LILLY ELI & CO
Form 10-K
February 19, 2014

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, 2013
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
6.57% Notes Due January 1, 2016	New York Stock Exchange
7 1/8% Notes Due June 1, 2025	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 ¨

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

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 ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant's knowledge, in the definitive proxy statement incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. þ

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 þ Accelerated filer ¨ Non-accelerated filer ¨ Smaller reporting company ¨

Indicate by check mark whether the Registrant is a shell company as defined in Rule 12b-2 under the Exchange Act: Yes ¨ 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 $46,911,000,000

Number of shares of common stock outstanding as of February 14, 2014: 1,119,713,084

Portions of the Registrant's Proxy Statement to be filed on or about March 24, 2014 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 governmental actions regarding pricing, importation, and reimbursement for pharmaceuticals, including U.S. health care reform;
- 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 current or future products as we are self-insured;
- unauthorized disclosure of trade secrets or other confidential data stored in our information systems and networks;
- changes in tax law;
- changes in inflation, interest rates, and foreign currency exchange rates;
- asset impairments and restructuring charges;
- changes in accounting standards promulgated by the Financial Accounting Standards Board and the Securities and Exchange Commission (SEC);
- acquisitions and business development transactions; and
- the impact of exchange rates and 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 strategy is to create value for all our stakeholders by accelerating the flow of innovative new medicines that provide improved outcomes for individual patients. 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.

We manufacture and distribute our products through facilities in the United States, Puerto Rico, and 11 other countries. Our products are sold in approximately 120 countries.

Human Pharmaceutical Products

Our human pharmaceutical products include:

Endocrinology products, including:

- Humalog®, Humalog Mix 75/25,™ and Humalog Mix 50/50,™ insulin analogs for the treatment of diabetes
- Humulin®, human insulin of recombinant DNA origin for the treatment of diabetes
- Trajenta®, an oral medication for the treatment of type 2 diabetes
- Jentadueto®, a combination tablet of Trajenta and metformin hydrochloride for use in the treatment of type 2 diabetes
- 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
- Axiron®, a topical solution of testosterone, applied by underarm applicator, for replacement therapy in men for certain conditions associated with a deficiency or absence of testosterone.

Neuroscience products, including:

- Cymbalta®, for the treatment of major depressive disorder, diabetic peripheral neuropathic pain, generalized anxiety disorder, and in the U.S. for the management of fibromyalgia and of 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 approved in 2012 in the U.S. and 2013 in the European Union (EU) 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 with another chemotherapy agent for the treatment of certain types of colorectal cancers; and as a single agent or in combination with radiation therapy for the treatment of certain types of head and neck cancers
- Gemzar®, for the treatment of pancreatic cancer; in combination with other agents, for the treatment of metastatic breast cancer, NSCLC, and advanced or recurrent ovarian cancer; and in the EU for the treatment of bladder cancer.

Cardiovascular products, including:

- Cialis®, for the treatment of erectile dysfunction and benign prostatic hyperplasia (BPH)
- 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 (PCI), including patients undergoing angioplasty, atherectomy, or stent placement
- ReoPro®, for use as an adjunct to PCI for the prevention of cardiac ischemic complications
- Adcirca®, for the treatment of pulmonary arterial hypertension.

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
- Posilac®, a protein supplement to improve milk productivity in dairy cows
- Paylean® and Optaflexx®, leanness and performance enhancers for swine and cattle, respectively
- Tylan®, an antibiotic used to control certain diseases in cattle, swine, and poultry
- Micotil®, Pulmotil®, and Pulmotil AC,™ antibiotics used to treat respiratory disease in cattle, swine, and poultry, respectively
- Coban®, Monteban®, and Maxiban®, anticoccidial agents for use in poultry
- Surmax™ (sold as Maxus™ in some countries), a performance enhancer for 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.

Marketing

We sell most of our products worldwide. We adapt our marketing methods and product emphasis in various countries to meet local 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 2013, 2012, and 2011, three wholesale distributors in the U.S.—AmerisourceBergen Corporation, McKesson Corporation, and Cardinal Health, Inc.—each accounted for between 10 percent and 19 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 advertise in medical journals, 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 (MCOs), government and long-term care institutions, hospitals, and certain retail pharmacies. We enter into arrangements with these organizations providing for discounts or rebates on Lilly products.

Human Pharmaceuticals—Outside the United States

Outside the U.S, we promote our human pharmaceutical products primarily through sales representatives. While the products marketed vary from country to country, endocrinology products constitute the largest single group in total revenue. Distribution patterns vary from country to country. In most countries, 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 co-market Cymbalta in Japan with Shionogi & Co. Ltd.
- Evista is marketed in major European markets by Daiichi Sankyo Europe GmbH, a subsidiary of Daiichi Sankyo Co., Ltd. (Daiichi Sankyo).
- Erbitux is marketed in the U.S. and Canada by Bristol-Myers Squibb. We have the option to co-promote Erbitux in the U.S. and Canada. Outside the U.S. and Canada, Erbitux is commercialized by Merck KGaA. We receive royalties from Bristol-Myers Squibb and Merck KGaA.
- Effient is co-promoted with us by Daiichi Sankyo or affiliated companies in the U.S., major European markets, Brazil, Mexico, and certain other countries. 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.
- Trajenta and Jentadueto are being jointly developed and commercialized with us by Boehringer Ingelheim pursuant to a collaboration agreement under which both parties contributed certain potential diabetes treatments in mid- and late-stage development to be jointly developed and commercialized by the parties.

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.

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 and processes. 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, together with our ability to continuously improve the productivity of our operations in a highly competitive environment. There can be no assurance that our research and development efforts will result in commercially successful products, and it is possible that our products will become uncompetitive from time to time as a result of products developed by our competitors.

Generic Pharmaceuticals

One of the biggest competitive challenges we face is from generic pharmaceuticals. In the U.S. and 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. 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

Some of our current products, including Humalog, Humulin, Erbitux, and ReoPro, and many of the new molecular entities 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 biologic for which marketing approval would be granted based on less than a full safety and efficacy package due to the physical/structural similarity of the biosimilar to an already-approved biologic as well as reliance on the finding of safety and efficacy of the already-approved 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.

Managed Care Organizations

The growth of MCOs in the U.S. is also a major factor in the competitive marketplace for human pharmaceuticals. It is estimated that approximately two-thirds of the U.S. population now participates in some version of managed care. MCOs can include medical insurance companies, medical plan administrators, health-maintenance organizations, Medicare Part D prescription drug plans, alliances of hospitals and physicians and other physician organizations. MCOs have been consolidating into fewer, larger entities, thus enhancing their purchasing strength and importance to us.

To successfully compete for business with MCOs, we must often demonstrate that our products offer not only medical benefits but also cost advantages as compared with other medicines or other forms of care. As noted above, generic drugs are exempt from costly and time-consuming clinical trials to demonstrate their safety and efficacy and, as such, typically have lower costs than brand-name drugs. MCOs that focus primarily on

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the immediate cost of drugs often favor generics for this reason. Many governments also 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. The substitution must be made unless the prescribing physician expressly forbids it. MCOs typically maintain formularies specifying which drugs are covered under their plans. Exclusion of a drug from a formulary can lead to its sharply reduced usage in the MCO patient population. Consequently, pharmaceutical companies compete aggressively to have their products included. Where possible, companies compete for inclusion based upon unique features of their products, such as greater efficacy, fewer side effects, or greater patient ease of use. A lower overall cost of therapy is also an important factor. Products that demonstrate fewer therapeutic advantages must compete for inclusion based primarily on price. We have been generally, although not always, successful in having our major products included on MCO formularies.

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 of Item 1, “Business.” 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 U.S. Patent and Trademark Office.
- 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 can result in severe and rapid decline in sales of 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.

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The base period of data package protection is five years in the U.S. (12 years for new biologics as described below), ten 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 (enacted in the U.S. in 2010), the FDA has the authority to approve similar versions (biosimilars) of innovative biologics. A competitor seeking approval of a biosimilar must file an application to show its molecule is highly similar to an approved innovator biologic, address the challenges of biologics manufacturing, and include a certain amount of safety and efficacy data which 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. If granted, this “pediatric exclusivity” provides an additional six months, which are 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.
- Under the U.S. orphan drug law, a specific use of a drug or biological product 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. Under the Trade-Related Aspects of Intellectual Property Agreement (TRIPs) administered by the World Trade Organization (WTO), more than 140 countries have now agreed to provide non-discriminatory protection for most pharmaceutical inventions and to assure that adequate and effective rights are available to patent owners. Because of TRIPs transition provisions, dispute resolution mechanisms, substantive limitations, and ineffectual implementation, it is difficult to assess when and how much we will benefit commercially from this protection.

Certain of our Elanco animal health products are covered by patents or other forms of intellectual property protection. In general, upon loss of effective market exclusivity for our animal health products, we have not 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 would 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 sometimes 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, and uses—particularly 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 larger or recently launched patent-protected marketed products is as follows:

- Alimta is protected by a compound patent (2016) plus pediatric exclusivity (2017), and a vitamin dosage regimen patent (2021) plus pediatric exclusivity (2022).

- Cialis is protected by compound and use patents (2017).
- Cymbalta was protected by a compound patent plus pediatric exclusivity until December 2013.
- Effient is protected by a compound patent (2017).
- Evista is protected by patents on the treatment and prevention of osteoporosis (March 2014).
- Humalog was protected by a compound patent until May 2013.
- Strattera is protected by a patent covering its use in treating attention deficit-hyperactivity disorder (2016) plus pediatric exclusivity (2017).
- 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.

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

- Alimta in major European countries (compound patent 2015, vitamin dosage regimen patent 2021) and Japan (compound patent 2015, patent covering use to treat cancer concomitantly with vitamins 2021)
- Cialis in major European countries (compound patent 2017)
- Cymbalta in major European countries (data package protection second half of 2014) and Japan (data package protection 2018)
- Zyprexa in Japan (compound patent 2015).

U.S. patent protection or data protection for our new molecular entities that have been submitted for regulatory review is as follows (additional information about these molecules is provided in Item 7, "Management’s Discussion and Analysis—Late-Stage Pipeline”):

- Dulaglutide - compound patent 2024 (not including possible patent extension)
- Empagliflozin - compound patent 2025 (not including possible patent extension)
- Ramucirumab - data package protection 12 years following approval
- Our new insulin glargine product has the same amino acid sequence as Sanofi-Aventis' Lantus ® and is not covered by any patent protection.

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 were discovered in our own laboratories and are not subject to significant license agreements. Two of our largest products, Cialis and Alimta, are subject to patent assignments or licenses granted to us by others.

- 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.
- The compound patent for Alimta is the subject of a license agreement with Princeton University, granting us an irrevocable exclusive worldwide license to the compound patents for the lives of the patents in the respective territories. The agreement calls for royalties of a single-digit percentage of net sales. The agreement is not subject to termination by Princeton for any reason other than a material breach by Lilly of the royalty obligation, after a substantial cure period. Alimta is also the subject of a worldwide, nonexclusive license to certain patents owned by Takeda Pharmaceutical Company Limited. The agreement calls for royalties of a single-digit percentage of net sales in

countries covered by a relevant patent. The agreement is subject to termination for material default and failure to cure by Lilly and in the event that Lilly becomes bankrupt or insolvent.

Patent Challenges

In the U.S., the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, made a complex set of changes to both patent and new-drug-approval laws for human pharmaceuticals. Before the Hatch-Waxman Act, no drug could be approved without providing the FDA complete safety and efficacy studies, i.e., a complete New Drug Application (NDA). The Hatch-Waxman Act authorizes the FDA to approve generic versions of innovative human pharmaceuticals (other than biologics) without such information 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. 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- to 42-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 an increasing 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 arising from their Paragraph IV certifications challenging the vitamin dosage regimen patent for Alimta. For more information on this litigation, see Item 8, "Financial Statements and Supplementary Data—Note 16, Contingencies."

Outside the United States, 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 vitamin dosage regimen patents in Europe, see Item 8, "Financial Statements and Supplementary Data—Note 16, Contingencies."

Government Regulation

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 are required to 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. 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 United States. 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 (USDA) and the U.S. Environmental Protection Agency also regulate some animal health products.

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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 (EMA) in the EU and the Ministry of Health, Labor and Welfare (MHLW) 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. See Item 3, “Legal Proceedings,” for information regarding a Corporate Integrity Agreement entered into by Lilly in connection with the resolution of a U.S. federal marketing practices investigation and certain related state investigations involving Zyprexa.

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. The SEC and the DOJ have increased their FCPA enforcement activities with respect to pharmaceutical companies. See Item 3, “Legal Proceedings,” for information about a SEC/DOJ investigation under the FCPA involving our operations in several countries.

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 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 Affecting Human Pharmaceutical Pricing, Reimbursement, and Access

In the United States, government and government-funded healthcare programs often impose direct and indirect price controls. 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 the payers' assessments of comparative effectiveness and value. The U.S. has established the Patient Centered Outcomes Research Institute (PCORI), a federally-funded, private, non-profit corporation empowered to fund and disseminate comparative effectiveness research and build infrastructure for improved outcomes analysis. While PCORI has no authority to impose formulary changes directly in government-funded health programs, they are expected to drive an increase in CER studies which payers can use for formulary decisions and/or medical societies can use to inform medical guidelines development. Many countries outside of the U.S. use formal health technology assessment (HTA) processes to determine formulary placement and purchase price.

