LILLY ELI & CO
Form 10-K
February 20, 2018

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, 2017
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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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. o
Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 under the Exchange Act. (Check one):

Large accelerated filer ý		Accelerated filer o
Non-accelerated filer o	(Do not check if a smaller reporting	Smaller reporting company o

company)

Emerging growth company 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 $79,941,000,000

Number of shares of common stock outstanding as of February 14, 2018: 1,095,597,580

Portions of the Registrant's Proxy Statement to be filed on or about March 19, 2018 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 and Section 21E of the Securities Exchange Act of 1934 (Exchange Act). 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, 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:

- the timing of anticipated regulatory approvals and launches of new products;
- market uptake of recently launched products;
- competitive developments affecting current products;
- 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 or misappropriation 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;
- 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; and
- the impact of global macroeconomic conditions.

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

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

Part I

Item 1. Business

Eli Lilly and Company (the “company” or “registrant” or "Lilly") was incorporated in 1901 in Indiana to succeed to the drug manufacturing business founded in Indianapolis, Indiana, in 1876 by Colonel Eli Lilly. We discover, develop, manufacture, and market products in 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, develop, and bring to market innovative new medicines.

Our animal health business, operating through our Elanco division, 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.

We manufacture and distribute our products through facilities in the United States (U.S.), Puerto Rico, and 14 other countries. Our products are sold in approximately 125 countries.

Human Pharmaceutical Products

Our human pharmaceutical products include:

Endocrinology products, including:

- Humalog®, Humalog Mix 75/25, Humalog U-100, Humalog U-200 and Humalog Mix 50/50, insulin analogs for the treatment of diabetes
- Humulin®, Humulin 70/30, Humulin N, Humulin R, and Humulin U-500, human insulins of recombinant DNA origin for the treatment of diabetes
- Trulicity®, for the treatment of type 2 diabetes (approved in the U.S. and Europe in 2014 and Japan in 2015)
- Trajenta®, for the treatment of type 2 diabetes
- Jentadueto® and Jentadueto XR, a combination of linagliptin (Trajenta) and metformin hydrochloride for use in the treatment of type 2 diabetes
- Jardiance®, for the treatment of type 2 diabetes (approved in the U.S., Europe, and Japan in 2014, cardiovascular data included in the European label in 2016) and to reduce the risk of cardiovascular death in adult patients with type 2 diabetes and established cardiovascular disease (approved in the U.S. in 2016)
- Glyxambi®, a combination tablet of linagliptin and empagliflozin (Jardiance) for the treatment of type 2 diabetes (approved in the U.S. in 2015 and Europe in 2016)
- Synjardy® and Synjardy XR, a combination tablet of empagliflozin and metformin hydrochloride for the treatment of type 2 diabetes (approved in the U.S. and Europe in 2015), extended release formulation approved in the U.S. in 2016
- Basaglar® (insulin glargine injection), a long-acting human insulin analog for the treatment of diabetes (launched in the U.S. in 2016 and in Japan and Europe in 2015 under the trade name Abasaglar)™
- Forteo®, for the treatment of osteoporosis in postmenopausal women and men at high risk for fracture and for glucocorticoid-induced osteoporosis in men and postmenopausal women

- 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
- Humatrope®, for the treatment of human growth hormone deficiency and certain pediatric growth conditions

Neuroscience products, including:

- Cymbalta®, for the treatment of major depressive disorder, diabetic peripheral neuropathic pain, generalized anxiety disorder, fibromyalgia, and chronic musculoskeletal pain due to chronic low back pain or chronic pain due to osteoarthritis
- Zyprexa®, for the treatment of schizophrenia, acute mixed or manic episodes associated with bipolar I disorder, and bipolar maintenance
- Strattera®, for the treatment of attention-deficit hyperactivity disorder
- Prozac®, for the treatment of major depressive disorder, obsessive-compulsive disorder, bulimia nervosa, and panic disorder
- 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

