LILLY ELI & CO
Form 10-K
February 19, 2019

United States
Securities and Exchange Commission
Washington, D.C. 20549
Form 10-K
Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
for the fiscal year ended December 31, 2018
Commission file number 001-06351

Eli Lilly and Company

An Indiana corporation I.R.S. employer identification no. 35-0470950
Lilly Corporate Center, Indianapolis, Indiana 46285
(317) 276-2000
Securities registered pursuant to Section 12(b) of the Exchange Act:

Title of Each Class	Name of Each Exchange On Which Registered
Common Stock (no par value)	New York Stock Exchange
1.00% Notes Due June 2, 2022	New York Stock Exchange
7.13% Notes Due June 1, 2025	New York Stock Exchange
1.63% Notes Due June 2, 2026	New York Stock Exchange
2.13% Notes Due June 3, 2030	New York Stock Exchange
6.77% Notes Due January 1, 2036	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Exchange Act: None
Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 under the Securities Act. Yes þ No o
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 o No þ
Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the preceding 12 months, and (2) has been subject to such filing requirements for the past 90 days. Yes þ No o
Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the Registrant was required to submit and post such files).
Yes þ No o
Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant’s knowledge, in the definitive proxy statement incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. þ
Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company,” and "emerging growth company" in Rule 12b-2 under the Exchange Act. (Check one):

Large accelerated filer ý	Accelerated filer o
Non-accelerated filer o	Smaller reporting company o
	Emerging growth company o

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

Indicate by check mark whether the Registrant is a shell company as defined in Rule 12b-2 under the Exchange Act: Yes o No þ

Aggregate market value of the common equity held by non-affiliates computed by reference to the price at which the common equity was last sold as of the last business day of the Registrant's most recently completed second fiscal quarter (Common Stock): approximately $78,196,000,000

Number of shares of common stock outstanding as of February 13, 2019: 1,035,418,562 Portions of the Registrant's Proxy Statement to be filed on or about March 22, 2019 have been incorporated by reference into Part III of this report.

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Forward-Looking Statements

This Annual Report on Form 10-K includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934 (Exchange Act), and the Private Securities Litigation Reform Act of 1995. Forward-looking statements include all statements that do not relate solely to historical or current facts, and can generally be identified by the use of words such as “may,” “believe,” “will,” “expect,” “project,” “estimate,” “intend,” “anticipate,” “plan,” “continue,” or similar expressions.

In particular, information appearing under “Business,” “Risk Factors,” and “Management's Discussion and Analysis of Financial Condition and Results of Operations” includes forward-looking statements. Forward-looking statements inherently involve many risks and uncertainties that could cause actual results to differ materially from those projected in these statements. Where, in any forward-looking statement, we express an expectation or belief as to future results or events, it is based on management's current plans and expectations, expressed in good faith and believed to have a reasonable basis. However, we can give no assurance that any such expectation or belief will result or will be achieved or accomplished. The following include some but not all of the factors that could cause actual results or events to differ materially from those anticipated:

- uncertainties in the pharmaceutical research and development process, including with respect to the timing of anticipated regulatory approvals and launches of new products;
- market uptake of recently launched products;
- competitive developments affecting current products and our pipeline;
- the expiration of intellectual property protection for certain of our products;
- our ability to protect and enforce patents and other intellectual property;
- the impact of actions of governmental and private payers affecting pricing of, reimbursement for, and access to pharmaceuticals;
- regulatory compliance problems or government investigations;
- regulatory actions regarding currently marketed products;
- unexpected safety or efficacy concerns associated with our products;
- issues with product supply stemming from manufacturing difficulties or disruptions;
- regulatory changes or other developments;
- changes in patent law or regulations related to data-package exclusivity;
- litigation involving past, current, or future products as we are largely self-insured;
- unauthorized disclosure, misappropriation, or compromise of trade secrets or other confidential data stored in our information systems, networks, and facilities, or those of third parties with whom we share our data;
- changes in tax law, including the impact of tax reform legislation enacted in December 2017 and related guidance;
- changes in foreign currency exchange rates, interest rates, and inflation;
- asset impairments and restructuring charges;
- changes in accounting standards promulgated by the Financial Accounting Standards Board and the Securities and Exchange Commission;
- acquisitions and business development transactions and related integration costs;
- information technology system inadequacies or operating failures;
- reliance on third-party relationships and outsourcing arrangements;
- the impact of global macroeconomic conditions; and
- uncertainties and risks related to timing and potential value to both Elanco and Lilly of the planned separation of the Elanco animal health business, including business, industry, and market risks, as well as risks involving the anticipated tax-free nature of the separation.

Investors should not place undue reliance on forward-looking statements. You should carefully read the factors described in the “Risk Factors” section of this Annual Report on Form 10-K for a description of certain risks that could, among other things, cause our actual results to differ from these forward-looking statements.

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

Part I

Item 1. Business

Eli Lilly and Company (the “company” or “registrant” or "Lilly") was incorporated in 1901 in Indiana to succeed to the drug manufacturing business founded in Indianapolis, Indiana, in 1876 by Colonel Eli Lilly. We discover, develop, manufacture, and market products in two business segments—human pharmaceutical products and animal health products.

The mission of our human pharmaceutical business is to make medicines that help people live longer, healthier, more active lives. Our vision is to make a significant contribution to humanity by improving global health in the 21st century. Most of the products we sell today were discovered or developed by our own scientists, and our success depends to a great extent on our ability to continue to discover or acquire, develop, and bring to market innovative new medicines.

Our animal health business, Elanco Animal Health Incorporated (Elanco), develops, manufactures, and markets products for both food animals and companion animals. Elanco food animal products help the food industry produce an abundant supply of safe, nutritious, and affordable food. Elanco companion animal products help pets live longer, healthier, happier lives.

In September 2018 Elanco completed an initial public offering of its common stock, which trades on the New York Stock Exchange under the symbol "ELAN." In February 2019, Elanco filed a registration statement to launch an exchange offer in which shareholders can exchange shares of Lilly common stock for Elanco common stock. For more information on the exchange offer, see Item 7, “Management’s Discussion and Analysis - Results of Operations - Executive Overview - Other Matters - Elanco Animal Health.”

We manufacture and distribute our products through facilities in the United States (U.S.), Puerto Rico, and 13 other countries. Our products are sold in approximately 125 countries.

Human Pharmaceutical Products

Our human pharmaceutical products include:

Cardiovascular products, including:

- Cialis®, for the treatment of erectile dysfunction and benign prostatic hyperplasia
- Effient®, for the reduction of thrombotic cardiovascular events (including stent thrombosis) in patients with acute coronary syndrome who are managed with an artery-opening procedure known as percutaneous coronary intervention, including patients undergoing angioplasty, atherectomy, or stent placement

Endocrinology products, including:

- Basaglar® (insulin glargine injection), a long-acting human insulin analog for the treatment of diabetes (launched in Japan and Europe under the trade name Abasaglar™)
- Evista®, for the prevention and treatment of osteoporosis in postmenopausal women and for the reduction of the risk of invasive breast cancer in postmenopausal women with osteoporosis and postmenopausal women at high risk for invasive breast cancer
- Forteo®, for the treatment of osteoporosis in postmenopausal women and men at high risk for fracture and for glucocorticoid-induced osteoporosis in men and postmenopausal women
- Glyxambi®, a combination tablet of linagliptin (Trajenta®) and empagliflozin (Jardiance®) for the treatment of type 2 diabetes
- Humalog®, Humalog Mix 75/25, Humalog U-100, Humalog U-200 and Humalog Mix 50/50, insulin analogs for the treatment of diabetes
- Humatrope®, for the treatment of human growth hormone deficiency and certain pediatric growth conditions
- Humulin®, Humulin 70/30, Humulin N, Humulin R, and Humulin U-500, human insulins of recombinant DNA origin for the treatment of diabetes

- Jardiance, for the treatment of type 2 diabetes and to reduce the risk of cardiovascular death in adult patients with type 2 diabetes and established cardiovascular disease
- Jentadueto® and Jentadueto XR, a combination of linagliptin and metformin hydrochloride for use in the treatment of type 2 diabetes
- Synjardy® and Synjardy XR, a combination tablet of empagliflozin and metformin hydrochloride for the treatment of type 2 diabetes
- Trajenta, for the treatment of type 2 diabetes
- Trulicity®, for the treatment of type 2 diabetes

Immunology products, including:

- Olumiant®, for the treatment of adults with moderately-to-severely active rheumatoid arthritis (approved in the European Union (EU) and Japan in 2017, and in the U.S. in 2018)
- Taltz®, for the treatment of moderate-to-severe plaque psoriasis (approved in the U.S. and EU in 2016) and active psoriatic arthritis (approved in Japan in 2016, in the U.S. in 2017, and in the EU in 2018)

Neuroscience products, including:

- Amyvid®, a radioactive diagnostic agent for positron emission tomography (PET) imaging of beta-amyloid neuritic plaques in the brains of adult patients with cognitive impairment who are being evaluated for Alzheimer's disease and other causes of cognitive decline
- Cymbalta®, for the treatment of major depressive disorder, diabetic peripheral neuropathic pain, generalized anxiety disorder, fibromyalgia, and chronic musculoskeletal pain due to chronic low back pain or chronic pain due to osteoarthritis
- Emgality®, a once-monthly subcutaneously injected calcitonin gene-related peptide (CGRP) antibody for the treatment of migraine prevention (approved in the U.S. and EU in 2018).
- Prozac®, for the treatment of major depressive disorder, obsessive-compulsive disorder, bulimia nervosa, and panic disorder
- Strattera®, for the treatment of attention-deficit hyperactivity disorder
- Zyprexa®, for the treatment of schizophrenia, acute mixed or manic episodes associated with bipolar I disorder, and bipolar maintenance

Oncology products, including:

- Alimta®, for the first-line treatment, in combination with another agent, of advanced non-small cell lung cancer (NSCLC) for patients with non-squamous cell histology; for the second-line treatment of advanced non-squamous NSCLC; as monotherapy for the maintenance treatment of advanced non-squamous NSCLC in patients whose disease has not progressed immediately following chemotherapy treatment; and in combination with another agent, for the treatment of malignant pleural mesothelioma
- Cyramza®, for the treatment of various cancers, with approvals as follows:
  - as a single agent and in combination with another agent as a second-line treatment of advanced or metastatic gastric cancer
  - in combination with another agent as a second-line treatment of metastatic NSCLC
  - as a second-line treatment of metastatic colorectal cancer
- Erbitux®, indicated both as a single agent and in combination with another chemotherapy agent for the treatment of certain types of colorectal cancers; and as a single agent, in combination with chemotherapy, or in combination with radiation therapy for the treatment of certain types of head and neck cancers
- Gemzar®, for the treatment of pancreatic cancer; in combination with other agents, for the treatment of metastatic breast cancer, NSCLC, and advanced or recurrent ovarian cancer; and in the EU for the treatment of bladder cancer
- Lartruvo®, approved in the U.S., and conditionally approved in the EU, in 2016 for use in combination with another agent for the treatment of soft tissue carcinoma. Following a negative result in a recent

clinical trial, we are suspending promotion of Lartruvo and are working with global regulators to determine the appropriate next steps.

- Portrazza®, approved in the U.S. for use in combination with other agents as a first-line treatment of metastatic squamous NSCLC, and approved in the EU for use in combination with other agents as a first-line treatment for epidermal growth factor receptor expressing squamous NSCLC
- Verzenio®, approved in 2017 in the U.S. for use as a single agent and in combination with endocrine therapy for the treatment of a certain type of metastatic breast cancer

Animal Health Products

Our products for food animals include:

- Clynav™, a vaccine to control pancreas disease in salmon
- Coban®, Maxiban®, and Monteban®, anticoccidial agents for use in poultry
- Denagard®, an antibiotic for the control and treatment of respiratory and enteric diseases in swine and poultry
- Imvixa™, to prevent and control infestation caused by sea lice in salmon
- Optaflexx® and Paylean®, leanness and performance enhancers for cattle and swine, respectively
- Rumensin®, a cattle feed additive that improves feed efficiency and growth and also controls and prevents coccidiosis
- Tylan®, an antibiotic used to control certain diseases in cattle, swine, and poultry

Our products for companion animals include:

- Comfortis®, a chewable tablet that kills fleas and prevents flea infestations on dogs
- Credelio®, a monthly chewable tablet for dogs that kills fleas, treats flea infestations, and treats and controls tick infestations
- Feline, canine, and rabies vaccines including: Duramune® and Ultra Duramune®, Duramune Lyme®, Bronchi-Shield®, Fel-O-Vax®, ULTRA™ Fel-O-Vax®, and Fel-O-Guard®, and Rabvac®
- Galliprant®, an anti-inflammatory tablet that targets the key receptor associated with canine osteoarthritis pain
- Interceptor® Plus, a monthly chewable tablet that prevents heartworm disease and treats and controls adult hookworm, roundworm, whipworm, and tapeworm in dogs
- Osurnia®, to treat otitis externa in dogs caused by certain strains of bacteria and yeast
- Trifexis®, a monthly chewable tablet for dogs that kills fleas, prevents flea infestations, prevents heartworm disease, and controls intestinal parasite infections

Marketing

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

Human Pharmaceuticals—U.S.

In the U.S., most of our pharmaceutical products are distributed through wholesalers that serve pharmacies, physicians and other health care professionals, and hospitals. In 2018, 2017, and 2016, three wholesale distributors in the U.S. - McKesson Corporation, AmerisourceBergen Corporation, and Cardinal Health, Inc. - each accounted for between 11 percent and 18 percent of our consolidated total revenue. No other distributor accounted for more than 10 percent of our consolidated total revenue in any of those years.

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

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

Human Pharmaceuticals—Outside the U.S.

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

Human Pharmaceutical Marketing Collaborations

Certain of our human pharmaceutical products are marketed in arrangements with other pharmaceutical companies, including the following:

- We and Boehringer Ingelheim have a diabetes alliance under which we jointly develop and commercialize Trajenta, Jentadueto, Jardiance, Glyxambi, Synjardy, and Basaglar in major markets.
- Outside the U.S. and Canada, Erbitux is commercialized by Merck KGaA.
- We and Daiichi Sankyo Co., Ltd. (Daiichi Sankyo) co-promote Effient in the U.S., Brazil, Mexico, and certain other countries. Effective January 2016, Daiichi Sankyo has been exclusively promoting Effient in major European markets; however, the economic results for these countries continue to be shared. We retain sole marketing rights in Canada, Australia, Russia, and certain other countries. Daiichi Sankyo retains sole marketing rights in Japan and certain other countries.

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

Animal Health Products

Our Elanco animal health business unit employs field salespeople throughout the U.S. and has an extensive sales force outside the U.S. Elanco sells its products primarily to wholesale distributors, and promotes its products primarily to producers and veterinarians for food animal products and to veterinarians for companion animal products. Elanco also advertises certain companion animal products directly to pet owners in markets where it is consistent with allowable promotional practices.

Competition

Our human pharmaceutical products compete globally with products of many other companies in highly competitive markets. Our animal health products compete globally with products of animal health care companies as well as pharmaceutical, chemical, and other companies that operate animal health businesses.

Important competitive factors for both human pharmaceutical and animal health products include effectiveness, safety, and ease of use; price and demonstrated cost-effectiveness; marketing effectiveness; and research and development of new products, processes, and uses. Most new products that we introduce must compete with other branded or generic products already on the market or products that are later developed by competitors. If competitors introduce new products or delivery systems with therapeutic or cost advantages, our products can be subject to decreased sales, progressive price reductions, or both.

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

Generic Pharmaceuticals

One of the biggest competitive challenges we face is from generic pharmaceuticals. In the U.S. and the EU, the regulatory approval process for human pharmaceuticals (other than biological products (biologics)) exempts generics from costly and time-consuming clinical trials to demonstrate their safety and efficacy, allowing generic

manufacturers to rely on the safety and efficacy of the innovator product. Therefore, generic manufacturers

generally invest far less than we do in research and development and can price their products much lower than our branded products. Accordingly, when a branded non-biologic human pharmaceutical loses its market exclusivity, it normally faces intense price competition from generic forms of the product. Public and private payers typically encourage the use of generics as alternatives to brand-name drugs in their healthcare programs. Laws in the U.S. generally allow, and in many cases require, pharmacists to substitute generic drugs that have been rated under government procedures to be essentially equivalent to a brand-name drug. Where substitution is mandatory, it must be made unless the prescribing physician expressly forbids it. In many countries outside the U.S., intellectual property protection is weak, and we must compete with generic or counterfeit versions of our products. Many of our animal health products also compete with generics.