We cannot predict the extent to which our business may be affected by these or other potential future legislative or regulatory 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 100 years. Our research and development activities are responsible for the discovery and development of most of the products we offer today. We invest heavily in research and development because we believe it is critical to our long-term competitiveness. At the end of 2013, we employed approximately 7,850 people in human pharmaceutical and animal health research and development activities, including a substantial number of physicians, scientists holding graduate or postgraduate degrees, and highly skilled technical personnel. Our research and development expenses were $5.53 billion in 2013, $5.28 billion in 2012, and $5.02 billion in 2011.

Our human pharmaceutical research and development focuses on five therapeutic categories: cancer; endocrine diseases, including diabetes and musculoskeletal disorders; central nervous system and related diseases; autoimmune diseases; and cardiovascular diseases. However, we remain opportunistic, selectively pursuing promising leads in other therapeutic areas. We are also investing in molecules with multi-pathway pharmacological efficacy to expand the potential of our therapeutic portfolio. We have a strong biotechnology research program, with approximately half of our clinical-stage pipeline, and more than half of our late-stage pipeline, currently consisting of biotechnology molecules. In addition to discovering and developing new molecular entities, we seek to expand the value of existing products through new uses, formulations, and therapeutic approaches that provide additional value to patients. Across all our therapeutic areas, we are increasingly focusing our efforts on tailored therapeutics, seeking to identify and use advanced diagnostic tools and other information to identify specific subgroups of patients for whom our medicines—or those of other companies—will be the best treatment option.

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 seek out external investments in research and technologies that hold the promise to complement and strengthen our own efforts. These investments

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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 needs. Our animal health scientists also leverage discoveries from our human health laboratories to develop products to enhance the health and wellbeing of livestock 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 12 to 15 years or longer. 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. After approval and launch of a product, we expend considerable resources on post-marketing surveillance and additional clinical studies to collect 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. Molecules that have the desired effect on the target and meet other design criteria become “lead” molecules and move to the next phase of development. The probability of any one such lead molecule becoming a commercial product is extremely low.

- Early Development Phase

The early development phase involves refining lead 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. The first human tests (often referred to as Phase I) are normally conducted in small groups of healthy volunteers to assess safety and find the potential dosing range. After a safe dose has been established, the drug is administered to small populations of patients (Phase II) to look for initial signs of efficacy in treating the targeted 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, typically less than 10 percent move on to the product phase. The early development phase normally takes several years to complete.

- Product Phase

Product phase (Phase III) molecules have already demonstrated safety 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 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, the time to final marketing approval can vary from six months to several years, depending on variables such as the disease state, the strength and complexity of the data

presented, the novelty of the target or compound, and the time required for the agency(ies) to evaluate the submission. There is no guarantee that a potential medicine will receive marketing approval, or that decisions on marketing approvals or indications will be consistent across geographic areas.

We believe our investments in research, both internally and in collaboration with others, have been rewarded by the large number of new molecules and new indications for existing molecules that we have in all stages of development. We currently have approximately 60 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 are potential therapies for diabetes, various cancers, Alzheimer's disease, pain, high-risk vascular disease, rheumatoid arthritis, lupus, psoriasis, and psoriatic arthritis. We are studying many other drug candidates in the earlier stages of development, including molecules targeting various cancers, diabetes, Alzheimer's disease, depression, pain, migraine, bipolar disorder, anemia, cardiovascular disease, musculoskeletal disorders, renal diseases, lupus, and Crohn's disease. We are also developing new uses, formulations, or delivery methods for many of these molecules as well as several currently marketed products, including Axiron, Cialis, Effient, Humalog, and Trajenta. See Item 7, "Management's Discussion and Analysis--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 principally from only one source. In the event one of these suppliers was unable to provide the materials or product, we generally have 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.

We produce most of our products in our own facilities. Our principal active ingredient manufacturing occurs at four owned sites in the U.S. as well as owned sites in Ireland, Puerto Rico, and the United Kingdom. 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 take a variety of actions including a company-wide, comprehensive quality system, 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 standards. These tests may involve chemical and physical chemical analyses, microbiological testing, testing in animals, or a combination. Additional assurance of quality is provided by a corporate quality-assurance group that audits

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and monitors all aspects of quality related to human pharmaceutical and animal health manufacturing procedures and systems in the parent company, subsidiaries and affiliates, and 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 5, 2014, or on the date his or her successor is chosen and qualified. No director or executive officer has a "family relationship" with any other director or executive officer of the company, as that term is defined for purposes of this disclosure requirement. There is no understanding between any executive officer and any other person pursuant to which the executive officer was selected.

Name	Age	Offices and Business Experience
John C. Lechleiter, Ph.D.	60	Chairman (since January 2009), President (since October 2005), Chief Executive Officer (since April 2008), and a Director (since October 2005)
Melissa S. Barnes	45	Senior Vice President, Enterprise Risk Management and Chief Ethics and Compliance Officer (since January 2013)
Enrique A. Conterno	47	Senior Vice President and President, Lilly Diabetes (since November 2009)
Maria A. Crowe	54	President, Manufacturing Operations (since January 2012)
Stephen F. Fry	48	Senior Vice President, Human Resources and Diversity (since February 2011) and interim Chief Information Officer (since May 2013)
Michael J. Harrington	51	Senior Vice President and General Counsel (since January 2013)
Jan M. Lundberg, Ph.D.	60	Executive Vice President, Science and Technology, and President, Lilly Research Laboratories (since January 2010). From 2002 until he joined Lilly in January 2010, Dr. Lundberg was executive vice president and head of discovery research at AstraZeneca.
Susan Mahony, Ph.D.	49	Senior Vice President and President, Lilly Oncology (since February 2011)
Barton R. Peterson	55	Senior Vice President, Corporate Affairs and Communications (since June 2009). Mr. Peterson served as mayor of Indianapolis, Indiana from 2000 to 2007. From 2008 to 2009, he was managing director at Strategic Capital Partners, LLC, and distinguished visiting professor of public policy at Ball State University.
Derica W. Rice	49	Executive Vice President, Global Services (since January 2010) and Chief Financial Officer (since May 2006)
David A. Ricks	46	Senior Vice President and President, Lilly Bio-Medicines (since January 2012)
Jeffrey N. Simmons	46	Senior Vice President and President, Elanco Animal Health (since January 2008)
Jacques Tapiero	55	Senior Vice President and President, Emerging Markets (since January 2010) (retired January 2014)
Fionnuala M. Walsh	54	Senior Vice President, Global Quality (since July 2007)
Alfonso Zulueta	51	Senior Vice President and President, Emerging Markets (since January 2014)

Employees

At the end of 2013, we employed approximately 37,925 people, including approximately 21,425 employees outside the United States. 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 19, 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 major 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 19, 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 foreign exchange risk through various hedging techniques including the use of foreign currency contracts.

Available Information on Our Website

We make available through our company website, free of charge, our company filings with the SEC as soon as reasonably practicable after we electronically file them with, or furnish them to, the SEC. These include our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements, registration statements, and any amendments to those documents. The company website link to our SEC filings is http://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 http://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.

- Pharmaceutical research and development is very costly and highly uncertain; we may not succeed in developing or acquiring commercially successful products to replace revenues of products losing 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 typically takes a decade or more and often costs well in excess of $1 billion. Failure can occur at any point in the process, including late in the process 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 and payer reimbursement, limited scope of approved uses, difficulty or excessive costs to manufacture, or infringement of the patents or intellectual property rights of others. Regulatory agencies are establishing increasingly high hurdles for the efficacy and safety of new products; delays and uncertainties in the FDA approval process and the approval processes in other countries can result in delays in product launches and lost market opportunity. In addition, it can be very difficult to predict sales growth rates of new products.

We cannot state with certainty when or whether our products now under development will be approved or launched; 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 sales 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.

- We face intense competition from multinational pharmaceutical companies, biotechnology companies, and lower-cost generic manufacturers.

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 versions of other products in the same therapeutic class as our branded products. See Item 1, “Business—Competition,” 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 may result in rapid and severe declines in revenues.

A number of our top-selling human pharmaceutical products recently have 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 United States, as illustrated in the tables below:

Product	U.S. Revenues (2013) ($ in millions)	Percent of Worldwide Revenues (2013)	U.S. Patent / Data Protection
Cymbalta	$3,960.8	17%	Compound patent plus pediatric exclusivity December 2013
Humalog	1,521.4	7%	Compound patent May 2013
Alimta	1,209.1	5%	Compound patent plus pediatric exclusivity 2017; Vitamin dosage regimen patent plus pediatric exclusivity 2022
Cialis	942.8	4%	Compound patent 2017
Evista	772.0	3%	Use patents March 2014
Strattera	446.3	2%	Compound patent plus pediatric exclusivity 2017
Effient	376.9	2%	Compound patent 2017

Product	Revenues Outside U.S. (2013) ($ in millions)	Percent of Worldwide Revenues (2013)	Patent / Data Protection - Major Europe / Japan
Alimta	$1,493.9	6%	Major European countries: compound patent 2015, vitamin dosage regimen patent 2021 Japan: compound patent 2015, use patent to treat cancer concomitantly with vitamins 2021
Cialis	1,216.6	5%	Major European countries: compound patent 2017
Cymbalta	1,123.6	5%	Major European countries: data package protection 2014 Japan: data package protection 2018
Zyprexa	1,071.2	5%	Japan: Compound patent 2015

For non-biological 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. For biological products (such as Humalog, Humulin, and Erbitux), 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—Legal, Regulatory, and Other Matters,” and Item 1, "Business—Patents, Trademarks, and Other Intellectual Property Rights," for more details.

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- Our long-term success depends on intellectual property protection; if our intellectual property rights are invalidated or circumvented, 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.

Intellectual property protection varies throughout the world and is subject to change over time. In the U.S., the Hatch-Waxman Act provides generic companies powerful incentives to seek to invalidate our human pharmaceutical patents; as a result, we expect that our U.S. patents on major pharmaceutical products will be routinely challenged, and there can be no assurance that our patents will be upheld. We face 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 sales. 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,” and Item 8, "Financial Statements and Supplementary Data—Note 16, Contingencies," for more details.

- Our human pharmaceutical business is subject to increasing government price controls and other restrictions on pricing, reimbursement, and access for our drugs.

The continuing prominence of U.S. budget deficits as both a policy and political issue increases the risk that taxes, fees, rebates, or other federal measures that would further reduce pharmaceutical companies’ revenue or increase expenses may be enacted. Certain federal and state health care proposals, including state price controls, continue to be debated, and could place downward pressure on pharmaceutical industry sales or prices. The Medicare Independent Payment Advisory Board established under the Affordable Care and Patient Protection Act is empowered to recommend cost reduction policies under certain circumstances. These proposals, if implemented, could negatively affect revenues.

International operations also are generally subject to extensive price and market regulations. Proposals for cost-containment measures are pending in a number of countries, including proposals that would directly or indirectly impose additional price controls, limit access to or reimbursement for our products, or reduce the value of our intellectual-property protection. Such proposals are expected to increase in both frequency and impact, given the pressures on national and regional health care budgets as a result of continued austerity measures being pursued in a number of countries and the desire to manage health expenses carefully even as economies recover. In addition, governments in many emerging markets are becoming increasingly active in expanding the country’s health care system offerings. Some governments may adopt a generics-only policy which reduces current and future access to our human pharmaceutical products. Others may use some of the approaches to restrict pricing, reimbursement and access outlined above.

We expect pricing, reimbursement, and access pressures from both governments and private payers inside and outside the U.S. to become more severe. See Item I, “Business—Regulations Affecting Human Pharmaceutical Pricing, Reimbursement, and Access,” for more details.

- 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 Lilly, 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, interruption of production leading to product shortages, and delays in the approvals of new products pending resolution of the issues. We are now operating under a Corporate Integrity Agreement with the Office of Inspector

General of the U.S. Department of Health and Human Services that requires us to maintain comprehensive compliance programs governing our research, manufacturing, and sales and marketing of pharmaceuticals. A material failure to comply with the agreement could result in severe sanctions to the company. See Item 1, “Business—Regulation of our Operations,” for more details.

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

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. 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 these sources 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 approval for marketing 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 primarily Byetta®, Darvon,™ Prozac, and Actos®. See Item 8, “Financial Statements and Supplementary Data—Note 16, Contingencies,” and Item 3, “Legal Proceedings,” for more information on our current product liability litigation. 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.

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

Pharmaceutical manufacturing is complex and highly regulated. Manufacturing difficulties at our facilities or contracted facilities, or the failure or refusal of a contract manufacturer to supply contracted quantities, could result in product shortages, leading to lost revenue. Such difficulties or disruptions could result from quality or regulatory compliance problems, natural disasters, or 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 of pharmaceutical manufacturing capacity, it is possible that we could have difficulty meeting demand for new products. See Item 1, “Business—Raw Materials and Product Supply,” for more details.

- We depend on information technology systems and infrastructure to operate our business; system inadequacies or operating failures could harm our business.

We rely to a large extent on the efficient and uninterrupted operation of complex information technology systems and networks, some of which are within the company and some of which are outsourced. These systems and networks are potentially vulnerable to damage or interruption from a variety of sources, including energy or telecommunications failures, breakdowns, natural disasters, terrorism, war, computer malware or other malicious intrusions, and random attacks. To date, system interruptions have been infrequent and have not had a material impact on our consolidated results of operations. We have implemented extensive measures to prevent, respond to, and minimize the impact of system interruptions. However, there can be no assurance that these efforts will prevent future interruptions that would have a material adverse effect on our business.