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
- 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
- Cyramza®, for the treatment of various cancers, with approvals as follows:
  - approved in 2014 in the U.S. and the European Union (EU), and in Japan in 2015, both as a single agent and in combination with another agent as a second-line treatment of advanced or metastatic gastric cancer
  - approved in 2014 in the U.S., and in the EU and Japan in 2016, in combination with another agent as a second-line treatment of metastatic NSCLC
  - approved in 2015 in the U.S., and in the EU and Japan in 2016, as a second-line treatment of metastatic colorectal cancer
- 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
- Portrazza®, approved in 2015 in the U.S. for use in combination with other agents as a first-line treatment of metastatic squamous NSCLC, and approved in 2016 in the EU for use in combination with other agents as a first-line treatment for epidermal growth factor receptor expressing squamous NSCLC
- 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
- Verzenio™, approved in the U.S. in 2017 indicated both as a single agent and in combination with another chemotherapy agent for the treatment of a certain type of advanced or metastatic breast cancer.

Immunology products, including:

- Olumiant®, approved in the EU and Japan in 2017 for the treatment of adults with moderately-to-severely active rheumatoid arthritis

- Taltz®, for the treatment of moderate-to-severe plaque psoriasis (approved 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)

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

Animal Health Products

Our products for food animals include:

- Rumensin®, a cattle feed additive that improves feed efficiency and growth and also controls and prevents coccidiosis
- Coban®, Maxiban®, and Monteban®, anticoccidial agents for use in poultry
- Posilac®, a protein supplement to improve milk productivity in dairy cows
- Optaflexx® and Paylean®, leanness and performance enhancers for cattle and swine, respectively
- Tylan®, an antibiotic used to control certain diseases in cattle, swine, and poultry
- Denagard®, an antibiotic for the control and treatment of respiratory and enteric diseases in swine and poultry

Our products for companion animals include:

- Trifexis®, a monthly chewable tablet for dogs that kills fleas, prevents flea infestations, prevents heartworm disease, and controls intestinal parasite infections
- Comfortis®, a chewable tablet that kills fleas and prevents flea infestations on dogs
- Interceptor® Plus, a monthly chewable tablet that prevents heartworm disease and treats and controls adult hookworm, roundworm, whipworm and tapeworm in dogs
- Galliprant®, an anti-inflammatory tablet that targets the key receptor associated with canine Osteoarthritis pain
- Feline, canine, and rabies vaccines including: Duramune® and UltraTM Duramune®, Duramune Lyme®, Bronchi-Shield®, Fel-O-Vax®, ULTRATM Fel-O-Vax®, and Fel-O-Guard®, and Rabvac®.

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—United States

In the U.S., we distribute human pharmaceutical products principally through independent wholesale distributors, with some sales directly to pharmacies. In 2017, 2016, and 2015, three wholesale distributors in the U.S. - McKesson Corporation, AmerisourceBergen Corporation, and Cardinal Health, Inc. - each accounted for between 9 percent and 18 percent of our consolidated total revenue. No other distributor accounted for more than 10 percent of 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 as appropriate to leverage our own resources and the strengths of our partners in various markets.

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 United States

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.
- Through September 30, 2015, Erbitux was marketed in the U.S. and Canada by Bristol-Myers Squibb Company and E.R. Squibb (collectively, BMS). Effective October 1, 2015, BMS transferred to us all commercialization rights for Erbitux in those two countries. Outside the U.S. and Canada, Erbitux is commercialized by Merck KGaA, and we receive royalties from Merck KGaA.
- Effient is co-promoted with us by Daiichi Sankyo Co., Ltd. (Daiichi Sankyo) in the U.S., Brazil, Mexico, and certain other countries. Through the end of 2015, we also co-promoted Effient with Daiichi Sankyo in major European markets. Effective January 2016, Daiichi Sankyo has been exclusively promoting Effient in major European markets; however, the economic results for these countries will continue to be shared in the same proportion as under the previous arrangement. 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. Elanco 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, Portrazza, and Taltz, 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 physical and/or structural similarity to the original product, is approved based on an abbreviated data package that relies in part on the full testing required of the originator product. Globally, governments have or are developing regulatory pathways to approve biosimilars as alternatives to innovator-developed biologics, but the patent for the existing, branded product 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 will compete with our product Humalog, and other companies are in the process of developing similar products. 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. This product 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 pharmaceutical benefit managers have been consolidating into fewer, larger entities, thus enhancing their purchasing strength and importance. Recently, CVS Health, a large pharmaceutical benefit manager and pharmacy chain, announced the planned acquisition of Aetna, a large national insurer.

