LILLY AND COMPANY AND SUBSIDIARIES (Dollars in millions) Year Ended December 31	2022	2021	2020
Cash Flows from Operating Activities			
Net income	**$ 6,244.8**	$ 5,581.7	$ 6,193.7
Adjustments to Reconcile Net Income to Cash Flows from Operating Activities:			
Depreciation and amortization	**1,522.5**	1,547.6	1,323.9
Debt extinguishment loss (Note 11)	**—**	405.2	—
Change in deferred income taxes	**(2,185.2)**	(802.3)	(134.5)
Stock-based compensation expense	**371.1**	342.8	308.1
Net investment (gains) losses	**420.0**	(178.0)	(1,438.5)
Acquired in-process research and development (Note 3)	**420.9**	874.9	660.4
Other non-cash operating activities, net	**304.8**	511.4	333.9
Other changes in operating assets and liabilities, net of acquisitions and divestitures:			
Receivables—(increase) decrease	**(299.6)**	(1,278.3)	(1,350.2)
Inventories—(increase) decrease	**(599.7)**	(235.9)	(533.4)
Other assets—(increase) decrease	**(793.5)**	1,515.4	(457.1)
Income taxes payable—increase (decrease)	**346.6**	(359.7)	322.0
Accounts payable and other liabilities—increase (decrease)	**1,331.7**	(664.1)	1,271.3
Net Cash Provided by Operating Activities	**7,084.4**	7,260.7	6,499.6
Cash Flows from Investing Activities			
Purchases of property and equipment	**(1,854.3)**	(1,309.8)	(1,387.9)
Proceeds from sales and maturities of short-term investments	**121.4**	47.4	129.7
Purchases of short-term investments	**(107.4)**	(83.5)	(11.4)
Proceeds from sales of noncurrent investments	**342.2**	800.0	757.1
Purchases of noncurrent investments	**(600.2)**	(929.9)	(358.7)
Purchases of in-process research and development	**(629.7)**	(563.4)	(641.2)
Cash paid for acquisitions, net of cash acquired (Note 3)	**(327.2)**	(747.4)	(849.3)
Other investing activities, net	**(206.4)**	24.3	102.8
Net Cash Used for Investing Activities	**(3,261.6)**	(2,762.3)	(2,258.9)
Cash Flows from Financing Activities			
Dividends paid	**(3,535.8)**	(3,086.8)	(2,687.1)
Net change in short-term borrowings	**1,498.0**	(4.0)	(1,494.2)
Proceeds from issuance of long-term debt	**—**	2,410.8	2,062.3
Repayments of long-term debt	**(1,560.0)**	(1,905.4)	(276.5)
Purchases of common stock	**(1,500.0)**	(1,250.0)	(500.0)
Other financing activities, net	**(308.9)**	(295.9)	(241.6)
Net Cash Used for Financing Activities	**(5,406.7)**	(4,131.3)	(3,137.1)
Effect of exchange rate changes on cash and cash equivalents	**(167.6)**	(205.7)	216.0
Net increase (decrease) in cash and cash equivalents	**(1,751.5)**	161.4	1,319.6
Cash and cash equivalents at beginning of year	**3,818.5**	3,657.1	2,337.5
Cash and Cash Equivalents at End of Year	**$ 2,067.0**	$ 3,818.5	$ 3,657.1

See notes to consolidated financial statements.

Notes to Consolidated Financial Statements

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

Note 1: Summary of Significant Accounting Policies 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.

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

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

Research and development costs are expensed as incurred. Research and development costs consist of expenses incurred in performing research and development activities, including but not limited to, compensation and benefits, facilities and overhead expense, clinical trial expense and fees paid to contract research organizations.

Acquired IPR&D and development milestones include 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. Additionally, milestone payment obligations related to these transactions that are incurred prior to regulatory approval of the compound are expensed when the event triggering an obligation to pay the milestone occurs.

Earnings Per Share (EPS)

All per-share amounts, unless otherwise noted in the footnotes, are presented on a diluted basis. We calculate basic EPS based on the weighted-average number of common shares outstanding plus the effect of incremental shares from potential participating securities. We calculate diluted EPS based on the weighted-average number of common shares outstanding plus the effect of incremental shares from our stock-based compensation programs.

Foreign Currency Translation

Operations in our subsidiaries outside the United States (U.S.) are recorded in the functional currency of each subsidiary which is determined by a review of the environment where each subsidiary primarily generates and expends cash. The results of operations for our subsidiaries outside the U.S. are translated from functional currencies into U.S. dollars using the weighted average currency rate for the period. Assets and liabilities are translated using the period end exchange rates. The U.S. dollar effects that arise from translating the net assets of these subsidiaries are recorded in other comprehensive income (loss).

Advertising Expenses

Costs associated with advertising are expensed as incurred and are included in marketing, selling, and administrative expenses. Advertising expenses, comprised primarily of television, radio, print media, and internet advertising, totaled approximately $1.0 billion, $1.2 billion, and $1.1 billion in 2022, 2021, and 2020, 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

Accounting Standards Update (ASU) 2021-10, *Government Assistance*, establishes annual disclosure requirements for companies that analogize to a grant or contribution accounting model for government assistance transactions. We adopted the standard as of January 1, 2022. The adoption did not impact our financial statement disclosures.

ASU 2020-04, *Reference Rate Reform*, as further modified by ASU 2021-01 and ASU 2022-06, provides for temporary optional expedients and exceptions in applying current GAAP to contracts, hedging relationships, and other transactions affected by the transition from the use of the London Interbank Offered Rate (LIBOR) to an alternative reference rate. The standard is currently applicable to contracts entered into before January 1, 2025. We adopted the standard in the first quarter of 2022. The adoption did not have a material impact on our consolidated financial statements.

Note 2: Revenue

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

	2022	2021	2020
Net product revenue	**$ 25,462.8**	$ 25,957.9	$ 22,694.8
Collaboration and other revenue [1]	**3,078.6**	2,360.5	1,845.0
Revenue	**$ 28,541.4**	$ 28,318.4	$ 24,539.8

[1] Collaboration and other revenue associated with prior period transfers of intellectual property was $163.4 million, $175.0 million, and $135.6 million during the years ended December 31, 2022, 2021, and 2020, 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 includes our share of profits from the collaborations, as well as royalties, upfront and milestone payments we receive under these types of contracts. See Note 4 for additional information related to our collaborations and other arrangements. Collaboration and other revenue disclosed above includes the revenue from the Jardiance® and Trajenta® families of products resulting from our collaboration with Boehringer Ingelheim discussed in Note 4. Substantially all of the remainder of collaboration and other revenue is related to contracts accounted for as contracts with customers.

Net Product Revenue

Revenue from sales of products is recognized at the point where the customer obtains control of the goods and we satisfy our performance obligation, which generally is at the time we ship the product to the customer. Payment terms differ by jurisdiction and customer, but payment terms in most of our major jurisdictions typically range from 30 to 70 days from date of shipment. Revenue for our product sales has not been adjusted for the effects of a financing component as we expect, at contract inception, that the period between when we transfer control of the product and when we receive payment will be one year or less. Any exceptions are either not material or we collect interest for payments made after the due date. Provisions for rebates, discounts, and returns are established in the same period the related product 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 healthcare professionals, and hospitals. For the years ended December 31, 2022, 2021, and 2020, our three largest wholesalers each accounted for between 16 percent and 21 percent of consolidated revenue. Further, they each accounted for between 18 percent and 29 percent of accounts receivable as of December 31, 2022 and 2021.

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 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 include rebates associated with sales covered by managed care, Medicare, Medicaid, and chargeback programs, as well as reductions in revenue related to our patient assistance programs, in the U.S. In determining the appropriate accrual amount, we consider our historical rebate payments for these programs, as well as patient assistance program costs, 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 revenue reductions related to these programs at the time we record the sale, the reduction related to that sale is typically paid up to six months later. Because of this time lag, in any particular period our net product revenue 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 discontinuations, or a changing competitive environment. We maintain a returns policy that allows most U.S. customers to return most of our products for dating issues within a specified period prior to and subsequent to the product's expiration date. Following the loss of exclusivity for a patent-dependent product, we expect to experience an elevated level of product returns as product inventory remaining in the wholesale and retail channels expires. Adjustments to the returns reserve have been and may in the future be required based on revised estimates to our assumptions. We record the return amounts as a deduction to arrive at our net product revenue. Once the product is returned, it is destroyed; we do not record a right of return asset. Our returns policies outside the U.S. are generally more restrictive than in the U.S. as returns are not allowed for reasons other than failure to meet product specifications in many countries. Our reserve for future product returns for product sales outside the U.S. is not material.
- As a part of our process to estimate a reserve for product returns, we regularly review the supply levels of our significant products at the major wholesalers in the U.S. and in major markets outside the U.S., primarily by reviewing periodic inventory reports supplied by our major wholesalers and available prescription volume information for our products, or alternative approaches. We attempt to maintain U.S. wholesaler inventory levels at an average of approximately one month or less on a consistent basis across our product portfolio. Causes of unusual wholesaler buying patterns include actual or anticipated product-supply issues, weather patterns, anticipated changes in the transportation network, redundant holiday stocking, and changes in wholesaler business operations. In the U.S., the current structure of our arrangements provides us with data on inventory levels at our wholesalers; however, our data on inventory levels in the retail channel is more limited. Wholesaler stocking and destocking activity historically has not caused any material changes in the rate of actual product returns.
- Actual U.S. product returns have been less than 2 percent of our U.S. revenue during each of the past three years and have not fluctuated significantly as a percentage of revenue, although fluctuations are more likely in periods following loss of patent exclusivity for major products in the U.S. market.

Adjustments to Revenue

Adjustments to increase revenue, recognized as a result of changes in estimates for our most significant U.S. sales returns, rebates, and discounts liability balances for products shipped in previous periods, were less than 1 percent of U.S. revenue during each of the years ended December 31, 2022, 2021, and 2020.

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.
- Profit-sharing due from our collaboration partners, which is based upon gross margins reported to us by our partners, is recognized as collaboration and other revenue as earned.
- Royalty revenue from licensees and certain of our collaboration partners, which is based on sales to third-parties of licensed products and technology, is recorded when the third-party sale occurs and the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). This royalty revenue is included in collaboration and other revenue.

- For arrangements involving multiple goods or services (e.g., research and development, marketing and selling, manufacturing, and distribution), each required good or service is evaluated to determine whether it is distinct. If a good or service does not qualify as distinct, it is combined with the other non-distinct goods or services within the arrangement and these combined goods or services are treated as a single performance obligation for accounting purposes. The arrangement's transaction price is then allocated to each performance obligation based on the relative standalone selling price of each performance obligation. For arrangements that involve variable consideration where we have sold intellectual property, we recognize revenue based on estimates of the amount of consideration we believe we will be entitled to receive from the other party, subject to a constraint. These estimates are adjusted to reflect the actual amounts to be collected when those facts and circumstances become known.
- Significant judgments must be made in determining the transaction price for our sales of intellectual property. Because of the risk that products in development will not receive regulatory approval, we generally do not recognize any contingent payments that would be due to us upon or after regulatory approval.

Contract Liabilities

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

The following table summarizes contract liability balances:

	2022	2021
Contract liabilities	**$ 219.2**	$ 262.6

The contract liabilities balances disclosed above as of December 31, 2022 and 2021 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, 2022, 2021, and 2020, revenue recognized from contract liabilities as of the beginning of the respective year was not material. Revenue expected to be recognized in the future from contract liabilities as the related performance obligations are satisfied is not expected to be material in any one year.