- Unauthorized disclosures of our trade secrets and other confidential data could impair our valuable intellectual property, harm our competitive position, and expose us to regulatory penalties.

A great deal of sensitive, confidential data is stored in our information systems and networks, including valuable trade secrets and intellectual property, corporate strategic plans, marketing plans, customer information, and personally identifiable information (such as employee and patient information). Some of this information is created, accessed, and/or maintained by third parties. The confidentiality of this information may be breached through malicious intrusions by private or governmental actors through human or electronic means, including “hacking” or “cyber-attacks,” or through negligent or wrongful conduct by employees or others with permitted access to our systems and data. The rapid growth of social media exacerbates the risk of confidentiality breaches. Unauthorized disclosure of trade secret information could impair our ability to secure and maintain patent rights and cause us to lose other competitive advantages. Unauthorized disclosure of personally identifiable information could expose us to sanctions for violations of data privacy laws and regulations and could damage the public trust in our company. Breaches of our data

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security may be very difficult to detect, and once detected, their impact may be very difficult to assess. To date, the data security breaches of which we have become aware have been infrequent in occurrence and, to the extent we have been able to measure their financial impact on our consolidated results of operations, such impact has not been material. We have invested and continue to invest to prevent, monitor, detect, and respond to data security breaches by strengthening our information technology systems, business processes, and training, and strengthening data protection requirements for third parties that hold our confidential information. However, despite these efforts, we expect data security breaches to continue, and there can be no assurance that these efforts will prevent data security breaches that would have a material adverse effect on our business.

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

We utilize third parties, including suppliers, alliances with other pharmaceutical and biotechnology companies, and third-party service providers, for selected aspects of product development, the manufacture and commercialization of certain products, support for information technology systems, and certain financial transactional processes. Outsourcing these functions involves the risk that the third parties may not perform to our standards or legal requirements, may not produce results 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 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, increased generic competition; 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 the 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.

- Worsening economic conditions could adversely affect our business and operating results.

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

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

Changes in tax laws, including laws related to the remittance of foreign earnings or investments in foreign countries with favorable tax rates, and settlements of federal, state, and foreign tax audits, can affect our results of operations. The Obama administration has proposed changes to the manner in which the U.S. would tax the international income of U.S.-based companies. There have also been tax proposals under discussion or introduced in the U.S. Congress that could change the manner in which, and rate at which, income of U.S. companies would be taxed. While it is uncertain how the U.S. Congress may address U.S. tax policy matters in the future, reform of U.S. taxation, including taxation of international income, will continue to be a topic of discussion for the U.S. Congress and the Obama administration. A significant change to the U.S. tax system, including changes to the taxation of international income, could have a material adverse effect on our results of operations.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our principal domestic and international executive offices are located in Indianapolis. At December 31, 2013, we owned 12 production and distribution sites in the U.S. and Puerto Rico. Together with the corporate administrative offices, these facilities contain an aggregate of approximately 10.1 million square feet of floor area dedicated to production, distribution, and administration. Major production sites include Indianapolis and Clinton, Indiana; Carolina, Puerto Rico; and Branchburg, New Jersey.

We own production and distribution sites in 11 countries outside the U.S. and Puerto Rico, containing an aggregate of approximately 3.4 million square feet of floor area. Major production sites include facilities in France, the United Kingdom, Spain, Ireland, Italy, Mexico, and Brazil.

In the U.S., our research and development facilities contain an aggregate of approximately 3.8 million square feet of floor area, primarily consisting of owned facilities located in Indianapolis. We also lease smaller sites in San Diego and New York City. Outside the U.S., we own smaller research and development facilities in the United Kingdom and 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 16, Contingencies." While it is not possible to determine the outcome of the legal actions, investigations, and proceedings brought against us, we believe that, except as otherwise specifically noted in Item 8—Note 16, 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 16 to the Consolidated Financial Statements

See Item 8, "Financial Statements and Supplementary Data—Note 16, Contingencies," for information on various legal proceedings, including but not limited to:

- The patent litigation and administrative proceedings involving Alimta
- The U.S. product liability litigation involving Prozac and Byetta
- The employee litigation in Brazil.

That information is incorporated into this Item by reference.

Other Product Liability Litigation

We are currently a defendant in a variety of other product liability lawsuits in the U.S. involving primarily Darvon, Actos, Cymbalta, diethylstilbestrol (DES), and Zyprexa.

Along with several other manufacturers, we have been named as a defendant in approximately 55 cases in the U.S. involving approximately 1,700 claimants related to the analgesic Darvon and related formulations of propoxyphene. Additionally, approximately 80 cases involving approximately 225 claimants were recently dismissed and are on appeal to the Sixth Circuit. Almost all of the active cases have been consolidated in a federal multi-district litigation in the Eastern District of Kentucky or are pending in a coordinated state court proceeding in California. A putative class action was filed in the U.S. District Court for the Eastern District of

Louisiana (Ballard, et al. v. Eli Lilly and Company et al.) against Lilly and other manufacturers seeking to assert product liability claims on behalf of U.S. residents who ingested propoxyphene pain products and allegedly sustained personal injuries. Lilly was dismissed from Ballard with prejudice on a dispositive motion and the dismissal is now final and non-appealable. We transferred the U.S. regulatory approvals and all marketing rights to our propoxyphene products in 2002 to NeoSan Pharmaceuticals, Inc. (an affiliate of aaiPharma, Inc.), which subsequently transferred all such approvals and marketing rights to Xanodyne Pharmaceuticals, Inc. We believe these claims are without merit and are prepared to defend against them vigorously.

We have been named along with Takeda Chemical Industries, Ltd., and Takeda affiliates as a defendant in product liability cases in the U.S. related to the diabetes medication Actos, which we co-promoted with Takeda in the U.S. from 1999 until September 2006. In addition, we have been named along with Takeda as a defendant in three purported product liability class actions in Canada related to Actos, including one in Ontario (Casseres et al. v. Takeda Pharmaceutical North America, Inc., et al.), one in Quebec (Whyte et al. v. Eli Lilly et al.), and one in Alberta (Epp v. Takeda Canada et al.). We promoted Actos in Canada until 2009. In general, plaintiffs in these actions allege that Actos caused or contributed to their bladder cancer. Under our agreement with Takeda, we will be indemnified by Takeda for our losses and expenses with respect to the U.S. litigation and other related expenses in accordance with the terms of the indemnification agreement. We believe these claims are without merit and are prepared to defend against them vigorously.

In October 2012, we were named as a defendant in a purported class-action lawsuit in the U.S. District Court for the Central District of California (Saavedra et al v. Eli Lilly and Company) involving Cymbalta. The plaintiffs assert claims under the consumer protection statutes of four states and seek declaratory, injunctive, and monetary relief for various alleged injuries arising from discontinuing treatment with Cymbalta. The plaintiffs purport to represent a class of all persons within the U.S. who purchased and/or paid for Cymbalta. We believe these claims are without merit and are prepared to defend against them vigorously.

We have been named as a defendant in fewer than 10 U.S. lawsuits involving fewer than 10 claimants seeking to recover damages for health issues experienced by children or grandchildren of women who were prescribed DES during pregnancy in the 1950s and 1960s. We believe these claims are without merit and are prepared to defend against them vigorously.

We are a defendant in approximately 10 Zyprexa product liability lawsuits in the U.S. covering approximately 10 plaintiffs. The lawsuits allege a variety of injuries from the use of Zyprexa. The claims seek substantial compensatory and punitive damages and typically accuse us of inadequately testing for and warning about side effects of Zyprexa. Many of the claims also allege that we improperly promoted the drug. We believe these claims are without merit and are prepared to defend against them vigorously.

Other Patent Litigation

In January 2014, Sanofi-Aventis U.S. LLC (Sanofi) filed a lawsuit against us in the U.S. District Court for the District of Delaware alleging patent infringement with respect to our insulin glargine product for which we are seeking approval from the FDA. See Item 7, "Management's Discussion and Analysis—Executive Overview, Late-Stage Pipeline," for additional details.

In Canada, several generic companies 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. and Teva Canada Limited, are separately pursuing claims for damages arising from Lilly’s enforcement of the patent under Canadian regulations. The total amount of damages that may be awarded will be determined through separate trials, which have not yet been scheduled.

Marketing Practices Investigations

In August 2003, we received notice that the staff of the SEC was conducting an investigation into the compliance by Lilly's Polish subsidiary with the FCPA. Subsequently, we were notified that the SEC had expanded its investigation to other countries and that the DOJ was conducting a parallel investigation. In December 2012, we announced that we had reached an agreement with the SEC to settle its investigation. The settlement relates to certain activities of Lilly subsidiaries in Brazil, China, Poland, and Russia from 1994 through 2009. Without admitting or denying the

allegations, we consented to pay a civil settlement amount of

$29.4 million and agreed to have an independent compliance consultant conduct a 60-day review of our internal controls and compliance program related to the FCPA. Our understanding is that the DOJ investigation remains open.
In January 2009, as part of the resolution of a government investigation related to our U.S. marketing and promotional practices with respect to Zyprexa, we entered into a Corporate Integrity Agreement with the U.S. Department of Health and Human Services Office of Inspector General which requires us to maintain our compliance program and to undertake a set of defined corporate integrity obligations for five years. The agreement also provides for an independent third-party review organization to assess and report on the company's systems, processes, procedures, and practices related to compliance with health care laws.

Shareholder Derivative Litigation

In 2011, the company received a letter sent on behalf of shareholder Kim Barovic demanding that the board of directors cause the company to take (1) legal action against certain of its current and former officers and board members for allegedly causing damage to the company by failing to exercise proper oversight over the company's compliance with the FCPA, and (2) all necessary actions to reform and improve certain corporate governance and internal procedures.The board established a committee of disinterested directors to consider the demands and determine what action, if any, the company should take in response. In February 2013, following its investigation, the committee determined, among other things, that it would not be in the best interests of the company to take any of the actions demanded by Ms. Barovic.
In August 2013, Ms. Barovic brought a shareholder derivative suit (Barovic v. Lechleiter, et al.), filed in Marion County (Indiana) Superior Court. The suit seeks to maintain the action purportedly on behalf of the company against certain current and former directors and officers of the company and alleges breach of fiduciary duty, waste of corporate assets, and unjust enrichment. The company is named in the suit as a nominal defendant. The suit does not seek damages from the company, but instead requests damages in an unspecified amount and certain equitable relief on the company's behalf. The company believes the suit is without merit and all of the individual defendants intend to defend themselves vigorously against the allegations in the complaint.
Other Matters
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)" and Item 8, "Financial Statements and Supplementary Data—Note 20, Selected Quarterly Data (unaudited).” That information is incorporated here by reference.

The following table summarizes the activity related to repurchases of our equity securities during the fourth quarter ended December 31, 2013:

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 2013	2,550.0	$50.40	2,550.0	$4,871.4
November 2013	7,378.9	50.32	7,378.9	4,500.0
December 2013	—	—	—	4,500.0
Total	9,928.9	50.34	9,928.9	

In October 2013, we announced a $5.00 billion share repurchase program. During the fourth quarter of 2013, we purchased $500.0 million of shares associated with that program. As of December 31, 2013, there were $4.5 billion of shares remaining in that program. During 2013 and 2012, we repurchased $1.10 billion and $400.0 million, respectively, of shares associated with the $1.50 billion share repurchase program announced in 2012. During 2012, we also repurchased $419.2 million of the shares remaining under the $3.00 billion share repurchase program announced in 2000. No shares were repurchased during the year ended December 31, 2011.

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 2009 through 2013. The graph assumes that, on December 31, 2008, 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 2008

Comparison of Five-Year Cumulative Total Return Among Lilly, S&P 500 Stock Index, Peer Group[1], and Peer Group (Previous)[2]

	Lilly	Peer Group	Peer Group (Previous)	S&P 500
Dec-08	$100.00	$100.00	$100.00	$100.00
Dec-09	$93.75	$113.71	$112.71	$126.46
Dec-10	$97.23	$112.80	$112.66	$145.51
Dec-11	$121.69	$130.63	$128.73	$148.59
Dec-12	$151.21	$153.53	$149.26	$172.37
Dec-13	$162.16	$211.87	$194.27	$228.19

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 2013: Abbott Laboratories; AbbVie Inc.; Allergan 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, Inc.; Merck & Co., Inc.; Novartis AG.; Pfizer Inc.; and Sanofi-Aventis.

2 In an effort to broaden our peer group for benchmarking purposes, we revised our peer group in 2013 by adding Allergan Inc., Biogen Idec Inc., Celgene Corporation, Gilead Sciences Inc., and Medtronic, Inc., and removed Takeda Pharmaceuticals Company. The new peer group includes biotech companies we directly compete with for talent and business, and improves the balance of companies with respect to revenue size. AbbVie Inc. was also added to the current peer group upon its spinoff from Abbott Laboratories.