Biosimilars

Several of our current products, including Cyramza, Erbitux, Trulicity, Taltz, and Emgality and many of the new molecular entities (NMEs) in our research pipeline are biologics. Competition for Lilly's biologics may be affected by the approval of follow-on biologics, also known as biosimilars. A biosimilar is a subsequent version of an approved innovator biologic that, due to its functional and structural similarity to the innovator biologic, is approved based on an abbreviated data package that relies in part on the full testing required of the innovator biologic. Globally, most governments have developed regulatory pathways to approve biosimilars as alternatives to innovator-developed biologics, but the patent and regulatory exclusivity for the existing innovator biologic must expire in a given market before biosimilars may enter that market. The extent to which a biosimilar, once approved, will be substituted for the innovator biologic in a way that is similar to traditional generic substitution for non-biologic products, is not yet entirely clear, and will depend on a number of regulatory and marketplace factors that are still developing.

Biosimilars may present both competitive challenges and opportunities. For example, a competitor company has developed a version of insulin lispro which competes with our product Humalog. On the other hand, with our partner Boehringer Ingelheim, we developed Basaglar, a new insulin glargine product, which has the same amino acid sequence as the product currently marketed by a competitor and has launched as a follow-on biologic in the U.S., and as a biosimilar in the EU and Japan.

U.S. Private Sector Dynamics

In the U.S. private sector, consolidation and integration among healthcare providers is also a major factor in the competitive marketplace for human pharmaceuticals. Health plans and pharmacy benefit managers have been consolidating into fewer, larger entities, thus enhancing their purchasing strength and importance. For example, in 2018 CVS Health, a large pharmacy benefit manager and pharmacy chain, acquired Aetna, a large national insurer, and Cigna Corporation acquired Express Scripts in a similar transaction.

Payers typically maintain formularies which specify coverage (the conditions under which drugs are included on a plan's formulary) and reimbursement (the associated out-of-pocket cost to the consumer). Formulary placement can lead to reduced usage of a drug for the relevant patient population due to coverage restrictions, such as prior authorizations and formulary exclusions, or due to reimbursement limitations which result in higher consumer out-of-pocket cost, such as non-preferred co-pay tiers, increased co-insurance levels, and higher deductibles. Consequently, pharmaceutical companies compete for formulary placement not only on the basis of product attributes such as efficacy, safety profile, or patient ease of use, but also by providing rebates. Value-based agreements, where pricing is based on achievement, or not, of specified outcomes, are another tool which may be utilized between payers and pharmaceutical companies as formulary placement and pricing are negotiated. Price is an increasingly important factor in formulary decisions, particularly in treatment areas in which the payer has taken the position that multiple branded products are therapeutically comparable. These downward pricing pressures could continue to negatively affect our future consolidated results of operations.

Patents, Trademarks, and Other Intellectual Property Rights

Overview

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

form of data protection under pharmaceutical regulatory laws.

The patent protection anticipated to be of most relevance to human pharmaceuticals is provided by national patents claiming the active ingredient (the compound patent), particularly those in major markets such as the

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

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

Loss of effective patent protection for human pharmaceuticals typically results in the loss of effective market exclusivity for the product, which often results in severe and rapid decline in revenues for the product. However, in some cases the innovator company may be protected from approval of generic or other follow-on versions of a new medicine beyond the expiration of the compound patent through manufacturing trade secrets, later-expiring patents on manufacturing processes, methods of use or formulations, or data protection that may be available under pharmaceutical regulatory laws. The primary forms of data protection are as follows:

- Regulatory authorities in major markets generally grant data package protection for a period of years following new drug approvals in recognition of the substantial investment required to complete clinical trials. Data package protection prohibits other manufacturers from submitting regulatory applications for marketing approval based on the innovator company's regulatory submission data for the drug. The base period of data package protection depends on the country. For example, the period is generally five years in the U.S. (12 years for new biologics as described below), effectively 10 years in the EU, and eight years in Japan. The period begins on the date of product approval and runs concurrently with the patent term for any relevant patent.
- Under the Biologics Price Competition and Innovation Act of 2009 (the BPCI Act), the FDA has the authority to approve biosimilars. A competitor seeking approval of a biosimilar must file an application to show its molecule is highly similar to an approved innovator biologic and include a certain amount of safety and efficacy data that the FDA will determine on a case-by-case basis. Under the data protection provisions of this law, the FDA cannot approve a biosimilar application until 12 years after initial marketing approval of the innovator biologic, subject to certain conditions.
- In the U.S., the FDA has the authority to grant additional data protection for approved drugs where the sponsor conducts specified testing in pediatric or adolescent populations within a specified time period. If granted, this "pediatric exclusivity" provides an additional six months of exclusivity, which is added to the term of data protection as well as to the term of any relevant patents, to the extent these protections have not already expired. While the term of the pediatric exclusivity attaches to the term of any relevant patent, pediatric exclusivity is a regulatory exclusivity, a bar to generic approval, not a patent right.
- Under the U.S. orphan drug law, a specific use of a drug or biologic can receive "orphan" designation if it is intended to treat a disease or condition affecting fewer than 200,000 people in the U.S., or affecting more than 200,000 people but not reasonably expected to recover its development and marketing costs through U.S. sales. Among other benefits, orphan designation entitles the particular use of the drug to seven years of market exclusivity, meaning that the FDA cannot (with limited exceptions) approve another marketing application for the same drug for the same indication until expiration of the seven-year period. Unlike pediatric exclusivity, the orphan exclusivity period is independent of

and runs in parallel with any applicable patents.

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

Certain of our Elanco animal health products are covered by patents or other forms of intellectual property protection. Historically, upon loss of effective market exclusivity for our animal health products, we have not generally experienced the rapid and severe declines in revenues that are common in the human pharmaceutical segment.

Our Intellectual Property Portfolio

We consider intellectual property protection for certain products, processes, uses, and formulations—particularly with respect to those products discussed below—to be important to our operations. For many of our products, in addition to the compound patent, we hold other patents on manufacturing processes, formulations, or uses that may extend exclusivity beyond the expiration of the compound patent.

The most relevant U.S. patent protection or data protection for our top-selling or recently launched patent-protected marketed products is as follows:

- Alimta is protected by a vitamin regimen patent (2021) plus pediatric exclusivity (2022).
- Cyramza is protected by a compound patent and biologics data package protection (2026).
- Emgality is protected by a compound patent (2033).
- Forteo is protected by use patents (August 2019).
- Jardiance, and the related combination products Glyxambi and Synjardy, are protected by ---a compound patent (2025, not including possible patent extension).
- Lartruvo is protected by a compound patent (2027, not including possible patent extension) and by biologics data package protection (2028). Following a negative result in a recent clinical trial, we are suspending promotion of Lartruvo and are working with global regulators to determine the appropriate next steps.
- Olumiant, is protected by a compound patent (2030, not including possible patent extension).
- Portrazza is protected by a compound patent (2025, not including possible patent extension), and by biologics data package protection (2027).
- Taltz is protected by a compound patent (2026, not including possible patent extension) and by biologic data package protection (2028).
- Trajenta and Jentadueto are protected by a compound patent (2023, not including possible patent extension).
- Trulicity is protected by a compound patent (2024, not including possible patent extension) and by biologics data package protection (2026).
- Verzenio is protected by a compound patent (2029, not including possible patent extension).

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

- Alimta in major European countries (vitamin regimen patent 2021) and Japan (patents covering use to treat cancer concomitantly with vitamins 2021).
- Cymbalta in Japan (data package protection January 2020).
- Forteo in Japan (patents covering its formulation and its use August 2019).

- Lartruvo in major European countries (compound patent and data package protection 2026, not including possible patent extension). Following a negative result in a recent clinical trial, we are suspending promotion of Lartruvo and are working with global regulators to determine the appropriate next steps.
- Olumiant in major European countries (compound patent 2029, not including possible patent extension) and Japan (compound patent 2033).
- Taltz in major European countries (data package protection 2026; compound patent 2031).

Nasal glucagon has been submitted for regulatory review in the U.S. and is protected by delivery device patents (latest expiring 2034), with data protection (3.5 years) expected upon approval. In Europe, nasal glucagon is protected by delivery device patents (latest expiring 2034), with data protection (6 years) expected upon approval.

Lasmiditan has been submitted for regulatory review in the U.S. and is protected by a compound patent (2025, not including possible patent extension).

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

Patent Licenses

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

Patent Challenges

In the U.S., the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, authorizes the FDA to approve generic versions of innovative human pharmaceuticals (other than biologics) without completion of safety and efficacy studies, i.e., a complete New Drug Application (NDA) by filing an Abbreviated New Drug Application (ANDA). In an ANDA, the generic manufacturer must demonstrate only “bioequivalence” between the generic version and the NDA-approved drug—not safety and efficacy. Establishing bioequivalence is generally straightforward and inexpensive for the generic company.

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

Generic manufacturers use Paragraph IV certifications extensively to challenge patents on innovative human pharmaceuticals. In addition, generic companies have shown willingness to launch “at risk,” i.e., after receiving ANDA approval but before final resolution of their patent challenge. We are currently in litigation with numerous generic manufacturers in Hatch-Waxman litigation involving Alimta, among other products. For more information on Hatch-Waxman litigation involving the company, see Item 8, “Financial Statements and Supplementary Data - Note 15, Contingencies” and Item 3, "Legal Proceedings."

Under the BPCI Act, the FDA cannot approve a biosimilar application until data protection expires, 12 years after initial marketing approval of the innovator biologic. However, the BPCI Act does provide a mechanism for a competitor to challenge the validity of an innovator’s patents as early as four years after initial marketing approval of the innovator biologic. The patent litigation scheme under the BPCI Act is complex, and interpretation of the BPCI Act is currently the subject of ongoing litigation. Specifically, courts have now held that biosimilar applicants are not required to engage in the BPCI Act litigation scheme. Patent holders still have the right to bring suit under normal patent law procedures if a biosimilar applicant attempts to commercialize a product prior to patent expiration.

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In addition, there is a procedure in U.S. patent law known as inter partes review (IPR), which allows any member of the public to file a petition with the USPTO seeking the review of any issued U.S. patent. IPRs are conducted before Administrative Patent Judges in the USPTO using a lower standard of proof than used in federal district court. In addition, the challenged patents are not accorded the presumption of validity as they are in federal district court. We are now seeing instances where generic drug companies and some investment firms are attempting to invalidate our patents by filing IPR challenges in the USPTO. For more information, see Item 8, “Financial Statements and Supplementary Data - Note 15, Contingencies.”

Outside the U.S., the legal doctrines and processes by which pharmaceutical patents can be challenged vary widely. In recent years, we have experienced an increase in patent challenges from generic manufacturers in many countries outside the U.S., and we expect this trend to continue. For more information on administrative challenges and litigation involving our Alimta patents in Europe and Japan, see Item 8, “Financial Statements and Supplementary Data - Note 15, Contingencies.”

Government Regulation of Our Operations

Our operations are regulated extensively by numerous national, state, and local agencies. The lengthy process of laboratory and clinical testing, data analysis, manufacturing development, and regulatory review necessary for governmental approvals is extremely costly and can significantly delay product introductions. Promotion, marketing, manufacturing, and distribution of human pharmaceutical and animal health products are extensively regulated in all major markets. We conduct extensive post-marketing surveillance of the safety of the products we sell. In addition, our operations are subject to complex federal, state, local, and foreign laws and regulations concerning the environment, occupational health and safety, and privacy. Animal health product regulations address the administration of the product in or on the animal, and in the case of food animal products, the impact on humans who consume the food as well as the impact on the environment at the production site. Compliance with the laws and regulations affecting the manufacture and sale of current products and the discovery, development, and introduction of new products will continue to require substantial effort, expense, and capital investment.

Of particular importance to our business is the FDA in the U.S. Pursuant to the Federal Food, Drug, and Cosmetic Act, the FDA has jurisdiction over all of our human pharmaceutical products and devices and certain animal health products in the U.S. and administers requirements covering the testing, safety, effectiveness, manufacturing, quality control, distribution, labeling, marketing, advertising, dissemination of information, and post-marketing surveillance of those products.

The FDA extensively regulates all aspects of manufacturing quality for human pharmaceuticals under its current Good Manufacturing Practices (cGMP) regulations. Outside the U.S., our products and operations are subject to similar regulatory requirements, notably by the European Medicines Agency in the EU and the Ministry of Health, Labor and Welfare in Japan. Specific regulatory requirements vary from country to country. We make substantial investments of capital and operating expenses to implement comprehensive, company-wide quality systems in our manufacturing, product development, and process development operations in an effort to ensure sustained compliance with cGMP and similar regulations. However, in the event we fail to adhere to these requirements in the future, we could be subject to interruptions in production, fines and penalties, and delays in new product approvals. Certain of our products are manufactured by third parties, and their failure to comply with these regulations could adversely affect us through failure to supply product to us or delays in new product approvals.

The U.S. Department of Agriculture and the U.S. Environmental Protection Agency also regulate some animal health products.

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

companies under these and other laws have resulted in corporate criminal sanctions and very substantial civil settlements.

The U.S. Foreign Corrupt Practices Act of 1977 (FCPA) prohibits certain individuals and entities, including U.S. publicly traded companies, from promising, offering, or giving anything of value to foreign officials with the corrupt intent of influencing the foreign official for the purpose of helping the company obtain or retain business or gain any improper advantage. The FCPA also imposes specific recordkeeping and internal controls requirements on U.S. publicly traded companies. As noted above, outside the U.S., our business is heavily regulated and therefore involves significant interaction with foreign officials. Additionally, in many countries outside the U.S., the health care providers who prescribe human pharmaceuticals are employed by the government and the purchasers of human pharmaceuticals are government entities; therefore, our interactions with these prescribers and purchasers are subject to regulation under the FCPA.

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

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

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

In the U.S., we are required to provide rebates to the federal government and respective state governments on their purchases of our human pharmaceuticals under state Medicaid and Medicaid Managed Care programs (minimum of 23.1 percent plus adjustments for price increases over time) and rebates to private payers who cover patients in certain types of health care facilities that serve low-income and uninsured patients (known as 340B facilities). No rebates are required at this time in the Medicare Part B (physician and hospital outpatient) program where reimbursement is set on an "average selling price plus 4.3 percent" formula. Additionally, an annual fee is imposed on pharmaceutical manufacturers and importers that sell branded prescription drugs to specified government programs. Beginning in 2019,the Bipartisan Budget Act requires manufacturers of brand-name drugs, biologics, and biosimilars to provide a discount of 70 percent of the cost of branded prescription drugs for Medicare Part D participants who are in the “doughnut hole” (the coverage gap in Medicare prescription drug coverage), up from the previous 50-percent discount. In January 2019, the Department of Health and Human Services released a proposed rule to reform the system of rebates paid to Medicare Part D plans, Medicaid Managed Care organizations, and pharmacy benefit managers. We are currently reviewing the proposed rule, the impact of which is uncertain at this time.

Rebates are also negotiated in the private sector. We give rebates to private payers who provide prescription drug benefits to seniors covered by Medicare and to private payers who provide prescription drug benefits to their customers. These rebates are affected by the introduction of competitive products and generics in the same class.

In May 2018, the White House released "American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs" (Blueprint). The Administration’s corresponding request for information included more than 30 proposed policy changes. We believe the effect of certain of these proposals would be positive for our business while others would have negative consequences to our business. The effect of these proposals, and other proposals that extend beyond the Blueprint, will depend on the details and timing of the final legislation, regulation, or guidance and could lead to a wide range of outcomes. Some of these outcomes could have a material adverse effect on our consolidated results of operations and cash flows. At the state level in the U.S., California, Nevada, and several other states have enacted legislation related to prescription drug pricing transparency. It is unclear the effect this legislation will have on our business.

In most international markets, we operate in an environment of government-mandated cost-containment programs, which may include price controls, international reference pricing (to other countries’ prices), discounts and rebates, therapeutic reference pricing (to other, often generic, pharmaceutical choices), restrictions on physician prescription levels, and mandatory generic substitution.

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

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

Research and Development

Our commitment to research and development dates back more than 140 years. We invest heavily in research and development because we believe it is critical to our long-term competitiveness. At the end of 2018, we employed approximately 8,500 people in human pharmaceutical and animal health research and development activities, including a substantial number of physicians, scientists holding graduate or postgraduate degrees, and highly skilled technical personnel.