Disaggregation of Revenue

The following table summarizes revenue by product:

	U.S.			Outside U.S.		
	2022	2021	2020	2022	2021	2020
Revenue—to unaffiliated customers:						
Diabetes:						
Trulicity®	**$ 5,688.8**	$ 4,914.4	$ 3,835.9	**$ 1,750.9**	$ 1,557.6	$ 1,232.2
Jardiance(1)	**1,194.5**	807.3	620.8	**871.5**	683.5	533.0
Humalog® (2)	**1,191.9**	1,320.7	1,485.6	**868.7**	1,132.3	1,140.3
Humulin®	**730.2**	832.9	866.4	**289.2**	389.6	393.2
Basaglar®	**470.7**	588.3	842.3	**289.7**	304.2	282.1
Mounjaro®	**366.6**	—	—	**115.9**	—	—
Other diabetes	**268.4**	255.7	258.1	**367.8**	401.6	344.5
Total diabetes	**9,911.1**	8,719.3	7,909.1	**4,553.7**	4,468.8	3,925.3
Oncology:						
Verzenio®	**1,653.2**	834.9	618.2	**830.3**	515.0	294.4
Cyramza®	**351.4**	358.1	381.9	**620.0**	674.8	650.8
Alimta®	**543.7**	1,233.9	1,265.3	**384.0**	827.5	1,064.7
Erbitux®	**500.1**	481.8	480.1	**66.4**	66.4	56.3
Tyvyt®	**—**	—	—	**293.3**	418.1	308.7
Other oncology	**169.7**	120.1	46.6	**254.1**	210.7	152.3
Total oncology	**3,218.1**	3,028.8	2,792.1	**2,448.1**	2,712.5	2,527.2
Immunology:						
Taltz®	**1,724.6**	1,542.4	1,288.5	**757.4**	670.4	500.0
Olumiant® (3)	**148.2**	324.1	63.8	**682.3**	791.0	575.0
Other immunology	**20.0**	15.3	20.0	**12.1**	17.6	14.6
Total immunology	**1,892.8**	1,881.8	1,372.3	**1,451.8**	1,479.0	1,089.6
Neuroscience:						
Emgality®	**462.8**	434.5	325.9	**188.1**	142.7	37.0
Zyprexa®	**30.4**	39.6	46.1	**306.5**	390.7	360.5
Cymbalta®	**33.7**	38.7	42.1	**249.6**	542.8	725.6
Other neuroscience	**85.5**	102.0	73.2	**189.6**	207.5	220.9
Total neuroscience	**612.4**	614.8	487.3	**933.8**	1,283.7	1,344.0
Other:						
COVID-19 antibodies(4)	**2,008.9**	1,978.0	850.0	**14.7**	261.4	21.2
Forteo®	**367.3**	441.6	510.3	**245.8**	360.3	536.0
Cialis®	**35.2**	10.6	61.8	**552.1**	707.9	545.4
Other	**144.2**	136.1	246.4	**151.3**	233.9	321.8
Total other	**2,555.7**	2,566.4	1,668.4	**964.0**	1,563.5	1,424.4
Revenue	**$ 18,190.0**	$ 16,811.0	$ 14,229.3	**$ 10,351.3**	$ 11,507.4	$ 10,310.5

Numbers may not add due to rounding.

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

(2) Humalog revenue includes insulin lispro.

(3) Olumiant revenue includes sales for baricitinib that were made pursuant to Emergency Use Authorization (EUA) or similar regulatory authorizations.

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

The following table summarizes revenue by geographical area:

	2022	2021	2020
Revenue—to unaffiliated customers[1]:			
U.S.	**$ 18,190.0**	$ 16,811.0	$ 14,229.3
Europe	**4,299.2**	4,776.8	4,187.7
Japan	**1,747.3**	2,367.0	2,583.1
China	**1,452.8**	1,661.4	1,116.9
Other foreign countries	**2,852.0**	2,702.2	2,422.7
Revenue	**$ 28,541.4**	$ 28,318.4	$ 24,539.8

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

Note 3: Acquisitions

We engage in various forms of business development activities to enhance our product pipeline, including acquisitions, collaborations, investments, and licensing arrangements. 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.

In December 2022, January 2021, and February 2020, we completed the acquisitions of Akouos, Inc. (Akouos), Prevail Therapeutics Inc. (Prevail), and Dermira, Inc. (Dermira), respectively. These transactions, as further discussed 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 2022, 2021, and 2020, which are further discussed below in Asset Acquisitions. Upon each acquisition, the cost allocated to acquired IPR&D was immediately expensed if the compound has no alternative future use. Milestone payment obligations incurred prior to regulatory approval of the compound are expensed when the event triggering an obligation to pay the milestone occurs. We recognized acquired IPR&D and development milestone charges of $908.5 million, $970.1 million, and $769.8 million for the years ended December 31, 2022, 2021, and 2020, respectively.

Acquisitions of Businesses

Akouos Acquisition

Overview of Transaction

In December 2022, we acquired all shares of Akouos for a purchase price that included $ 12.50 per share in cash (or an aggregate of $ 327.2 million, net of cash acquired) plus one non-tradable contingent value right (CVR) per share. The CVR entitles the Akouos shareholders up to an additional $ 3.00 per share in cash (or an aggregate of approximately $122 million) payable, subject to certain terms and conditions, upon the achievement of certain specified milestones.

Under the terms of the agreement, we acquired potential gene therapy treatments for hearing loss and other inner ear conditions. The lead gene therapies in clinical development that we acquired included GJB2 (which encodes connexin 26) for a common form of monogenic deafness and hearing loss; AK-OTOF for hearing loss due to mutations in the otoferlin gene; AK-CLRN1 for Usher Type 3A, an autosomal recessive disorder characterized by progressive loss of both hearing and vision; and AK-antiVEGF for vestibular schwannoma.

Assets Acquired and Liabilities Assumed

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

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

Estimated Fair Value at December 1, 2022		
Cash	$	153.2
Acquired IPR&D[(1)]		184.0
Goodwill[(2)]		181.2
Other assets and liabilities, net		28.9
Acquisition date fair value of consideration transferred		547.3
Less:		
Cash acquired		(153.2)
Fair value of CVR liability[(3)]		(66.9)
Cash paid, net of cash acquired	$	327.2

(1) Acquired IPR&D intangibles primarily relate to GJB2.
(2) The goodwill recognized from this acquisition is attributable primarily to future unidentified projects and products and the assembled workforce for Akouos and is not deductible for tax purposes.
(3) See Note 7 for a discussion on the estimation of the CVR liability.

The results of operations attributable to Akouos for the year ended December 31, 2022 were immaterial.

Pro forma information has not been included as this acquisition did not have a material impact on our consolidated statements of operations for the years ended December 31, 2022 and 2021.

Prevail Acquisition

Overview of Transaction

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

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

Assets Acquired and Liabilities Assumed

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

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

[1] Acquired IPR&D intangibles primarily relate to PR001. In the third quarter of 2022, we impaired the intangible asset related to PR001. See Note 5 for additional information.
[2] The goodwill recognized from this acquisition is not deductible for tax purposes.
[3] See Note 7 for a discussion on the estimation of the CVR liability.

The results of operations attributable to Prevail for the years ended December 31, 2022 and 2021 were immaterial.

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

Dermira Acquisition

Overview of Transaction

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

Assets Acquired and Liabilities Assumed

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

Revenue attributable to assets acquired in the Dermira acquisition did not have a material impact on our consolidated statement of operations for the years ended December 31, 2022, 2021, and 2020. We are unable to provide the results of operations for the years ended December 31, 2022, 2021, and 2020 attributable to Dermira as those operations were substantially integrated into our legacy business.

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

Asset Acquisitions

The following table summarizes our significant asset acquisitions during 2022, 2021, and 2020.

Counterparty	Compound(s),Therapy, or Asset	Acquisition Month	Phase of Development[1]	Acquired IPR&D Expense
BioMarin Pharmaceutical Inc.	Priority Review Voucher	February 2022	Not applicable	**$ 110.0**
Foghorn Therapeutics Inc.	Pre-clinical targets that could lead to potential new oncology medicines	December 2021	Pre-clinical	316.6
Rigel Pharmaceuticals, Inc.	R552, a receptor-interacting serine/threonine-protein kinase 1 (RIPK1) inhibitor, for the potential treatment of autoimmune and inflammatory diseases	March 2021	Phase I	125.0
Precision Biosciences, Inc.	Potential in vivo therapies for genetic disorders	January 2021	Pre-clinical	107.8
Innovent Biologics, Inc. (Innovent)	Sintilimab injection, an anti-PD-1 monoclonal antibody immuno-oncology medicine, for geographies outside of China[2]	October 2020	Phase III	200.0
Petra Pharma Corporation (Petra)	Mutant-selective PI3Kα inhibitor that could lead to potential new medicine	May 2020	Pre-clinical	174.8
Disarm Therapeutics, Inc.	Disease-modifying therapeutics program for patients with axonal degeneration	October 2020	Pre-clinical	126.3

[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] In 2022, we terminated our license for sintilimab injection for geographies outside of China and reverted rights to Innovent.

In connection with our acquisition of Petra, we were required to make milestone payments to Petra shareholders contingent upon the occurrence of certain future events linked to the success of the mutant-selective PI3Kα inhibitor. In 2022, we entered into agreements with substantially all Petra shareholders to acquire their rights to receive any future milestone payments in exchange for a one-time payment. As a result of these agreements, we recognized a charge of $333.8 million as a development milestone in 2022. Any remaining contingent milestones payments linked to the success of the mutant-selective PI3Kα are not expected to be material. We did not recognize other significant development milestones during the years ended December 31, 2022, 2021, and 2020.

Note 4: Collaborations and Other Arrangements

We often enter into collaborative and other similar arrangements to develop and commercialize drug candidates. Collaborative activities may include research and development, marketing and selling (including promotional activities and physician detailing), manufacturing, and distribution. These arrangements often require milestone as well as royalty or profit-share payments, contingent upon the occurrence of certain future events linked to the success of the asset in development, as well as expense reimbursements from or payments to the collaboration partner. See Note 2 for amounts of collaboration and other revenue recognized from these types of arrangements.

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

Boehringer Ingelheim Diabetes Collaboration

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

In connection with the regulatory approvals of Jardiance, Trajenta, and Basaglar in the U.S., Europe, and Japan, milestone payments made for Jardiance and Trajenta were capitalized as intangible assets and are being amortized to cost of sales, and milestone payments received for Basaglar were recorded as contract liabilities and are being amortized to collaboration and other revenue. The milestones pertaining to Jardiance and Trajenta are being amortized through their respective term under the collaboration, which, depending on country or region, is determined based on the latest to occur of (a) a defined number of years following launch date, (b) the expiration of the compound patent, or (c) the expiration of marketing authorization exclusivity. The milestones pertaining to Basaglar are being amortized through 2029. The table below summarizes the net milestones capitalized with respect to the Jardiance and Trajenta families of products and the net milestones deferred with respect to Basaglar as of December 31:

	Net Milestones Capitalized (Deferred)[1]	
	2022	2021
Jardiance	**$ 116.2**	$ 136.1
Trajenta	**63.5**	88.5
Basaglar	**(130.6)**	(149.3)

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

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

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

	2022	2021	2020
Jardiance	**$ 2,066.0**	$ 1,490.8	$ 1,153.8
Basaglar	**760.4**	892.5	1,124.4
Trajenta	**383.7**	372.5	358.5

Olumiant

We have a worldwide license and collaboration agreement with Incyte Corporation (Incyte), which provides us the development and commercialization rights to baricitinib, which is branded and trademarked as Olumiant, and certain follow-on compounds, for the treatment of inflammatory and autoimmune diseases and COVID-19. Incyte has the right to receive tiered, double digit royalty payments on worldwide net sales with rates ranging up to 20 percent. Incyte has the right to receive an additional royalty ranging up to the low teens on worldwide net sales for the treatment of COVID-19 that exceed a specified aggregate worldwide net sales threshold. The agreement calls for payments by us to Incyte associated with certain development, success-based regulatory, and sales-based milestones.

In connection with the regulatory approvals of Olumiant in the U.S., Europe, and Japan, as well as achievement of a sales-based milestone, milestone payments of $330.0 million and $260.0 million were capitalized as intangible assets as of December 31, 2022 and 2021, 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, 2022, Incyte is eligible to receive up to $ 100.0 million of additional payments from us in potential sales-based milestones.

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

	2022	2021	2020
Olumiant	**$ 830.5**	$ 1,115.1	$ 638.9

COVID-19 Antibodies

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

We have a license and collaboration agreement with Shanghai Junshi Biosciences Co., Ltd. (Junshi Biosciences) to co-develop therapeutic antibodies for the potential prevention and treatment of COVID-19, including etesevimab, for which we hold development and commercialization rights outside of mainland China and the Special Administrative Regions of Hong Kong and Macau. Junshi Biosciences received royalty payments in the mid-teens on our net sales of etesevimab.

Pursuant to EUAs or similar regulatory authorizations, we recognized $ 2.02 billion, $2.24 billion, and $871.2 million of net product revenue associated with our sales of our COVID-19 antibodies during the years ended December 31, 2022, 2021, and 2020, respectively.