Item 6. Selected Financial Data (unaudited)

ELI LILLY AND COMPANY AND SUBSIDIARIES (Dollars in millions, except revenue per employee and per-share data)	2013	2012	2011	2010	2009
Operations					
Revenue	$23,113.1	$22,603.4	$24,286.5	$23,076.0	$21,836.0
Cost of sales	4,908.1	4,796.5	5,067.9	4,366.2	4,247.0
Research and development	5,531.3	5,278.1	5,020.8	4,884.2	4,326.5
Marketing, selling, and administrative	7,125.6	7,513.5	7,879.9	7,053.4	6,892.5
Other	(341.2)	(392.9)	968.4	247.0	1,012.2
Income before income taxes	5,889.3	5,408.2	5,349.5	6,525.2	5,357.8
Income taxes	1,204.5	1,319.6	1,001.8	1,455.7	1,029.0
Net income	4,684.8	4,088.6	4,347.7	5,069.5	4,328.8
Net income as a percent of revenue	20.3%	18.1%	17.9%	22.0%	19.8%
Net income per share— diluted	$4.32	$3.66	$3.90	$4.58	$3.94
Dividends declared per share	1.96	1.96	1.96	1.96	1.96
Weighted-average number of shares outstanding—diluted (thousands)	1,084,766	1,117,294	1,113,967	1,105,813	1,098,367
Financial Position					
Current assets	$13,104.7	$13,038.7	$14,248.2	$14,840.0	$12,486.5
Current liabilities	8,916.6	8,389.5	8,930.9	6,926.9	6,568.1
Property and equipment—net	7,975.5	7,760.2	7,760.3	7,940.7	8,197.4
Total assets	35,248.7	34,398.9	33,659.8	31,001.4	27,460.9
Long-term debt	4,200.3	5,519.4	5,464.7	6,770.5	6,634.7
Total equity	17,640.7	14,773.9	13,535.6	12,412.8	9,525.3
Supplementary Data					
Return on total equity	29.5%	27.8%	31.4%	46.1%	51.0%
Return on assets	13.8%	12.3%	13.4%	17.7%	15.8%
Capital expenditures	$1,012.1	$905.4	$672.0	$694.3	$765.0
Depreciation and amortization	1,445.6	1,462.2	1,373.6	1,328.2	1,297.8
Effective tax rate	20.5%	24.4%	18.7%	22.3%	19.2%
Revenue per employee	$609,000	$590,000	$638,000	$602,000	$540,000
Number of employees	37,925	38,350	38,080	38,350	40,360
Number of shareholders of record	31,900	33,600	35,200	36,700	38,400

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

RESULTS OF OPERATIONS

Executive Overview

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

Financial Results

Worldwide total revenue increased 2 percent to $23.11 billion in 2013, driven by growth in several products, including Cialis®, Humalog®, Trajenta®, Alimta®, Forteo®, and animal health products, partially offset by the continued erosion of Zyprexa® sales following the loss of patent exclusivity in the U.S. and most major markets outside Japan. In 2013, net income increased 15 percent to $4.68 billion and EPS increased 18 percent to $4.32, compared to 2012 net income and EPS of $4.09 billion and $3.66, respectively. The increases were due to higher gross margin, lower marketing, selling, and administrative expenses, and, to a lesser extent, a lower effective tax rate, partially offset by higher research and development expenses and lower other income. EPS in 2013 also benefited from a lower number of shares outstanding compared to 2012 as a result of our share repurchase programs.

The following highlighted items affect comparisons of our 2013 and 2012 financial results:

2013

Collaborations (Note 4 to the consolidated financial statements)

- We recognized income of $495.4 million (pretax), or $0.29 per share, related to the transfer to Amylin Pharmaceuticals, Inc. (Amylin) of exenatide commercial rights in all markets outside the United States.

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

- We recognized acquired IPR&D charges of $57.1 million (pretax), or $0.03 per share, resulting from our acquisition of all development and commercial rights for a calcitonin gene-related peptide (CGRP) antibody currently being studied as a potential treatment for the prevention of frequent, recurrent migraine headaches, following a successful Phase II proof-of-concept study.

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

- We recognized charges of $120.6 million (pretax), or $0.08 per share, primarily related to severance costs for actions taken to reduce our cost structure and global workforce, as well as other costs associated with the anticipated closure of a packaging and distribution facility in Germany.

2012

Collaborations (Note 4 to the consolidated financial statements)

- We recognized income of $787.8 million (pretax), or $0.43 per share, related to the early payment of the exenatide revenue-sharing obligation following the completion of Amylin's acquisition by Bristol-Myers Squibb (BMS).

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

- We recognized asset impairment, restructuring, and other special charges of $281.1 million (pretax), or $0.16 per share, consisting of an intangible asset impairment related to liprotamase, restructuring charges related to initiatives to reduce our cost structure and global workforce, charges associated with the decision to stop development of a delivery device platform, and charges related to changes in returns reserve estimates for the withdrawal of Xigris™.

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 60 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 submitted for regulatory review for potential use in the disease described. The quarter the NME initially was submitted for any indication is shown in parentheses:

Dulaglutide* (Q3 2013)—a long-acting analog of glucagon-like peptide 1 for the treatment of type 2 diabetes.

Empagliflozin (Q1 2013)—a sodium glucose co-transporter-2 (SGLT-2) inhibitor for the treatment of type 2 diabetes (in collaboration with Boehringer Ingelheim).

New insulin glargine product (Q2 2013)—a new insulin glargine product for the treatment of type 1 and type 2 diabetes (in collaboration with Boehringer Ingelheim).

Ramucirumab* (Q3 2013)—an anti-vascular endothelial growth factor receptor-2 (VEGFR-2) monoclonal antibody submitted for regulatory review as a single agent for the treatment of gastric cancer. We intend to submit an application for ramucirumab in combination with paclitaxel for the treatment of gastric cancer to regulatory authorities in 2014. We also intend to submit our first application for ramucirumab in combination with chemotherapy (docetaxel) in patients with second-line non-small cell lung cancer (NSCLC) to regulatory authorities in 2014. In addition, we are currently studying ramucirumab in Phase III studies for the treatment of liver cancer and colorectal cancer.

The following NMEs are currently in Phase III clinical trial testing for potential use in the diseases described. The quarter in which the NME initially entered Phase III for any indication is shown in parentheses:

Baricitinib (Q4 2012)—a Janus tyrosine kinase (JAK 1 and JAK 2) inhibitor for the treatment of rheumatoid arthritis (in collaboration with Incyte Corporation).

Basal insulin peglispro (formerly known as novel basal insulin analog)* (Q4 2011)—a novel basal insulin for the treatment of type 1 and type 2 diabetes.

Evacetrapib (Q4 2012)—a cholesteryl ester transfer protein (CETP) inhibitor for the treatment of high-risk vascular disease.

Ixekizumab* (Q4 2011)—a neutralizing monoclonal antibody to interleukin-17A (IL-17) for the treatment of psoriasis and psoriatic arthritis.

Necitumumab* (Q4 2009)—an anti-epidermal growth factor receptor (EGFR) monoclonal antibody for the treatment of squamous NSCLC.

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

Tabalumab* (Q4 2010)—an anti-B-cell activating factor (BAFF) monoclonal antibody for the treatment of systemic lupus erythematosus (lupus).

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)). Tanezumab is currently subject to a partial clinical hold by the U.S. Food and Drug Administration (FDA) (see Note 4 to the consolidated financial statements).

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

The following are late-stage pipeline updates since January 1, 2013:

Basal insulin peglispro—In January 2013, we announced plans for the 2013 and 2014 initiation of the remainder of the pre-planned clinical trials for the molecule. These studies will be conducted to support regulatory submissions and evaluate safety, efficacy, and differentiation of the molecule. These studies are in addition to the five ongoing IMAGINE clinical trials.

Dulaglutide—In April 2013, we announced that the Phase III AWARD-2 and AWARD-4 trials studying dulaglutide as an investigational once-weekly treatment for type 2 diabetes met the primary endpoints related to reduction in hemoglobin A1c (HbA1c) compared to insulin glargine, and that the 1.5 mg dose demonstrated statistically superior reduction in HbA1c from baseline compared to insulin glargine in both trials. In the third quarter of 2013, we filed for regulatory review in both the U.S. and Europe.

Edivoxetine—In December 2013, we announced the decision to stop development of edivoxetine as an add-on treatment for depression due to lack of efficacy in three acute randomized placebo-controlled Phase III studies. The decision was not based on safety concerns.

Empagliflozin—In January 2013, we announced positive top-line results for four completed Phase III clinical trials studying empagliflozin for treatment of patients with type 2 diabetes. In all four studies, the primary efficacy endpoint, defined as significant change in HbA1c from baseline compared to placebo, was met with empagliflozin (10 and 25 mg) taken once daily. The pivotal studies for empagliflozin were completed in 2012. In the first quarter of 2013, Boehringer Ingelheim filed for regulatory review in both the U.S. and Europe. The Boehringer Ingelheim manufacturing facility where empagliflozin is being produced is subject to an FDA warning letter; however, it is not clear if this will impact the timing of FDA action for empagliflozin. In the fourth quarter of 2013, Boehringer Ingelheim filed for regulatory review in Japan.

Enzastaurin—In May 2013, we announced the decision to stop development of enzastaurin as a result of negative clinical trial results from the Phase III PRELUDE study, which explored the molecule as a monotherapy in the prevention of relapse for patients with diffuse large B-cell lymphoma.

Ixekizumab—In January 2013, we initiated Phase III clinical trial testing for ixekizumab as a potential treatment for psoriatic arthritis.

Liprotamase—In December 2013, we made the decision to discontinue further development of liprotamase.

Necitumumab—In August 2013, we announced that the Phase III study, SQUIRE, met its primary endpoint, finding that patients with stage IV metastatic squamous NSCLC experienced increased overall survival when administered necitumumab in combination with gemcitabine and cisplatin as a first-line treatment, as compared to chemotherapy alone. We anticipate filing for regulatory review before the end of 2014.

New insulin glargine product—In July 2013, we and Boehringer Ingelheim announced that the marketing authorization application for our new insulin glargine product, filed in June 2013 through the biosimilar pathway, was accepted for review by the European Medicines Agency. In the fourth quarter of 2013, we filed for regulatory review in the U.S. and Japan.

In January 2014, Sanofi-Aventis U.S. LLC (Sanofi) filed a lawsuit against us in the U.S. District Court for the District of Delaware alleging patent infringement with respect to our insulin glargine product for which we are seeking approval from the FDA. Sanofi asserts infringement of two patents relating to pen injector devices and two patents relating to insulin glargine formulations. Under the Hatch-Waxman Act, the initiation of the lawsuit automatically invokes a stay of FDA approval of the product for a period of 30 months, which may be shortened in the event of an earlier decision in our favor. We believe the lawsuit is without merit, and we are prepared to vigorously defend against the allegations.

Ramucirumab—Our rolling submission to the FDA for ramucirumab as a single-agent biologic therapy in patients with advanced gastric cancer following progression on prior chemotherapy was completed in the third quarter of 2013, and received Priority Review status by the FDA in October 2013. Our regulatory submission in Europe for the same indication was also completed in the third quarter of 2013. In September 2013, we announced that the RAINBOW trial, a global Phase III study of ramucirumab in combination with paclitaxel in patients with advanced gastric cancer, met its primary endpoint of improved overall survival and a secondary endpoint of improved progression-free survival. We intend to submit an application for this indication to regulatory authorities in 2014. In September 2013, we also announced that a separate global Phase III study of ramucirumab in women with locally recurrent or metastatic breast cancer, ROSE, did not meet its primary endpoint of

progression-free survival. We do not plan to submit an application to regulatory authorities for ramucirumab in the first-line treatment of locally recurrent or metastatic HER2-negative breast cancer based on the results from the ROSE study. In February 2014, we announced that the REVEL trial, a global Phase III study of ramucirumab in combination with chemotherapy (docetaxel) in patients with second-line NSCLC, met its primary endpoint of improved overall survival and a secondary endpoint of improved progression-free survival. We intend to submit the first application for this indication to regulatory authorities in 2014.

Tabalumab—In February 2013, we announced our decision to discontinue the Phase III rheumatoid arthritis program for tabalumab due to lack of efficacy. The decision was not based on safety concerns. The tabalumab Phase III program for lupus is continuing as planned.

Tanezumab—In October 2013, we entered into a collaboration agreement with Pfizer to jointly develop and globally commercialize tanezumab for the potential treatment of osteoarthritis pain, chronic low back pain, and cancer pain. Tanezumab is currently in Phase III clinical development and is subject to a partial clinical hold by the FDA pending submission of nonclinical data to the FDA. Pfizer anticipates submitting that data in 2014. See Note 4 to the consolidated financial statements for additional details.

There are many difficulties and uncertainties inherent in pharmaceutical research and development (R&D) and the introduction of new products. A high rate of failure is inherent in new drug discovery and development. The process to bring a drug from the discovery phase to regulatory approval can take 12 to 15 years or longer and cost more than $1 billion. Failure can occur at any point in the process, including late in the process after substantial investment. As a result, most 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. Delays and uncertainties in the regulatory approval processes in the U.S. and other countries can result in delays in product launches and lost market opportunities. Consequently, it is very difficult to predict which products will ultimately be approved and the sales growth of those products.

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

Legal, Regulatory, and Other Matters

We depend on patents or other forms of intellectual-property protection for most of our revenues, cash flows, and earnings. Cymbalta® lost patent exclusivity in the U.S. in December 2013, resulting in the immediate entry of several generic competitors. We also expect the loss of U.S. patent protection for Evista® in March 2014 to result in immediate generic competition. We will lose our data package protection for Cymbalta in major European countries in 2014; however, we do not anticipate the entry of generic competition in most of these countries until 2015. The entry of generic competition in each of these markets is expected to cause a rapid and severe decline in revenue from the affected products, having a material adverse effect on our consolidated results of operations and cash flows.