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. 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 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 is delayed during examination by the United States Patent and Trademark Office (USPTO).
- Patent term restoration is a statutory right provided to U.S. patents that claim inventions subject to review by the U.S. Food and Drug Administration (FDA). A single patent for a human pharmaceutical product may be eligible for patent term restoration to make up for a portion of the time invested in clinical trials and the FDA review process. 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, 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 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 five years in the U.S. (12 years for new biologics as described below), 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 2010, 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.

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.

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).
- Cialis is protected by a compound patent plus pediatric exclusivity (May 2018) and a unit dose patent (exclusivity expected through at least September 2018).
- Cyramza is protected by biologics data package protection (2026).
- Effient is protected by patents covering methods of using Effient with aspirin (2023). The method patents were held unpatentable in an inter partes review (IPR) and we are appealing those decisions (for further information see Item 8, "Financial Statements and Supplementary Data - Note 15, Contingencies").
- Forteo is protected by patents primarily covering its formulation and related processes (December 2018) and use patents (August 2019).

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- 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).
- 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), and Boehringer Ingelheim has applied for a patent extension to 2025 under the patent restoration laws.
- 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 2018).
- Forteo in Japan (data package protection July 2018; patent covering its formulation and related process August 2019).
- Lartruvo in major European countries (compound patent and data package protection 2026, not including possible patent extension).
- Olumiant in major European countries (compound patent 2029, not including possible patent extension) and Japan (compound patent 2033).
- Taltz in major European countries (compound patent and data package protection 2026, not including possible patent extension).

Baricitinib (Olumiant), has been submitted for regulatory review in the U.S. and is protected by a compound patent in the U.S. until 2030 (not including possible patent extension). Galcanezumab has been submitted for regulatory review in the U.S. and is protected by a compound patent (2033). Additional information about this molecule is provided in Item 7, "Management’s Discussion and Analysis - Executive Overview - Late-Stage Pipeline.”

Worldwide, we sell all of our major products under trademarks that we consider in the aggregate to be important to our operations. Trademark protection varies throughout the world, with protection continuing in some countries as long as the mark is used, and in other countries as long as it is registered. Registrations are normally for fixed but renewable terms.

Patent Licenses

Most of our major products are not subject to significant license agreements. The compound patent for Cialis is the subject of a license agreement with GlaxoSmithKline (Glaxo), which assigns to us exclusively all rights in the compound. The agreement calls for royalties of a single-digit percentage of net sales. The agreement is not subject to termination by Glaxo for any reason other than a material breach by Lilly of the royalty obligation, after a substantial cure period. For information on our license and collaboration agreement with 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 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 Forteo, Alimta, and Effient, 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 Biologics Price Competition and Innovation Act of 2009 (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 Act does provide a mechanism for a competitor to challenge the validity of an innovator's patents as early as 4 years after initial marketing approval of the innovator biologic. The patent litigation scheme under the BPCI Act is complex, and interpretation of the BPCI Act is currently the subject of ongoing litigation. Specifically, courts have now held that biosimilar applicants are not required to engage in the BPCI Act litigation scheme. Patent holders still have the right to bring suit under normal patent law procedures if a biosimilar applicant attempts to commercialize a product prior to patent expiration.

In addition, there is a procedure in U.S. patent law known as 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 funds 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 world 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 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 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 U.S. Department of Agriculture and the U.S. Environmental Protection Agency also regulate some animal health 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 to ensure sustained compliance with cGMP and similar regulations. However, in the event we fail to adhere to these requirements in the future, we could be subject to interruptions in production, fines and penalties, and delays in new product approvals. Certain of our products are manufactured by third parties, and their failure to comply with these regulations could adversely affect us through failure to supply product to us or delays in new product approvals.

The marketing, promotional, and pricing practices of human pharmaceutical manufacturers, as well as the manner in which manufacturers interact with purchasers and prescribers, 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, the FDA, the DOJ, and many of these other agencies have increased their enforcement activities with respect to pharmaceutical companies and increased the inter-agency coordination of enforcement activities. Several claims brought by these agencies against Lilly 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.