Our internal human pharmaceutical research focuses primarily on the areas of oncology, diabetes, neurodegeneration, immunology, and pain. We believe that we have a strong biotechnology research program, with more than half of our clinical-stage pipeline currently consisting of biologics. In addition to discovering and developing NMEs, we seek to expand the value of existing products through new uses, formulations, and therapeutic approaches that provide additional value to patients.

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

Our Elanco animal health innovation strategy is focused on identifying and developing promising technologies and potential products from internal and external sources to meet unmet veterinary, food producer, and pet owner needs. Our animal health scientists also leverage discoveries from our human health laboratories to develop products to enhance the health and well-being of farm animals and pets.

Human pharmaceutical development is time-consuming, expensive, and risky. On average, only one out of many thousands of molecules discovered by researchers ultimately becomes an approved medicine. The process from discovery to regulatory approval can take over a decade. Drug candidates can fail at any stage of the process, and even late-stage drug candidates sometimes fail to receive regulatory approval or achieve commercial success. The rate of innovation cycles leading to medical improvements over initial inventions is accelerating, which has increased the risk that we opt not to develop a late-stage asset or that new products fail to achieve commercial success due to technical obsolescence - displacement by follow-on competitor products - before the period of exclusivity has ended. After approval and launch of a product, we expend considerable resources on post-marketing surveillance and additional clinical studies to collect data and understand the benefits and potential risks of medicines as they are used as therapeutics. The following describes in more detail the research and development process for human pharmaceutical products:

Phases of New Drug Development

- Discovery Phase

The earliest phase of new drug research and development, the discovery phase, can take many years. Scientists identify, design, and synthesize promising molecules, screening tens of thousands of molecules for their effect on biological targets that appear to play an important role in one or more diseases. Targets can be part of the body, such as a protein, receptor, or gene; or foreign, such as a virus or bacteria. Some targets have been proven to affect disease processes, but often the target is unproven and may later prove to be irrelevant to the disease or to yield insufficient clinical benefit. Molecules that have the desired effect on the target and meet other design criteria become candidate

molecules and move to the next phase of development. The probability of any one candidate molecule becoming a commercial product is extremely low.

- Early Development Phase

The early development phase involves refining candidate molecules, understanding how to manufacture them efficiently, and completing initial testing for safety and efficacy. Safety testing is done first in laboratory tests and animals as necessary, to identify toxicity and other potential safety issues that would preclude use in humans. In general, the first human tests (often referred to as Phase I) are conducted in small groups of healthy volunteers or patients to assess safety and find the potential dosing range. After a safe dose range has been established, the drug is typically administered to small populations of patients (Phase II) to look for initial signs of efficacy in treating the targeted disease, or biomarkers of the disease, and to continue to assess safety. In parallel, scientists work to identify safe, effective, and economical manufacturing processes. Long-term animal studies continue to test for potential safety issues. Of the molecules that enter the early development phase, approximately 10 percent move on to the product phase. The early development phase can take several years to complete.

- Product Phase

Product phase (Phase III) molecules have met initial safety requirements and, typically, shown initial evidence of efficacy. As a result, these molecules generally have a higher likelihood of success. The molecules are tested in much larger patient populations to demonstrate efficacy to a predetermined level of statistical significance and to continue to develop the safety profile. These trials are generally global in nature and are designed to generate the data necessary to submit the molecule to regulatory agencies for marketing approval. The potential new drug is generally compared with existing competitive therapies, placebo, or both. The resulting data is compiled and may be submitted to regulatory agencies around the world. Phase III testing varies by disease state, but can often last from three to four years.

- Submission Phase

Once a molecule is submitted to regulatory agencies, the time to final marketing approval can vary from several months to several years, depending on variables such as the disease state, the strength and complexity of the data presented, the novelty of the target or compound, and the time required for the agency(ies) to evaluate the submission. There is no guarantee that a potential medicine will receive marketing approval, or that decisions on marketing approvals or indications will be consistent across geographic areas.

We believe our investments in research, both internally and in collaboration with others, have been rewarded by the large number of new molecules and new indications for existing molecules that we have in all stages of development. We currently have approximately 45 drug candidates across all stages of human testing and a larger number of projects in preclinical development. Among our new investigational molecules currently in the product phase of development or awaiting regulatory approval or launch are potential therapies for various cancers; Alzheimer’s disease; pain; migraine; diabetes; severe hypoglycemia; and autoimmune diseases, including rheumatoid arthritis, systemic lupus erythematosus, psoriasis, atopic dermatitis, and ulcerative colitis. We are studying many other drug candidates in the earlier stages of development in our chosen priority areas. We are also developing new uses, formulations, or delivery methods for many of these molecules as well as several currently marketed products. See Item 7, "Management's Discussion and Analysis - Results of Operations - Executive Overview - Late-Stage Pipeline," for more information on certain of our product candidates.

Raw Materials and Product Supply

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

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

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

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

Quality Assurance

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

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

Executive Officers of the Company

The following table sets forth certain information regarding our executive officers. Except as otherwise noted, all executive officers have been employed by the company in management or executive positions during the last five years.

The term of office for each executive officer expires on the date of the annual meeting of the Board of Directors, to be held on May 6, 2019, or on the date his or her successor is chosen and qualified. No director or executive officer has a “family relationship” with any other director or executive officer of the company, as that term is defined for purposes of this disclosure requirement. There is no understanding between any executive officer or director and any other person pursuant to which the executive officer was selected.

Name	Age	Offices and Business Experience
David A. Ricks	51	President, Chief Executive Officer, director (since January 2017) and board chair (since June 2017)
Melissa S. Barnes	50	Senior Vice President, Enterprise Risk Management and Chief Ethics and Compliance Officer (since January 2013)
Enrique A. Conterno	52	Senior Vice President and President, Lilly Diabetes (since November 2009) and President, Lilly USA (since February 2017)
Stephen F. Fry	53	Senior Vice President, Human Resources and Diversity (since February 2011)
Michael J. Harrington	56	Senior Vice President and General Counsel (since January 2013)
Johna L. Norton	52	Senior Vice President, Global Quality (since April 2017)
Myles O'Neill	60	Senior Vice President and President, Manufacturing Operations (since January 2018)
Leigh Ann Pusey	56	Senior Vice President, Corporate Affairs and Communications (since June 2017). Prior to joining Lilly, Ms. Pusey served as president and CEO of the American Insurance Association.
Aarti Shah, Ph.D.	54	Senior Vice President and Chief Information and Digital Officer (since January 2018)
Christi Shaw	52	Senior Vice President and President, Lilly Bio-Medicines (since April 2017). Prior to returning to Lilly, Ms. Shaw served as U.S. country head and president of Novartis

		Pharmaceutical Corporation from 2014 to 2016, and as North American region head of Novartis Oncology from 2010 to 2014.
Daniel Skovronsky, M.D., Ph.D.	45	Senior Vice President and Chief Scientific Officer (since June 2018)
Joshua L. Smiley	49	Senior Vice President and Chief Financial Officer (since January 2018)
Alfonso Zulueta	56	Senior Vice President and President, Lilly International (since February 2017)
Anne E. White	50	Senior Vice President and President, Lilly Oncology (since September 2018)

Employees

At the end of 2018, we employed approximately 38,680 people, including approximately 21,975 employees outside the U.S. A substantial number of our employees have long records of continuous service.

Information Available on Our Website

Our company website is https://www.lilly.com. None of the information accessible on or through our website is incorporated into this Form 10-K. We make available through the website, free of charge, our company filings with the Securities and Exchange Commission (SEC) as soon as reasonably practicable after we electronically file them with, or furnish them to, the SEC. These include our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements, registration statements, and any amendments to those documents. The company website link to our SEC filings is https://investor.lilly.com/financial-information/sec-filings.

In addition, the Corporate Governance portion of our website includes our corporate governance guidelines, board and committee information (including committee charters), and our articles of incorporation and by-laws. The link to our corporate governance information is

https://www.lilly.com/about/corporate-governance/Pages/corporate-governance.aspx.

We will provide paper copies of our SEC filings free of charge upon request to the company’s secretary at the address listed on the front of this Form 10-K.

Item 1A. Risk Factors

In addition to the other information contained in this Form 10-K, the following risk factors should be considered carefully in evaluating our company. It is possible that our business, financial condition, liquidity, or results of operations could be materially adversely affected by any of these risks. Certain of these risks could also adversely affect the company's reputation.

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

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

We cannot state with certainty when or whether our products now under development will be approved or launched; whether, if initially granted, such approval will be maintained; whether we will be able to develop, license, or otherwise acquire additional product candidates or products; or whether our products, once launched, will be commercially successful. We must maintain a continuous flow of successful new products and successful new indications or brand extensions for existing products sufficient both to cover our substantial research and development costs and to replace revenues that are lost as profitable products lose intellectual property exclusivity or are displaced by competing products or therapies. Failure to do so in the short-term or long-term would have a material adverse effect on our business, results of operations, cash flows, financial position, and prospects. See Item 7, “Management’s Discussion and Analysis - Results of Operations - Executive Overview - Late-Stage Pipeline,” for more details.

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

A number of our top-selling human pharmaceutical products have recently lost, or will lose in the next several years, significant patent protection and/or data protection in the U.S. as well as key countries outside the U.S., as illustrated in the tables below:

Product	U.S. Revenues (2018) ($ in millions)	Percent of Worldwide Revenues (2018)	Patent / Data Protection - U.S.
Alimta	1,131.0	5%	Vitamin regimen patent plus pediatric exclusivity will expire in 2022
Cialis	1,129.2	5%	Compound patent plus pediatric exclusivity expired in May 2018 and unit dose patent expired in September 2018
Forteo	757.9	3%	Formulation and related process patents expired in December 2018 and use patents will expire in August 2019

Product	Revenues Outside U.S. (2018) ($ in millions)	Percent of Worldwide Revenues (2018)	Patent / Data Protection - Major Europe / Japan
Alimta	$ 1,001.9	4%	Major European countries: vitamin regimen patent will expire in 2021 Japan: use patents to treat cancer concomitantly with vitamins will expire in 2021
Forteo	817.7	3%	Japan: data package protection expired in July 2018; formulation and use patents will expire in August 2019
Cymbalta	653.7	3%	Japan: data package protection will expire in January 2020

Certain other significant products no longer have effective exclusivity through patent protection or data protection. For non-biologic products, loss of exclusivity (whether by expiration or as a consequence of litigation) typically results in the entry of one or more generic competitors, leading to a rapid and severe decline in revenues, especially in the U.S. Historically, outside the U.S. the market penetration of generics following loss of exclusivity has not been as rapid or pervasive as in the U.S.; however, generic market penetration is increasing in many markets outside the U.S., including Japan, Europe, and many countries in the emerging markets. For biologics (such as Humalog, Humulin, Erbitux, Cyramza, Trulicity, Taltz, and Emgality), loss of exclusivity may or may not result in the near-term entry of competitor versions (i.e., biosimilars) due to development timelines, manufacturing challenges, and/or uncertainties in the regulatory pathways for approval of the competitor versions.

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

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

Our long-term success depends on our ability to continually discover or acquire, develop, and commercialize innovative new pharmaceutical products. Without strong intellectual property protection, we would be unable to

generate the returns necessary to support the enormous investments in research and development and capital as well as other expenditures required to bring new drugs to the market.

Intellectual property protection varies throughout the world and is subject to change over time. In the U.S., in addition to the process for challenging patents which applies to our biologic products, the Hatch-Waxman Act provides generic companies powerful incentives to seek to invalidate our other human pharmaceutical patents. As a result, we expect that our U.S. patents on major pharmaceutical products will continue to be routinely challenged in litigation and administrative proceedings, and may not be upheld. In addition, a separate IPR process allows competitors to request review of issued patents by the USPTO without the protections of the Hatch-Waxman Act. Our patents may be invalidated via this review process. Although such a decision can be appealed to the courts, in certain circumstances a loss in such a proceeding could result in a competitor entering the market, while a win provides no precedential value - the same patent can still be challenged by other competitors. We face many generic manufacturer challenges to our patents outside the U.S. as well. The entry of generic competitors typically results in rapid and severe declines in revenues. In addition, competitors or other third parties may claim that our activities infringe patents or other intellectual property rights held by them. If successful, such claims could result in our being unable to market a product in a particular territory or being required to pay significant damages for past infringement or royalties on future sales. See Item 1, “Business - Patents, Trademarks, and Other Intellectual Property Rights,” Item 3, "Legal Proceedings," and Item 8, "Financial Statements and Supplementary Data - Note 15, Contingencies," for more details.

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

Public and private payers are taking increasingly aggressive steps to control their expenditures for human pharmaceuticals by placing restrictions on pricing and reimbursement for, and patient access to, our medications. These pressures could continue to negatively affect our future revenues and net income.

We expect pricing, reimbursement, and access pressures from both governments and private payers inside and outside the U.S. to become more severe. For more details, see Item 1, “Business - Regulations and Private Payer Actions Affecting Human Pharmaceutical Pricing, Reimbursement, and Access,” and Item 7, “Management’s Discussion and Analysis - Results of Operations - Executive Overview - Other Matters - Trends Affecting Pharmaceutical Pricing, Reimbursement, and Access.”

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

We compete with a large number of multinational pharmaceutical companies, biotechnology companies, and generic pharmaceutical companies. To compete successfully, we must continue to deliver to the market innovative, cost-effective products that meet important medical needs. Our product revenues can be adversely affected by the introduction by competitors of branded products that are perceived as superior by the marketplace, by generic or biosimilar versions of our branded products, and by generic or biosimilar versions of other products in the same therapeutic class as our branded products. Our revenues can also be adversely affected by treatment innovations that eliminate or minimize the need for treatment with our drugs. See Item 1, “Business - Competition” and "Business - Research and Development," for more details.

- Changes in foreign currency rates or devaluation of a foreign currency can materially affect our revenue, cost of sales, and operating expenses.

As a global company with substantial operations outside the U.S., we face foreign currency risk exposure from fluctuating currency exchange rates. While we seek to manage a portion of these exposures through hedging and other risk management techniques, significant fluctuations in currency rates can have a material impact, either positive or negative, on our revenue, cost of sales, and operating expenses. In the event of an extreme devaluation of local currency, the price of our products could become unsustainable in the relevant market. See Item 7, “Management’s Discussion and Analysis - Financial Condition” for more details.

- Unanticipated changes in our tax rates or exposure to additional tax liabilities could increase our income taxes and decrease our net income.

We are subject to income taxes in the U.S. and numerous foreign jurisdictions. Changes in the relevant tax laws, regulations, administrative practices, principles, and interpretations could adversely affect our future effective tax rates. The U.S. enacted tax reform legislation significantly revising the U.S. tax law, effective January 2018, and a number of other countries are actively considering or enacting tax changes. Modifications to key elements of the U.S. or international tax framework could have a material adverse effect on our consolidated operating results and cash flows. See Item 7, “Management’s Discussion and Analysis - Results of Operations - Executive Overview - Other Matters” and Item 8, "Financial Statements and Supplementary Data - Note 13, Income Taxes," for more details.

- Failure, inadequacy, or breach of our information technology systems, infrastructure, and business information or violations of data protection laws could result in material harm to our business and reputation.

A great deal of confidential information owned by both us and our business partners is stored in our information systems, networks, and facilities or those of third parties. This includes valuable trade secrets and intellectual property, clinical trial information, corporate strategic plans, marketing plans, customer information, and personally identifiable information, such as employee and patient information (collectively, “confidential information”). We also rely to a large extent on the efficient and uninterrupted operation of complex information technology systems, infrastructure, and hardware (together “IT systems”), some of which are within the company’s control and some of which are within the control of third parties, to accumulate, process, store, and transmit large amounts of confidential information and other data. Maintaining the confidentiality, integrity and availability of our IT systems and confidential information is vital to our business.