The U.S. compound patent for Humalog expired in May 2013. The loss of compound patent protection for Humalog has not resulted in a rapid and severe decline in revenue. To date, no biosimilar version of Humalog has been approved in the U.S. or Europe; however, we are aware that other manufacturers have efforts underway to develop biosimilar forms of Humalog, and it is difficult to predict the likelihood, timing, and impact of biosimilars entering the market.

The continuing prominence of U.S. budget deficits as both a policy and political issue increases the risk that taxes, fees, rebates, or other federal measures that would further reduce pharmaceutical companies' revenue

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or increase expenses may be enacted. Certain federal and state health care proposals, including state price controls, continue to be debated, and could place downward pressure on pharmaceutical industry sales or prices. These federal and state proposals, or state price pressures, could have a material adverse effect on our consolidated results of operations.

International operations also are generally subject to extensive price and market regulations. Proposals for cost-containment measures are pending in a number of countries, including proposals that would directly or indirectly impose additional price controls, limit access to or reimbursement for our products, or reduce the value of our intellectual-property protection. Such proposals are expected to increase in both frequency and impact, given the pressures on national and regional health care budgets as a result of continued austerity measures being pursued in a number of countries; the desire to manage health expenses carefully even as economies recover; and the effort in some countries to expand access to health care coverage while seeking savings from the biopharmaceutical sector.

The Obama administration has proposed changes to the manner in which the U.S. would tax the international income of U.S.-based companies. There also have been tax proposals under discussion or introduced in the U.S. Congress that could change the manner in which, and the rate at which, income of U.S. companies would be taxed. While it is uncertain how the U.S. Congress may address U.S. tax policy matters in the future, reform of U.S. taxation, including taxation of international income, will continue to be a topic of discussion for Congress and the Obama administration. A significant change to the U.S. tax system, including changes to the taxation of international income, could have a material adverse effect on our consolidated results of operations. In addition, the Organization for Economic Co-operation and Development recently launched an initiative to analyze and potentially influence international tax policy in the major countries in which we operate. While the outcomes of this initiative are uncertain, significant changes to key elements of the global international tax framework could have a material adverse effect on our consolidated results of operations.

Operating Results—2013

Revenue

Our worldwide revenue for 2013 increased 2 percent, to $23.11 billion, compared with 2012 as an increase of 5 percent due to higher prices was partially offset by a decrease of 2 percent due to the unfavorable impact of foreign exchange rates and a 1 percent decrease due to lower volume. Total revenue in the U.S. increased 5 percent, to $12.89 billion, due to higher prices, partially offset by volume declines for Cymbalta and Zyprexa due to the loss of patent exclusivity. Revenue outside the U.S. decreased 1 percent, to $10.22 billion, due primarily to the unfavorable impact of the continued weakness of the Japanese yen and, to a lesser extent, lower prices, partially offset by increased volume.

The following table summarizes our revenue activity in 2013 compared with 2012:

	Year Ended December 31, 2013			Year Ended December 31, 2012	Percent Change from 2012
Product	U.S.[1]	Outside U.S.	Total	Total	
	(Dollars in millions)				
Cymbalta	$3,960.8	$1,123.6	$5,084.4	$4,994.1	2
Alimta	1,209.1	1,493.9	2,703.0	2,594.3	4
Humalog	1,521.4	1,089.8	2,611.2	2,395.5	9
Cialis	942.8	1,216.6	2,159.4	1,926.8	12
Humulin®	677.2	638.6	1,315.8	1,239.1	6
Forteo	511.4	733.5	1,244.9	1,151.0	8
Zyprexa	123.6	1,071.2	1,194.8	1,701.4	(30)
Evista	772.0	278.4	1,050.4	1,010.1	4
Strattera®	446.3	262.9	709.2	621.4	14
Effient®	376.9	131.8	508.7	457.2	11
Other pharmaceutical products	639.5	1,032.8	1,672.3	1,843.0	(9)
Animal health products	1,226.6	924.9	2,151.5	2,036.5	6
Total net product sales	12,407.6	9,998.0	22,405.6	21,970.4	2
Collaboration and other revenue[2]	482.1	225.4	707.5	633.0	12
Total revenue	$12,889.7	$10,223.4	$23,113.1	$22,603.4	2

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

2 Collaboration and other revenue in 2013 consists primarily of royalties for Erbitux® and revenue associated with Trajenta. Collaboration and other revenue in 2012 also includes revenue associated with exenatide in the United States.

Sales of Cymbalta, a product for the treatment of major depressive disorder, diabetic peripheral neuropathic pain, generalized anxiety disorder, and in the U.S. for the treatment of chronic musculoskeletal pain and the management of fibromyalgia, increased 1 percent in the U.S., driven by higher prices, largely offset by lower demand due to the loss of U.S. patent exclusivity in December 2013, which is causing rapid and severe declines in our Cymbalta sales. Sales outside the U.S. increased 4 percent, driven primarily by increased volume, partially offset by lower prices and the unfavorable impact of foreign exchange rates.

We will lose effective exclusivity for Cymbalta in major European countries upon expiration of our data package protection in 2014; however, because generic manufacturers cannot file for regulatory approval until after our data package protection expires, we do not anticipate the entry of generic competition in most of these countries until 2015. While it is difficult to predict the precise impact on Cymbalta sales, we expect the introduction of generics in these markets to result in a rapid and severe decline in our Cymbalta sales, which will have a material adverse effect on our consolidated results of operations and cash flows.

Sales of Alimta, a treatment for various cancers, increased 8 percent in the U.S., due to higher prices and increased demand. Sales outside the U.S. increased 1 percent, driven by increased volume, partially offset by the unfavorable impact of foreign exchange rates and lower prices.

Sales of Humalog, our injectable human insulin analog for the treatment of diabetes, increased 11 percent in the U.S., driven by higher prices, wholesaler buying patterns, and increased demand. Sales outside the U.S. increased 6 percent, driven by increased volume, partially offset by the unfavorable impact of foreign exchange rates.

Sales of Cialis, a treatment for erectile dysfunction and benign prostatic hyperplasia (BPH), increased 21 percent in the U.S., driven by higher prices. Sales outside the U.S. increased 6 percent, driven by higher prices and increased volume, partially offset by the unfavorable impact of foreign exchange rates.

Sales of Humulin, an injectable human insulin for the treatment of diabetes, increased 14 percent in the U.S., driven by higher prices, partially offset by decreased demand. Sales outside the U.S. decreased 1 percent, driven by the unfavorable impact of foreign exchange rates, partially offset by increased volume.

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Sales of Forteo, an injectable treatment for osteoporosis in postmenopausal women and men at high risk for fracture and for glucocorticoid-induced osteoporosis in men and postmenopausal women, increased 5 percent in the U.S., driven primarily by higher prices. Sales outside the U.S. increased 11 percent, due to increased volume, primarily in Japan, partially offset by the unfavorable impact of foreign exchange rates.

Sales of Zyprexa, a treatment for schizophrenia, acute mixed or manic episodes associated with bipolar I disorder, and bipolar maintenance, decreased 66 percent in the U.S. due to the continued erosion following patent expiration in 2011. Sales outside the U.S. decreased 20 percent, driven by the unfavorable effect of foreign exchange rates, lower volume in markets outside of Japan, and lower prices. Zyprexa sales in Japan were approximately $510 million in 2013, compared to approximately $585 million in 2012, and were negatively impacted by the continued weakness of the Japanese yen.

Sales of Evista, a product for the prevention and treatment of osteoporosis in postmenopausal women and for reduction of risk of invasive breast cancer in postmenopausal women with osteoporosis and postmenopausal women at high risk for invasive breast cancer, increased 10 percent in the U.S., driven by higher prices, partially offset by decreased demand. Sales outside the U.S. decreased 10 percent, driven by the unfavorable impact of foreign exchange rates and lower prices, partially offset by increased volume in Japan.

We will lose effective patent exclusivity for Evista in the U.S. on March 2, 2014. We expect generic competition immediately following the loss of exclusivity. While it is difficult to predict the precise impact on Evista sales, we expect the introduction of generics to result in a rapid and severe decline in our U.S. Evista sales, which will have a material adverse effect on our consolidated results of operations and cash flows.

Sales of Strattera, a treatment for attention-deficit hyperactivity disorder, increased 16 percent in the U.S., driven primarily by higher prices. Sales outside the U.S. increased 11 percent, driven primarily by increased volume in Japan, partially offset by lower prices and the unfavorable impact of foreign exchange rates.

Sales of Effient, a product 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, increased 11 percent in the U.S., driven primarily by higher prices. Sales outside the U.S. increased 12 percent, driven primarily by increased volume.

Animal health product sales in the U.S. increased 6 percent driven primarily by increased volume for Trifexis® and, to a lesser extent, higher prices. Sales outside the U.S. increased 6 percent, driven by increased volume and, to a lesser extent, higher prices, partially offset by the unfavorable impact of foreign exchange rates.

Gross Margin, Costs, and Expenses

Gross margin as a percent of total revenue remained at 78.8 percent in 2013 as higher prices were offset by the adverse impact of foreign exchange rates on international inventories sold, which significantly decreased the cost of sales in 2012.

Marketing, selling, and administrative expenses decreased 5 percent to $7.13 billion in 2013, driven primarily by lower selling and marketing expenses resulting from ongoing cost-containment efforts, including the previously announced reduction in U.S. sales and marketing activities in anticipation of the loss of patent exclusivity for Cymbalta and Evista, as well as the impact of foreign exchange rates.

Research and development expenses increased 5 percent to $5.53 billion in 2013, due to higher research and clinical development expenses, including $97.2 million of milestone payments made to Boehringer Ingelheim following regulatory submissions for empagliflozin.

We recognized an acquired IPR&D charge of $57.1 million in 2013 resulting from our acquisition of a CGRP antibody currently being studied as a potential treatment for the prevention of frequent, recurrent migraine headaches, following a successful Phase II proof-of-concept study. There were no acquired IPR&D charges in 2012. See Note 3 to the consolidated financial statements for additional information.

We recognized asset impairment, restructuring, and other special charges of $120.6 million in 2013. These charges included $30.0 million of asset impairments primarily associated with the anticipated closure of a packaging and distribution facility in Germany, and $90.6 million of severance costs to reduce our cost structure and global workforce. In 2012, we recognized asset impairment, restructuring, and other special charges of $281.1 million. These

charges included $122.6 million related to an intangible asset impairment for

liprotamase, $74.5 million related to restructuring to reduce our cost structure and global workforce, $64.0 million related to the asset impairment of a delivery device platform, and $20.0 million related to the withdrawal of Xigris. See Note 5 to the consolidated financial statements for additional information.

Other—net, (income) expense was income of $518.9 million in 2013, compared with income of $674.0 million in 2012. The decrease was driven primarily by lower income related to the termination of the exenatide collaboration with Amylin of $495.4 million in 2013 compared with $787.8 million in 2012, partially offset by milestone payments received from Boehringer Ingelheim for regulatory submissions in the U.S., Europe, and Japan. See Notes 4 and 18 to the consolidated financial statements for additional information.

Our effective tax rate was 20.5 percent in 2013, compared with 24.4 percent in 2012. The 2012 effective tax rate reflected the expiration of the R&D tax credit at the end of 2011 and the tax impact of the payment received from Amylin, partially offset by the tax benefit related to the intangible asset impairment for liprotamase. The decrease in the 2013 effective tax rate reflects the reinstatement of the R&D tax credit in the U.S. effective January 1, 2013 as well as the one-time impact of the reinstatement of the R&D tax credit for 2012 that was recorded in the first quarter of 2013. See Note 14 to the consolidated financial statements for additional information.

Operating Results—2012

Financial Results

Worldwide total revenue decreased 7 percent to $22.60 billion in 2012, driven by steep sales declines for Zyprexa due to the loss of patent exclusivity in most major markets, partially offset by growth in certain other products. Net income and EPS decreased 6 percent to $4.09 billion and $3.66, respectively, in 2012 compared with net income of $4.35 billion and EPS of $3.90 in 2011. The decreases in net income and EPS were due to the loss of patent exclusivity for Zyprexa, partially offset by growth in certain other products and higher other income from the early payment of the exenatide revenue-sharing obligation from Amylin.

The 2012 highlighted items are summarized in the "Executive Overview" section. The 2011 highlighted items are summarized as follows:

Collaborations (Note 4 to the consolidated financial statements)

- We incurred acquired IPR&D charges associated with the diabetes collaboration with Boehringer Ingelheim of $388.0 million (pretax), or $0.23 per share.

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

- We recognized charges of $316.4 million (pretax), or $0.24 per share, primarily related to severance costs from strategic actions to reduce our cost structure and global workforce.
- We incurred a charge of $85.0 million (pretax), or $0.05 per share, primarily for returned product and contractual commitments related to the withdrawal of Xigris.

Revenue

Our worldwide revenue for 2012 decreased 7 percent, to $22.60 billion, driven by the loss of patent exclusivity for Zyprexa in most major markets, partially offset by growth in Cymbalta, Forteo, Effient, Alimta, and our animal health portfolio. Worldwide sales volume decreased 7 percent and the unfavorable impact of foreign exchange rates contributed 2 percent of revenue decline, partially offset by an increase of 2 percent due to higher prices. The decrease in volume was driven by the loss of patent exclusivity for Zyprexa in most major markets, partially offset by volume gains for certain other products. Total revenue in the U.S. decreased 5 percent, to $12.31 billion, due to the loss of patent exclusivity for Zyprexa, partially offset by higher prices and increased demand for certain other products. Revenue outside the U.S. decreased 9 percent, to $10.29 billion, driven by the loss of patent exclusivity for Zyprexa in markets outside of Japan, the unfavorable effect of foreign exchange rates, and lower prices, partially offset by increased demand for certain other products.