Tyvyt

We have a collaboration agreement with Innovent to jointly develop and commercialize sintilimab injection in China, where it is branded and trademarked as Tyvyt. We record our sales of Tyvyt to third parties as net product revenue, with payments made to Innovent for its portion of the gross margin reported as cost of sales. We report as collaboration and other revenue our portion of the gross margin for Tyvyt sales made by Innovent to third parties. The following table summarizes our revenue recognized in China with respect to Tyvyt:

	2022	2021	2020
Tyvyt	**$ 293.3**	$ 418.1	$ 308.7

Lebrikizumab

We have a worldwide license agreement with F. Hoffmann-La Roche Ltd and Genentech, Inc. (collectively, Roche), which provides us the worldwide development and commercialization rights to lebrikizumab. Roche has the right to receive tiered royalty payments on future worldwide net sales ranging in percentages from high single digits to high teens if the product is successfully commercialized. As of December 31, 2022, Roche is eligible to receive up to $165.0 million of additional 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. During the year ended December 31, 2022, milestone payments to Roche were not material.

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, 2022, we are eligible to receive additional payments of $65.0 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. There were no remaining contract liabilities as of December 31, 2022. As of December 31, 2021 and 2020, contract liabilities were not material. During the years ended December 31, 2022, 2021, and 2020, collaboration and other revenue recognized was 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:

	2022	2021	2020
Asset impairment (gain) and other special charges	**$ 221.6**	$ 303.1	$ (20.0)
Severance	**23.0**	13.0	151.2
Total asset impairment, restructuring, and other special charges	**$ 244.6**	$ 316.1	$ 131.2

Asset impairment, restructuring, and other special charges recognized during the year ended December 31, 2022 were primarily related to an intangible asset impairment for GBA1 Gene Therapy (PR001), acquired in the Prevail acquisition, as a result of changes in key assumptions used in the valuation due to delays in estimated launch timing.

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

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

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:

	2022	2021
Finished products	**$ 901.2**	$ 761.9
Work in process	**2,597.7**	2,372.7
Raw materials and supplies	**801.9**	717.2
Total (approximates replacement cost)	**4,300.8**	3,851.8
Increase to LIFO cost	**8.9**	34.2
Inventories	**$ 4,309.7**	$ 3,886.0

Inventories valued under the LIFO method comprised $ 1.23 billion and $ 1.36 billion of total inventories at December 31, 2022 and 2021, respectively.

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

Note 7: Financial Instruments

Investments in Equity and Debt Securities

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 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, 2022, 2021, and 2020 were not material.

The net gains (losses) recognized in our consolidated statements of operations for equity securities were $(410.7) million, $176.9 million, and $ 1.44 billion for the years ended December 31, 2022, 2021, and 2020, respectively. The net gains (losses) recognized for the years ended December 31, 2022, 2021, and 2020 on equity securities sold during the respective periods were not material.

As of December 31, 2022, we had approximately $ 957 million of unfunded commitments to invest in venture capital funds, which we anticipate will be paid over a period of up to 10 years.

We record our available-for-sale debt securities at fair value, with changes in fair value reported as a component of accumulated other comprehensive income (loss). We periodically assess our investment in available-for-sale securities for impairment losses and credit losses. The amount of credit losses are determined by comparing the difference between the present value of future cash flows expected to be collected on these securities and the amortized cost. Factors considered in assessing credit losses include the position in the capital structure, vintage and amount of collateral, delinquency rates, current credit support, and geographic concentration. Impairment and credit losses related to available-for-sale securities were not material for the years ended December 31, 2022, 2021, and 2020.

The table below summarizes the contractual maturities of our investments in debt securities measured at fair value as of December 31, 2022:

		Maturities by Period			
	Total	Less Than 1 Year	1-5 Years	6-10 Years	More Than 10 Years
Fair value of debt securities	$ 646.3	$ 86.2	$ 242.0	$ 104.0	$ 214.1

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

	2022	2021
Unrealized gross gains	**$ 0.6**	$ 9.7
Unrealized gross losses	**49.2**	5.2
Fair value of securities in an unrealized gain position	**46.8**	250.7
Fair value of securities in an unrealized loss position	**568.7**	290.2

As of December 31, 2022, 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 99 percent of the fixed-rate debt securities in a loss position are investment-grade debt securities. As of December 31, 2022, 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 a material default on interest or principal payments for our debt securities.

Activity related to our available-for-sale securities was as follows:

	2022	2021	2020
Proceeds from sales	**$ 132.9**	$ 174.7	$ 264.8
Realized gross gains on sales	**0.4**	2.8	4.5
Realized gross losses on sales	**9.7**	1.7	8.2

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.

Fair Value of Investments

The following table summarizes certain fair value information at December 31, 2022 and 2021 for investment assets measured at fair value on a recurring basis, as well as the carrying amount and amortized cost of certain other investments:

			Fair Value Measurements Using			
	Carrying Amount	Cost[1]	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Fair Value
December 31, 2022						
Cash equivalents[2]	**$ 657.4**	**$ 657.4**	**$ 650.4**	**$ 7.0**	**$ —**	**$ 657.4**
Short-term investments:						
U.S. government and agency securities	**$ 30.8**	**$ 31.1**	**$ 30.8**	**$ —**	**$ —**	**$ 30.8**
Corporate debt securities	**53.4**	**53.5**	**—**	**53.4**	**—**	**53.4**
Asset-backed securities	**2.0**	**2.0**	**—**	**2.0**	**—**	**2.0**
Other securities	**58.6**	**58.6**	**—**	**39.1**	**19.5**	**58.6**
Short-term investments	**$ 144.8**					
Noncurrent investments:						
U.S. government and agency securities	**$ 146.4**	**$ 163.2**	**$ 146.4**	**$ —**	**$ —**	**$ 146.4**
Corporate debt securities	**213.9**	**235.8**	**—**	**213.9**	**—**	**213.9**
Mortgage-backed securities	**149.2**	**161.5**	**—**	**149.2**	**—**	**149.2**
Asset-backed securities	**50.6**	**52.5**	**—**	**50.6**	**—**	**50.6**
Other securities	**398.6**	**34.5**	**—**	**311.0**	**87.6**	**398.6**
Marketable equity securities	**683.6**	**484.7**	**683.6**	**—**	**—**	**683.6**
Equity investments without readily determinable fair values[3]	**478.4**					
Equity method investments[3]	**781.1**					
Noncurrent investments	**$ 2,901.8**					
December 31, 2021						
Cash equivalents[2]	$ 2,379.5	$ 2,379.5	$ 2,361.0	$ 18.5	$ —	$ 2,379.5
Short-term investments:						
U.S. government and agency securities	$ 25.7	$ 25.6	$ 25.7	$ —	$ —	$ 25.7
Corporate debt securities	43.7	43.7	—	43.7	—	43.7
Mortgage-backed securities	0.2	0.2	—	0.2	—	0.2
Asset-backed securities	6.2	6.2	—	6.2	—	6.2
Other securities	14.3	14.3	—	—	14.3	14.3
Short-term investments	$ 90.1					
Noncurrent investments:						
U.S. government and agency securities	$ 137.0	$ 136.8	$ 137.0	$ —	$ —	$ 137.0
Corporate debt securities	235.3	232.7	—	235.3	—	235.3
Mortgage-backed securities	109.8	108.1	—	109.8	—	109.8
Asset-backed securities	23.1	23.1	—	23.1	—	23.1
Other securities	108.1	22.2	—	—	108.1	108.1
Marketable equity securities	1,279.7	487.0	1,279.7	—	—	1,279.7
Equity investments without readily determinable fair values[3]	548.1					
Equity method investments[3]	771.5					
Noncurrent investments	$ 3,212.6					

[1] For available-for-sale debt securities, amounts disclosed represent the securities' amortized cost.
[2] 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.
[3] Fair value disclosures are not applicable for equity method investments and investments accounted for under the measurement alternative for equity investments.

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

Fair Value of Debt

The following table summarizes certain fair value information at December 31, 2022 and 2021 for our short-term and long-term debt:

			Fair Value Measurements Using			
	Carrying Amount	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Fair Value
Short-term commercial paper borrowings					
December 31, 2022	**$ (1,498.0)**	**$ —**	**$ (1,492.0)**	**$ —**	**$ (1,492.0)**
December 31, 2021	—	—	—	—	—
Long-term debt, including current portion					
December 31, 2022	**$ (14,740.6)**	**$ —**	**$ (12,329.3)**	**$ —**	**$ (12,329.3)**
December 31, 2021	(16,884.7)	—	(18,157.7)	—	(18,157.7)

Risk Management and Related 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 investment grade credit ratings.

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 $422.1 million and $550.5 million of accounts receivable as of December 31, 2022 and 2021, respectively, under these factoring arrangements. The costs of factoring such accounts receivable on our consolidated results of operations for the years ended December 31, 2022, 2021, and 2020 were not material.

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 income (loss) (see Note 17) 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 income (loss) (see Note 17). 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, Chinese yuan, Japanese yen, and Swiss franc). 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, 2022, we had outstanding foreign currency forward commitments as follows, all of which have settlement dates within 180 days:

December 31, 2022			
Purchase		Sell	
Currency	Amount (in millions)	Currency	Amount (in millions)
U.S. dollars	2,516.2	Euro	2,369.2
Euro	3,371.1	U.S. dollars	3,575.3
U.S. dollars	199.8	Chinese yuan	1,396.2
Japanese yen	14,139.9	U.S. dollars	105.3
U.S. dollars	90.9	Japanese yen	12,212.2
British pounds	207.1	U.S. dollars	254.7
Swiss franc	101.4	U.S. dollars	109.3

Foreign currency exchange risk is also managed through the use of foreign currency debt, cross-currency interest rate swaps, and foreign currency forward contracts. Our foreign currency-denominated notes had carrying amounts of $6.83 billion and $7.90 billion as of December 31, 2022 and 2021, respectively, of which $5.45 billion and $5.79 billion have been designated as, and are effective as, economic hedges of net investments in certain of our foreign operations as of December 31, 2022 and 2021, respectively. At December 31, 2022, we had outstanding cross currency swaps with notional amounts of $1.02 billion swapping U.S. dollars to euro and $ 1.00 billion swapping Swiss francs to U.S. dollars which have settlement dates ranging through 2028. Our cross-currency interest rate swaps, for which a majority convert a portion of our U.S. dollar-denominated fixed-rate debt to foreign-denominated fixed rate debt, have also been designated as, and are effective as, economic hedges of net investments. At December 31, 2022, we had outstanding foreign currency forward contracts to sell 325.0 million euro and to sell 1.82 billion Chinese yuan, with settlement dates ranging through 2023, which have 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, 2022, substantially all of our total long-term debt is at a fixed rate. We have converted approximately 10 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) (see Note 17) 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, 2022, the total notional amounts of forward-starting interest rate contracts in designated cash flow hedging instruments were $1.85 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:

	2022	2021	2020
Fair value hedges:			
Effect from hedged fixed-rate debt	**$ (209.8)**	$ (78.5)	$ 86.9
Effect from interest rate contracts	**209.8**	78.5	(86.9)
Cash flow hedges:			
Effective portion of losses on interest rate contracts reclassified from accumulated other comprehensive loss	**16.5**	16.6	16.4
Cross-currency interest rate swaps	**8.6**	41.8	(102.4)
Net (gains) losses on foreign currency exchange contracts not designated as hedging instruments	**191.3**	204.6	(123.7)
Total	**$ 216.4**	$ 263.0	$ (209.7)

During the years ended December 31, 2022, 2021, and 2020, 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:

	2022	2021	2020
Net investment hedges:			
Foreign currency-denominated notes	**$ 324.9**	$ 435.0	$ (404.0)
Cross-currency interest rate swaps	**52.0**	213.7	(207.9)
Foreign currency forward contracts	**(15.4)**	—	—
Cash flow hedges:			
Forward-starting interest rate swaps	**391.5**	97.6	(110.9)
Cross-currency interest rate swaps	**29.8**	42.3	(53.7)

During the next 12 months, we expect to reclassify $ 16.8 million of pretax net losses on cash flow hedges from accumulated other comprehensive income (loss) to other–net, (income) expense. During the years ended December 31, 2022, 2021, and 2020, the amounts excluded from the assessment of hedge effectiveness recognized in other comprehensive income (loss) were not material.