It is possible that we could become subject to additional 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. Drug manufacturers are required to provide a discount of 50 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). Additionally, an annual fee is imposed on pharmaceutical manufacturers and importers that sell branded prescription drugs to specified government programs.

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

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

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

Research and Development

Our commitment to research and development dates back more than 140 years. We invest heavily in research and development because we believe it is critical to our long-term competitiveness. At the end of 2017, we employed approximately 9,000 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. This number decreased to approximately 8,200 as of January 31, 2018, following a voluntary early retirement program in the U.S. Our research and development expenses were $5.28 billion in 2017, $5.24 billion in 2016, and $4.80 billion in 2015.

Our internal human pharmaceutical research focuses primarily on the areas of cancer, diabetes, neurodegeneration, immunology, and pain. 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 hold the promise to 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 wellbeing 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. This 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 Research 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.

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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 40 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, rheumatoid arthritis, psoriatic arthritis, and severe hypoglycemia. 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 - 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 materials primarily from only one source. In the event one of these suppliers was unable to provide the materials or product, we generally seek to maintain sufficient inventory to supply the market until an alternative source of supply can be implemented. However, in the event of an extended failure of a supplier, it is possible that we could experience an interruption in supply until we established new sources or, in some cases, implemented alternative processes.

The majority of our revenue comes from products produced in our own facilities. Our principal active ingredient manufacturing occurs at sites we own in the U.S., Ireland, and Puerto Rico. Finishing operations, including formulation, filling, assembling, delivery device manufacturing, and packaging, take place at a number of sites throughout the world. We utilize third parties for certain active ingredient manufacturing and finishing operations. We manage our supply chain (including our own facilities, contracted arrangements, and inventory) in a way that should 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 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 7, 2018, or on the date his or her successor is chosen and qualified. Dr. Lundberg will retire from the company effective May 31, 2018; he will be succeeded by Dr. Daniel Skovronsky, M.D., Ph.D, effective June 1, 2018. 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 and any other person pursuant to which the executive officer was selected.

Name	Age	Offices and Business Experience
David A. Ricks	50	President, Chief Executive Officer, and a director (since January 2017) and board chair (since June 2017)
Melissa S. Barnes	49	Senior Vice President, Enterprise Risk Management and Chief Ethics and Compliance Officer (since January 2013)
Enrique A. Conterno	51	Senior Vice President and President, Lilly Diabetes (since November 2009) and President, Lilly USA (since February 2017)
Stephen F. Fry	52	Senior Vice President, Human Resources and Diversity (since February 2011)
Michael J. Harrington	55	Senior Vice President and General Counsel (since January 2013)
Jan M. Lundberg, Ph.D.	64	Executive Vice President, Science and Technology, and President, Lilly Research Laboratories (since January 2010)
Susan Mahony, Ph.D.	53	Senior Vice President and President, Lilly Oncology (since February 2011)
Johna L. Norton	51	Senior Vice President, Global Quality (since April 2017)
Myles O'Neill	59	Senior Vice President and President, Manufacturing Operations (since January 2018)
Leigh Ann Pusey	55	Senior Vice President, Corporate Affairs and Communications (since June 2017). Prior to joining Lilly, Pusey served as president and CEO of the American Insurance Association (AIA).
Aarti Shah, Ph.D.	53	Senior Vice President, Information Technology, and Chief Information Officer (since January 2018)
Christi Shaw	51	Senior Vice President and President, Lilly Bio-Medicines (since April 2017). Prior to returning to Lilly, 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.	44	Senior Vice President, Science and Technology, and President, Lilly Research Laboratories (effective June 2018). Prior to joining the company in 2010, Dr. Skovronsky was CEO and founder of Avid Radiopharmaceutical Inc.
Joshua L. Smiley	48	Senior Vice President and Chief Financial Officer (since January 2018)
Jeffrey N. Simmons	50	Senior Vice President and President, Elanco Animal Health (since January 2008)
Alfonso Zulueta	55	Senior Vice President and President, Lilly International (since February 2017)

Employees

At the end of 2017, we employed approximately 40,655 people, including approximately 22,235 employees outside the U.S. These numbers decreased to approximately 38,350 total employees, including approximately 21,950 employees outside the U.S., as of January 31, 2018, following a voluntary early retirement program in the U.S. A substantial number of our employees have long records of continuous service.