The following table summarizes our revenue activity in 2012 compared with 2011:

Product	Year Ended December 31, 2012			Year Ended December 31, 2011	Percent Change from 2011
	U.S.[1]	Outside U.S.	Total	Total	
	(Dollars in millions)				
Cymbalta	$3,917.8	$1,076.3	$4,994.1	$4,161.8	20
Alimta	1,122.4	1,471.9	2,594.3	2,461.1	5
Humalog	1,370.9	1,024.6	2,395.5	2,367.6	1
Cialis	782.2	1,144.6	1,926.8	1,875.6	3
Zyprexa	360.4	1,341.0	1,701.4	4,622.0	(63)
Humulin	592.1	647.0	1,239.1	1,248.8	(1)
Forteo	488.2	662.8	1,151.0	949.8	21
Evista	699.5	310.6	1,010.1	1,066.9	(5)
Strattera	384.1	237.3	621.4	620.1	—
Effient	339.0	118.2	457.2	302.5	51
Other pharmaceutical products	593.4	1,249.6	1,843.0	2,250.0	(18)
Animal health products	1,161.8	874.7	2,036.5	1,678.6	21
Total net product sales	11,811.8	10,158.6	21,970.4	23,604.8	(7)
Collaboration and other revenue[2]	501.3	131.7	633.0	681.7	(7)
Total revenue	$12,313.1	$10,290.3	$22,603.4	$24,286.5	(7)

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

[2] Collaboration and other revenue consists primarily of royalties for Erbitux and revenue associated with exenatide in the United States.

Sales of Cymbalta increased 23 percent in the U.S., due to higher prices and, to a lesser extent, increased demand. Sales outside the U.S. increased 9 percent, driven by increased demand, partially offset by the unfavorable impact of foreign exchange rates.

Sales of Alimta increased 13 percent in the U.S., driven by increased demand and higher prices. Sales outside the U.S. remained flat, as increased demand was offset by lower prices in Japan and the unfavorable impact of foreign exchange rates.

Sales of Humalog decreased 2 percent in the U.S., due to increased government and commercial rebates as well as the product's removal from a large formulary in 2012. Sales outside the U.S. increased 6 percent, due to increased demand, partially offset by the unfavorable impact of foreign exchange rates.

Sales of Cialis increased 11 percent in the U.S., driven by increased demand and higher prices. Sales outside the U.S. decreased 2 percent, driven by the unfavorable impact of foreign exchange rates, partially offset by increased demand and higher prices.

Sales of Zyprexa decreased 83 percent in the United States. Sales outside the U.S. decreased 45 percent. The decreases were due to the loss of patent exclusivity in the U.S. and most major international markets outside of Japan, partially offset by growth in Japan. Zyprexa sales in Japan were approximately $585 million in 2012, compared to approximately $540 million in 2011.

Sales of Humulin increased 1 percent in the U.S., driven by higher prices, largely offset by decreased demand. U.S. sales of Humulin were negatively affected by the product's removal from a large formulary in 2012, as well as the continued decline in the market for human insulin and the termination of the Humulin ReliOn agreement with Walmart. Sales outside the U.S. decreased 2 percent, driven by the unfavorable impact of foreign exchange rates, partially offset by increased volume.

Sales of Forteo increased 8 percent in the U.S., driven by higher prices, partially offset by decreased volume. Sales outside the U.S. increased 33 percent, primarily due to the increased demand in Japan.

Sales of Evista decreased 1 percent in the U.S., driven by decreased demand, largely offset by higher prices. Sales outside the U.S. decreased 14 percent, driven by decreased volume and, to a lesser extent, the unfavorable impact of foreign exchange rates.

Sales of Strattera decreased 2 percent in the U.S., due to decreased demand, partially offset by higher prices. Sales outside the U.S. increased 4 percent, driven by increased demand in Japan, partially offset by lower prices and the unfavorable impact of foreign exchange rates.

Sales of Effient increased 52 percent in the U.S., driven by increased demand and, to a lesser extent, higher prices. Sales outside the U.S. increased 47 percent, due to increased demand, partially offset by the unfavorable impact of foreign exchange rates.

Animal health product sales in the U.S. increased 30 percent, primarily due to increased demand for companion animal products. Sales outside the U.S. increased 12 percent, driven primarily by the impact of the acquisition of certain Janssen animal health assets in Europe (see Note 3 to the consolidated financial statements), and the growth of other products, partially offset by the unfavorable impact of foreign exchange rates.

Gross Margin, Costs, and Expenses

Gross margin as a percent of total revenue decreased by 0.3 percentage points in 2012 to 78.8 percent. This decrease was primarily due to lower sales of Zyprexa and, to a lesser extent, higher miscellaneous manufacturing costs, partially offset by the impact of foreign exchange rates on international inventories sold, which decreased cost of sales in 2012 and increased cost of sales in 2011.

Marketing, selling, and administrative expenses decreased 5 percent in 2012 to $7.51 billion, driven by lower marketing expense resulting from our cost-containment efforts. Research and development expenses increased 5 percent to $5.28 billion, due to higher late-stage clinical trial costs.

No acquired IPR&D charges were incurred in 2012, compared with $388.0 million in 2011, all of which was associated with the diabetes collaboration with Boehringer Ingelheim. We recognized asset impairment, restructuring, and other special charges of $281.1 million in 2012. These charges comprised $122.6 million related to an intangible asset impairment for liprotamase, $74.5 million related to restructuring to reduce our cost structure and global workforce, $64.0 million related to the asset impairment of a delivery device platform, and $20.0 million related to the withdrawal of Xigris. In 2011, we recognized asset impairment, restructuring, and other special charges of $401.4 million, of which $316.4 million primarily related to severance costs from strategic actions and $85.0 million related to the withdrawal of Xigris. See Notes 4 and 5 to the consolidated financial statements for additional information.

Other—net, (income) expense was income of $674.0 million in 2012, compared with expense of $179.0 million in 2011. The increase was driven by income of $787.8 million recognized from the early payment of the exenatide revenue-sharing obligation by Amylin. See Note 18 to the consolidated financial statements for additional information.

Our effective tax rate was 24.4 percent in 2012, compared with 18.7 percent in 2011. The increase in 2012 reflects the tax impact of the payment received from Amylin and the expiration of the research and development tax credit at the end of 2011, partially offset by the tax benefit related to the intangible asset impairment for liprotamase. The effective tax rate for 2011 was lower due to a tax benefit on the IPR&D charge associated with the diabetes collaboration with Boehringer Ingelheim, as well as a benefit from the resolution in 2011 of the IRS audits of tax years 2005-2007, along with certain matters related to 2008-2009. See Note 14 to the consolidated financial statements for additional information.

FINANCIAL CONDITION

As of December 31, 2013, cash and cash equivalents decreased to $3.83 billion compared with $4.02 billion at December 31, 2012, as cash flow from operations of $5.74 billion was more than offset by dividends paid of $2.12 billion, share repurchases of $1.70 billion, net purchases of investments of $1.02 billion, and purchases of property and equipment of $1.01 billion. In addition to our cash and cash equivalents, we held total investments of $9.19 billion and $7.98 billion as of December 31, 2013 and December 31, 2012, respectively. See Note 7 to the consolidated financial statements for additional details.

As of December 31, 2013, total debt was $5.21 billion, a decrease of $318.4 million compared with $5.53 billion at December 31, 2012. The decrease is due primarily to the decrease in fair value of our hedged debt. We intend to refinance $1.00 billion of debt that is maturing in March 2014. A portion of the interest rate risk associated with the anticipated refinancing has been hedged through the use of forward-starting interest rate swaps. See Note 7 to the consolidated financial statements for additional details. We currently have $1.36 billion of unused committed bank credit facilities, $1.20 billion of which backs our commercial paper program.

Capital expenditures of $1.01 billion during 2013 were $106.7 million more than in 2012. We expect 2014 capital expenditures to be approximately $1.3 billion as we invest in the long-term growth of our diabetes-care product portfolio and additional biotechnology capacity while continuing investments to improve the quality, productivity, and capability of our manufacturing, research, and development facilities.

For the 129th consecutive year, we distributed dividend payments to our shareholders. Dividends of $1.96 per share were paid in both 2013 and 2012. In the fourth quarter of 2013, effective for the dividend to be paid in the first quarter of 2014, the quarterly dividend was maintained at $0.49 per share, resulting in an indicated annual rate for 2014 of $1.96 per share.

During 2013, we repurchased the remaining $1.10 billion of shares associated with our $1.50 billion share repurchase program announced in 2012. In October 2013, we announced a new $5.00 billion share repurchase program which will be completed over time. We purchased $500.0 million of shares under the new repurchase program in 2013.

At December 31, 2013, we had an aggregate of $11.61 billion of cash and investments at our foreign subsidiaries. A significant portion of this amount would be subject to tax payments if such cash and investments were repatriated to the United States. We record U.S. deferred tax liabilities for certain unremitted earnings, but when foreign earnings are expected to be indefinitely reinvested outside the U.S., no accrual for U.S. income taxes is provided. We believe cash provided by operating activities in the U.S. and planned repatriations of foreign earnings for which tax has been provided should be sufficient to fund our domestic operating needs, dividends paid to shareholders, share repurchases, and capital expenditures. Various risks and uncertainties, including those discussed in "Forward-Looking Statements" and Item 1A, “Risk Factors,” may affect our operating results and cash generated from operations.

In December 2013, we lost U.S. patent protection for Cymbalta. In 2014, we will lose U.S. patent protection for Evista and data package protection for Cymbalta in major European countries. See "Executive Overview—Legal, Regulatory, and Other Matters" for additional information.

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

In the normal course of business, our operations are exposed to fluctuations in interest rates and currency values. These fluctuations can vary the costs of financing, investing, and operating. We address a portion of these risks through a controlled program of risk management that includes the use of derivative financial instruments. The objective of controlling these risks is to limit the impact on earnings of fluctuations in interest and currency exchange rates. All derivative activities are for purposes other than trading.

Our primary interest rate risk exposure results from changes in short-term U.S. dollar interest rates. In an effort to manage interest rate exposures, we strive to achieve an acceptable balance between fixed and floating rate debt positions and may enter into interest rate derivatives to help maintain that balance. Based on our overall interest rate exposure at December 31, 2013 and 2012, including derivatives and other interest rate risk-sensitive instruments, a hypothetical 10 percent change in interest rates applied to the fair value of the instruments as of December 31, 2013 and 2012, respectively, would not have a material impact on earnings, cash flows, or fair values of interest rate risk-sensitive instruments over a one-year period.

Our foreign currency risk exposure results from fluctuating currency exchange rates, primarily the U.S. dollar against the euro and the Japanese yen, and the British pound against the euro. We face transactional currency exposures that arise when we enter into transactions, generally on an intercompany basis, denominated in currencies other than the local currency. We also face currency exposure that arises from

translating the results of our global operations to the U.S. dollar at exchange rates that have fluctuated from the beginning of the period. We may enter into foreign currency forward contracts to reduce the effect of fluctuating currency exchange rates (principally the euro, the British pound, and the Japanese yen). Our policy outlines the minimum and maximum hedge coverage of such exposures. Gains and losses on these derivative positions offset, in part, the impact of currency fluctuations on the existing assets, liabilities, commitments, and anticipated revenues. Considering our derivative financial instruments outstanding at December 31, 2013 and 2012, a hypothetical 10 percent change in exchange rates (primarily against the U.S. dollar) as of December 31, 2013 and 2012, respectively, would not have a material impact on earnings, cash flows, or fair values of foreign currency rate risk-sensitive instruments over a one-year period. These calculations do not reflect the impact of the exchange gains or losses on the underlying positions that would be offset, in part, by the results of the derivative instruments.

Off-Balance Sheet Arrangements and Contractual Obligations

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

Individually, these arrangements are not material in any one annual reporting period. However, if milestones for multiple products covered by these arrangements would happen to be reached in the same reporting period, the aggregate charge to expense could be material to the results of operations in that period. See Item 8, "Financial Statements and Supplementary Data—Note 4, Collaborations," for additional details. These arrangements often give us the discretion to unilaterally terminate development of the product, which would allow us to avoid making the contingent payments; however, we are unlikely to cease development if the compound successfully achieves milestone objectives. We also note that, from a business perspective, we view these payments as positive because they signify that the product is successfully moving through development and is now generating or is more likely to generate cash flows from sales of products.

Our current noncancelable contractual obligations that will require future cash payments are as follows (in millions):

	Payments Due by Period				
	Total	Less Than 1 Year	1-3 Years	3-5 Years	More Than 5 Years
Long-term debt, including interest payments[1]	$7,589.0	$1,136.3	$495.3	$1,473.0	$4,484.4
Capital lease obligations	27.3	10.3	13.8	3.2	—
Operating leases	620.0	136.5	218.4	147.2	117.9
Purchase obligations[2]	13,199.5	12,310.1	455.8	279.0	154.6
Other long-term liabilities reflected on our balance sheet[3]	1,989.2	—	861.5	260.5	867.2
Other[4]	476.9	476.9	—	—	—
Total	$23,901.9	$14,070.1	$2,044.8	$2,162.9	$5,624.1

1 Our long-term debt obligations include both our expected principal and interest obligations and our interest rate swaps. We used the interest rate forward curve at December 31, 2013, to compute the amount of the contractual obligation for interest on the variable rate debt instruments and swaps.