Fair Value of Risk-Management Instruments

The following table summarizes certain fair value information at December 31, 2022 and 2021 for risk-management assets and liabilities measured at fair value on a recurring basis:

	Carrying Amount	Fair Value Measurements Using: Quoted Prices in Active Markets for Identical Assets (Level 1)	Fair Value Measurements Using: Significant Other Observable Inputs (Level 2)	Fair Value Measurements Using: Significant Unobservable Inputs (Level 3)	Fair Value
December 31, 2022					
Risk-management instruments					
Interest rate contracts designated as fair value hedges:					
Other noncurrent liabilities	$ (134.3)	—	$ (134.3)	—	$ (134.3)
Interest rate contracts designated as cash flow hedges:					
Other receivables	162.9	—	162.9	—	162.9
Other noncurrent assets	246.0	—	246.0	—	246.0
Cross-currency interest rate contracts designated as net investment hedges:					
Other receivables	67.6	—	67.6	—	67.6
Cross-currency interest rate contracts designated as cash flow hedges:					
Other noncurrent assets	53.1	—	53.1	—	53.1
Foreign exchange contracts designated as hedging instruments:					
Other current liabilities	(38.3)	—	(38.3)	—	(38.3)
Foreign exchange contracts not designated as hedging instruments:					
Other receivables	26.6	—	26.6	—	26.6
Other current liabilities	(21.5)	—	(21.5)	—	(21.5)
Contingent consideration liabilities:					
Other current liabilities	(39.5)	—	—	(39.5)	(39.5)
Other noncurrent liabilities	(70.6)	—	—	(70.6)	(70.6)

	Carrying Amount	Fair Value Measurements Using: Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Fair Value
December 31, 2021					
Risk-management instruments					
Interest rate contracts designated as fair value hedges:					
Other receivables	$ 4.8	$ —	$ 4.8	$ —	$ 4.8
Other noncurrent assets	78.3	—	78.3	—	78.3
Other noncurrent liabilities	(7.6)	—	(7.6)	—	(7.6)
Interest rate contracts designated as cash flow hedges:					
Other noncurrent assets	49.2	—	49.2	—	49.2
Other noncurrent liabilities	(31.7)	—	(31.7)	—	(31.7)
Cross-currency interest rate contracts designated as net investment hedges:					
Other noncurrent assets	31.3	—	31.3	—	31.3
Other current liabilities	(1.2)	—	(1.2)	—	(1.2)
Cross-currency interest rate contracts designated as cash flow hedges:					
Other noncurrent assets	33.2	—	33.2	—	33.2
Other noncurrent liabilities	(1.3)	—	(1.3)	—	(1.3)
Foreign exchange contracts not designated as hedging instruments:					
Other receivables	9.9	—	9.9	—	9.9
Other current liabilities	(35.3)	—	(35.3)	—	(35.3)
Contingent consideration liabilities:					
Other noncurrent liabilities	(70.5)	—	—	(70.5)	(70.5)

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.

Contingent consideration liabilities relate to our liabilities arising in connection with the CVRs issued as a result of both the Akouos and Prevail acquisitions. The fair values of the CVR liabilities were estimated using a discounted cash flow analysis and Level 3 inputs, including projections representative of a market participant's view of the expected cash payments associated with the agreed upon regulatory milestones based on probabilities of technical success, timing of the potential milestone events for the compounds, and estimated discount rates. See Note 3 for additional information related to the CVR arrangements for both Akouos and Prevail.

Note 8: Goodwill and Other Intangibles

Goodwill

Goodwill results from excess consideration in a business combination over the fair value of identifiable net assets acquired. Goodwill is not amortized but is reviewed for impairment at least annually, or more frequently if impairment indicators are present, by first assessing qualitative factors to determine whether it is more likely than not that the fair value is less than its carrying amount. If we conclude it is more likely than not that the fair value is less than the carrying amount, a quantitative test that compares the fair value to its carrying value is performed to determine the amount of any impairment. The change in goodwill during 2022 was primarily related to our acquisition of Akouos. See Note 3 for additional information.

No impairments occurred with respect to the carrying value of goodwill for the years ended December 31, 2022, 2021, and 2020.

Other Intangibles

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

	2022			2021		
	Carrying Amount, Gross	Accumulated Amortization	Carrying Amount, Net	Carrying Amount, Gross	Accumulated Amortization	Carrying Amount, Net
Finite-lived intangible assets:						
Marketed products	**$ 7,922.1**	**$ (2,589.9)**	**$ 5,332.2**	$ 7,987.2	$ (2,229.2)	$ 5,758.0
Other	**35.4**	**(32.8)**	**2.6**	69.4	(60.5)	8.9
Total finite-lived intangible assets	**7,957.5**	**(2,622.7)**	**5,334.8**	8,056.6	(2,289.7)	5,766.9
Indefinite-lived intangible assets:						
Acquired IPR&D	**1,871.8**	**—**	**1,871.8**	1,925.0	—	1,925.0
Other intangibles	**$ 9,829.3**	**$ (2,622.7)**	**$ 7,206.6**	$ 9,981.6	$ (2,289.7)	$ 7,691.9

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 significant 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 decrease in acquired IPR&D intangibles in 2022 is due to the impairment of an intangible asset for GBA1 Gene Therapy (PR001). See Note 5 for additional information. This decrease was partially offset by acquired IPR&D assets recognized from the acquisition of Akouos. See Note 3 for additional information.

Indefinite-lived intangible assets are reviewed for impairment at least annually, or more frequently if impairment indicators are present, by first assessing qualitative factors to determine whether it is more likely than not that the fair value of the asset is less than its carrying amount. If we conclude it is more likely than not that the fair value is less than the carrying amount, a quantitative test that compares the fair value of the intangible asset to its carrying value is performed to determine the amount of any impairment. Finite-lived intangible assets are reviewed for impairment when an indicator of impairment is present. When required, a comparison of fair value to the carrying amount of assets is performed to determine the amount of any impairment. When determining the fair value of indefinite-lived acquired IPR&D as well as the fair value of finite-lived intangible assets for impairment testing purposes, we utilize the "income method" discussed above.

Intangible assets with finite lives are capitalized and are amortized primarily to cost of sales over their estimated useful lives, ranging from one to 20 years. As of December 31, 2022, the remaining weighted-average amortization period for finite-lived intangible assets was approximately 13 years.

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

	2022	2021	2020
Amortization expense	**$ 579.7**	$ 628.8	$ 428.2

The estimated amortization expense for each of the next five years associated with our finite-lived intangible assets as of December 31, 2022 is as follows:

	2023	2024	2025	2026	2027
Estimated amortization expense	$ 497.5	$ 447.7	$ 435.5	$ 424.8	$ 422.9

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:

	2022	2021
Land	**$ 256.6**	$ 258.7
Buildings	**7,915.9**	7,588.1
Equipment	**9,406.3**	8,937.2
Construction in progress	**2,798.6**	2,177.8
	20,377.4	18,961.8
Less accumulated depreciation	**(10,233.4)**	(9,976.7)
Property and equipment, net	**$ 10,144.0**	$ 8,985.1

Depreciation expense related to property and equipment was as follows:

	2022	2021	2020
Depreciation expense	**$ 816.6**	$ 787.0	$ 765.2

Capitalized interest costs were not material for the years ended December 31, 2022, 2021, and 2020.

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

	2022	2021
Long-lived assets[(1)]:		
U.S. and Puerto Rico	**$ 7,709.7**	$ 6,620.0
Ireland	**1,898.5**	1,702.3
Other foreign countries	**1,625.9**	1,691.0
Long-lived assets	**$ 11,234.1**	$ 10,013.3

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

Note 10: Leases

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

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

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

Lease expense for operating lease assets, which is recognized on a straight-line basis over the lease term, was $ 148.8 million, $159.4 million, and $154.6 million during the years ended December 31, 2022, 2021, and 2020, 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, 2022, 2021, and 2020. Short-term lease expense was not material during the years ended December 31, 2022, 2021, and 2020.

Supplemental balance sheet information related to operating leases as of December 31, 2022 and 2021 was as follows:

	2022	2021
Weighted-average remaining lease term	**7 years**	7 years
Weighted-average discount rate	**3.6 %**	3.0 %

Supplemental cash flow information related to operating leases during the years ended December 31, 2022, 2021, and 2020 was as follows:

	2022	2021	2020
Operating cash flows from operating leases	**$ 149.7**	$ 156.7	$ 160.9
Right-of-use assets obtained in exchange for new operating lease liabilities	**155.4**	163.5	136.7

The annual minimum lease payments of our operating lease liabilities as of December 31, 2022 were as follows:

2023	$ 154.2
2024	131.4
2025	115.1
2026	96.1
2027	76.3
After 2027	250.3
Total lease payments	823.4
Less imputed interest	95.2
Total	$ 728.2

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:

	2022	2021
Short-term commercial paper borrowings	**$ 1,498.0**	$ —
Long-term notes	**14,815.3**	16,741.2
Other long-term debt	**6.9**	10.8
Unamortized debt issuance costs	**(77.2)**	(84.2)
Fair value adjustment on hedged long-term notes	**(4.4)**	216.9
Total debt	**16,238.6**	16,884.7
Less current portion	**(1,501.1)**	(1,538.3)
Long-term debt	**$ 14,737.5**	$ 15,346.4

The weighted-average effective borrowing rate on short-term commercial paper borrowings at December 31, 2022 was 4.20 percent.

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

	2022	2021
2.35% notes due 2022	**$ —**	$ 750.0
3.00% notes due 2022	**—**	99.2
1.00% euro denominated notes due 2022	**—**	678.2
0.15% Swiss franc denominated notes due 2024	**649.5**	654.7
7.125% notes due 2025	**217.5**	217.5
2.75% notes due 2025	**560.6**	560.6
1.625% euro denominated notes due 2026	**799.3**	847.7
5.5% notes due 2027	**364.3**	364.3
3.1% notes due 2027	**401.5**	401.5
0.45% Swiss franc denominated notes due 2028	**433.0**	436.4
3.375% notes due 2029	**930.6**	930.6
0.42% Japanese yen denominated notes due 2029	**172.1**	199.0
2.125% euro denominated notes due 2030	**799.3**	847.7
0.625% euro denominated notes due 2031	**639.4**	678.2
0.50% euro denominated notes due 2033	**639.4**	678.2
0.56% Japanese yen denominated notes due 2034	**69.7**	80.5
6.77% notes due 2036	**158.6**	158.6
5.55% notes due 2037	**444.7**	444.7
5.95% notes due 2037	**266.8**	266.8
3.875% notes due 2039	**240.3**	240.3
1.625% British pound denominated notes due 2043	**301.2**	337.1
4.65% notes due 2044	**38.3**	38.3
3.7% notes due 2045	**386.8**	386.8
3.95% notes due 2047	**347.0**	347.0
3.95% notes due 2049	**958.2**	958.2
1.70% euro denominated notes due 2049	**1,065.7**	1,130.3
0.97% Japanese yen denominated notes due 2049	**57.4**	66.3
2.25% notes due 2050	**1,250.0**	1,250.0
1.125% euro denominated notes due 2051	**532.9**	565.2
4.15% notes due 2059	**591.3**	591.3
2.50% notes due 2060	**850.0**	850.0
1.375% euro denominated notes due 2061	**746.0**	791.2
Unamortized note discounts	**(96.1)**	(105.2)
Total long-term notes	**$ 14,815.3**	$ 16,741.2

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

At December 31, 2022, we had a total of $ 7.33 billion of unused committed bank credit facilities, which consisted primarily of a $ 3.00 billion credit facility that expires in December 2026 and a $4.00 billion 364-day facility that expires in September 2023, both of which are available to support our commercial paper program. We have not drawn against the $3.00 billion and $4.00 billion facilities as of December 31, 2022. Of the remaining committed bank credit facilities, the outstanding balances as of December 31, 2022 and 2021 were not material. Compensating balances and commitment fees are not material, and there are no conditions that are probable of occurring under which the lines may be withdrawn.

In September 2021, we issued euro-denominated notes consisting of € 600.0 million of 0.50 percent fixed-rate notes due in September 2033, with interest to be paid annually. The net proceeds from the offering have been, and will continue to be, used to fund, in whole or in part, eligible projects designed to advance one or more of our environmental, social, and governance objectives.