Financial Information Relating to Business Segments and Classes of Products

You can find financial information relating to our business segments and classes of products in Item 8, "Financial Statements and Supplementary Data - Note 18, Segment Information." That information is incorporated here by reference.

The relative contribution of any particular product to our consolidated revenue changes from year to year. This is due to several factors, including the introduction of new products by us and by other manufacturers and the introduction of generic pharmaceuticals upon patent expirations. Our product revenues are generally not seasonal.

Financial Information Relating to Foreign and Domestic Operations

You can find financial information relating to foreign and domestic operations in Item 8, “Financial Statements and Supplementary Data - Note 18, Segment Information.” That information is incorporated here by reference. To date, our overall operations abroad have not been significantly deterred by local restrictions on the transfer of funds from branches and subsidiaries located abroad, including the availability of U.S. dollar exchange. We cannot predict what effect these restrictions or the other risks inherent in foreign operations, including possible nationalization, might have on our future operations or what other restrictions may be imposed in the future. In addition, changing currency values can either favorably or unfavorably affect our financial position, liquidity, and results of operations. We mitigate certain foreign exchange risks through various hedging techniques including the use of foreign currency contracts.

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/sec.cfm.

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.

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 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 - 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 (2017) ($ in millions)	Percent of Worldwide Revenues (2017)	Patent / Data Protection - U.S.
Cialis	$ 1,358.6	6%	Compound patent plus pediatric exclusivity (May 2018) and unit dose patent with exclusivity expected through September 2018
Alimta	1,034.3	5%	Vitamin regimen patent plus pediatric exclusivity 2022
Forteo	965.2	4%	Formulation and related process patents December 2018; use patents August 2019
Effient	340.1	1%	Compound patent plus pediatric exclusivity October 2017
Strattera	284.9	1%	Use patent plus pediatric exclusivity May 2017

Product	Revenues Outside U.S. (2017) ($ in millions)	Percent of Worldwide Revenues (2017)	Patent / Data Protection - Major Europe / Japan
Alimta	$ 1,028.2	4%	Major European countries: vitamin regimen patent 2021 Japan: use patents to treat cancer concomitantly with vitamins 2021
Cialis	964.5	4%	Major European countries: compound patent November 2017
Forteo	783.8	3%	Japan: data package protection July 2018; formulation and related process patent August 2019
Cymbalta	642.2	3%	Japan: data package protection January 2018

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, and Taltz), 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. See Item 7, “Management’s Discussion and Analysis - Executive Overview - Other 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, 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.

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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. As a result, our patents may be invalided 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 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 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 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 - Executive Overview - Other Matters.”

- 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 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. recently enacted tax reform legislation significantly revising the U.S. tax law 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 - 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 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 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 prevent, detect, respond to, and minimize 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 and reputation.

- Significant economic downturns 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.

- 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 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, Cymbalta, and Prozac 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 could become subject to large numbers of product liability claims for these or other products in the future, which could 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. It is possible that we could become subject to such investigations and that the outcome 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 failures, 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 utilize 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 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 operating 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.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our principal domestic and international executive offices are located in Indianapolis. At December 31, 2017, we owned 14 production and distribution sites in the U.S. and Puerto Rico. Together with the corporate administrative offices, these facilities contain an aggregate of approximately 11.2 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 14 countries outside the U.S. and Puerto Rico, containing an aggregate of approximately 5.6 million square feet of floor area. Major production sites include facilities in France, Ireland, 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 China.

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 and Effient
- The product liability litigation involving Actos and Cymbalta
- The employee litigation in Brazil.

That information is incorporated into this Item by reference.

Other Product Liability Litigation

We are named as a defendant in approximately 510 Byetta product liability lawsuits in the U.S. involving approximately 775 plaintiffs. Approximately 60 of these lawsuits, covering about 320 plaintiffs, are filed in California state court and coordinated in a Los Angeles Superior Court. Approximately 450 lawsuits, covering about 450 plaintiffs, are filed in federal court, the majority of which are coordinated in a multidistrict 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 500 of the lawsuits, involving approximately 735 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. 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. 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 and claims are without merit and are prepared to defend against them vigorously.