2 We have included the following:

- Purchase obligations consist primarily of all open purchase orders as of December 31, 2013. Some of these purchase orders may be cancelable; however, for purposes of this disclosure, we have not distinguished between cancelable and noncancelable purchase obligations.
- Contractual payment obligations with each of our significant vendors, which are noncancelable and are not contingent.

3 We have included long-term liabilities consisting primarily of our nonqualified supplemental pension funding requirements and deferred compensation liabilities. We excluded long-term income taxes payable of $1.08 billion, because we cannot reasonably estimate the timing of future cash outflows associated with those liabilities.

4 This category consists of various miscellaneous items expected to be paid in the next year, none of which are individually material. We excluded unfunded commitments of $142.2 million, because we cannot reasonably estimate the timing of future cash outflows associated with those commitments.

The contractual obligations table is current as of December 31, 2013. We expect the amount of these obligations to change materially over time as new contracts are initiated and existing contracts are completed, terminated, or modified.

APPLICATION OF CRITICAL ACCOUNTING ESTIMATES

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

Revenue Recognition and Sales Return, Rebate, and Discount Accruals

We recognize revenue from sales of products at the time title of goods passes to the buyer and the buyer assumes the risks and rewards of ownership. Provisions for returns, rebates, and discounts are established in the same period the related sales are recorded.

We regularly review the supply levels of our significant products sold to major wholesalers in the U.S. and in major markets outside the U.S., primarily by reviewing periodic inventory reports supplied by our major

wholesalers and available prescription volume information for our products, or alternative approaches. We attempt to maintain U.S. wholesaler inventory levels at an average of approximately one month or less on a consistent basis across our product portfolio. Causes of unusual wholesaler buying patterns include actual or anticipated product-supply issues, weather patterns, anticipated changes in the transportation network, redundant holiday stocking, and changes in wholesaler business operations. In the U.S., the current structure of our arrangements does not provide an incentive for speculative wholesaler buying and provides us with data on inventory levels at our wholesalers. When we believe wholesaler purchasing patterns have caused an unusual increase or decrease in the sales of a major product compared with underlying demand, we disclose this in our product sales discussion if we believe the amount is material to the product sales trend; however, we are not always able to accurately quantify the amount of stocking or destocking. Wholesaler stocking and destocking activity historically has not caused any material changes in the rate of actual product returns.

When sales occur, we estimate a reserve for future product returns related to those sales. This estimate is based on several factors, including: historical return rates, expiration date by product (generally, 24 to 36 months after the initial sale of a product to our customer), and estimated levels of inventory in the wholesale and retail channels, among others, as well as any other specifically-identified anticipated returns due to known factors such as the loss of patent exclusivity, product recalls and discontinuances, or a changing competitive environment. We maintain a returns policy that allows U.S. pharmaceutical customers to return product within a specified period prior to and subsequent to the product's expiration date. Following the loss of exclusivity for a patent-dependent product, we expect to experience an elevated level of product returns as product inventory remaining in the wholesale and retail channels expires. Additional adjustments to the returns reserve may be required in the future based on revised estimates to our assumptions, which would have an impact on our consolidated results of operations. We record the return amounts as a deduction to arrive at our net product sales. Once the product is returned, it is destroyed. Actual product returns have been less than 1 percent of our net sales over the past three years and have not fluctuated significantly as a percentage of sales. However, we expect the ratio of actual product returns as a percentage of net sales to increase in future periods as we begin to experience elevated return levels for both Zyprexa and Cymbalta following the recent losses of patent exclusivity for these products in several major markets.

We establish sales rebate and discount accruals in the same period as the related sales. The rebate and discount amounts are recorded as a deduction to arrive at our net product sales. Sales rebates and discounts that require the use of judgment in the establishment of the accrual include Medicaid, managed care, Medicare, chargebacks, long-term care, hospital, patient assistance programs, and various other programs. We base these accruals primarily upon our historical rebate and discount payments made to our customer segment groups and the provisions of current rebate and discount contracts.

The largest of our sales rebate and discount amounts are rebates associated with sales covered by Medicaid. In determining the appropriate accrual amount, we consider our historical Medicaid rebate payments by product as a percentage of our historical sales as well as any significant changes in sales trends (e.g., patent expiries), an evaluation of the current Medicaid rebate laws and interpretations, the percentage of our products that are sold to Medicaid recipients, and our product pricing and current rebate and discount contracts. Although we accrue a liability for Medicaid rebates at the time we record the sale (when the product is shipped), the Medicaid rebate related to that sale is typically paid up to six months later. Because of this time lag, in any particular period our rebate adjustments may incorporate revisions of accruals for several periods.

Most of our rebates outside the U.S. are contractual or legislatively mandated and are estimated and recognized in the same period as the related sales. In some large European countries, government rebates are based on the anticipated budget for pharmaceutical payments in the country. A best estimate of these rebates, updated as governmental authorities revise budgeted deficits, is recognized in the same period as the related sale. If our estimates are not reflective of the actual pharmaceutical costs incurred by the government, we adjust our rebate reserves.

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

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sales return, rebate, and discount liability at December 31, 2013 would lead to an approximate $138 million effect on our income before income taxes.

The portion of our global sales return, rebate, and discount liability resulting from sales of our products in the U.S. was 88 percent and 83 percent as of December 31, 2013 and 2012, respectively.

The following represents a roll-forward of our most significant U.S. sales return, rebate, and discount liability balances, including Medicaid (in millions):

	2013	2012
Sales return, rebate, and discount liabilities, beginning of year	$1,584.5	$1,597.9
Reduction of net sales due to sales returns, discounts, and rebates[1]	4,723.3	3,563.5
Cash payments of discounts and rebates	(4,092.3)	(3,576.9)
Sales return, rebate, and discount liabilities, end of year [2]	$2,215.5	$1,584.5

1 Adjustments of the estimates for these returns, rebates, and discounts to actual results were less than 1.0 percent of net sales for each of the years presented.

2 The increase in our most significant U.S. sales return, rebate, and discount liability balances as of December 31, 2013, as compared to December 31, 2012, is primarily due to an increase in our returns reserve for sales of Cymbalta, which lost U.S. patent exclusivity in December 2013.

Product Litigation Liabilities and Other Contingencies

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

We also consider the insurance coverage we have to diminish the exposure for periods covered by insurance. In assessing our insurance coverage, we consider the policy coverage limits and exclusions, the potential for denial of coverage by the insurance company, the financial condition of the insurers, and the possibility of and length of time for collection. Due to a very restrictive market for product liability insurance, we are self-insured for product liability losses for all our currently marketed products.

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

Pension and Retiree Medical Plan Assumptions

Pension benefit costs include assumptions for the discount rate, retirement age, and expected return on plan assets. Retiree medical plan costs include assumptions for the discount rate, retirement age, expected return on plan assets, and health-care-cost trend rates. These assumptions have a significant effect on the amounts reported. In addition to the analysis below, see Note 15 to the consolidated financial statements for additional information regarding our retirement benefits.

Annually, we evaluate the discount rate and the expected return on plan assets in our defined benefit pension and retiree health benefit plans. We use an actuarially determined, plan-specific yield curve of high quality, fixed income debt instruments to determine the discount rates. In evaluating the expected rate of return, we consider many factors, with a primary analysis of current and projected market conditions, asset returns and asset allocations (approximately 80 percent of which are growth investments); and the views of leading financial advisers and economists. We may also review our historical assumptions compared with actual results, as well as the discount rates, expected return on plan assets, and health-care-cost trend rates of other companies, where applicable. In evaluating our expected retirement age assumption, we consider the retirement ages of our past employees eligible for pension and medical benefits together with our expectations of future retirement ages.

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If the health-care-cost trend rates were to increase by one percentage point, the aggregate of the service cost and interest cost components of the 2013 annual expense would increase by $9.4 million. A one-percentage-point decrease would decrease the aggregate of the 2013 service cost and interest cost by $7.6 million. If the 2013 discount rate for the U.S. defined benefit pension and retiree health benefit plans (U.S. plans) were to change by a quarter percentage point, income before income taxes would change by $40.6 million. If the 2013 expected return on plan assets for U.S. plans were to change by a quarter percentage point, income before income taxes would change by $20.1 million. If our assumption regarding the 2013 expected age of future retirees for U.S. plans were adjusted by one year, our income before income taxes would be affected by $57.6 million. The U.S. plans, including Puerto Rico, represent approximately 80 percent of both the total projected benefit obligation and total plan assets at December 31, 2013.

Impairment of Indefinite-Lived and Long-Lived Assets

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

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

Several methods may be used to determine the estimated fair value of the IPR&D acquired in a business combination, all of which require multiple assumptions. We utilize the "income method," which applies a probability weighting that considers the risk of development and commercialization to the estimated future net cash flows that are derived from projected sales revenues and estimated costs. These projections are based on factors such as relevant market size, patent protection, historical pricing of similar products, and expected industry trends. The estimated future net cash flows are then discounted to the present value using an appropriate discount rate. This analysis is performed for each project independently.

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

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

Income Taxes

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

We have recorded valuation allowances against certain of our deferred tax assets, primarily those that have been generated from net operating losses and tax credit carryforwards in certain taxing jurisdictions. In

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evaluating whether we would more likely than not recover these deferred tax assets, we have not assumed any future taxable income or tax planning strategies in the jurisdictions associated with these carryforwards where history does not support such an assumption. Implementation of tax planning strategies to recover these deferred tax assets or future income generation in these jurisdictions could lead to the reversal of these valuation allowances and a reduction of income tax expense.

As of December 31, 2013, a 5 percent change in the amount of the uncertain tax positions and the valuation allowance would result in a change in net income of $26.2 million and $32.4 million, respectively.

LEGAL AND REGULATORY MATTERS

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

FINANCIAL EXPECTATIONS FOR 2014

For the full year of 2014, we expect EPS to be in the range of $2.77 to $2.85. EPS expectations for 2014 reflect completed share repurchases in 2013 and potential share repurchases in 2014. We anticipate that total revenue will be between $19.2 billion and $19.8 billion. Patent expirations are expected to drive a rapid and severe decline in U.S. sales of Cymbalta and Evista. These revenue declines are expected to be partially offset by growth from a portfolio of other products including Humalog, Trajenta, Cialis, Forteo and Alimta, as well as our animal health business. In addition, strong revenue growth is expected in China, while a weaker Japanese yen is expected to dampen revenue growth in Japan.

We anticipate that gross margin as a percent of revenue will be approximately 74 percent in 2014. Marketing, selling, and administrative expenses are expected to be in the range of $6.2 billion to $6.5 billion. Research and development expense is expected to be in the range of $4.4 billion to $4.7 billion. Other—net, (income) expense is expected to be in a range between $100 million and $200 million of income, benefited by gains of $150 million to $200 million on the sale of equity investments acquired as part of past business development transactions. Operating cash flows are expected to be sufficient to pay our dividend of approximately $2.1 billion, allow for capital expenditures of approximately $1.3 billion, and fund potential business development activity and share repurchases.

Our 2014 financial guidance does not include a potential charge related to the collaboration with Pfizer to develop and commercialize tanezumab. If the partial clinical hold for the molecule is removed and we and Pfizer move forward with development, we will pay a $200 million upfront fee to Pfizer. This charge would reduce EPS by approximately $0.12.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

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

Item 8. Financial Statements and Supplementary Data

Consolidated Statements of Operations

ELI LILLY AND COMPANY AND SUBSIDIARIES Year Ended December 31 (Dollars in millions, except per-share data)	2013	2012	2011
Revenue	$23,113.1	$22,603.4	$24,286.5
Cost of sales	4,908.1	4,796.5	5,067.9
Research and development	5,531.3	5,278.1	5,020.8
Marketing, selling, and administrative	7,125.6	7,513.5	7,879.9
Acquired in-process research and development (Notes 3 and 4)	57.1	—	388.0
Asset impairment, restructuring, and other special charges (Note 5)	120.6	281.1	401.4
Other—net, (income) expense (Note 18)	(518.9)	(674.0)	179.0
	17,223.8	17,195.2	18,937.0
Income before income taxes	5,889.3	5,408.2	5,349.5
Income taxes (Note 14)	1,204.5	1,319.6	1,001.8
Net income	$4,684.8	$4,088.6	$4,347.7
Earnings per share—basic (Note 13)	$4.33	$3.67	$3.90
Earnings per share—diluted (Note 13)	$4.32	$3.66	$3.90

See notes to consolidated financial statements.

Consolidated Statements of Comprehensive Income

ELI LILLY AND COMPANY AND SUBSIDIARIES (Dollars in millions)	Year Ended December 31	2013	2012	2011
Net income		$4,684.8	$4,088.6	$4,347.7
Other comprehensive income (loss):				
Foreign currency translation gains (losses)		36.2	160.9	(244.8)
Net unrealized gains (losses) on securities		204.3	88.5	(178.5)
Defined benefit pension and retiree health benefit plans (Note 15)		2,592.2	(128.6)	(1,240.2)
Effective portion of cash flow hedges		(123.8)	8.7	44.8
Other comprehensive income (loss) before income taxes		2,708.9	129.5	(1,618.7)
Provision for income taxes related to other comprehensive income (loss) items		(914.5)	(68.0)	430.2
Other comprehensive income (loss) (Note 17)		1,794.4	61.5	(1,188.5)
Comprehensive income		$6,479.2	$4,150.1	$3,159.2

See notes to consolidated financial statements.