IT systems are vulnerable to system inadequacies, operating failures, service interruptions or failures, security breaches, malicious intrusions, or cyber-attacks from a variety of sources. Cyber-attacks are growing in their frequency, sophistication, and intensity, and are becoming increasingly difficult to detect, mitigate, or prevent. Cyber-attacks come in many forms, including the deployment of harmful malware, exploitation of vulnerabilities, denial-of-service attacks, the use of social engineering, and other means to compromise the confidentiality, integrity and availability of our IT systems, confidential information, and other data. Breaches resulting in the compromise, loss, theft, destruction, or unauthorized disclosure or use of confidential information, or the unauthorized access to, disruption of, or interference with our products and services, can occur in a variety of ways, including but not limited to, negligent or wrongful conduct by employees or others with permitted access to our systems and information, or wrongful conduct by hackers, competitors, certain governments, or other current or former company personnel. Our third party partners face similar risks.

The failure or inadequacy of our IT systems, the compromise, loss, theft, destruction, or unauthorized disclosure or use of confidential information, or the unauthorized access to, disruption of, or interference with our products and services that rely on IT systems, could impair our ability to secure and maintain intellectual property rights; result in a product manufacturing interruption or failure, or in the interruption or failure of products or services that rely on IT systems; damage our operations, customer relationships, or reputation; or cause us to lose trade secrets or other competitive advantages. Unauthorized disclosure of personally identifiable information could expose us to significant sanctions for violations of data privacy laws and regulations around the world and could damage public trust in our company.

To date, system inadequacies, operating failures, unauthorized access, service interruptions or failures, security breaches, malicious intrusions, cyber-attacks, and the compromise, loss, theft, destruction, or unauthorized disclosure or use of confidential information have not had a material impact on our consolidated results of operations. We have implemented measures to protect, detect, respond to, and minimize or prevent these risks; however, these measures may not be successful. If they are not successful, any of these events could result in material financial, legal, business, or reputational harm to our business .

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

While human pharmaceuticals and companion animal health products have not generally been sensitive to overall economic cycles, prolonged economic slowdowns could lead to decreased utilization of our products, affecting our sales volume. Our food animal business may be affected by depressed prices for our customers' end products. Declining tax revenues attributable to economic downturns increase the pressure on governments to reduce human health care spending, leading to increasing government efforts to control drug prices and utilization. Additionally, some customers, including governments or other entities reliant upon government funding, may be unable to pay in a timely manner for our products. Also, if our customers, suppliers, or collaboration partners experience financial difficulties, we could experience slower customer collections, greater bad debt expense, and performance defaults by suppliers or collaboration partners. Similarly, in the event of a significant economic downturn, we could have difficulty accessing credit markets.

Significant portions of our business are conducted in Europe, including the U.K.; Asia; and other international geographies. Interruptions in international relationships such as the current negotiations between U.K. and the EU on the U.K.'s exit from the EU ("Brexit"), and trade disputes such as the current trade negotiations between the U.S. and China, could result in changes to regulations governing our products and our intellectual property, or otherwise affect our ability to do business. While we do not expect either circumstance to materially affect our business in a direct manner, these and similar events could adversely affect us, or our business partners or customers.

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

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

- We face many product liability claims and are self-insured; we could face large numbers of claims in the future, which could adversely affect our business.

We are subject to a substantial number of product liability claims involving Actos®, Axiron®, Byetta®, Cialis, and Cymbalta among other products. See Item 8, "Financial Statements and Supplementary Data - Note 15, Contingencies," and Item 3, "Legal Proceedings," for more information on our current product liability litigation. Because of the nature of pharmaceutical products, we are and could in the future become subject to large numbers of product liability claims for these or other products in the future, which require substantial expenditures to resolve and, if involving marketed products, could adversely affect sales of the product. Due to a very restrictive market for product liability insurance, we are self-insured for product liability losses for all our currently marketed products.

- Regulatory compliance problems could be damaging to the company.

The marketing, promotional, and pricing practices of human pharmaceutical manufacturers, as well as the manner in which manufacturers interact with purchasers, prescribers, and patients, are subject to extensive regulation. Many companies, including us, have been subject to claims related to these practices asserted by federal, state, and foreign governmental authorities, private payers, and consumers. These claims have resulted in substantial expense and other significant consequences to us. We are and could in the future become subject to such investigations, the outcomes of which could include criminal charges and fines, penalties, or other monetary or non-monetary remedies, including exclusion from U.S. federal and other health care programs. In addition, regulatory issues concerning compliance with cGMP regulations (and comparable foreign regulations) for pharmaceutical products can lead to product recalls and seizures, fines and penalties, interruption of production leading to product shortages, and delays in the approvals of new products pending resolution of the issues. See Item 1, "Business - Government Regulation of Our Operations," for

more details.

- Manufacturing difficulties or disruptions could lead to product supply problems.

Pharmaceutical and animal health manufacturing is complex and highly regulated. Manufacturing difficulties at our facilities or contracted facilities, or the failure or refusal of a contract manufacturer to supply contracted quantities, could result in product shortages, leading to lost revenue. Such difficulties or disruptions could result from quality or regulatory compliance problems; natural disasters; mechanical or information technology system vulnerabilities, such as system inadequacies, operating failures, service interruptions or failures, security breaches, malicious intrusions, or cyber-attacks from a variety of sources; or inability to obtain sole-source raw or intermediate materials. In addition, given the difficulties in predicting sales of new products and the very long lead times necessary for the expansion and regulatory qualification of pharmaceutical manufacturing capacity, it is possible that we could have difficulty meeting unanticipated demand for new products. See Item 1, “Business - Raw Materials and Product Supply,” for more details.

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

We rely on third parties, including suppliers, distributors, alliances with other pharmaceutical and biotechnology companies, and third-party service providers, for selected aspects of product development, manufacture, commercialization, support for information technology systems, product distribution, and certain financial transactional processes. For example, we outsource the day-to-day management and oversight of our clinical trials to contract research organizations. Outsourcing these functions involves the risk that the third parties may not perform to our standards or legal requirements; may not produce reliable results; may not perform in a timely manner; may not maintain the confidentiality, integrity, and availability of our proprietary information; or may fail to perform at all. Failure of these third parties to meet their contractual, regulatory, confidentiality, or other obligations to us could have a material adverse effect on our business.

- Our animal health segment faces risks related to increased generic competition, food and animal safety concerns, factors affecting global agricultural markets, and other risks.

The animal health segment may be impacted by, among other things, emerging restrictions and bans on the use of antibacterials in food-producing animals; perceived adverse effects on human health linked to the consumption of food derived from animals that utilize our products; increased regulation or decreased governmental support relating to the raising, processing, or consumption of food-producing animals; an outbreak of infectious disease carried by animals; adverse weather conditions and the availability of natural resources; adverse global economic conditions affecting agricultural markets; and failure of our research and development, acquisition, and licensing efforts to generate new products. The failure to manage these risks could have a material adverse effect on our revenues and income.

- We may not realize the anticipated value or tax treatment for the divestiture of our interest in Elanco.

There are uncertainties and risks related to the timing and potential value to Elanco, Lilly, and our and their shareholders of the planned separation of the Elanco animal health business, including business, industry, and market risks, as well as risks involving realizing the anticipated tax-free nature of the separation. Failure to implement the separation effectively could result in a lower value to Lilly and to shareholders.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our principal domestic and international executive offices are located in Indianapolis. At December 31, 2018, we owned 12 production and distribution sites in the U.S. and Puerto Rico. Together with the corporate administrative offices, these facilities contain an aggregate of approximately 10.6 million square feet of floor area dedicated to production, distribution, and administration. Major production sites include Indianapolis and Clinton, Indiana; Carolina, Puerto Rico; Fort Dodge, Iowa; and Branchburg, New Jersey.

We own production and distribution sites in 13 countries outside the U.S. and Puerto Rico, containing an aggregate of approximately 5.9 million square feet of floor area. Major production sites include facilities in Ireland, France, China, the U.K., Spain, and Italy.

In the U.S., our research and development facilities contain an aggregate of approximately 4.2 million square feet of floor area, primarily consisting of owned facilities located in Indianapolis. We also lease smaller sites in San Diego, California and New York City, New York. Outside the U.S., we own smaller research and development facilities in the U.K., Australia, Spain, and lease smaller sites in Singapore.

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

Item 3. Legal Proceedings

We are a party to various currently pending legal actions, government investigations, and environmental proceedings, and we anticipate that such actions could be brought against us in the future. The most significant of these matters are described below or, as noted, in Item 8, "Financial Statements and Supplementary Data - Note 15, Contingencies." While it is not possible to determine the outcome of the legal actions, investigations, and proceedings brought against us, we believe that, except as otherwise specifically noted in Item 8, "Financial Statements and Supplementary Data - Note 15, Contingencies," the resolution of all such matters will not have a material adverse effect on our consolidated financial position or liquidity, but could be material to our consolidated results of operations in any one accounting period.

Legal Proceedings Described in Note 15 to the Consolidated Financial Statements

See Item 8, "Financial Statements and Supplementary Data - Note 15, Contingencies," for information on various legal proceedings, including but not limited to:

- The patent litigation and administrative proceedings involving Alimta;
- The patent arbitration involving Adocia;
- The product liability litigation involving Cymbalta;
- The employee litigation in Brazil; and
- The insulin and glucagon pricing litigation.

That information is incorporated into this Item by reference.

Other Product Liability Litigation

We are named along with Takeda Chemical Industries, Ltd. and Takeda affiliates (collectively, Takeda) as a defendant in three purported product liability class actions in Canada related to Actos, which we commercialized with Takeda in Canada until 2009, including one in Ontario (Casseres et al. v. Takeda Pharmaceutical North America, Inc., et al.), one in Quebec (Whyte et al. v. Eli Lilly et al.), and one in Alberta (Epp v. Takeda Canada et al.). In general, plaintiffs in these actions alleged that Actos caused or contributed to their bladder cancer. We believe these lawsuits are without merit, and we and Takeda are defending against them vigorously.

We are named as a defendant in approximately 535 Byetta product liability lawsuits in the U.S. involving approximately 795 plaintiffs. Approximately 59 of these lawsuits, covering about 316 plaintiffs, are filed in California state court and coordinated in a Los Angeles Superior Court. Approximately 475 of the lawsuits, covering about 480 plaintiffs, are filed in federal court, the majority of which are coordinated in a multi-district litigation (MDL) in the U.S. District Court for the Southern District of California. Three lawsuits, representing

approximately five plaintiffs, have also been filed in various state courts. Approximately 525 of the lawsuits, involving approximately 760 plaintiffs, contain allegations that Byetta caused or contributed to the plaintiffs' cancer (primarily pancreatic cancer or thyroid cancer); most others allege Byetta caused or contributed to pancreatitis. In addition, two suits involving approximately nine plaintiffs allege that Byetta caused or contributed to renal injuries and one case alleges that Byetta caused or contributed to ampullary cancer. The federal and state trial courts granted summary judgment in favor of us and our co-defendants on the claims alleging pancreatic cancer. The plaintiffs appealed those rulings. In November 2017, the U.S. Court of Appeals for the Ninth Circuit reversed the U.S. District Court’s grant of summary judgment based on that court's discovery rulings and remanded the cases for further proceedings. In November 2018, the California Court of Appeal reversed the state court’s grant of summary judgment based on that court’s discovery rulings and remanded for further proceedings. We are aware of approximately 20 additional claimants who have not yet filed suit. These additional claims allege damages for pancreatic cancer or thyroid cancer. We believe these lawsuits are without merit and are defending against them vigorously.

We are named as a defendant in approximately 500 Axiron product liability lawsuits in the U.S. involving approximately 550 plaintiffs. In about one-third of the cases, other manufacturers of testosterone are named as co-defendants. Nearly all of these lawsuits have been consolidated in a federal MDL in the U.S. District Court for the Northern District of Illinois. A small number of lawsuits have been filed in state courts. The cases generally allege cardiovascular and related injuries. We have reached agreement on a settlement framework that provides for a comprehensive resolution of nearly all of these personal injury claims alleging cardiovascular and related injuries from Axiron treatment. There can be no assurances, however, that a final settlement will be reached. We have also been engaged in litigation with Medical Mutual of Ohio (“MMO”) who has filed a class action complaint against multiple manufacturers of testosterone products, including us, in the U.S. District Court for the Northern District of Illinois, on behalf of third-party payers who paid for those products seeking damages under the Federal Racketeer Influenced and Corrupt Organizations Act. MMO's motion for class certification was denied, and in February 2019, the District Court granted summary judgment in favor of defendants, dismissing MMO's lawsuit with prejudice. We continue to believe all of these lawsuits are without merit and are defending against them vigorously.

We are named as a defendant in approximately 295 Cialis product liability lawsuits in the U.S. These cases, many of which were originally filed in various federal courts, contain allegations that Cialis caused or contributed to the plaintiffs' cancer (melanoma). In December 2016, the Judicial Panel on Multidistrict Litigation (JPML) granted the plaintiffs' petition to have filed cases and an unspecified number of future cases coordinated into a federal MDL in the U.S. District Court for the Northern District of California, alongside an existing coordinated proceeding involving Viagra®. The JPML ordered the transfer of the existing cases to the now-renamed MDL In re: Viagra (Sildenafil Citrate) and Cialis (Tadalafil) Products Liability Litigation. We believe these lawsuits are without merit and are defending against them vigorously.

Other Patent Litigation

Boehringer Ingelheim, our partner in marketing and development of Jardiance, initiated U.S. patent litigation in the U.S. District Court of Delaware involving Jardiance, Glyxambi, and Synjardy in accordance with the procedures set out in the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act). Several companies submitted ANDAs seeking approval to market generic versions of Jardiance prior to the expiration of the relevant patents, alleging certain patents, including in some allegations the compound patent, are invalid or would not be infringed.

We have been named as a defendant in litigation filed by Genentech, Inc. in the U.S. District Court for the Southern District of California seeking a ruling that Genentech’s patent would be infringed by our continued sales of Taltz. We believe this lawsuit is without merit and are defending against it vigorously.

We have been named as a defendant in litigation filed by Teva Pharmaceuticals International GMBH and Teva Pharmaceuticals USA, Inc. (collectively, Teva) in the U.S. District Court for the District of Massachusetts seeking a ruling that various patents would be infringed by our launch and continued sales of Emgality for the prevention of migraine in adults. We believe this lawsuit is without merit and are defending against it vigorously.

We have been engaged in U.S. patent litigation involving Forteo brought pursuant to procedures set out in the Hatch-Waxman Act. In January 2018, we reached a settlement agreement with Teva Pharmaceuticals USA, Inc. In

April 2018, we filed a patent infringement suit against Apotex, Inc. (Apotex) and Apotex Corp. asserting

our Forteo pen injector device patent and this suit was dismissed in December 2018 by agreement between the parties. We do not expect generic Forteo to enter the market earlier than August 2019.

In Canada, several generic companies previously challenged the validity of our Zyprexa compound patent. In 2012, the Canadian Federal Court of Appeals affirmed the lower court's decision that the patent was invalid for lack of utility. In 2013, our petition for leave to appeal the decision to the Supreme Court of Canada was denied. Two of the generic companies, Apotex and Teva Canada Limited (Teva Canada), pursued claims for damages arising from our enforcement of the patent under Canadian regulations. The Apotex litigation is ongoing and trial is expected in 2020. In 2017, the court issued a ruling that Teva Canada is entitled to damages and the Canadian Federal Court of Appeals affirmed the lower court ruling. In November 2018, the Supreme Court of Canada denied our leave application. We then filed a motion asking the Supreme Court of Canada to reconsider its decision based on conflicting precedent handed down shortly after the denial of our leave application. We expect a decision on our reconsideration motion in the first quarter of 2019.

Other Matters

We are named as a defendant in litigation filed by Research Corporation Technologies, Inc. (RCT) in the U.S. District Court for the District of Arizona. RCT is seeking damages for breach of contract, unjust enrichment, and conversion related to processes used to manufacture certain products, including Humalog and Humulin. A trial date has not been set. We believe this lawsuit is without merit and are defending against it vigorously.

We are named as a defendant in a lawsuit in the U.S. District Court for the Eastern District of Texas seeking damages under the federal anti-kickback statute and state and federal false claims acts for certain patient support programs related to our products Humalog, Humulin, and Forteo. We believe this lawsuit is without merit and are defending against it vigorously.

We have received a civil investigative demand from the U.S. Attorney’s Office for the Southern District of New York requesting documents and information relating to our contracts with, services performed by, and payments to pharmacy benefit managers. We are cooperating with this investigation.

The China National Development and Reform Commission is investigating our distributor pricing practices in China in connection with a broader inquiry into pharmaceutical industry pricing. We are cooperating with this investigation.