We are aware of approximately 100 claims primarily related to allegations that the antidepressant Prozac caused or contributed to birth defects in the children of women who ingested the drug during pregnancy. These claims have not yet been filed. We believe these claims are without merit and are prepared to defend against them vigorously.

We are named as a defendant in approximately 550 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. Medical Mutual of Ohio has filed a class action complaint against multiple manufacturers of testosterone products in the Northern District of Illinois, on behalf of third party payers who paid for those products. The plaintiff is seeking damages under the federal Racketeer Influenced and Corrupt Organizations Act (the federal RICO Act). We believe all of these lawsuits and claims are without merit and are prepared to defend against them vigorously.

We are named as a defendant in approximately 150 Cialis product liability lawsuits in the U.S. These cases, 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 the 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 and claims are without merit and are prepared to defend against them vigorously.

Other Patent Litigation

In October 2017, Teva Pharmaceuticals International GMBH filed a lawsuit against us in U.S District Court for the District of Massachusetts seeking a ruling that various patents would be infringed if we launch galcanezumab for the prevention of migraine in adults. Teva Pharmaceuticals USA, Inc. (collectively with Teva Pharmaceuticals International GMBH, Teva) was added as a plaintiff in January 2018. In February 2018, Teva filed another lawsuit in the District of Massachusetts seeking a ruling that two recently granted Teva patents would also be infringed if we launch galcanezumab for the prevention of migraine in adults. We believe these lawsuits are without merit and we are prepared to defend against them vigorously.

We have been engaged in U.S. patent litigation involving Forteo brought pursuant to procedures set out in the Drug Price Competition and Patent Term Restoration Act of 1984. Teva Pharmaceuticals USA, Inc. filed an ANDA with the FDA seeking approval to market a generic version of Forteo and filed a notice alleging that a number of our patents covering various formulations and methods of use for Forteo are invalid and/or not infringed. In March 2016, we filed a patent infringement suit against Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. asserting six different patents. A settlement agreement has been reached, and we do not expect competitive products to enter the market earlier than the second half of 2019.

Boehringer Ingelheim, our partner in marketing and development of Trajenta, is engaged in various U.S. patent litigation matters involving Trajenta/Jentadueto in accordance with the procedures set out in the Drug Price Competition and Patent Term Restoration Act of 1984. Eleven groups of companies submitted Abbreviated New Drug Applications seeking approval to market generic versions of Trajenta prior to the expiration of Trajenta/Jentadueto patents, alleging certain patents, including in some allegations the compound patent, are invalid or would not be infringed. Trial is currently scheduled for the second quarter of 2018.

In Canada, several generic companies previously challenged the validity of our Zyprexa patent. In September 2012, the Canadian 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 Inc. (Apotex) and Teva Canada Limited (Teva Canada), pursued claims for damages arising from our enforcement of the patent under Canadian regulations. In April 2014, the Supreme Court of Canada dismissed Apotex's damages suit. Teva Canada's claim for damages remains, and in January 2017, the court issued a ruling that Teva Canada is entitled to damages. We have appealed the ruling and a decision is expected in the first half of 2018.

Other Matters

We have been named a respondent in an arbitration filed by Adocia, S.A. (Adocia), with whom we entered into agreements for the co-development of an ultra-rapid insulin product. Adocia alleges that we refused to make a milestone payment and misused Adocia’s intellectual property. We believe that Adocia’s claims are without merit and are prepared to defend against them vigorously.

We are named as co-defendants 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 and these claims are without merit and are prepared to defend against them 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.