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

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

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

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

	2023	2024	2025	2026	2027
Maturities on long-term debt	$ 3.1	$ 649.5	$ 778.1	$ 799.3	$ 765.8

We have converted approximately 10 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, 2022 and 2021, including the effects of interest rate swaps for hedged debt obligations, were 2.87 percent and 2.27 percent, respectively.

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

	2022	2021	2020
Cash payments for interest on borrowings	**$ 323.7**	$ 338.0	$ 345.8

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:

	2022	2021	2020
Stock-based compensation expense	**$ 371.1**	$ 342.8	$ 308.1
Tax benefit	**77.9**	72.0	64.7

At December 31, 2022, stock-based compensation awards may be granted under the 2002 Lilly Stock Plan for not more than 50.0 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, 2022, 2021, and 2020 were $234.93, $198.57, and $137.33, respectively. The number of shares ultimately issued for the PA program is dependent upon the EPS achieved during the vesting period. Pursuant to this program, approximately 0.7 million shares, 0.7 million shares, and 1.1 million shares were issued during the years ended December 31, 2022, 2021, and 2020, respectively. Approximately 0.5 million shares are expected to be issued in 2023. As of December 31, 2022, the total remaining unrecognized compensation cost related to nonvested PAs was $38.4 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, 2022, 2021, and 2020 were $ 203.88, $230.19, and $139.14, respectively, determined using the following assumptions:

	2022	2021	2020
Expected dividend yield	**1.60 %**	2.50 %	2.50 %
Risk-free interest rate	**1.57**	0.19	1.38
Volatility	**32.99**	31.42	20.90

Pursuant to this program, approximately 0.5 million shares, 1.0 million shares, and 0.8 million shares were issued during the years ended December 31, 2022, 2021, and 2020, respectively. Approximately 0.3 million shares are expected to be issued in 2023. As of December 31, 2022, the total remaining unrecognized compensation cost related to nonvested SVAs was $43.3 million, which will be amortized over the weighted-average remaining requisite service period of 21 months.

Relative Value Award Program

RVAs 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 the growth of our stock price at the end of the three-year vesting period compared to our peers. We measure the fair value of the RVA unit on the grant date using a Monte Carlo simulation model. The model utilizes multiple input variables that determine the probability of satisfying the market condition stipulated in the award grant and calculates the fair value of the award. Expected volatilities utilized in the model are based on implied volatilities from traded options on our stock, historical volatility of our stock price and our peers' stock price, and other factors. Similarly, the dividend yield is based on historical experience and our estimate of future dividend yields. The risk-free interest rate is derived from the U.S. Treasury yield curve in effect at the time of grant. The weighted-average fair value of the RVA units granted during the years ended December 31, 2022, 2021 and 2020 were $230.00, $286.71, and $179.90, respectively, determined using the following assumptions:

	2022	2021	2020
Expected dividend yield	**1.60 %**	2.50 %	2.50 %
Risk-free interest rate	**1.57**	0.19	1.38
Volatility	**32.86**	30.95	19.89

Approximately 0.1 million shares are expected to be issued in 2023. As of December 31, 2022, the total remaining unrecognized compensation cost related to nonvested RVAs was $17.5 million, which will be amortized over the weighted-average remaining requisite service period of 22 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 weighted-average fair values of RSU awards granted during the years ended December 31, 2022, 2021, and 2020 were $239.88, $196.30, and $135.42, respectively. The number of shares ultimately issued for the RSU program remains constant with the exception of forfeitures. Pursuant to this program, 1.0 million, 0.7 million, and 1.1 million shares were granted and approximately 0.8 million, 0.6 million, and 0.6 million shares were issued during the years ended December 31, 2022, 2021, and 2020, respectively. Approximately 0.6 million shares are expected to be issued in 2023. As of December 31, 2022, the total remaining unrecognized compensation cost related to nonvested RSUs was $221.6 million, which will be amortized over the weighted-average remaining requisite service period of 25 months.

Note 13: Shareholders' Equity

In 2022, 2021, and 2020, we repurchased $1.50 billion, $1.25 billion, and $500.0 million, respectively, of shares associated with our share repurchase programs. As of December 31, 2022, we had $3.25 billion remaining under our $5.00 billion share repurchase program that our board authorized in May 2021.

We have 5.0 million authorized shares of preferred stock. As of December 31, 2022 and 2021, 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, 2022 and 2021, 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, 2022 and 2021, 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, 2022, 2021, and 2020.

Note 14: Income Taxes

Deferred taxes are recognized for the future tax effects of temporary differences between financial and income tax reporting based on enacted tax laws and rates. Deferred taxes related to global intangible low-taxed income (GILTI) are also recognized for the future tax effects of temporary differences.

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

Following is the composition of income tax expense:

	2022	2021	2020
Current:			
Federal[1]	**$ 2,153.6**	$ 938.5	$ 567.6
Foreign	**547.7**	466.0	650.4
State	**45.5**	(28.4)	(47.3)
Total current tax expense	**2,746.8**	1,376.1	1,170.7
Deferred:			
Federal	**(1,992.4)**	(977.5)	(97.4)
Foreign	**(78.2)**	174.6	(16.6)
State	**(114.6)**	0.6	(20.5)
Total deferred tax benefit	**(2,185.2)**	(802.3)	(134.5)
Income taxes	**$ 561.6**	$ 573.8	$ 1,036.2

[1] The 2022, 2021, and 2020 current tax expense includes $189.5 million, $64.7 million, and $144.4 million of tax benefit, respectively, from utilization of net operating loss and other tax carryforwards.

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

	2022	2021
Deferred tax assets:		
Purchases of intangible assets	**$ 2,071.3**	$ 2,347.4
Compensation and benefits	**427.9**	634.7
Tax credit carryforwards	**477.6**	463.7
Tax loss and other tax carryforwards and carrybacks	**626.0**	645.4
Sales rebates and discounts	**1,312.9**	832.3
Correlative tax adjustments	**752.5**	560.8
Foreign tax redeterminations	**267.8**	274.9
Operating lease liabilities	**147.5**	150.0
Capitalized research and development	**1,615.4**	275.1
Other	**361.0**	477.9
Total gross deferred tax assets	**8,059.9**	6,662.2
Valuation allowances	**(775.1)**	(875.6)
Total deferred tax assets	**7,284.8**	5,786.6
Deferred tax liabilities:		
Earnings of foreign subsidiaries	**(1,226.0)**	(1,583.3)
Intangibles	**(1,387.9)**	(1,516.1)
Inventories	**(639.5)**	(596.4)
Prepaid employee benefits	**(546.5)**	(560.6)
Property and equipment	**(433.5)**	(338.7)
Financial instruments	**(215.0)**	(303.0)
Operating lease assets	**(130.7)**	(132.6)
Total deferred tax liabilities	**(4,579.1)**	(5,030.7)
Deferred tax assets - net	**$ 2,705.7**	$ 755.9

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, 2022, based on filed tax returns we have tax credit carryforwards and carrybacks of $ 873.6 million available to reduce future income taxes; $148.8 million, if unused, will expire by 2026, and $ 27.1 million, if unused, will expire between 2028 and 2042. The remaining portion of the tax credit carryforwards is related to federal tax credits of $68.6 million, international tax credits of $ 118.6 million, and state tax credits of $ 510.5 million, all of which are fully reserved.

At December 31, 2022, based on filed tax returns we had net operating losses and other carryforwards for international and U.S. federal income tax purposes of $2.52 billion: $319.1 million will expire by 2027; $ 1.44 billion will expire between 2028 and 2042; and $ 762.0 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 $246.2 million are fully reserved as of December 31, 2022.

At December 31, 2022 and 2021, prepaid expenses and other current assets included prepaid taxes of $ 2.37 billion and $ 1.98 billion, respectively.

Domestic and Puerto Rican companies contributed approximately 33 percent, 28 percent, and 39 percent for the years ended December 31, 2022, 2021, and 2020, 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, which was amended in 2022 to apply the alternate tax regime established by recently enacted Puerto Rico legislation starting in 2023.

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, 2022 and 2021, 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:

	2022	2021	2020
Cash payments of income taxes	**$ 2,672.9**	$ 1,598.8	$ 954.6

In December 2017, the Tax Cuts and Job Act (2017 Tax Act) was signed into law. The 2017 Tax Act included significant changes to the U.S. corporate income tax system, including a one-time repatriation transition tax (also known as the 'Toll Tax') on unremitted foreign earnings. The 2017 Tax Act provided an election to taxpayers subject to the Toll Tax to make payments over an eight-year period beginning in 2018 through 2025. Having made this election, our future cash payments relating to the Toll Tax as of December 31, 2022 are as follows:

	Total	Less than 1 Year	1-3 Years
2017 Tax Act Toll Tax	$ 1,895.8	$ 475.7	$ 1,420.1

As of December 31, 2022, we have additional noncurrent income tax payables of $ 2.28 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:

	2022	2021	2020
Income tax at the U.S. federal statutory tax rate	**$ 1,429.3**	$ 1,292.6	$ 1,518.3
Add (deduct):			
International operations, including Puerto Rico[(1)]	**(299.5)**	(447.5)	(297.2)
General business credits	**(155.0)**	(100.5)	(97.9)
Foreign-derived intangible income deduction	**(287.5)**	(86.7)	(71.5)
Valuation allowance release	**(116.4)**	(19.0)	(10.0)
Other	**(9.3)**	(65.1)	(5.5)
Income taxes	**$ 561.6**	$ 573.8	$ 1,036.2

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

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

	2022	2021	2020
Beginning balance at January 1	**$ 2,798.3**	$ 2,551.9	$ 2,108.6
Additions based on tax positions related to the current year	**274.2**	310.3	225.6
Additions for tax positions of prior years	**34.6**	98.6	310.8
Reductions for tax positions of prior years	**(10.9)**	(8.1)	(52.4)
Settlements	**(44.8)**	(38.5)	(72.0)
Lapses of statutes of limitation	**(11.8)**	(49.7)	(41.7)
Changes related to the impact of foreign currency translation	**(52.6)**	(66.2)	73.0
Ending balance at December 31	**$ 2,987.0**	$ 2,798.3	$ 2,551.9

The total amount of unrecognized tax benefits that, if recognized, would affect our effective tax rate was $ 1.70 billion at both December 31, 2022 and 2021.

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

The U.S. examination of tax years 2016-2018 began in 2019 and remains ongoing. While it is reasonably possible that the Internal Revenue Service examination of these tax years could conclude within the next 12 months, final resolution of certain matters is dependent upon several factors, including the potential for formal administrative proceedings. As a result, an estimate of the range of reasonably possible changes in unrecognized tax benefits cannot be made.

Interest and penalties related to unrecognized tax benefits are recognized in income tax expense and were not material for the years ended December 31, 2022, 2021, and 2020. Our accrued interest and penalties related to unrecognized tax benefits were $271.5 million and $220.1 million at December 31, 2022 and 2021, 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	
	2022	2021	2022	2021
Change in benefit obligation:				
Benefit obligation at beginning of year	**$ 17,565.0**	$ 18,225.5	**$ 1,663.8**	$ 1,753.7
Service cost	**351.7**	369.2	**46.6**	49.2
Interest cost	**398.1**	337.8	**37.8**	32.5
Actuarial (gain) loss	**(4,158.9)**	(564.3)	**(395.9)**	(86.1)
Benefits paid	**(608.9)**	(630.1)	**(86.8)**	(79.3)
Foreign currency exchange rate changes and other adjustments	**(325.0)**	(173.1)	**(6.7)**	(6.2)
Benefit obligation at end of year	**13,222.0**	17,565.0	**1,258.8**	1,663.8
Change in plan assets:				
Fair value of plan assets at beginning of year	**16,416.0**	14,579.0	**3,361.4**	3,227.0
Actual return on plan assets	**(2,388.1)**	2,458.1	**(796.0)**	202.6
Employer contribution	**118.1**	131.2	**13.9**	11.1
Benefits paid	**(608.9)**	(630.1)	**(86.8)**	(79.3)
Foreign currency exchange rate changes and other adjustments	**(341.3)**	(122.2)	**—**	—
Fair value of plan assets at end of year	**13,195.8**	16,416.0	**2,492.5**	3,361.4
Funded status	**(26.2)**	(1,149.0)	**1,233.7**	1,697.6
Unrecognized net actuarial (gain) loss	**2,687.2**	3,908.2	**54.5**	(497.2)
Unrecognized prior service (benefit) cost	**8.4**	11.2	**(62.2)**	(117.6)
Net amount recognized	**$ 2,669.4**	$ 2,770.4	**$ 1,226.0**	$ 1,082.8
Amounts recognized in the consolidated balance sheet consisted of:				
Other noncurrent assets	**$ 1,208.0**	$ 668.5	**$ 1,383.4**	$ 1,910.2
Other current liabilities	**(70.4)**	(68.3)	**(8.4)**	(7.9)
Accrued retirement benefits	**(1,163.8)**	(1,749.3)	**(141.3)**	(204.8)
Accumulated other comprehensive (income) loss before income taxes	**2,695.6**	3,919.5	**(7.7)**	(614.7)
Net amount recognized	**$ 2,669.4**	$ 2,770.4	**$ 1,226.0**	$ 1,082.8

The unrecognized net actuarial (gain) loss and unrecognized prior service (benefit) cost have not yet been recognized in net periodic pension costs and were included in accumulated other comprehensive loss at December 31, 2022 and 2021.