We, along with another pharmaceutical manufacturer, are named as co-defendants in United States et al. ex rel. Streck v. Takeda Pharm. Am., Inc., et al. , which was unsealed in the U.S. District Court for the Northern District of Illinois. The complaint alleges that the defendants should have treated certain credits from distributors as retroactive price increases and included such increases in calculating Average Manufacturer Prices (AMP). This complaint is connected to an inquiry that the U.S. Attorney’s Office for the Eastern District of Pennsylvania and the Civil Division of the DOJ began in September 2015 concerning the treatment by various pharmaceutical companies, including us, of certain distribution service agreements with wholesalers when calculating and reporting AMP in connection with the Medicaid drug rebate program. We have since received a civil investigative demand from the Civil Division of the DOJ in connection with that inquiry and this lawsuit, and we are cooperating with that investigation.

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

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

Item 4. Mine Safety Disclosures

Not applicable.

Part II

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

You can find information relating to the principal market for our common stock and related stockholder matters at Item 6, "Selected Financial Data (unaudited)", Item 7, "Management's Discussion and Analysis of Results of Operations and Financial Condition", and Item 8, "Financial Statements and Supplementary Data - Note 19, Selected Quarterly Data (unaudited).” That information is incorporated here by reference.

The following table summarizes the activity related to repurchases of our equity securities during the fourth quarter ended December 31, 2018:

Period	Total Number of Shares Purchased (in thousands)	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs (in thousands)	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs (dollars in millions)
October 2018	8,972.2	$ 111.46	8,972.2	$ 6,000.0
November 2018	895.5	111.65	895.5	5,900.0
December 2018	—	—	—	5,900.0
Total	9,867.7	111.47	9,867.7	

During the three months ended December 31, 2018, we repurchased $1.10 billion of shares under the $8.00 billion share repurchase program authorized in June 2018.

PERFORMANCE GRAPH

This graph compares the return on Lilly stock with that of the Standard & Poor's 500 Stock Index and our peer group for the years 2014 through 2018. The graph assumes that, on December 31, 2013, a person invested $100 each in Lilly stock, the S&P 500 Stock Index, and the peer groups' common stock. The graph measures total shareholder return, which takes into account both stock price and dividends. It assumes that dividends paid by a company are reinvested in that company's stock.

Value of $100 Invested on Last Business Day of 2013

Comparison of Five-Year Cumulative Total Return Among Lilly, S&P 500 Stock Index, Peer Group[1]

	Lilly	Peer Group	S&P 500
Dec-13	$100.00	$ 100.00	$100.00
Dec-14	$139.75	$ 114.39	$113.69
Dec-15	$175.21	$ 116.56	$115.26
Dec-16	$157.03	$ 112.80	$129.05
Dec-17	$185.04	$ 128.90	$157.22
Dec-18	$259.88	$ 136.56	$150.33

(1) We constructed the peer group as the industry index for this graph. It comprises the companies in the pharmaceutical and biotech industries that we used to benchmark the compensation of our executive officers for 2018: AbbVie Inc.; Amgen Inc.; AstraZeneca PLC; Baxter International Inc.; Biogen Idec Inc.; Bristol-Myers Squibb Company; Celgene Corporation; Gilead Sciences Inc.; GlaxoSmithKline plc; Johnson & Johnson; Medtronic plc; Merck & Co., Inc.; Novartis AG.; Pfizer Inc.; Roche Holdings AG; Sanofi; and Shire plc.

Item 6. Selected Financial Data (unaudited)

ELI LILLY AND COMPANY AND SUBSIDIARIES (Dollars in millions, except revenue per employee and per-share data)	2018	2017	2016	2015	2014
Operations					
Revenue	$24,555.7	$22,871.3	$21,222.1	$19,958.7	$19,615.6
Cost of sales	6,430.0	6,150.8	5,710.1	5,054.5	4,959.2
Research and development	5,307.1	5,357.3	5,310.3	4,816.3	4,760.2
Marketing, selling, and administrative	6,631.8	6,680.1	6,528.0	6,548.3	6,643.4
Other[1]	2,391.1	2,485.7	299.7	749.6	252.5
Income before income taxes	3,795.7	2,197.4	3,374.0	2,790.0	3,000.3
Income taxes[2]	563.7	2,401.5	636.4	381.6	609.8
Net income (loss)	3,232.0	(204.1)	2,737.6	2,408.4	2,390.5
Net income (loss) as a percent of revenue	13.2%	(0.9)%	12.9%	12.1%	12.2%
Net income (loss) per share—diluted	$3.13	$(0.19)	$2.58	$2.26	$2.23
Dividends declared per share	2.33	2.12	2.05	2.01	1.97
Weighted-average number of shares outstanding—diluted (thousands)	1,033,667	1,052,023	1,061,825	1,065,720	1,074,286
Financial Position					
Current assets	$20,549.6	$19,202.1	$15,101.4	$12,573.6	$11,928.3
Current liabilities	11,888.1	14,535.9	10,986.6	8,229.6	9,741.0
Property and equipment—net	8,919.5	8,826.5	8,252.6	8,053.5	7,963.9
Total assets	43,908.4	44,981.0	38,805.9	35,568.9	36,307.6
Long-term debt	11,639.7	9,940.5	8,367.8	7,972.4	5,332.8
Total equity	10,909.1	11,667.9	14,080.5	14,590.3	15,388.1
Supplementary Data					
Return on total equity	25.7%	(1.5)%	18.5%	16.1%	13.7%
Return on assets	7.3%	(0.5)%	7.5%	6.8%	6.8%
Capital expenditures	$1,210.6	$1,076.8	$1,037.0	$1,066.2	$1,162.6
Depreciation and amortization	1,609.0	1,567.3	1,496.6	1,427.7	1,379.0
Effective tax rate[2]	14.9%	109.3%	18.9%	13.7%	20.3%
Revenue per employee	$635,000	$563,000	$506,000	$484,000	$501,000
Number of employees	38,680	40,655	41,975	41,275	39,135
Number of shareholders of record	24,000	25,300	26,800	28,000	29,300

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

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

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

RESULTS OF OPERATIONS

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

General

Management’s discussion and analysis of results of operations and financial condition is intended to assist the reader in understanding and assessing significant changes and trends related to the results of operations and financial position of our consolidated company. This discussion and analysis should be read in conjunction with the consolidated financial statements and accompanying footnotes in Item 8 of Part II of this Annual Report on Form 10-K. Certain statements in this Item 7 of Part II of this Annual Report on Form 10-K constitute forward-looking statements. Various risks and uncertainties, including those discussed in "Forward-Looking Statements" and Item 1A, “Risk Factors,” may cause our actual results, financial position, and cash generated from operations to differ materially from these forward-looking statements.

Executive Overview

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

Financial Results

The following table summarizes our key operating results:

	Year Ended December 31,		Percent Change
	2018	2017	
Revenue	$24,555.7	$22,871.3	7
Gross margin	18,125.7	16,720.5	8
Gross margin as a percent of revenue	73.8 %	73.1 %	
Operating expense	$11,938.9	$12,037.4	(1)
Acquired in-process research and development	1,983.9	1,112.6	78
Asset impairment, restructuring, and other special charges	482.0	1,673.6	(71)
Income before income taxes	3,795.7	2,197.4	73
Income taxes	563.7	2,401.5	(77)
Net income (loss)	3,232.0	(204.1)	NM
Earnings (loss) per share	3.13	(0.19)	NM

NM - not meaningful

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

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

2018

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

- We recognized acquired IPR&D charges of $1.98 billion (pretax), or $1.83 per share, primarily related to the acquisition of ARMO Biosciences Inc. (ARMO) and the collaboration with Dicerna Pharmaceuticals (Dicerna).

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

- We recognized charges of $482.0 million (pretax), or $0.41 per share, primarily associated with asset impairments related to the sale of the Posilac® (rbST) brand and the related sale of the Augusta, Georgia manufacturing site, as well as the suspension of commercial activities for Imrestor®. The charges also include expenses associated with the initial public offering (IPO) and separation of the Elanco animal health business, as well as efforts to reduce our cost structure.

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

- We recognized $313.3 million of income tax benefit, or $0.30 per share, primarily due to measurement period adjustments to the Toll Tax and GILTI.

2017

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

- We recognized acquired IPR&D charges of $1.11 billion (pretax), or $0.97 per share, primarily related to the acquisition of CoLucid Pharmaceuticals, Inc. (CoLucid).

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

- We recognized charges of $1.67 billion (pretax), or $1.23 per share, primarily associated with efforts to reduce our cost structure, including the United States (U.S.) voluntary early retirement program.

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

- We recognized a provisional tax expense of $1.91 billion, or $1.81 per share, due to the 2017 Tax Act.

Late-Stage Pipeline

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

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

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

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

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

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

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

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

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

Nasal glucagon* (Q2 2018)—a glucagon nasal powder formulation for the treatment of severe hypoglycemia in patients with diabetes treated with insulin. In the U.S., nasal glucagon is protected by a delivery device patent (2034), with data protection (3.5 years) expected upon approval. In Europe, nasal glucagon is protected by a delivery device patent (2034), with data protection (6 years) expected upon approval.

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

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

Mirikizumab* (Q2 2018)—a monoclonal antibody designed for the treatment of autoimmune diseases.

Pegilodecakin* (Q1 2017)—a PEGylated IL-10, which has demonstrated clinical benefit as a single agent, and in combination with both chemotherapy and checkpoint inhibitor therapy, across several tumor types.

Solanezumab* (Q2 2009)—an anti-amyloid beta monoclonal antibody for the treatment of preclinical Alzheimer’s disease.

Tanezumab* (Q3 2008)—an anti-nerve growth factor monoclonal antibody for the treatment of osteoarthritis pain, chronic low back pain, and cancer pain (in collaboration with Pfizer Inc.).

Tirzepatide* (Q4 2018)—a long-acting, combination therapy of glucose-dependent insulinotropic polypeptide (GIP) and glucagon-like peptide 1 for the treatment of type 2 diabetes.

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

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

**Diagnostic agent

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

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

Compound	Indication	U.S.	Europe	Japan	Developments
Immunology					
Mirikizumab	Psoriasis	Phase III			Phase III trials were initiated during the second quarter of 2018.
	Ulcerative colitis	Phase III			Phase III trial was initiated during the second quarter of 2018.
Olumiant	Rheumatoid arthritis	Launched			Granted approval of 2mg dose by FDA and launched in U.S. in second quarter of 2018.
	Atopic dermatitis	Phase III			In the first quarter of 2019, announced Phase III trials met primary endpoint. Additional Phase III trials are ongoing.
	Systemic lupus erythematosus	Phase III			Phase III trials were initiated during the third quarter of 2018. Granted Fast Track designation[1] from the FDA in fourth quarter of 2018.
Neuroscience					
Emgality	Cluster headache	Submitted		Phase III	In the second quarter of 2018, announced Phase III trial met primary endpoint for episodic cluster headache. Received Breakthrough Therapy Designation[2] in the third quarter of 2018. Submitted to FDA in fourth quarter of 2018 and to European regulatory authorities in first quarter of 2019. Granted Priority Review[3] from FDA in first quarter of 2019. A separate Phase III trial did not meet primary endpoint for chronic cluster headache.
	Migraine prevention	Launched		Phase III	Approved and launched in the U.S. in the third and fourth quarters of 2018, respectively. Approved and launched in Europe in the fourth quarter of 2018 and first quarter of 2019, respectively.
Flortaucipir	Alzheimer's disease	Phase III			In the third quarter of 2018, announced Phase III trial met primary endpoints. In discussions with regulatory authorities to determine next steps.
Lanabecestat	Early and mild Alzheimer's disease	Discontinued			Phase III trials discontinued in second quarter of 2018.
Lasmiditan	Migraine	Submitted	Phase III		Submitted to FDA in fourth quarter of 2018. Phase III trials are ongoing.
Solanezumab	Preclinical Alzheimer's disease	Phase III			Phase III trial is ongoing.
Tanezumab	Osteoarthritis pain	Phase III			In the third quarter of 2018 and the first quarter of 2019, announced multiple Phase III trials met primary endpoints. We anticipate additional readouts from the program to be available in 2019.
	Chronic low back pain	Phase III			In the first quarter of 2019, announced Phase III trial met primary endpoint for the 10mg dose and did not meet primary endpoint on the 5mg dose. We anticipate additional readouts from the program to be available in 2019.
	Cancer pain	Phase III			Phase III trial is ongoing.

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

(1) The FDA's fast track designation is designed to expedite the development and review of new therapies to treat serious conditions and address unmet medical needs.
(2) The Breakthrough Therapy Designation is designed to expedite the development and review of potential medicines that are intended to treat a serious condition where preliminary clinical evidence indicates that the treatment may demonstrate substantial improvement over available therapy on a clinically significant endpoint.
(3) Priority Review is designed to expedite the review of potential medicines that, if approved, would be significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications.

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

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

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Other Matters

Elanco Animal Health

On September 24, 2018, Elanco Animal Health Incorporated (Elanco), a subsidiary, completed its IPO of 72.3 million shares of its common stock, which represents 19.8 percent of Elanco's outstanding shares, at $24 per share. In addition, Elanco completed a debt offering and entered into a term loan facility during the third quarter of 2018. See Notes 3 and 10 to the consolidated financial statements for additional details.

We have announced our intent to divest our remaining 293,290,000 shares of Elanco common stock through an exchange offer and on February 8, 2019, Elanco filed a registration statement on Form S-4 with the Securities and Exchange Commission (SEC). In the exchange offer, our shareholders can exchange all, some, or none of their shares of our common stock for shares of Elanco common stock owned by us, subject to the specific terms and conditions of the offer described in Elanco's registration statement. The completion of the exchange offer is subject to certain conditions, including at least 146,645,000 shares of Elanco common stock being distributed in exchange for shares of our common stock validly tendered in the exchange offer, and the receipt of an opinion of counsel that the exchange offer will qualify for tax-free treatment to us and our participating shareholders. However, the conditions of the exchange offer may not be satisfied; we may exchange less than our entire interest in Elanco; or we may decide to waive one or more of these conditions, to the extent legally permissible, and consummate the exchange offer even if all of the conditions are not satisfied. If the exchange offer is not fully subscribed, we intend, from time to time, to complete subsequent exchange offers and/or pro rata spin-off of our remaining interest in Elanco.

Lartruvo

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

Patent Matters

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

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

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

Our compound patent protection for Cialis® (tadalafil) and Adcirca® (tadalafil) expired in major European markets and the U.S. in November 2017; however, in the U.S., we were granted pediatric exclusivity through May 2018. Pursuant to a settlement agreement related to our unit dose patent in the U.S., generic tadalafil entered the U.S. market in September 2018. We expect that the entry of additional generic competition into these markets following the loss of exclusivity will continue to cause a rapid and severe decline in revenue, which will, in the aggregate, have a material adverse effect on our consolidated results of operations and cash flows.

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

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The Alimta® vitamin regimen patents, which provide us with patent protection for Alimta through June 2021 in Japan and major European countries, and through May 2022 in the U.S., have been challenged in each of these jurisdictions. Our vitamin regimen patents have also been challenged in other smaller European jurisdictions. Our compound patent for Alimta expired in the U.S. in January 2017, and expired in major European countries and Japan in December 2015. We expect that the entry of generic competition for Alimta following the loss of effective patent protection will cause a rapid and severe decline in revenue for the product, which will, in the aggregate, have a material adverse effect on our consolidated results of operations and cash flows. See Note 15 to the consolidated financial statements for a more detailed account of the legal proceedings currently pending in the U.S., Europe, and Japan regarding our Alimta patents.

The compound patent for Humalog® (insulin lispro) has expired in major markets. Global regulators have different legal pathways to approve similar versions of insulin lispro. A similar version of insulin lispro launched in the U.S. in the second quarter of 2018 and in certain European markets in 2017. While it is difficult to estimate the severity of the impact of similar insulin lispro products entering the market, we do not expect and have not experienced a rapid and severe decline in revenue; however, we expect additional pricing pressure and some loss of market share that would continue over time.