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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 Sanofi and Novo Nordisk, are named as defendants in a consolidated purported class action lawsuit, In re. Insulin Pricing Litigation, in the U.S. District Court of New Jersey relating to insulin pricing. The consolidated lawsuit incorporates three other purported class action lawsuits, Barnett v. Novo Nordisk Inc., Boss v. CVS Health Corp., and Christensen v. Novo Nordisk Inc., which were previously filed in the same court against the three manufacturers and various pharmacy benefit managers. The plaintiffs in In re. Insulin Pricing Litigation are seeking damages under various state consumer protection laws and the federal RICO Act. We believe these claims are without merit and are prepared to defend against them vigorously. Separately, we, along with Sanofi, Novo Nordisk, and various pharmacy benefit managers, were named as defendants in a purported class action lawsuit in the U.S. District Court of Western District of Texas, MSP Recovery Claims, Series, LLC et al. v. CVS Health Corp., et al., relating to insulin pricing. That case was dismissed without prejudice on January 19, 2018 to allow plaintiffs to refile in the District of New Jersey. The plaintiffs have since filed MSP Recovery Claims, Series, LLC et al. v. Sanofi Aventis U.S. LLC in the District of New Jersey against the manufacturers and are seeking damages under various state consumer protection laws, common law fraud, unjust enrichment, and the federal RICO Act.
We have received civil investigative demands from the Offices of the Attorney General from State of Washington, New Mexico, and Minnesota relating to the pricing and sale of our insulin products. We are cooperating with these investigations. The Offices of Attorney General in Mississippi, Washington D.C., California, and Florida have requested information relating to the pricing and sale of our insulin products. We are cooperating with these requests.
We, along with Novo Nordisk and various pharmacy benefit managers, are named as defendants in a lawsuit seeking class action status in the U.S. District Court of New Jersey (transferred from the U.S. District Court of the Western District of Washington) relating to glucagon pricing. The plaintiffs are seeking damages under various state consumer protection laws, the federal RICO Act, the Sherman Act, and other state and federal laws. We believe this lawsuit and these claims are without merit and are prepared to defend against them vigorously.
We, among other pharmaceutical manufacturers, 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 Northern District of Illinois. The complaint alleges that the defendants should have treated certain credits with 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, 2017:

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 2017	151.0	$ 82.52	151.0	$ 2,138.0
November 2017	1,047.5	83.40	1,047.5	2,050.7
December 2017	—	—	—	2,050.7
Total	1,198.5	83.29	1,198.5	

During the fourth quarter of 2017, we repurchased $99.8 million of shares associated with our $5.00 billion share repurchase program announced in October 2013.

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 2013 through 2017. The graph assumes that, on December 31, 2012, 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 2012

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

	Lilly	Peer Group	S&P 500
Dec-12	$100.00	$ 100.00	$100.00
Dec-13	$107.24	$ 138.74	$132.39
Dec-14	$149.87	$ 158.83	$150.51
Dec-15	$187.89	$ 161.53	$152.59
Dec-16	$168.40	$ 157.25	$170.84
Dec-17	$198.43	$ 181.79	$208.14

(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 executive officers for 2017: 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)	2017	2016	2015	2014	2013
Operations					
Revenue	$22,871.3	$21,222.1	$19,958.7	$19,615.6	$23,113.1
Cost of sales	6,070.2	5,654.9	5,037.2	4,932.5	4,908.1
Research and development	5,281.8	5,243.9	4,796.4	4,733.6	5,531.3
Marketing, selling, and administrative	6,588.1	6,452.0	6,533.0	6,620.8	7,125.6
Other[1]	2,733.8	497.3	802.1	328.4	(341.2)
Income before income taxes	2,197.4	3,374.0	2,790.0	3,000.3	5,889.3
Income taxes[2]	2,401.5	636.4	381.6	609.8	1,204.5
Net income (loss)	(204.1)	2,737.6	2,408.4	2,390.5	4,684.8
Net income (loss) as a percent of revenue	(0.9)%	12.9 %	12.1 %	12.2 %	20.3 %
Net income (loss) per share—diluted	$(0.19)	$2.58	$2.26	$2.23	$4.32
Dividends declared per share	2.12	2.05	2.01	1.97	1.96
Weighted-average number of shares outstanding—diluted (thousands)	1,052,023	1,061,825	1,065,720	1,074,286	1,084,766
Financial Position					
Current assets	$19,202.1	$15,101.4	$12,573.6	$11,928.3	$12,820.4
Current liabilities	14,535.9	10,986.6	8,229.6	9,741.0	8,123.8
Property and equipment—net	8,826.5	8,252.6	8,053.5	7,963.9	7,975.5
Total assets	44,981.0	38,805.9	35,568.9	36,307.6	35,210.8
Long-term debt	9,940.5	8,367.8	7,972.4	5,332.8	4,200.3
Total equity	11,667.9	14,080.5	14,590.3	15,388.1	17,640.7
Supplementary Data					
Return on total equity	(1.5)%	18.5 %	16.1 %	13.7 %	29.5 %
Return on assets	(0.5)%	7.5 %	6.8 %	6.8 %	14.1 %
Capital expenditures	$1,076.8	$1,037.0	$1,066.2	$1,162.6	$1,012.1
Depreciation and amortization	1,567.3	1,496.6	1,427.7	1,379.0	1,445.6
Effective tax rate[2]	109.3 %	18.9 %	13.7 %	20.3 %	20.5 %
Revenue per employee	$563,000	$506,000	$484,000	$501,000	$609,000
Number of employees	40,655	41,975	41,275	39,135	37,925
Number of shareholders of record	25,300	26,800	28,000	29,300	31,900