The $4.75 billion and $750.4 million declines in benefit obligation in 2022 and 2021, respectively, were both driven primarily by increases in the discount rates.

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

	Defined Benefit Pension Plans			Retiree Health Benefit Plans		
(Percents)	2022	2021	2020	2022	2021	2020
Discount rate for benefit obligation	**5.1 %**	2.8 %	2.4 %	**5.2 %**	3.0 %	2.6 %
Discount rate for net benefit costs	**2.8**	2.4	3.0	**3.0**	2.6	3.3
Rate of compensation increase for benefit obligation	**4.3**	3.5	3.3			
Rate of compensation increase for net benefit costs	**3.5**	3.3	3.3			
Expected return on plan assets for net benefit costs	**8.1**	6.8	7.3	**7.3**	5.0	6.0

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

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

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

	2023	2024	2025	2026	2027	2028-2032
Defined benefit pension plans	$ 648.2	$ 664.5	$ 682.6	$ 705.9	$ 732.7	$ 4,079.4
Retiree health benefit plans	89.0	91.6	92.4	92.8	93.4	468.3

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

	2022	2021
Projected benefit obligation	**$ 2,211.2**	$ 3,360.3
Fair value of plan assets	**977.1**	1,542.8

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	
	2022	2021	2022	2021
Accumulated benefit obligation	**$ 1,721.7**	$ 2,532.0	**$ 149.8**	$ 212.6
Fair value of plan assets	**652.7**	973.4	**—**	—

The total accumulated benefit obligation for our defined benefit pension plans was $ 12.01 billion and $16.44 billion at December 31, 2022 and 2021, respectively.

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

	Defined Benefit Pension Plans			Retiree Health Benefit Plans		
	2022	2021	2020	2022	2021	2020
Components of net periodic (benefit) cost:						
Service cost	**$ 351.7**	$ 369.2	$ 325.5	**$ 46.6**	$ 49.2	$ 40.8
Interest cost	**398.1**	337.8	425.8	**37.8**	32.5	43.7
Expected return on plan assets	**(947.6)**	(949.3)	(901.5)	**(152.1)**	(146.2)	(158.1)
Amortization of prior service (benefit) cost	**2.4**	4.2	4.5	**(54.8)**	(59.6)	(59.5)
Recognized actuarial (gain) loss	**342.4**	487.7	396.3	**0.9**	3.2	(3.0)
Net periodic (benefit) cost	**$ 147.0**	$ 249.6	$ 250.6	**$ (121.6)**	$ (120.9)	$ (136.1)

The following represents the amounts recognized in other comprehensive income (loss) for the years ended December 31, 2022 , 2021, and 2020:

	Defined Benefit Pension Plans			Retiree Health Benefit Plans		
	2022	2021	2020	2022	2021	2020
Actuarial gain (loss) arising during period	**$ 823.6**	$ 2,072.4	$ (663.0)	**$ (552.2)**	$ 142.5	$ 238.8
Plan amendments during period	**—**	—	(2.2)	**—**	—	—
Amortization of prior service (benefit) cost included in net income	**2.4**	4.2	4.5	**(54.8)**	(59.6)	(59.5)
Amortization of net actuarial (gain) loss included in net income	**342.4**	487.7	396.3	**0.9**	3.2	(3.0)
Foreign currency exchange rate changes and other	**55.5**	47.2	(71.5)	**(0.9)**	1.9	2.4
Total other comprehensive income (loss) during period	**$ 1,223.9**	$ 2,611.5	$ (335.9)	**$ (607.0)**	$ 88.0	$ 178.7

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 $170.6 million, $167.3 million, and $164.3 million for the years ended December 31, 2022, 2021, and 2020, 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, 2022, 2021, and 2020 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 85 percent of our global investments. Given the long-term nature of our liabilities, these plans have the flexibility to manage an above-average degree of risk in the asset portfolios. At the investment-policy level, there are no specifically prohibited investments. However, within individual investment manager mandates, restrictions and limitations are contractually set to align with our investment objectives, ensure risk control, and limit concentrations.

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

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

The defined benefit pension and retiree health benefit plan allocation for the U.S. and Puerto Rico currently comprises approximately 75 percent growth investments and 25 percent fixed-income investments. The growth investment allocation encompasses U.S. and international public equity securities, hedge funds, private equity-like investments, and real estate. These portfolio allocations are intended to reduce overall risk by providing diversification, while seeking moderate to high returns over the long term.

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

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

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

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

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

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

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

Other than hedge funds, private equity-like investments, and a portion of the real estate holdings, which are discussed above, we determine fair values based on a market approach using quoted market values, significant other observable inputs for identical or comparable assets or liabilities, or discounted cash flow analyses.

The fair values of our defined benefit pension plan and retiree health plan assets as of December 31, 2022 by asset category were as follows:

		Fair Value Measurements Using			
Asset Class	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Investments Valued at Net Asset Value[1]
Defined Benefit Pension Plans					
Public equity securities:					
U.S.	$ 1,132.4	$ 396.6	$ 0.1	$ —	$ 735.7
International	1,177.1	369.4	300.9	—	506.8
Fixed income:					
Developed markets	2,445.5	19.8	2,058.2	0.1	367.4
Developed markets - repurchase agreements	(706.6)	6.4	(713.0)	—	—
Emerging markets	273.5	10.6	32.0	—	230.9
Private alternative investments:					
Hedge funds	3,249.0	—	—	—	3,249.0
Equity-like funds	4,014.1	—	—	25.4	3,988.7
Real estate	349.1	234.9	—	—	114.2
Other	1,261.7	251.0	(131.8)	—	1,142.5
Total	$ 13,195.8	$ 1,288.7	$ 1,546.4	$ 25.5	$ 10,335.2
Retiree Health Benefit Plans					
Public equity securities:					
U.S.	$ 104.2	$ 35.7	$ —	$ —	$ 68.5
International	72.0	31.9	—	—	40.1
Fixed income:					
Developed markets	63.1	—	63.1	—	—
Emerging markets	21.0	—	—	—	21.0
Private alternative investments:					
Hedge funds	294.9	—	—	—	294.9
Equity-like funds	332.8	—	—	2.4	330.4
Cash value of trust owned insurance contract	1,470.8	—	1,470.8	—	—
Real estate	21.6	21.6	—	—	—
Other	112.1	24.2	(19.9)	—	107.8
Total	$ 2,492.5	$ 113.4	$ 1,514.0	$ 2.4	$ 862.7

[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, 2022. The activity in the Level 3 investments during the year ended December 31, 2022 was not material.

The fair values of our defined benefit pension plan and retiree health plan assets as of December 31, 2021 by asset category were as follows:

Asset Class	Total	Fair Value Measurements Using: Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Investments Valued at Net Asset Value[1]
Defined Benefit Pension Plans					
Public equity securities:					
U.S.	$ 1,325.4	$ 430.4	$ 0.1	$ 1.2	$ 893.7
International	2,722.7	815.0	—	—	1,907.7
Fixed income:					
Developed markets	4,496.0	2.6	3,356.6	—	1,136.8
Developed markets - repurchase agreements	(1,376.2)	—	(1,376.2)	—	—
Emerging markets	611.0	11.3	250.5	0.1	349.1
Private alternative investments:					
Hedge funds	3,046.8	—	—	—	3,046.8
Equity-like funds	3,816.4	2.1	—	5.5	3,808.8
Real estate	630.3	363.8	7.5	10.7	248.3
Other	1,143.6	103.2	263.2	(2.1)	779.3
Total	$ 16,416.0	$ 1,728.4	$ 2,501.7	$ 15.4	$ 12,170.5
Retiree Health Benefit Plans					
Public equity securities:					
U.S.	$ 124.7	$ 40.9	$ —	$ 0.1	$ 83.7
International	180.6	47.7	—	—	132.9
Fixed income:					
Developed markets	102.2	—	80.5	—	21.7
Emerging markets	51.6	—	23.7	—	27.9
Private alternative investments:					
Hedge funds	275.4	—	—	—	275.4
Equity-like funds	317.8	—	—	0.5	317.3
Cash value of trust owned insurance contract	2,166.8	—	2,166.8	—	—
Real estate	36.2	34.5	0.7	1.0	—
Other	106.1	24.4	18.3	(0.1)	63.5
Total	$ 3,361.4	$ 147.5	$ 2,290.0	$ 1.5	$ 922.4

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

No material transfers between Level 1, Level 2, or Level 3 occurred during the year ended December 31, 2021. The activity in the Level 3 investments during the year ended December 31, 2021 was not material.

In 2023, we expect to contribute approximately $ 30 million to our defined benefit pension plans to satisfy minimum funding requirements for the year. We do not currently expect to make material discretionary contributions in 2023.

Note 16: Contingencies

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

We believe the legal proceedings in which we are named as defendants are without merit and we are defending against them vigorously. It is not possible to determine the final outcome of these matters, and we cannot reasonably estimate the maximum potential exposure or the range of possible loss in excess of amounts accrued for any of these matters; however, we believe that the resolution of all such matters will not have a material adverse effect on our consolidated financial position or liquidity, but could possibly be material to our consolidated results of operations in any one accounting period.

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

Because of the nature of pharmaceutical products, it is possible that we could become subject to large numbers of additional product liability and related claims in the future. Due to a very restrictive market for litigation liability insurance, we are self-insured for litigation liability losses for all our currently and previously marketed products.

Patent Litigation

Alimta European Patent Litigation

In Europe, Alimta (pemetrexed) was protected by a patent through June 2021. A number of legal proceedings that were initiated prior to patent expiration are ongoing.

Emgality Patent Litigation

We are a named 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 three different Teva patents would be infringed by our launch and continued sales of Emgality for the prevention of migraine in adults.

Following a trial, in November 2022, a jury returned a verdict in favor of Teva. The parties have filed post-trial motions on which the court will rule and then enter final judgment in the case. We intend to appeal the jury verdict if necessary. Pursuant to agreement by the parties, the award, if any, will not become due until completion of the appeal process. This matter is ongoing.

In June 2021, we were named as a defendant in a second litigation filed by Teva in the U.S. District Court for the District of Massachusetts seeking a ruling that two of Teva's patents, which are directed toward use of the active ingredient in Emgality to treat migraine, would be infringed by our continued sales of Emgality. We challenged these two patents by filing requests for Inter Partes Review with the Patent Trial and Appeal Board (PTAB) and in October 2022, the PTAB granted our requests.The corresponding district court litigation is stayed while this PTAB proceeding is ongoing.

Jardiance Patent Litigation

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

Taltz Patent Litigation

Beginning in May 2020, Lilly and Novartis Pharma AG (Novartis) had been litigating the validity and alleged infringement by Taltz of certain patents Novartis acquired from Genentech, Inc. (Genentech). As of October 2022, we had pending cases in Ireland, Italy, Switzerland, and the Netherlands where Novartis sought injunctions to stop Taltz commercialization.

In October 2022, we entered into a cashless (no-payment) settlement and mutual release agreement with Novartis, which resolved such disputes. Without any admission of liability or wrongdoing, we and Novartis have agreed to mutual releases for past claims and mutual covenants not to sue the other in relation to Taltz and the patents Novartis purchased from Genentech. This matter is closed.