Foreign Currency Exchange Rates

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

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

Trends Affecting Pharmaceutical Pricing, Reimbursement, and Access

United States

In the U.S., public concern over access to and affordability of pharmaceuticals continues to drive the regulatory and legislative debate. These policy and political issues increase the risk that taxes, fees, rebates, or other cost control measures may be enacted to manage federal and state budgets. Key health policy proposals affecting biopharmaceuticals include a reduction in biologic data exclusivity, modifications to Medicare Parts B and D, language that would allow the Department of Health and Human Services to negotiate prices for biologics and drugs in Medicare, proposals that would require biopharmaceutical manufacturers to disclose proprietary drug pricing information, and state-level proposals related to prescription drug prices and reducing the cost of pharmaceuticals purchased by government health care programs. California and several other states have enacted legislation related to prescription drug pricing transparency and it is unclear the effect this legislation will have on our business. The Bipartisan Budget Act, enacted in February 2018, requires manufacturers of brand-name drugs, biologics, and biosimilars to pay a 70 percent discount in the Medicare Part D Coverage Gap, up from the previous 50 percent discount. This increase in Coverage Gap discounts became effective at the beginning of 2019. We expect this increase in the Coverage Gap discounts to negatively impact our results of operations by approximately $200 million in 2019.

In May 2018, the White House released "American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs" (Blueprint). The Administration’s corresponding request for information included more than 30 proposed policy changes. We believe the effect of certain of these proposals would be positive for our business while others would have negative consequences to our business. The effect of these proposals, and those that extend beyond the Blueprint, will depend on the details and timing of the final legislation, regulation, or guidance and could lead to a wide range of outcomes. Some of these outcomes could have a material adverse effect on our consolidated results of operations and cash flows. In January 2019, the Department of Health and Human Services released a proposed rule to reform the system of rebates paid to Medicare Part D plans, Medicaid Managed Care organizations, and pharmacy benefit managers. We are currently reviewing the proposed rule, the impact of which is uncertain at this time.

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

The main coverage expansion provisions of the Affordable Care Act (ACA) are currently in effect through both state-based exchanges and the expansion of Medicaid. A trend has been the prevalence of benefit designs containing high out-of-pocket costs for patients, particularly for pharmaceuticals. In addition to the coverage expansions, many employers in the commercial market, driven in part by ACA changes such as the 2022 implementation of the excise tax on employer-sponsored health care coverage for which there is an excess benefit (the so-called "Cadillac tax"), continue to evaluate strategies such as private exchanges and wider use of consumer-driven health plans to reduce their healthcare liabilities over time. Federal legislation, litigation, or administrative actions to repeal or modify some or all of the provisions of the ACA could have a material adverse effect on our consolidated results of operations and cash flows. At the same time, the broader paradigm shift towards performance-based reimbursement and the launch of

several value-based purchasing initiatives have placed demands on the pharmaceutical industry to offer products with proven real-world outcomes data and a favorable economic profile.

International

International operations also are generally subject to extensive price and market regulations. Cost-containment measures exist in a number of countries, including additional price controls and mechanisms to limit reimbursement for our products. Such policies are expected to increase in impact and reach, given the pressures on national and regional health care budgets that come from a growing aging population and ongoing economic challenges. As additional reforms are finalized, we will assess their impact on future revenues. In addition, governments in many emerging markets are becoming increasingly active in expanding health care system offerings. Given the budget challenges of increasing health care coverage for citizens, policies may be proposed that promote generics and biosimilars only and reduce current and future access to branded human pharmaceutical products.

Tax Matters

We are subject to income taxes in the U.S. and numerous foreign jurisdictions. Changes in the relevant tax laws, regulations, administrative practices, and interpretations could adversely affect our future effective tax rates. The U.S. recently enacted tax reform legislation, including the 2017 Tax Act, significantly revising U.S. tax law, and other countries are actively considering or enacting tax law changes. Further, organizations such as the Organisation for Economic Co-operation and Development and the European Commission are active regarding tax-related matters, which could influence international tax policy in countries in which we operate. While outcomes of these initiatives continue to develop and remain uncertain, modifications to key elements of the U.S. or international tax framework could have a material adverse effect on our consolidated results of operations and cash flows.

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

Acquisitions

We strategically invest in external research and technologies that we believe to complement and strengthen our own efforts. These investments can take many forms, including licensing arrangements, collaborations, and acquisitions. We view our business development activity as an important way to achieve our strategies, as we seek to bolster our pipeline and enhance shareholder value. We continue to evaluate business development transactions that have the potential to strengthen our business. Since January 1, 2019, we have acquired Loxo Oncology, Inc. (Loxo). for a purchase price of $235 per share, or approximately $8 billion. We also entered into a license and collaboration agreement with AC Immune SA for an upfront fee of CHF80.0 million and $50.0 million in exchange for a note, convertible to equity at a premium. See Note 3 to the consolidated financial statements for further discussion regarding our recent acquisitions of businesses and assets.

Operating Results—2018

Revenue

The following table summarizes our revenue activity by region:

	Year Ended December 31,		
	2018	2017	Percent Change
U.S.[1]	$13,875.2	$12,785.1	8
Outside U.S.	10,680.5	10,086.3	6
Revenue	$24,555.7	$22,871.3	7

Numbers may not add due to rounding.

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

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

	2018 vs. 2017		
	U.S.	Outside U.S.	Consolidated
Volume	9 %	7 %	8 %
Price	(1)%	(3)%	(1)%
Foreign exchange rates	— %	2 %	1 %
Percent change	8 %	6 %	7 %

Numbers may not add due to rounding.

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

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

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

	Year Ended December 31, 2018			2017	
Product	U.S.[1]	Outside U.S.	Total	Total	Percent Change
Trulicity	$2,515.8	$ 683.3	$3,199.1	$2,029.8	58
Humalog	1,787.8	1,208.7	2,996.5	2,865.2	5
Alimta	1,131.0	1,001.9	2,132.9	2,062.5	3
Cialis	1,129.2	722.7	1,851.8	2,323.1	(20)
Forteo	757.9	817.7	1,575.6	1,749.0	(10)
Humulin®	910.2	421.2	1,331.4	1,335.4	—
Taltz	738.7	198.7	937.5	559.2	68
Cyramza®	291.5	529.9	821.4	758.3	8
Basaglar	622.8	178.5	801.2	432.1	85
Cymbalta®	54.3	653.7	708.0	757.2	(6)
Jardiance[2]	400.2	258.1	658.3	447.5	47
Erbitux®	531.6	103.8	635.3	645.9	(2)
Trajenta®[3]	224.2	350.5	574.7	537.9	7
Zyprexa	36.2	435.1	471.3	581.2	(19)
Strattera	89.7	361.1	450.8	618.2	(27)
Other human pharmaceutical products	1,131.1	1,136.2	2,267.4	1,694.3	34
Animal health products	1,523.0	1,619.5	3,142.5	3,085.6	2
Revenue	$13,875.2	$ 10,680.5	$24,555.7	$22,871.3	7

Numbers may not add due to rounding.

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

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

[3] Trajenta revenue includes Jentadueto®.

Revenue of Trulicity, a treatment for type 2 diabetes, increased 56 percent in the U.S., driven by higher demand. Revenue outside the U.S. increased 63 percent primarily driven by increased volume and, to a lesser extent, the favorable impact of foreign exchange rates, partially offset by lower realized prices.

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

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

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

Revenue of Forteo, an injectable treatment for osteoporosis in postmenopausal women and men at high risk for fracture and for glucocorticoid-induced osteoporosis in men and postmenopausal women, decreased 21 percent in the U.S., driven by decreased demand, and, to a lesser extent, lower realized prices. Revenue outside the U.S. increased 4 percent, driven by increased volume and the favorable impact of foreign exchange rates, partially offset by lower realized prices. Our formulation patent for Forteo expired in December 2018 in major European markets and the U.S. Our use patent for Forteo expires in August 2019 in major European markets and the U.S. Both the formulation patent and the use patent expire in 2019 in Japan. While it is difficult to estimate the severity of the impact of generic and/or biosimilar competition in these markets, we expect a rapid and severe decline in revenue in the U.S. as a result of generic competition when the U.S. patents expire. Outside the U.S., we expect a decline in revenue following patent expirations, however the decline may not be rapid and severe. See "Executive Overview - Other Matters - Patent Matters" for more information.

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

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

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

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

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

Worldwide animal health revenue increased 2 percent, driven by higher prices, partially offset by lower volume. The overall increase in revenue included increased revenue in the companion animal disease prevention, future protein and health, and companion animal therapeutics product categories, partially offset by decreased revenue of products that are being exited.

Gross Margin, Costs, and Expenses

Gross margin as a percent of total revenue was 73.8 percent in 2018, an increase of 0.7 percentage points compared with 2017, primarily due to manufacturing efficiencies and lower amortization expenses, offset by the impact of foreign exchange rates on international inventories sold, the timing of manufacturing production, and the negative impact of price on revenue.

Research and development expenses decreased 1 percent to $5.31 billion in 2018 driven by lower development expenses for lanabecestat, partially offset by higher expenses for other late-stage assets.

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Marketing, selling, and administrative expenses decreased 1 percent to $6.63 billion in 2018 due to lower expenses related to late life-cycle products, partially offset by increased marketing expenses for newer products.

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

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

We recognized asset impairment, restructuring, and other special charges of $482.0 million in 2018. The charges are primarily associated with asset impairments related to the sale of the Posilac (rbST) brand and the related sale of the Augusta, Georgia manufacturing site, as well as the suspension of commercial activities for Imrestor. The charges also include expenses associated with the initial public offering and separation of the Elanco animal health business, as well as efforts to reduce our cost structure. In 2017, we recognized $1.67 billion of asset impairment, restructuring, and other special charges primarily associated with efforts to reduce our cost structure, including the U.S. voluntary early retirement program, asset impairments related to lower projected revenue for Posilac (rbST), and asset impairments and other special charges related to product rationalizations and site closures resulting from our acquisition and integration of Novartis Animal Health (Novartis AH).

Other—net, (income) expense was income of $74.8 million in 2018 compared to income of $300.5 million in 2017 driven by lower net gains on sales of investments.

During 2018, we recorded income tax expense of $563.7 million while earning $3.80 billion of income before income taxes. We recognized $313.3 million of income tax benefit primarily due to measurement period adjustments to the Toll Tax and GILTI. During 2017, we recorded income tax expense of $2.40 billion, which included a provisional tax charge of $1.91 billion, despite earning $2.20 billion of income before income taxes. The provisional tax charge was a result of the 2017 Tax Act, including the Toll Tax.

Operating Results—2017

Financial Results

The following table summarizes our key operating results:

	Year Ended December 31,		Percent Change
	2017	2016	
Revenue	$22,871.3	$21,222.1	8
Gross margin	16,720.5	15,512.0	8
Gross margin as a percent of revenue	73.1 %	73.1 %	
Operating expense	$12,037.4	$11,838.3	2
Acquired in-process research and development	1,112.6	30.0	NM
Asset impairment, restructuring, and other special charges	1,673.6	382.5	NM
Income before income taxes	2,197.4	3,374.0	(35)
Income taxes	2,401.5	636.4	NM
Net income (loss)	(204.1)	2,737.6	NM
Earnings (loss) per share	(0.19)	2.58	NM

NM - not meaningful

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

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

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

- We recognized acquired IPR&D charges of $30.0 million (pretax), or $0.02 per share, related to upfront fees paid in connection with a collaboration agreement with AstraZeneca to co-develop MEDI1814, a potential disease-modifying treatment for Alzheimer's disease.

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

- We recognized charges of $382.5 million (pretax), or $0.29 per share, related to integration and severance costs related to the acquisition of Novartis AH, other global severance costs, and asset impairments primarily related to the closure of an animal health manufacturing facility in Ireland.

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

- We recognized charges of $203.9 million (pretax), or $0.19 per share, related to the impact of the Venezuelan financial crisis, including the significant deterioration of the bolívar.

Revenue

The following table summarizes our revenue activity by region:

	Year Ended December 31,		
	2017	2016	Percent Change
U.S. [1]	$12,785.1	$11,506.2	11
Outside U.S.	10,086.3	9,715.9	4
Revenue	$22,871.3	$21,222.1	8

Numbers may not add due to rounding.

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

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

	2017 vs. 2016		
	U.S.	Outside U.S.	Consolidated
Volume	6 %	5 %	6 %
Price	5 %	(1)%	2 %
Foreign exchange rates	—%	— %	— %
Percent change	11%	4 %	8 %

Numbers may not add due to rounding.

In the U.S., the revenue increase in 2017 was driven by increased volume for newer pharmaceutical products, including Trulicity, Taltz, Basaglar, Lartruvo, and Jardiance, and higher realized prices for several pharmaceutical products, primarily Forteo and Cialis, as well as increased volume for companion animal products from the acquisition of Boehringer Ingelheim Vetmedica, Inc.'s U.S. feline, canine, and rabies vaccine portfolio and other related assets (BIVIVP). The increase in revenue was partially offset by decreased volume due to loss of exclusivity for Strattera and Effient, as well as decreased demand for Cialis and food animal products. Cymbalta revenue declined, as 2016 revenue benefited from reductions to the reserve for expected product returns of approximately $175 million.

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

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

	Year Ended December 31, 2017			2016	
Product	U.S.[1]	Outside U.S.	Total	Total	Percent Change
Humalog	$1,717.8	$ 1,147.4	$2,865.2	$2,768.8	3
Cialis	1,358.6	964.5	2,323.1	2,471.6	(6)
Alimta	1,034.3	1,028.2	2,062.5	2,283.3	(10)
Trulicity	1,609.8	419.9	2,029.8	925.5	NM
Forteo	965.2	783.8	1,749.0	1,500.0	17
Humulin	884.6	450.7	1,335.4	1,365.9	(2)
Cyramza	278.8	479.6	758.3	614.1	23
Cymbalta	114.9	642.2	757.2	930.5	(19)
Erbitux	541.7	104.2	645.9	687.0	(6)
Strattera	284.9	333.3	618.2	854.7	(28)
Zyprexa	75.5	505.7	581.2	725.3	(20)
Taltz	486.0	73.2	559.2	113.1	NM
Trajenta[2]	213.2	324.7	537.9	436.6	23
Jardiance[3]	290.4	157.0	447.5	201.9	NM
Basaglar	311.1	121.0	432.1	86.1	NM
Effient	340.1	48.8	388.9	535.2	(27)
Other human pharmaceutical products	767.0	927.5	1,694.3	1,564.3	8
Animal health products	1,511.1	1,574.5	3,085.6	3,158.2	(2)
Revenue	$12,785.1	$ 10,086.3	$22,871.3	$21,222.1	8

Numbers may not add due to rounding.

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

[2] Trajenta revenue includes Jentadueto.

[3] Jardiance revenue includes Glyxambi and Synjardy.

NM - not meaningful

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

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

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

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

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

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

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

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

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

Revenue of Strattera, a treatment for attention-deficit hyperactivity disorder, decreased 47 percent in the U.S., driven by the loss of exclusivity in the second quarter of 2017, partially offset by higher realized prices. The entry of generic competition following the loss of effective patent protection has caused a rapid and severe decline in revenue.

Revenue outside the U.S. increased 4 percent, driven by increased volume in Japan, partially offset by lower realized prices and the unfavorable impact of foreign exchange rates, primarily the Japanese yen.

Worldwide food animal revenue decreased 8 percent, primarily driven by market access and competitive pressure in the U.S. for Posilac (rbST) and Optaflexx®, respectively. Worldwide companion animal revenue increased 10 percent, driven by the inclusion of $216.7 million in revenue from the acquisition of BIVIVP, partially offset by competitive pressure.

Gross Margin, Costs, and Expenses

Gross margin as a percent of total revenue was 73.1 percent in 2017, which remained flat compared with 2016.

Research and development expenses increased 1 percent to $5.36 billion in 2017.

Marketing, selling, and administrative expenses increased 2 percent to $6.68 billion in 2017, driven by increased marketing expenses for new products that were partially offset by decreased expenses related to late life-cycle products.

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

We recognized asset impairment, restructuring, and other special charges of $1.67 billion in 2017. The charges are primarily associated with efforts to reduce our cost structure, including the U.S. voluntary early retirement program, asset impairments related to lower projected revenue for Posilac (rbST), and asset impairments and other special charges related to product rationalizations and site closures resulting from our acquisition and integration of Novartis AH. In 2016, we recognized $382.5 million of asset impairment, restructuring, and other special charges primarily associated with integration and severance costs related to the acquisition of Novartis AH, other global severance costs associated with actions taken to reduce cost structure, and asset impairments primarily related to the closure of an animal health manufacturing facility in Ireland. See Note 5 to the consolidated financial statements for additional information.