[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 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 (loss) 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
	2017	2016	
Revenue	$22,871.3	$21,222.1	8
Gross margin	16,801.1	15,567.2	8
Gross margin as a percent of revenue	73.5 %	73.4 %	
Operating expense [(1)]	$11,869.9	$11,695.9	1
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

[(1)] Operating expense consists of research and development and marketing, selling, and administrative expenses.

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 in-process research and development (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. Refer to "Results of Operations - Executive Overview - Other Matters - Tax Matters" for further discussion of the 2017 Tax Act.

The following highlighted items affect comparisons of our 2017 and 2016 financial results:

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 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. Refer to "Results of Operations - Executive Overview - Other Matters - Tax Matters" for further discussion of the 2017 Tax Act.

2016

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 Animal Health (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.

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 40 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 inhibitor for the treatment of moderate-to-severe active rheumatoid arthritis (in collaboration with Incyte Corporation).

Olaratumab* (Lartruvo™) (Q4 2016)—a human lgG1 monoclonal antibody for the treatment of advanced soft tissue sarcoma.

The following NME has 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 the NME initially was submitted in any major geography for any indication is shown in parentheses:

Galcanezumab* (Q3 2017)—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 NMEs and diagnostic agent are currently in Phase III clinical trial testing for potential use in the diseases described. The first quarter in which each NME and 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.

Lanabecestat (Q2 2016)—an oral beta-secretase cleaving enzyme (BACE) inhibitor for the treatment of early and mild Alzheimer's disease (in collaboration with AstraZeneca).

Lasmiditan (Q2 2015)—an oral 5-HT_{1F} agonist for the acute treatment of migraine.

Nasal glucagon* (Q3 2013)—a glucagon nasal powder formulation for the treatment of severe hypoglycemia in patients with diabetes treated with insulin.

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. (Pfizer)).

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 each NME and diagnostic agent within our late-stage pipeline and recently approved products including developments since January 1, 2017:

Compound	Indication	U.S.	Europe	Japan	Developments
Endocrinology					
Nasal glucagon	Severe hypoglycemia	Phase III			Development of commercial manufacturing process is ongoing.
Ultra-rapid Lispro	Type 1 and 2 diabetes	Phase III			Initiated Phase III studies in third quarter of 2017.
Immunology					
Olumiant	Rheumatoid arthritis	Submitted	Launched		Approved and launched in Europe in first quarter of 2017. Received complete response letter from the U.S. Food and Drug Administration (FDA) in second quarter of 2017. Approved and launched in Japan in third quarter of 2017. Resubmitted in the U.S. in fourth quarter of 2017.
	Atopic dermatitis	Phase III			Initiated Phase III studies in fourth quarter of 2017.

Compound	Indication	U.S.	Europe	Japan	Developments
Neuroscience					
Flortaucipir	Alzheimer's disease	Phase III			Phase III trial is ongoing.
	Cluster headache	Phase III			Phase III trials are ongoing.
Galcanezumab	Migraine prevention	Submitted		Phase III	Three Phase III trials met primary endpoints. Submitted to regulatory authorities in the U.S. and Europe in third and fourth quarters of 2017, respectively.
Lanabecestat	Early and mild Alzheimer's disease	Phase III			Phase III trials are ongoing.
Lasmiditan	Migraine	Phase III			Acquired from CoLucid in first quarter of 2017. In third quarter of 2017, announced Phase III trial met primary endpoint. Submission to FDA expected in second half of 2018. See Note 3 to the consolidated financial statements for information on the acquisition.
Solanezumab					