Zyprexa Canada Patent Litigation

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

Product Liability Litigation

Byetta® Product Liability

We have been named as a defendant in over 500 Byetta product liability lawsuits in the U.S. that were first initiated in March 2009 and involved over 800 plaintiffs. These lawsuits have been filed in various state and federal jurisdictions, including California state court (coordinated in Los Angeles County Superior Court), and various federal courts, the majority of which are coordinated in a multi-district litigation (MDL) in the U.S. District Court for the Southern District of California. The majority of these suits contained allegations that Byetta caused or contributed to the plaintiffs' cancer (primarily pancreatic cancer or thyroid cancer). All of the MDL and state court lawsuits have been dismissed as of January 2023 and we consider these matters closed.

Environmental Proceedings

Under the Comprehensive Environmental Response, Compensation, and Liability Act, commonly known as "Superfund," we have been designated as one of several potentially responsible parties with respect to the cleanup of fewer than 10 sites. Under Superfund, each responsible party may be jointly and severally liable for the entire amount of the cleanup.

Other Matters

340B Litigation and Investigations

We are the plaintiff in a lawsuit filed in January 2021 in the U.S. District Court for the Southern District of Indiana against the U.S. Department of Health and Human Services (HHS), the Secretary of HHS, the Health Resources and Services Administration (HRSA), and the Administrator of HRSA. The lawsuit challenges HHS's December 30, 2020 advisory opinion stating that drug manufacturers are required to deliver discounts under the 340B program to all contract pharmacies and HHS's Administrative Dispute Resolution regulations. We seek a declaratory judgment that the defendants violated the Administrative Procedure Act and the U.S. Constitution, a preliminary injunction enjoining implementation of the administrative dispute resolution process created by defendants and, with it, their application of the advisory opinion, and other related relief. In March 2021, the court entered an order preliminarily enjoining the government's enforcement of the administrative dispute resolution process against us. In May 2021, HRSA notified us that it determined that our policy was contrary to the 340B statute. In response, in May 2021, we amended our complaint to bring claims related to HRSA's determination and filed a motion for preliminary injunction and temporary restraining order requesting that the U.S. District Court for the Southern District of Indiana enjoin defendants from taking any action against us relating to the 340B drug pricing program until after the court issues a final judgment on the aforementioned litigation. In May 2021, the court denied our motion for a temporary restraining order but deferred resolution of our motion for preliminary injunction. In June 2021, the defendants withdrew the HHS December 30, 2020 advisory opinion. In July 2021, the court held oral argument on the parties' cross motions for summary judgment, the defendants' motion to dismiss, and our motion for preliminary injunction related to HRSA's May 2021 enforcement letter. In October 2021, the court denied the defendants' motion to dismiss, and granted in part and denied in part the parties' cross motions for summary judgment. Both parties filed notices of appeal related to the court's summary judgment order. In October 2022, the U.S. Court of Appeals for the Seventh Circuit held oral argument. This matter is ongoing.

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

In July 2021, we, along with Sanofi-Aventis U.S., LLC (Sanofi), Novo Nordisk Inc. (Novo Nordisk), and AstraZeneca Pharmaceuticals LP, were named as a defendant in a purported class action lawsuit filed in the U.S. District Court for the Western District of New York by Mosaic Health, Inc. alleging antitrust and unjust enrichment claims related to the defendants' 340B distribution programs. We, with Sanofi and Novo Nordisk, filed a motion to dismiss the lawsuit, which was granted in September 2022. In October 2022, the plaintiffs filed a motion for leave to amend their complaint. This matter is ongoing.

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

Branchburg Manufacturing Facility

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

Brazil Litigation – Cosmopolis Facility

Labor Attorney Litigation

First initiated in 2008, our subsidiary in Brazil, Eli Lilly do Brasil Limitada (Lilly Brasil), is named in a Public Civil Action brought by the Labor Public Attorney (LPA) for the 15th Region in the Labor Court of Paulinia, State of Sao Paulo, Brazil, (the Labor Court) alleging possible harm to employees and former employees caused by alleged exposure to soil and groundwater contaminants at a former Lilly Brasil manufacturing facility in Cosmopolis, Brazil, operated by the company between 1977 and 2003. In May 2014, the Labor Court judge ruled against Lilly Brasil, ordering it to undertake several remedial and compensatory actions including health coverage for a class of individuals and certain of their children. In July 2018, the appeals court (TRT) generally affirmed our appeal of the Labor Court's ruling, which included a liquidated award of 300 million Brazilian reais, which, when adjusted for inflation and the addition of pre and post judgment interest using the current Central Bank of Brazil's special system of clearance and custody rate, is approximately one billion Brazilian reais (approximately $184 million as of December 31, 2022). In August 2019, Lilly Brasil filed an appeal to the superior labor court (TST) and in June 2021, the TRT published its decision on the admissibility of Lilly Brasil's appeal, allowing the majority of the elements, which were allowed to proceed in June 2021; elements not proceeding are subject to an interlocutory appeal to the TST that was filed in June 2021. In September 2019, the TRT stayed a number of elements of its trial court decision pending the determination of Lilly Brasil's appeal to the TST.

In June 2019 and September 2020, the LPA filed applications in the Labor Court for enforcement of certain remedies granted by the TRT in its July 2018 decision, requested restrictions on Lilly Brasil’s assets in Brazil, and required Lilly Brasil and Antibióticos do Brasil Ltda. (ABL) to submit a list of potential beneficiaries of the Public Civil Action. In July 2019, the Labor Court issued a ruling requiring a freeze of Lilly Brasil’s immovable property or, alternatively, a security deposit or lien of 500 million Brazilian reais, which ruling was subsequently limited in scope and the security was reduced to 100 million Brazilian reais. ABL and LPA appealed the June 2021 Labor Court ruling to the TST, which appeal is under review. The Labor Court is currently assessing the status of Lilly Brasil’s and ABL’s compliance with such portion of the July 2018 TRT decision and an inspection in the industrial plant is expected. These matters are ongoing.

Individual Former Employee Litigation

Lilly Brasil is also named in various pending lawsuits filed in the Labor Court by individual former employees making related claims. These individual lawsuits are at various stages in the litigation process.

Puerto Rico Tax Matter

In May 2013, the Municipality of Carolina in Puerto Rico (Municipality) filed a lawsuit against us alleging noncompliance with respect to a contract with the Municipality and seeking a declaratory judgment. In December 2020, the Puerto Rico Appellate Court (AP) reversed the summary judgment previously granted by the Court of First Instance (CFI) in our favor, dismissing the Municipality's complaint in its entirety. The AP remanded the case to the CFI for trial on the merits. The trial began in May 2022; however, the Municipality filed a new motion requesting the CFI to award damages. The request was denied by the CFI in our favor and the Municipality filed for revision at the AP, which we opposed, staying the case. In February 2023, the AP denied the Municipality's motion for revision. This matter is ongoing.

Average Manufacturer Price Litigation

In November 2014, we, along with another pharmaceutical manufacturer, were named as co-defendants in *United States et al. ex rel. Streck v. Takeda Pharm. Am., Inc., et al.*, which was filed in November 2014 and unsealed in the U.S. District Court for the Northern District of Illinois. The complaint alleges that the defendants should have treated certain credits from distributors as retroactive price increases and included such increases in calculating average manufacturer prices. Following a trial in August 2022, the jury returned a verdict in favor of the plaintiff. The case is proceeding with post-trial motions after which the court will enter final judgment in the case. This matter is ongoing.

Health Choice Alliance

We are named as a defendant in two 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, for certain patient support programs related to our products Humalog, Humulin, and Forteo. The Texas state court action has been stayed. The New Jersey state court action was dismissed with prejudice pending an ongoing appeal before the Appellate Division of the New Jersey Superior Court. This matter is ongoing.

Pricing Litigation

We, along with Sanofi, Novo Nordisk, and in some matters certain pharmacy benefit managers, have been named in lawsuits related to insulin pricing that assert various theories, including consumer protection, fraud, false advertising, unjust enrichment, civil conspiracy, federal and state RICO statutes, deceptive trade practices, and unfair competition claims. These lawsuits include In re. Insulin Pricing Litigation, a putative consumer class action (U.S. District Court for the District of New Jersey, 2017); *MSP Recovery Claims, Series, LLC et al. v. Sanofi Aventis U.S. LLC et al.* (U.S. District Court for the District of New Jersey, 2018); *FWK Holdings, LLC v. Novo Nordisk Inc., et al.* , a putative class action brought by direct purchasers of insulin (U.S. District Court for the District of New Jersey, 2020), and suits brought by the State of Minnesota (U.S. District Court for the District of New Jersey, 2018), State of Kentucky (Franklin County Circuit Court, 2019), State of Mississippi (U.S. District Court for the Southern District of Mississippi, 2021), State of Arkansas (U.S. District Court for the Eastern District of Arkansas, 2022), County of Albany, New York (U.S. District Court for the Northern District of New York, 2022), State of Montana (U.S. District Court for the District of Montana, 2022), State of Kansas (U.S. District Court for the District of Kansas, 2022), State of Illinois (U.S. District Court for the Northern District of Illinois, 2022), State of California (Los Angeles County Superior Court, 2023), Jackson County, Missouri in a putative class action on behalf of Missouri counties and municipalities (Jackson County Circuit Court, 2023), and the Government of Puerto Rico (Court of First Instance Superior Court, San Juan, 2023). These lawsuits are at various stages in the litigation process.

Investigations, Subpoenas, and Inquiries

In connection with the pricing and sale of our insulin and other products, we have been subject to various investigations and received subpoenas, civil investigative demand requests, information requests, interrogatories, and other inquiries from various governmental entities. These include subpoenas from the New York and Vermont Attorney General Offices, civil investigative demands from the Washington, New Mexico, Colorado, Louisiana, Texas and Ohio Attorney General Offices, the U.S. Department of Justice and the U.S. Federal Trade Commission, as well as information requests from the Mississippi, Washington D.C., California, Florida, Hawaii, and Nevada Attorney General Offices. In January 2022, the Michigan Attorney General filed a petition in Michigan state court seeking authorization to investigate Lilly for potential violations of the Michigan Consumer Protection Act (MCPA), and a complaint seeking a declaratory judgment that the Attorney General has authority to investigate Lilly's sale of insulin under the MCPA. The court authorized the proposed investigation and the issuance of civil investigative subpoenas. In April 2022, the parties entered into a stipulation providing that the State of Michigan will not issue any civil investigative subpoena to us under the MCPA until the declaratory judgment action is resolved. In July 2022, the court dismissed the case in its entirety. The Michigan Attorney General filed a notice of appeal to the Michigan Court of Appeals, which remains pending.

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

We are cooperating with all of the 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. In October 2021, the court issued a summary judgment decision finding in favor of RCT on certain issues, including with respect to a disputed royalty. Both parties filed motions for reconsideration, which were denied. We filed supplemental summary judgment motions. In November 2022, the court stayed proceedings so the parties can pursue mediation. A trial date has not been set. Potential damages payable under the litigation, if finally awarded after an appeal, could be material but are not currently reasonably estimable. This matter is ongoing.