Other-net, (income) expense was income of $300.5 million in 2017, compared with income of $112.8 million in 2016. Other-net, (income) expense in 2016 included a $203.9 million charge related to the impact of the Venezuelan financial crisis, including the significant deterioration of the bolívar. See Note 17 to the consolidated financial statements for additional information.

During 2017, we recorded income tax expense of $2.40 billion, which included a provisional tax charge of $1.91 billion, despite earning $2.20 billion of income before income taxes. The provisional tax charge was a result of the 2017 Tax Act. The effective tax rate in 2016 was 18.9 percent.

FINANCIAL CONDITION

As of December 31, 2018, cash and cash equivalents were $8.00 billion, an increase of $1.46 billion, compared with $6.54 billion at December 31, 2017. Refer to the Consolidated Statements of Cash Flows for additional details on the significant sources and uses of cash for the years ended December 31, 2018 and December 31, 2017.

In addition to our cash and cash equivalents, we held total investments of $2.11 billion and $7.18 billion as of December 31, 2018 and December 31, 2017, respectively. See Note 7 to the consolidated financial statements for additional details.

As of December 31, 2018, total debt was $12.77 billion, a decrease of $876.2 million compared with $13.65 billion at December 31, 2017. The decrease was primarily due to the net decrease in the balance of commercial paper outstanding of $2.20 billion and the repayment of $1.01 billion of long term debt, partially offset by the debt incurred by Elanco as a result of a notes offering and entry into credit facilities totaling $2.48 billion. See Note 10 to the consolidated financial statements for additional details.

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

In September 2018, Elanco entered into a revolving credit agreement providing for a five-year $750.0 million senior unsecured revolving credit facility, which expires in September 2023. See Note 10 to the consolidated financial statements for additional details.

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

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

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

We have separately announced our intent to divest our remaining interest in Elanco through an exchange offer. In the exchange offer, our shareholders can exchange all, some, or none of their shares of our common stock at a discount for shares of Elanco common stock owned by us, subject to the terms and conditions of the offer described in Elanco's registration statement, filed with the SEC on February 8, 2019.

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

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

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

Both domestically and abroad, we continue to monitor the potential impacts of the economic environment; the creditworthiness of our wholesalers and other customers, including foreign government-backed agencies and suppliers; the uncertain impact of health care legislation; and various international government funding levels.

In the normal course of business, our operations are exposed to fluctuations in interest rates and currency values. These fluctuations can vary the costs of financing, investing, and operating. We seek to address a

portion of these risks through a controlled program of risk management that includes the use of derivative financial instruments. The objective of controlling these risks is to limit the impact on earnings of fluctuations in interest and currency exchange rates. All derivative activities are for purposes other than trading.

Our primary interest rate risk exposure results from changes in short-term U.S. dollar interest rates. In an effort to manage interest rate exposures, we strive to achieve an acceptable balance between fixed and floating rate debt positions and may enter into interest rate derivatives to help maintain that balance. Based on our overall interest rate exposure at December 31, 2018 and 2017, including derivatives and other interest rate risk-sensitive instruments, a hypothetical 10 percent change in interest rates applied to the fair value of the instruments as of December 31, 2018 and 2017, respectively, would not have a material impact on earnings, cash flows, or fair values of interest rate risk-sensitive instruments over a one-year period.

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

Off-Balance Sheet Arrangements and Contractual Obligations

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

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

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

(Dollars in millions)	Payments Due by Period				
	Total	Less Than 1 Year	1-3 Years	3-5 Years	More Than 5 Years
Long-term debt, including interest payments[1]	$16,605.7	$927.7	$1,690.5	$2,800.2	$11,187.3
Capital lease obligations	11.8	4.5	5.9	1.4	—
Operating leases	805.2	155.8	217.0	132.9	299.5
Purchase obligations[2]	17,019.6	16,805.5	204.5	9.6	—
2017 Tax Act one-time Toll Tax[3]	2,836.5	159.8	509.8	732.9	1,434.0
Other long-term liabilities reflected on our balance sheet[4]	1,571.6	—	412.4	190.9	968.3
Total	$38,850.4	$18,053.3	$3,040.1	$3,867.9	$13,889.1

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

[2] We have included the following:

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

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

[4] We have included long-term liabilities consisting primarily of our nonqualified supplemental pension funding requirements and other post-employment benefit liabilities. We excluded long-term income taxes payable of $1.05 billion, because we cannot reasonably estimate the timing of future cash outflows associated with those liabilities.

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

APPLICATION OF CRITICAL ACCOUNTING ESTIMATES

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

Revenue Recognition and Sales Return, Rebate, and Discount Accruals

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

Financial Statement Impact

We believe that our accruals for sales returns, rebates, and discounts are reasonable and appropriate based on current facts and circumstances. Our global rebate and discount liabilities are included in sales rebates and discounts on our consolidated balance sheet. Our global sales return liability is included in other current liabilities and other noncurrent liabilities on our consolidated balance sheet. As of December 31, 2018, a 5 percent change in our global sales return,

rebate, and discount liability would have led to an approximate $275 million effect on our income before income taxes.

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

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

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

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

Product Litigation Liabilities and Other Contingencies

Background and Uncertainties

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

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

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

Impairment of Indefinite-Lived and Long-Lived Assets

Background and Uncertainties

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

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

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

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

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

Retirement Benefits Assumptions

Background and Uncertainties

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

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

Financial Statement Impact

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

Income Taxes

Background and Uncertainties

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

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

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

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

Financial Statement Impact

As of December 31, 2018, a 5 percent change in the amount of uncertain tax positions and the valuation allowance would result in a change in net income of $74.5 million and $29.8 million, respectively.

Acquisitions

Background and Uncertainties

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

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

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

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

The fair value of any contingent consideration liability that results from a business combination is determined using a market approach based on quoted market values, significant other observable inputs for identical or comparable assets or liabilities, or a discounted cash flow analysis. Estimating the fair value of contingent consideration requires the use of significant estimates and judgments, including, but not limited to, revenue and the discount rate.

Financial Statement Impact

As of December 31, 2018, a 5 percent change in the contingent consideration liability would result in a change in income before income taxes of $3.71 million.

LEGAL AND REGULATORY MATTERS

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

FINANCIAL EXPECTATIONS FOR 2019

For the full year of 2019, we expect EPS to be in the range of $4.57 to $4.67, reflecting the anticipated impacts of the Loxo acquisition and the suspension of promotion of Lartruvo. We anticipate that total revenue will be between $25.1 billion and $25.6 billion. Revenue growth is expected to be driven by volume from newer products including Trulicity, Taltz, Basaglar, Jardiance, Verzenio, Cyramza, and Olumiant.

We anticipate that gross margin as a percent of revenue will be approximately 75 percent in 2019. Research and development expenses are expected to be in the range of $5.8 billion to $6.0 billion, reflecting additional expenses associated with the acquisition of Loxo. Marketing, selling, and administrative expenses are expected to be in the range of $6.4 billion to $6.7 billion. Other—net, (income) expense is expected to be expense in the range of $175 million to $325 million, reflecting additional interest expense associated with the acquisition of Loxo.

The 2019 tax rate is expected to be approximately 16.5 percent.

The individual elements of the 2019 financial guidance outlined above include consolidated financial expectations for both our human pharmaceutical business and Elanco.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

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

Item 8. Financial Statements and Supplementary Data

Consolidated Statements of Operations

ELI LILLY AND COMPANY AND SUBSIDIARIES

(Dollars in millions and shares in thousands, except per-share data) Year Ended December 31	2018	2017	2016
Revenue	$24,555.7	$22,871.3	$21,222.1
Costs, expenses, and other:			
Cost of sales	6,430.0	6,150.8	5,710.1
Research and development	5,307.1	5,357.3	5,310.3
Marketing, selling, and administrative	6,631.8	6,680.1	6,528.0
Acquired in-process research and development (Notes 3)	1,983.9	1,112.6	30.0
Asset impairment, restructuring, and other special charges (Note 5)	482.0	1,673.6	382.5
Other—net, (income) expense (Note 17)	(74.8)	(300.5)	(112.8)
	20,760.0	20,673.9	17,848.1
Income before income taxes	3,795.7	2,197.4	3,374.0
Income taxes (Note 13)	563.7	2,401.5	636.4
Net income (loss)	$3,232.0	$(204.1)	$2,737.6
Earnings (loss) per share:			
Basic	$3.14	$(0.19)	$2.59
Diluted	$3.13	$(0.19)	$2.58
Shares used in calculation of earnings (loss) per share:			
Basic	1,027,721	1,052,023	1,058,324
Diluted	1,033,667	1,052,023	1,061,825

See notes to consolidated financial statements.

Consolidated Statements of Comprehensive Income (Loss)

ELI LILLY AND COMPANY AND SUBSIDIARIES (Dollars in millions)	Year Ended December 31	2018	2017	2016
Net income (loss)		$3,232.0	$(204.1)	$2,737.6
Other comprehensive income (loss):				
Change in foreign currency translation gains (losses)		(440.7)	501.9	(436.4)
Change in net unrealized gains (losses) on securities		(8.8)	(181.3)	303.0
Change in defined benefit pension and retiree health benefit plans (Note 14)		569.4	(576.6)	(512.8)
Change in effective portion of cash flow hedges		(6.0)	27.8	11.7
Other comprehensive income (loss) before income taxes		113.9	(228.2)	(634.5)
Benefit (provision) for income taxes related to other comprehensive income (loss) items		(30.3)	402.7	(10.6)
Other comprehensive income (loss) (Note 16)[1]		83.6	174.5	(645.1)
Comprehensive income (loss)		$3,315.6	$(29.6)	$2,092.5

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

See notes to consolidated financial statements.

Consolidated Balance Sheets

ELI LILLY AND COMPANY AND SUBSIDIARIES (Dollars in millions, shares in thousands)	December 31	2018	2017
Assets			
Current Assets			
Cash and cash equivalents (Note 7)		$7,998.2	$6,536.2
Short-term investments (Note 7)		88.2	1,497.9
Accounts receivable, net of allowances of $32.5 (2018) and $38.7 (2017)		5,246.5	4,546.3
Other receivables		958.4	715.9
Inventories (Note 6)		4,111.8	4,458.3
Prepaid expenses and other		2,146.5	1,447.5
Total current assets		20,549.6	19,202.1
Other Assets			
Investments (Note 7)		2,020.7	5,678.8
Goodwill (Note 8)		4,347.5	4,370.1
Other intangibles, net (Note 8)		3,521.0	4,029.2
Deferred tax assets (Note 13)		2,657.7	1,166.4
Sundry		1,892.4	1,707.9
Total other assets		14,439.3	16,952.4
Property and equipment, net (Note 9)		8,919.5	8,826.5
Total assets		$43,908.4	$44,981.0
Liabilities and Equity			
Current Liabilities			
Short-term borrowings and current maturities of long-term debt (Note 10)		$1,131.2	$3,706.6
Accounts payable		1,412.3	1,410.7
Employee compensation		1,054.5	997.9
Sales rebates and discounts		5,021.9	4,465.1
Dividends payable		650.8	590.6
Income taxes payable (Note 13)		404.0	532.9
Other current liabilities		2,213.4	2,832.1
Total current liabilities		11,888.1	14,535.9
Other Liabilities			
Long-term debt (Note 10)		11,639.7	9,940.5
Accrued retirement benefits (Note 14)		2,911.3	3,513.9
Long-term income taxes payable (Note 13)		3,724.6	3,776.5
Other noncurrent liabilities		2,835.6	1,546.3
Total other liabilities		21,111.2	18,777.2
Commitments and Contingencies (Note 15)			
Eli Lilly and Company Shareholders' Equity (Notes 11 and 12)			
Common stock—no par value			
Authorized shares: 3,200,000		661.0	687.9
Issued shares: 1,057,639 (2018) and 1,100,672 (2017)			
Additional paid-in capital		6,583.6	5,817.8
Retained earnings		11,395.9	13,894.1
Employee benefit trust		(3,013.2)	(3,013.2)
Accumulated other comprehensive loss (Note 16)		(5,729.2)	(5,718.6)
Cost of common stock in treasury		(69.4)	(75.8)

Total Eli Lilly and Company shareholders' equity	9,828.7	11,592.2
Noncontrolling interests	1,080.4	75.7
Total equity	10,909.1	11,667.9
Total liabilities and equity	$43,908.4	$44,981.0

See notes to consolidated financial statements.

Consolidated Statements of Shareholders' Equity

ELI LILLY AND COMPANY AND SUBSIDIARIES (Dollars in millions, shares in thousands)	Equity of Eli Lilly and Company Shareholders								Noncontrolling Interest
	Common Stock		Additional Paid-in Capital	Retained Earnings	Employee Benefit Trust	Accumulated Other Comprehensive Loss	Common Stock in Treasury		
	Shares	Amount					Shares	Amount	
Balance at January 1, 2016	1,106,063	$691.3	$5,552.1	$16,011.8	$(3,013.2)	$(4,580.7)	796	$(90.0)	$19.0
Net income				2,737.6					16.3
Other comprehensive income (loss), net of tax						(693.3)			48.2
Cash dividends declared per share: $2.05				(2,167.6)					
Retirement of treasury shares	(7,306)	(4.6)		(535.5)			(7,306)	540.1	
Purchase of treasury shares			(60.0)				7,306	(540.1)	
Issuance of stock under employee stock plans, net	2,829	1.8	(106.8)				(85)	9.5	
Stock-based compensation			255.3						
Other									(10.7)
Balance at December 31, 2016	1,101,586	688.5	5,640.6	16,046.3	(3,013.2)	(5,274.0)	711	(80.5)	72.8
Net income (loss)				(204.1)					30.5
Other comprehensive income (loss), net of tax						199.0			(24.5)
Cash dividends declared per share: $2.12				(2,234.6)					
Retirement of treasury shares	(4,390)	(2.7)		(357.1)			(4,390)	359.8	
Purchase of treasury shares			60.0				4,390	(359.8)	
Issuance of stock under employee stock plans, net	3,476	2.1	(164.1)				(47)	4.7	
Stock-based compensation			281.3						
				643.6		(643.6)			

Reclassification of stranded tax effects (Note 2)									
Other								(3.1)	
Balance at December 31, 2017	1,100,672	687.9	5,817.8	13,894.1	(3,013.2)	(5,718.6)	664	(75.8)	75.7
Net income				3,232.0					3.7
Other comprehensive income (loss), net of tax						85.6			(2.0)
Cash dividends declared per share: $2.33				(2,372.0)					
Retirement of treasury shares	(45,882)	(28.7)		(4,122.0)			(45,882)	4,150.7	
Purchase of treasury shares							45,882	(4,150.7)	
Issuance of stock under employee stock plans, net	2,849	1.8	(139.0)				(60)	6.4	
Stock-based compensation			279.5						
Adoption of new accounting standards (Note 2)				763.8		(105.2)			
Sale of Elanco Stock (Note 3)			629.2			9.0			1,017.2
Other			(3.9)						(14.2)
Balance at December 31, 2018	1,057,639	$661.0	$6,583.6	$11,395.9	$(3,013.2)	$(5,729.2)	604	$(69.4)	$1,080.4

See notes to consolidated financial statements.

Consolidated Statements of Cash Flows

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

See notes to consolidated financial statements.

Notes to Consolidated Financial Statements
ELI LILLY AND COMPANY AND SUBSIDIARIES
(Tables present dollars in millions, except per-share data)

Note 1: Summary of Significant Accounting Policies

Basis of presentation

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

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

On September 24, 2018, Elanco Animal Health Incorporated (Elanco), one of our subsidiaries, completed its initial public offering (IPO) of 72.3 million shares of its common stock, which represents 19.8 percent of Elanco's outstanding shares, at $24 per share. In addition, Elanco completed a debt offering and entered into a term loan facility during the third quarter of 2018. See Notes 3 and 10 to the consolidated financial statements for additional information.

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

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

Adoption of Revenue Accounting Standard

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

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

	2018	2017	2016
Net product revenue	$22,928.8	$21,671.4	$20,388.4
Collaboration and other revenue[(1)]	1,626.9	1,199.9	833.7
Revenue	$24,555.7	$22,871.3	$21,222.1

(1) Collaboration and other revenue associated with prior year transfers of intellectual property was $303.2 million, $145.8 million, and $146.1 million during the years ended 2018, 2017, and 2016, respectively.