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)	Foreign Currency Translation Gains (Losses)	Unrealized Net Gains (Losses) on Securities	Defined Benefit Pension and Retiree Health Benefit Plans	Effective Portion of Cash Flow Hedges	Accumulated Other Comprehensive Loss
Beginning balance at January 1, 2020	$ (1,678.0)	$ 4.9	$ (4,638.6)	$ (211.9)	$ (6,523.6)
Other comprehensive income (loss) before reclassifications	250.5	6.8	(379.7)	(133.8)	(256.2)
Net amount reclassified from accumulated other comprehensive loss	—	3.1	267.3	13.0	283.4
Net other comprehensive income (loss)	250.5	9.9	(112.4)	(120.8)	27.2
Balance at December 31, 2020	(1,427.5)	14.8	(4,751.0)	(332.7)	(6,496.4)
Other comprehensive income (loss) before reclassifications	(122.7)	(11.9)	1,823.4	106.6	1,795.4
Net amount reclassified from accumulated other comprehensive loss	—	0.8	344.0	13.1	357.9
Net other comprehensive income (loss)	(122.7)	(11.1)	2,167.4	119.7	2,153.3
Balance at December 31, 2021	(1,550.2)	3.7	(2,583.6)	(213.0)	(4,343.1)
Other comprehensive income (loss) before reclassifications	**(324.4)**	**(52.2)**	**291.5**	**332.8**	**247.7**
Net amount reclassified from accumulated other comprehensive loss	**0.4**	**11.4**	**229.8**	**9.2**	**250.8**
Net other comprehensive income (loss)	**(324.0)**	**(40.8)**	**521.3**	**342.0**	**498.5**
Ending balance at December 31, 2022	**$ (1,874.2)**	**$ (37.1)**	**$ (2,062.3)**	**$ 129.0**	**$ (3,844.6)**

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)	2022	2021	2020
Foreign currency translation gains/losses	**$ (75.9)**	$ (136.2)	$ 128.3
Unrealized net gains/losses on securities	**12.4**	4.7	(4.3)
Defined benefit pension and retiree health benefit plans	**(95.6)**	(532.0)	44.8
Effective portion of cash flow hedges	**(90.9)**	(31.8)	32.1
Benefit/(provision) for income taxes allocated to other comprehensive income (loss) items	**$ (250.0)**	$ (695.3)	$ 200.9

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, 2022	2021	2020	Affected Line Item in the Consolidated Statements of Operations
Amortization of retirement benefit items:				
Prior service benefits, net	**$ (52.4)**	$ (55.4)	$ (55.0)	Other—net, (income) expense
Actuarial losses	**343.3**	490.9	393.3	Other—net, (income) expense
Total before tax	**290.9**	435.5	338.3	
Tax benefit	**(61.1)**	(91.5)	(71.0)	Income taxes
Net of tax	**229.8**	344.0	267.3	
Other, net of tax	**21.0**	13.9	16.1	Other—net, (income) expense
Total reclassifications for the period, net of tax	**$ 250.8**	$ 357.9	$ 283.4	

Note 18: Other–Net, (Income) Expense

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

	2022	2021	2020
Interest expense	**$ 331.6**	$ 339.8	$ 359.6
Interest income	**(62.8)**	(25.4)	(33.0)
Net investment (gains) losses on equity securities (Note 7)	**410.7**	(176.9)	(1,442.2)
Debt extinguishment loss (Note 11)	**—**	405.2	—
Retirement benefit plans	**(372.9)**	(289.7)	(251.8)
Other (income) expense	**14.3**	(51.4)	195.5
Other–net, (income) expense	**$ 320.9**	$ 201.6	$ (1,171.9)

Management's Reports

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

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

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

The consolidated financial statements have been audited by Ernst & Young LLP, an independent registered public accounting firm (PCAOB ID: 42). Their responsibility is to examine our consolidated financial statements in accordance with generally accepted auditing standards of the Public Company Accounting Oversight Board (United States). Ernst & Young's opinion with respect to the fairness of the presentation of the statements is included in Item 8 of our Annual Report on Form 10-K. Ernst & Young reports directly to the audit committee of the board of directors.

Our audit committee includes five nonemployee members of the board of directors, all of whom are independent from our company. The committee charter, which is available on our website, outlines the members' roles and responsibilities. It is the audit committee's responsibility to appoint an independent registered public accounting firm subject to shareholder ratification, 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, 2022. 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, 2022 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 Ricks
Chair, President, and Chief Executive Officer

Anat Ashkenazi
Executive Vice President and Chief Financial Officer

February 22, 2023

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, 2022 and 2021, 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, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022, 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, 2022, 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 22, 2023 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, 2022 the Company had $8,784.1 million in sales rebate and discount accruals. A large portion of these accruals are rebates associated with sales in the United States for which payment for purchase of the product is covered by Medicaid, Managed Care, and Medicare.

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

How We Addressed the Matter in Our Audit

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

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

Retirement Benefits - Valuation of Alternative Investments

Description of the Matter

As described in Note 15 to the consolidated financial statements under the caption "Benefit Plan Investments," the Company's benefit plan investment policies are set with specific consideration of return and risk requirements in relationship to the respective liabilities. At December 31, 2022 the Company had $15,688.3 million in plan assets related to the defined benefit pension plans and retiree health benefit plans. Approximately 50 percent of the total pension and retiree health assets are in hedge funds and private equity-like investment funds ("alternative investments"). These alternative investments are valued using significant unobservable inputs or are valued at net asset value (NAV) reported by the counterparty, adjusted as necessary.

Auditing the fair value of these alternative investments is challenging because of the higher estimation uncertainty of the inputs to the fair value calculations, including the underlying net asset values ("NAVs"), discounted cash flow valuations, comparable market valuations, and adjustments for currency, credit, liquidity and other risks. Additionally, certain information regarding the fair value of these alternative investments is based on unaudited information available to management at the time of valuation.

How We Addressed the Matter in Our Audit

We tested the Company's controls addressing the risks of material misstatement relating to valuation of alternative investments. This included testing management's review controls over alternative investment valuation, which included a comparison of returns to benchmarks and monitoring of investment firms' 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. 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 22, 2023

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, 2022, 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, 2022, 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, 2022 and 2021, 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, 2022, and the related notes and our report dated February 22, 2023 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 22, 2023

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 Ricks, president and chief executive officer, and Anat Ashkenazi, executive vice president and chief financial officer, evaluated our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934) as of December 31, 2022, 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, 2022 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, 2022.

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 2022, there were no changes in our internal control over financial reporting that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

Part III

Item 10. Directors, Executive Officers, and Corporate Governance

Directors and Executive Officers

Information relating to our board of directors is found in our Definitive Proxy Statement, to be dated on or about March 17, 2023 (Proxy Statement), under "Governance - How We Build an Effective Board" 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 - How We Operate an Effective Board - Governance Practices - Board Oversight - Key Areas of Oversight by the Board and Its Committees - Governance - 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 "Governance - How We Build an Effective Board - Director Nominations - Shareholder Director Candidates" and is incorporated in this Annual Report on Form 10-K by reference.

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

Section 16(a) Reporting Compliance

Information about our compliance with Section 16(a) is found in our Proxy Statement under "Ownership of Common Stock - Delinquent Section 16(a) Reports" and is incorporated in this Annual Report on Form 10-K by reference.

Item 11. Executive Compensation

Information on director compensation, executive compensation, and talent and compensation committee matters can be found in the Proxy Statement under "Governance - How We Operate an Effective Board - Board Alignment - Director Compensation," "- How We Operate an Effective Board - Board Structure - Meetings of the Board and Its Committees - Committees of the Board - Talent and Compensation Committee," "Compensation - Compensation Discussion and Analysis," "- Talent and Compensation Committee Matters," 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, 2022 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	—	$ —	49,953,648
Equity compensation plan not approved by security holders	—	—	—
Total	—	—	49,953,648

[1] 4,175,980 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 - How We Operate an Effective Board - Board Alignment - 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 - How We Build an Effective Board - Director Qualifications - 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 4. Ratification of the Appointment of the Independent Auditor - 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, 2022, 2021, and 2020
- Consolidated Statements of Comprehensive Income (Loss)—Years Ended December 31, 2022, 2021, and 2020
- Consolidated Balance Sheets—December 31, 2022 and 2021
- Consolidated Statements of Shareholders' Equity—Years Ended December 31, 2022, 2021, and 2020
- Consolidated Statements of Cash Flows—Years Ended December 31, 2022, 2021, and 2020
- Notes to Consolidated Financial Statements

(a)2. Financial Statement Schedules

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

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

(a)3. Exhibits

The following documents are filed as part of this report:

Exhibit	Description
3.1	Amended Articles of Incorporation, incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on May 4, 2022
3.2	Bylaws, as amended, incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed on May 4, 2022
4.1	Indenture, dated February 1, 1991, between the Company and Deutsche Bank Trust Company Americas, as successor trustee to Citibank, N.A., as Trustee, incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-3, Registration No. 333-186979
4.2	Tripartite Agreement, dated September 13, 2007, appointing Deutsche Bank Trust Company Americas as Successor Trustee under the Indenture listed in Exhibit 4.1, incorporated by reference to Exhibit 4.2 to the Company's Annual Report on Form 10-K for the year ended December 31, 2008
4.3	Description of the Company's Common Stock, incorporated by reference to Exhibit 4.3 to the Company's Annual Report on Form 10-K for the year ended December 31, 2019
4.4	Description of the Company's 1.625% Notes due 2026 and 2.125% Notes due 2030, incorporated by reference to Exhibit 4.4 to the Company's Annual Report on Form 10-K for the year ended December 31, 2019
4.5	Description of the Company's 6.77% Notes due 2036, incorporated by reference to Exhibit 4.5 to the Company's Annual Report on Form 10-K for the year ended December 31, 2019
4.6	Description of the Company's 7 1/8% Notes due 2025, incorporated by reference to Exhibit 4.6 to the Company's Annual Report on Form 10-K for the year ended December 31, 2019
4.7	Description of the Company's 0.625% Notes due 2031 and 1.700% Notes due 2049, incorporated by reference to Exhibit 4.7 to the Company's Annual Report on Form 10-K for the year ended December 31, 2019

4.8	Description of the Company's 0.500% Notes due 2033, 1.125% Notes due 2051, and 1.375% Notes due 2061, incorporated by reference to Exhibit 4.8 to the Company's Annual Report on Form 10-K for the year ended December 31, 2021
4.9	Description of the Company's 1.625% Notes due 2043, incorporated by reference to Exhibit 4.9 to the Company's Annual Report on Form 10-K for the year ended December 31, 2021
10.1	Amended and Restated 2002 Lilly Stock Plan (1), incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2018
10.2	Form of Performance Award under the 2002 Lilly Stock Plan (1)*
10.3	Form of Shareholder Value Award under the 2002 Lilly Stock Plan (1)*
10.4	Form of Relative Value Award under the 2002 Lilly Stock Plan (1)*
10.5	Form of Non-Compete Payment Agreement (1)*
10.6	The Lilly Deferred Compensation Plan, as amended (1), incorporated by reference to Exhibit 10.5 to the Company's annual report on Form 10-K for the year ended December 31, 2013
10.7	The Lilly Directors' Deferral Plan, as amended (1), incorporated by reference to Exhibit 10 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2017
10.8	The Eli Lilly and Company Bonus Plan, as amended (1), incorporated by reference to Exhibit 10.14 to the Company's Annual Report on Form 10-K for the year ended December 31, 2020
10.9	The Loxo Oncology, Inc. Bonus Plan (1), incorporated by reference to Exhibit 10.17 to the Company's Annual Report on Form 10-K for the year ended December 31, 2021
10.10	2007 Change in Control Severance Pay Plan for Select Employees, as amended (1), incorporated by reference to Exhibit 10.15 to the Company's Annual Report on Form 10-K for the year ended December 31, 2020
21	List of Subsidiaries*
23	Consent of Independent Registered Public Accounting Firm*
31.1	Rule 13a-14(a) Certification of David Ricks, Chair, President, and Chief Executive Officer*
31.2	Rule 13a-14(a) Certification of Anat Ashkenazi, Executive Vice President and Chief Financial Officer*
32	Section 1350 Certification*
101	Interactive Data File*
104	Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101)*

(1) Indicates management contract or compensatory plan.
* Filed herewith.

Item 16. Form 10-K Summary

Not applicable.

Signatures

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Eli Lilly and Company

By /s/ David Ricks
David Ricks
Chair, President, and Chief Executive Officer

February 22, 2023

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below on February 22, 2023 by the following persons on behalf of the Registrant and in the capacities indicated.

Signature	Title
/s/ David Ricks DAVID RICKS	Chair, President, and Chief Executive Officer (principal executive officer)
/s/ Anat Ashkenazi ANAT ASHKENAZI	Executive Vice President and Chief Financial Officer (principal financial officer)
/s/ Donald Zakrowski DONALD ZAKROWSKI	Senior 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/ Erik Fyrwald ERIK FYRWALD	Director
/s/ Mary Lynne Hedley, Ph.D. MARY LYNNE HEDLEY, Ph. D.	Director
/s/ Jamere Jackson JAMERE JACKSON	Director
/s/ Kimberly Johnson KIMBERLY JOHNSON	Director
/s/ William Kaelin, Jr., M.D. WILLIAM KAELIN, JR., M.D.	Director
/s/ Juan Luciano JUAN LUCIANO	Director
/s/ Marschall Runge, M.D., Ph.D. MARSCHALL RUNGE, M.D., Ph.D.	Director
/s/ Gabrielle Sulzberger GABRIELLE SULZBERGER	Director
/s/ Jackson Tai JACKSON 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.

Byetta® is a trademark of Amylin Pharmaceuticals, Inc.

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

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