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

Net Product Revenue

Revenue from sales of products is recognized at the point where the customer obtains control of the goods and we satisfy our performance obligation, which generally is at the time we ship the product to the customer. Payment terms differ by jurisdiction and customer, but payment terms in most of our major jurisdictions typically range from 30 to 75 days from date of shipment. Revenue for our product sales has not been adjusted for the effects of a financing component as we expect, at contract inception, that the period between when we transfer control of the product and when we receive payment will be one year or less. Any exceptions are either not material or we collect interest for payments made after the due date. Provisions for rebates and discounts, and returns are established in the same period the related sales are recognized. We generally ship product shortly after orders are received; therefore, we generally only have a few days of orders received but not yet shipped at the end of any reporting period. Shipping and handling activities are considered to be fulfillment activities and are not considered to be a separate performance obligation. We exclude from the measurement of the transaction price all taxes assessed by a governmental authority that are imposed on our sales of product and collected from a customer.

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

Sales Rebates and Discounts - Background and Uncertainties

Most of our pharmaceutical products are sold to wholesalers that serve pharmacies, physicians and other health care professionals, and hospitals. Most of our animal health products are sold to wholesale distributors. We initially invoice our customers at contractual list prices. Contracts with direct and indirect customers may provide for various rebates and discounts that may differ in each contract. As a consequence, to determine the appropriate transaction price for our product sales at the time we recognize a sale to a direct customer, we must estimate any rebates or discounts that ultimately will be due to the direct customer and other customers in the distribution chain under the terms of our contracts. Significant judgments are required in making these estimates.

- The rebate and discount amounts are recorded as a deduction to arrive at our net product revenue. Sales rebates and discounts that require the use of judgment in the establishment of the accrual include managed care, Medicare, Medicaid, chargebacks, long-term care, hospital, patient assistance programs, and various other programs. We estimate these accruals using an expected value approach.
- The largest of our sales rebate and discount amounts are rebates associated with sales covered by managed care, Medicare, Medicaid, and chargeback contracts in the United States (U.S.) In determining the appropriate accrual amount, we consider our historical rebate payments for these programs by product as a percentage of our historical sales as well as any significant changes in sales trends (e.g., patent expiries and product launches), an evaluation of the current contracts for these programs, the percentage of our products that are sold via these programs, and our product pricing. Although we accrue a liability for rebates related to these programs at the time we record the sale, the rebate related to that sale is typically paid up to six months later. Because of this time lag, in any particular period our rebate adjustments may incorporate revisions of accruals for several periods.
- Most of our rebates outside the U.S. are contractual or legislatively mandated and are estimated and recognized in the same period as the related sales. In some large European countries, government rebates are based on the anticipated budget for pharmaceutical payments in the country. An estimate of these rebates, updated as governmental authorities revise budgeted deficits, is recognized in the same period as the related sale.

Sales Returns - Background and Uncertainties

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

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

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

Adjustments to Revenue

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

Disaggregation of Revenue

Our disaggregated revenue is disclosed in Note 18.

Collaborations and Other Arrangements

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

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

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of each performance obligation. For arrangements that involve variable consideration where we have sold intellectual property, we recognize revenue based on estimates of the amount of consideration we believe we will be entitled to receive from the other party, subject to a constraint. These estimates are adjusted to reflect the actual amounts to be collected when those facts and circumstances become known.

Significant judgments must be made in determining the transaction price for our sales of intellectual property.

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

Contract Liabilities

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

We have the following amounts recorded for contract liabilities:

	2018	2017
Contract liabilities	$299.3	$335.2

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

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

Revenue recognized from contract liabilities as of January 1, 2018, during the year ended December 31, 2018 was not material. Revenue expected to be recognized in the future from contract liabilities as the related performance obligations are satisfied is not expected to be material in any one year.

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

Research and development expenses include the following:

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

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

Earnings per share

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

Foreign Currency Translation

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

Other significant accounting policies

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

Note 2: Implementation of New Financial Accounting Pronouncements

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

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

Accounting Standards Update 2017-07, Compensation-Retirement Benefits: Improving the Presentation of Net Periodic Pension Cost and Net Periodic Postretirement Benefit Cost	This standard was issued to improve the transparency and comparability among organizations by requiring entities to separate their net periodic pension cost and net periodic postretirement benefit cost into a service cost component and other components. Previously, the costs of the other components along with the service cost component were classified based upon the function of the employee. This standard requires entities to classify the service cost component in the same financial statement line item or items as other compensation costs arising from services rendered by pertinent employees. The other components of net benefit cost are now presented separately from the line items that include the service cost component. When applicable, the service cost component is now the only component eligible for capitalization. An entity should apply the new standard retrospectively for the classification of the service cost and other components and prospectively for the capitalization of the service cost component.	Upon adoption of this standard, pension and postretirement benefit cost components other than service costs are presented in other–net, (income) expense. The application of the new standard resulted in reclassification to other income of $248.1 million for the year ended December 31, 2017, while increasing cost of sales by $80.6 million, research and development expenses by $75.5 million, and marketing, selling, and administrative expenses by $92.0 million for the same period. The application of the new standard resulted in reclassification to other income of $197.6 million for the year ended December 31, 2016, while increasing cost of sales by $55.2 million, research and development expenses by $66.4 million, and marketing, selling, and administrative expenses by $76.0 million for the same period. We do not expect application of the new standard to have a material impact on an ongoing basis.

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

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

Standard	Description	Effective Date	Effect on the financial statements or other significant matters
Accounting Standards Update 2016-02, Leases	This standard was issued to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities, including leases classified as operating leases under current GAAP, on the balance sheet and requiring additional disclosures about leasing arrangements. An entity can apply the new leases standard retrospectively to each prior reporting period presented or with the cumulative effect of initially applying the standard recognized at the date of initial application in retained earnings. We plan to use the latter approach.	This standard was effective January 1, 2019, and we adopted on that date.	We expect to record a right-of-use asset and lease liability for operating leases of approximately $650 million on our consolidated balance sheet as of January 1, 2019. Our accounting for capital leases will remain substantially unchanged. This standard will not have a material impact on our consolidated statement of operations.

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Note 3: Divestiture and Acquisitions

Divestiture

Formation of Elanco and Initial Public Offering

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

In connection with the completion of the IPO, through a series of equity and other transactions, we transferred to Elanco the animal health businesses that form its business going forward. In exchange, Elanco transferred to us, or will transfer to us, consideration of approximately $4.2 billion, which consists primarily of the net proceeds from the IPO, the net proceeds from the debt offering completed by Elanco in August 2018, and the term loan facility entered into by Elanco during the period (see Note 10). The consideration that we receive is intended to be used for debt repayment, dividends, and/or share repurchases. The excess of the net proceeds from the IPO over the net book value of our divested interest was $629.2 million and was recorded in additional paid-in capital. Of our consolidated cash and cash equivalents as of December 31, 2018, approximately $475 million is retained by Elanco for working capital purposes.

We continue to consolidate Elanco, as we retain control over Elanco. The earnings attributable to the divested, noncontrolling interest for the period from the IPO until December 31, 2018 were not material. As of December 31, 2018, the noncontrolling interest of $1.02 billion associated with Elanco is reflected in noncontrolling interests in the consolidated balance sheet.

We have announced our intent to divest our remaining 293,290,000 shares of Elanco common stock through an exchange offer and on February 8, 2019, Elanco filed a registration statement on Form S-4 with the SEC. In the exchange offer, our shareholders can exchange all, some, or none of their shares of our common stock for shares of Elanco common stock owned by us, subject to the specific terms and conditions of the offer described in Elanco's registration statement. The completion of the exchange offer is subject to certain conditions, including at least 146,645,000 shares of Elanco common stock being distributed in exchange for shares of our common stock validly tendered in the exchange offer, and the receipt of an opinion of counsel that the exchange offer will qualify for tax-free treatment to us and our participating shareholders. However, the conditions of the exchange offer may not be satisfied; we may exchange less than our entire interest in Elanco; or we may decide to waive one or more of these conditions, to the extent legally permissible, and consummate the exchange offer even if all of the conditions are not satisfied. If the exchange offer is not fully subscribed, we intend, from time to time, to complete subsequent exchange offers and/or pro rata spin-off of our remaining interest in Elanco.

Acquisitions

During 2017, we completed the acquisition of Boehringer Ingelheim Vetmedica, Inc.'s U.S. feline, canine, and rabies vaccine portfolio and other related assets (BIVIVP). This transaction, as further discussed in this note below in Acquisitions of Businesses was accounted for as a business combination under the acquisition method of accounting. We also had an immaterial acquisition of a business in 2016. Under this method, the assets acquired and liabilities assumed were recorded at their respective fair values as of the acquisition date in our consolidated financial statements. The determination of estimated fair value required management to make significant estimates and assumptions. The excess of the purchase price over the fair value of the acquired net assets, where applicable, has been recorded as goodwill. The results of operations of this acquisition have been included in our consolidated financial statements from the date of acquisition.

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

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Acquisitions of Businesses

Boehringer Ingelheim Vetmedica, Inc. Vaccine Portfolio Acquisition

Overview of Transaction

On January 3, 2017, we acquired BIVIVP in an all-cash transaction for $882.1 million. Under the terms of the agreement, we acquired a manufacturing and research and development site and a U.S. vaccine portfolio including vaccines used for the treatment of bordetella, Lyme disease, rabies, and parvovirus, among others.

Assets Acquired and Liabilities Assumed

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

Estimated Fair Value at January 3, 2017	
Inventories	$108.6
Marketed products[(1)]	297.0
Property and equipment	148.2
Other assets and liabilities - net	8.2
Total identifiable net assets	562.0
Goodwill[(2)]	320.1
Total consideration transferred - net of cash acquired	$882.1

(1) These intangible assets, which are being amortized to cost of sales on a straight-line basis over their estimated useful lives, were expected to have a weighted average useful life of 10 years.

(2) The goodwill recognized from this acquisition is attributable primarily to expected synergies from combining the operations of BIVIVP with our legacy animal health business, future unidentified projects and products, and the assembled workforce of BIVIVP. The goodwill associated with this acquisition is deductible for tax purposes.

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

Overview of transaction

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

Assets Acquired and Liabilities Assumed

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

Asset Acquisitions

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

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

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

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

Subsequent Event - AC Immune SA

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

Note 4: Collaborations and Other Arrangements

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

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

Boehringer Ingelheim Diabetes Collaboration

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

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

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

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

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

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

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

In the most significant markets, we and Boehringer Ingelheim share equally the ongoing development costs, commercialization costs, and agreed upon gross margin for any product resulting from the collaboration. We record our portion of the gross margin associated with Boehringer Ingelheim's products as collaboration and other revenue. We record our sales of Basaglar to third parties as net product revenue with the payments made to Boehringer Ingelheim for their portion of the gross margin recorded as cost of sales. For all compounds under this collaboration, we record our portion of the development and commercialization costs as research and development expense and marketing, selling, and administrative expense, respectively. Each company is entitled to potential performance payments depending on the sales of the molecules it contributes to the collaboration. These performance payments result in the owner of the molecule retaining a greater share of the agreed upon gross margin of that product. Subject

to achieving these thresholds, in a given period, our reported revenue for Trajenta and Jardiance may be reduced by any performance payments we make related to these products. Similarly, performance payments we may receive related to Basaglar effectively reduce Boehringer Ingelheim's share of the gross margin, which reduces our cost of sales.

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

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

Erbitux®

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

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

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

Bristol-Myers Squibb Company

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

Merck KGaA

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

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

Olumiant®

We have a worldwide license and collaboration agreement with Incyte Corporation (Incyte) which provides us the development and commercialization rights to its Janus tyrosine kinase (JAK) inhibitor compound, now known as Olumiant, and certain follow-on compounds, for the treatment of inflammatory and autoimmune diseases. Incyte has the right to receive tiered, double-digit royalty payments on future global sales with rates ranging up to 20 percent if the product is successfully commercialized. The agreement provides Incyte with options to co-develop these compounds on an indication-by-indication basis by funding 30 percent of the associated development costs from the initiation of a Phase IIb trial through regulatory approval in exchange for increased tiered royalties ranging up to percentages in the high twenties. Incyte exercised its option to co-develop Olumiant in rheumatoid arthritis in 2010 and psoriatic arthritis, atopic dermatitis, alopecia areata, and systemic lupus erythematosus (SLE) in 2017. The agreement calls for payments by us to Incyte associated with certain development, success-based regulatory, and sales-based milestones. The following table summarizes our milestones achieved:

Year	Event	Classification	Amount
2018	Regulatory approval in the U.S.	Intangible asset	$ 100.0
	Began Phase III testing for SLE	R&D Expense	20.0
2017	Regulatory approval in Europe	Intangible asset	65.0
	Regulatory approval in Japan	Intangible asset	15.0
	Began Phase III testing for atopic dermatitis	R&D expense	30.0
2016	Regulatory submissions in the U.S. and Europe	R&D expense	55.0

As of December 31, 2018, Incyte is eligible to receive up to $130.0 million of additional payments from us contingent upon certain development and success-based regulatory milestones. Incyte is also eligible to receive up to $150.0 million of potential sales-based milestones.

Effient®

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

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

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

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

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

	2018	2017	2016
Revenue	$122.2	$388.9	$535.2

Tanezumab

We have a collaboration agreement with Pfizer Inc. (Pfizer) to jointly develop and globally commercialize tanezumab for the treatment of osteoarthritis pain, chronic low back pain and cancer pain. Under the agreement, the companies share equally the ongoing development costs and, if successful, in gross margins and certain commercialization expenses. As of December 31, 2018, Pfizer is eligible to receive up to $350.0 million in success-based regulatory milestones and up to $1.23 billion in a series of sales-based milestones, contingent upon the commercial success of tanezumab.

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

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

	2018	2017	2016
Severance:			
Human pharmaceutical products	$127.8	$601.0	$85.9
Animal health products	14.8	96.4	40.8
Total severance	142.6	697.4	126.7
Pension and post-retirement medical charges associated with U.S. voluntary early retirement program (see Note 14):			
Human pharmaceutical products	—	446.7	—
Animal health products	—	67.0	—
Total pension and post-retirement medical charges associated with U.S. voluntary early retirement program	—	513.7	—
Asset impairment (gains from facility sales) and other special charges:			
Human pharmaceutical products	46.0	81.7	(13.0)
Animal health products	293.4	380.8	268.8
Total asset impairment and other special charges	339.4	462.5	255.8
Total asset impairment, restructuring, and other special charges	$482.0	$1,673.6	$382.5

Severance costs recognized during the years ended December 31, 2018, 2017 and 2016 were incurred as a result of actions taken to reduce our cost structure. Severance costs recognized in 2017 were associated with the U.S. voluntary early retirement program. During 2017, severance costs recognized in the U.S. and outside the U.S. were $412.5 million and $284.9 million, respectively. Substantially all of the severance costs incurred in 2016 and 2017 have been paid. Of the severance costs incurred during the year ended December 31, 2018, approximately half will be paid in 2019 and half will be paid in 2020.

Asset impairment and other special charges recognized during the year ended December 31, 2018 resulted primarily from asset impairment and other special charges related to the sale of the Posilac® (rbST) brand and the associated Augusta, Georgia manufacturing site, as well as the decision to suspend commercialization of Imrestor®, an animal health product. We also incurred expenses associated with the IPO and separation of Elanco.

Asset impairment and other special charges related to animal health products recognized during the year ended December 31, 2017 resulted primarily from asset impairments related to lower projected revenue for Posilac (rbST). The assets associated with Posilac (rbST) were written down to their fair values, which were determined based upon a discounted cash flow valuation. Impairment charges were recorded for the associated fixed assets and intangible asset of $151.5 million and $50.0 million, respectively. In addition, we incurred approximately $43.4 million of costs associated with the temporary shut down of our Puerto Rico facility following Hurricane Maria. The remaining asset impairment and other special charges recognized in 2017 and 2016 were primarily related to integration costs and asset impairments due to product rationalizations and site closures resulting from our acquisition and integration of Novartis Animal Health, including the closure of a manufacturing facility in Ireland in 2016 (refer to Note 8 for further detail relating to intangible asset impairments).

Note 6: Inventories

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

Inventories at December 31 consisted of the following:

	2018	2017
Finished products	$988.1	$1,211.4
Work in process	2,628.2	2,697.7
Raw materials and supplies	506.5	488.8
Total (approximates replacement cost)	4,122.8	4,397.9
Increase (reduction) to LIFO cost	(11.0)	60.4
Inventories	$4,111.8	