Consolidated Balance Sheets
ELI LILLY AND COMPANY AND SUBSIDIARIES
(Dollars in millions, shares in thousands)

December 31	2013	2012
Assets		
Current Assets		
Cash and cash equivalents (Note 7)	$3,830.2	$4,018.8
Short-term investments (Note 7)	1,567.1	1,665.5
Accounts receivable, net of allowances of $100.3 (2013) and $108.5 (2012)	3,434.4	3,336.3
Other receivables	588.4	552.0
Inventories (Note 6)	2,928.8	2,643.8
Prepaid expenses and other	755.8	822.3
Total current assets	13,104.7	13,038.7
Other Assets		
Investments (Note 7)	7,624.9	6,313.9
Goodwill and other intangibles, net (Note 8)	4,331.1	4,752.7
Sundry	2,212.5	2,533.4
Total other assets	14,168.5	13,600.0
Property and equipment, net (Note 9)	7,975.5	7,760.2
Total assets	$35,248.7	$34,398.9
Liabilities and Equity		
Current Liabilities		
Short-term borrowings and current maturities of long-term debt (Note 10)	$1,012.6	$11.9
Accounts payable	1,119.3	1,188.3
Employee compensation	943.9	940.3
Sales rebates and discounts	1,941.7	1,777.2
Dividends payable	523.5	541.4
Income taxes payable (Note 14)	254.4	143.5
Deferred income taxes (Note 14)	792.8	1,048.0
Other current liabilities	2,328.4	2,738.9
Total current liabilities	8,916.6	8,389.5
Other Liabilities		
Long-term debt (Note 10)	4,200.3	5,519.4
Accrued retirement benefits (Note 15)	1,549.4	3,012.4
Long-term income taxes payable (Note 14)	1,078.7	1,334.3
Other noncurrent liabilities	1,863.0	1,369.4
Total other liabilities	8,691.4	11,235.5
Commitments and contingencies (Note 16)		
Eli Lilly and Company Shareholders' Equity (Notes 11 and 12)		
Common stock—no par value		
Authorized shares: 3,200,000	698.5	716.6
Issued shares: 1,117,628 (2013) and 1,146,493 (2012)		
Additional paid-in capital	5,050.0	4,963.1
Retained earnings	16,992.4	16,088.2
Employee benefit trust	(3,013.2)	(3,013.2)
Accumulated other comprehensive loss (Note 17)	(2,002.7)	(3,797.1)
Cost of common stock in treasury, 833 shares (2013) and 2,850 shares (2012)	(93.6)	(192.4)
Total Eli Lilly and Company shareholders' equity	17,631.4	14,765.2
Noncontrolling interests	9.3	8.7
Total equity	17,640.7	14,773.9

Total liabilities and equity	$35,248.7	$34,398.9

See notes to consolidated financial statements.

Consolidated Statements of Shareholders' Equity

ELI LILLY AND COMPANY AND SUBSIDIARIES (Dollars in millions, shares in thousands)	Common Stock		Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive Loss	Common Stock in Treasury		Other[1]	Shareholders' Equity
	Shares	Amount				Shares	Amount		
Balance at January 1, 2011	1,154,018	$721.3	$4,798.5	$12,732.6	$(2,670.1)	864	$(96.4)	$(3,065.6)	$12,420.3
Net income				4,347.7					4,347.7
Other comprehensive income (loss), net of tax					(1,188.5)				(1,188.5)
Cash dividends declared per share: $1.96				(2,182.5)					(2,182.5)
Retirement of treasury shares	(1)		(0.1)			(1)	0.1		—
Issuance of stock under employee stock plans-net	4,627	2.8	(108.7)			(10)	1.0		(104.9)
Stock-based compensation			147.4						147.4
ESOP transactions			49.7					52.4	102.1
Other								0.1	0.1
Balance at December 31, 2011	1,158,644	724.1	4,886.8	14,897.8	(3,858.6)	853	(95.3)	(3,013.1)	13,541.7
Net income				4,088.6					4,088.6
Other comprehensive income (loss), net of tax					61.5				61.5
Cash dividends declared per share: $1.96				(2,186.5)					(2,186.5)
Retirement of treasury shares	(14,912)	(9.3)		(711.7)		(14,912)	721.1		0.1
Purchase for treasury						16,918	(819.2)		(819.2)
Issuance of stock under employee stock plans-net	2,761	1.8	(65.2)			(9)	1.0		(62.4)
Stock-based compensation			141.5						141.5
Other								(0.1)	(0.1)
	1,146,493	716.6	4,963.1	16,088.2	(3,797.1)	2,850	(192.4)	(3,013.2)	14,765.2

Balance at December 31, 2012									
Net income				4,684.8					4,684.8
Other comprehensive income (loss), net of tax					1,794.4				1,794.4
Cash dividends declared per share: $1.96				(2,102.8)					(2,102.8)
Retirement of treasury shares	(32,406)	(20.3)		(1,677.8)		(32,406)	1,698.1		—
Purchase for treasury						30,400	(1,600.0)		(1,600.0)
Issuance of stock under employee stock plans-net	3,541	2.2	(58.0)			(11)	0.7		(55.1)
Stock-based compensation			144.9						144.9
Balance at December 31, 2013	1,117,628	$698.5	$5,050.0	$16,992.4	$(2,002.7)	833	$(93.6)	$(3,013.2)	$17,631.4

[1] Includes activity related to shares held by an employee benefit trust and employee stock ownership plan (ESOP). See Note 12 for additional details.

Consolidated Statements of Cash Flows

ELI LILLY AND COMPANY AND SUBSIDIARIES (Dollars in millions)	Year Ended December 31 2013	2012	2011
Cash Flows from Operating Activities			
Net income	$4,684.8	$4,088.6	$4,347.7
Adjustments to Reconcile Net Income to Cash Flows from Operating Activities			
Depreciation and amortization	1,445.6	1,462.2	1,373.6
Change in deferred income taxes	285.9	126.0	(268.5)
Stock-based compensation expense	144.9	141.5	147.4
Impairment charges, indefinite lived intangibles	—	205.0	151.5
Acquired in-process research and development, net of tax	37.1	—	252.2
Income related to termination of the exenatide collaboration with Amylin (Note 4)	(495.4)	(787.8)	—
Other operating activities, net	25.1	120.5	(17.8)
Changes in operating assets and liabilities, net of acquisitions:			
Receivables—(increase) decrease	(152.7)	361.8	(188.8)
Inventories—(increase) decrease	(286.5)	(307.9)	203.1
Other assets—(increase) decrease	116.5	231.0	642.7
Accounts payable and other liabilities—increase (decrease)	(70.3)	(336.1)	591.4
Net Cash Provided by Operating Activities	5,735.0	5,304.8	7,234.5
Cash Flows from Investing Activities			
Purchases of property and equipment	(1,012.1)	(905.4)	(672.0)
Disposals of property and equipment	179.4	22.0	25.3
Proceeds from sales and maturities of short-term investments	3,320.1	2,547.5	1,807.9
Purchases of short-term investments	(1,531.0)	(2,172.4)	(2,058.8)
Proceeds from sales and maturities of noncurrent investments	11,235.0	4,355.7	2,138.5
Purchases of noncurrent investments	(14,041.9)	(7,618.6)	(4,459.4)
Purchase of product rights	(24.1)	(138.8)	(632.9)
Purchases of in-process research and development	(57.1)	—	(388.0)
Cash paid for acquisitions, net of cash acquired	(43.7)	(199.3)	(307.8)
Net change in loan to collaboration partner (Note 4)	—	165.0	(165.0)
Proceeds from prepayment of revenue-sharing obligation (Note 4)	—	1,212.1	—
Other investing activities, net	(97.4)	(100.6)	(112.2)
Net Cash Used for Investing Activities	(2,072.8)	(2,832.8)	(4,824.4)
Cash Flows from Financing Activities			
Dividends paid	(2,120.7)	(2,187.4)	(2,180.1)
Net change in short-term borrowings	—	—	(134.1)
Repayments of long-term debt	(10.5)	(1,511.1)	(61.7)
Purchases of common stock	(1,698.1)	(721.1)	—
Other financing activities, net	—	—	6.0
Net Cash Used for Financing Activities	(3,829.3)	(4,419.6)	(2,369.9)
Effect of exchange rate changes on cash and cash equivalents	(21.5)	43.9	(110.9)
Net decrease in cash and cash equivalents	(188.6)	(1,903.7)	(70.7)
Cash and cash equivalents at beginning of year	4,018.8	5,922.5	5,993.2
Cash and Cash Equivalents at End of Year	$3,830.2	$4,018.8	$5,922.5

See notes to consolidated financial statements.

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

Note 1: Summary of Significant Accounting Policies

Basis of presentation

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

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

All per-share amounts, unless otherwise noted in the footnotes, are presented on a diluted basis, that is, based on the weighted-average number of outstanding common shares plus the effect of dilutive stock options and other incremental shares.

Cash equivalents

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

Inventories

We state all inventories at the lower of cost or market. We use the last-in, first-out (LIFO) method for the majority of our inventories located in the continental United States. Other inventories are valued by the first-in, first-out (FIFO) method. FIFO cost approximates current replacement cost.

Investments

Substantially all of our investments in debt and marketable equity securities are classified as available-for-sale. Investment securities with maturity dates of less than one year from the date of the balance sheet are classified as short-term. Available-for-sale securities are carried at fair value with the unrealized gains and losses, net of tax, reported in other comprehensive income (loss). The credit portion of unrealized losses on our debt securities considered to be other-than-temporary is recognized in earnings. The remaining portion of the other-than-temporary impairment on our debt securities is then recorded, net of tax, in other comprehensive income (loss). The entire amount of other-than-temporary impairment on our equity securities is recognized in earnings. We do not evaluate cost-method investments for impairment unless there is an indicator of impairment. We review these investments for indicators of impairment on a regular basis. Realized gains and losses on sales of available-for-sale securities are computed based upon specific identification of the initial cost adjusted for any other-than-temporary declines in fair value that were recorded in earnings. Investments in companies over which we have significant influence but not a controlling interest are accounted for using the equity method with our share of earnings or losses reported in other–net, (income) expense. We own no investments that are considered to be trading securities.

Risk-management instruments

Our derivative activities are initiated within the guidelines of documented corporate risk-management policies and do not create additional risk because gains and losses on derivative contracts offset losses and gains on the assets, liabilities, and transactions being hedged. As derivative contracts are initiated, we designate the instruments individually as either a fair value hedge or a cash flow hedge. Management reviews the correlation and effectiveness of our derivatives on a quarterly basis.

For derivative contracts that are designated and qualify as fair value hedges, the derivative instrument is marked to market with gains and losses recognized currently in income to offset the respective losses and gains recognized on the underlying exposure. For derivative contracts that are designated and qualify as cash flow hedges, the effective portion of gains and losses on these contracts is reported as a component of accumulated other comprehensive loss and reclassified into earnings in the same period the hedged transaction affects earnings. Hedge ineffectiveness is immediately recognized in earnings. Derivative contracts that are not designated as hedging instruments are recorded at fair value with the gain or loss recognized in current earnings during the period of change.

We may enter into foreign currency forward contracts to reduce the effect of fluctuating currency exchange rates (principally the euro, the British pound, and the Japanese yen). Foreign currency derivatives used for hedging are put in place using the same or like currencies and duration as the underlying exposures. Forward contracts are principally used to manage exposures arising from subsidiary trade and loan payables and receivables denominated in foreign currencies. These contracts are recorded at fair value with the gain or loss recognized in other–net, (income) expense.

We may enter into foreign currency forward contracts and currency swaps as fair value hedges of firm commitments. Forward contracts generally have maturities not exceeding 12 months.

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

Interest rate swaps or collars that convert our fixed-rate debt to a floating rate are designated as fair value hedges of the underlying instruments. Interest rate swaps or collars that convert floating-rate debt to a fixed rate are designated as cash flow hedges. Interest expense on the debt is adjusted to include the payments made or received under the swap agreements.

We may enter into forward contracts and designate them as cash flow hedges to limit the potential volatility of earnings and cash flow associated with forecasted sales of available-for-sale securities.

We may enter into forward-starting interest rate swaps as part of any anticipated future debt issuances in order to reduce the risk of cash flow volatility from future changes in interest rates. Upon completion of a debt issuance and termination of the swap, the change in fair value of these instruments is recorded as part of other comprehensive income (loss) and is amortized to interest expense over the life of the debt agreement.

Goodwill and other intangibles

Goodwill results from excess consideration in a business combination over the fair value of identifiable net assets acquired. Goodwill is not amortized.

Intangible assets with finite lives are capitalized and are amortized on a straight-line basis over their estimated useful lives, ranging from 3 to 20 years.

The costs of in-process research and development (IPR&D) projects acquired directly in a transaction other than a business combination are capitalized if the projects have an alternative future use; otherwise, they are expensed. The fair values of IPR&D projects acquired in business combinations are capitalized as other intangible assets. Several methods may be used to determine the estimated fair value of the IPR&D acquired in a business combination. We utilize the “income method,” which applies a probability weighting that considers the risk of development and commercialization, to the estimated future net cash flows that are derived from projected sales revenues and estimated costs. These projections are based on factors such as relevant market size, patent protection, historical pricing of similar products, and expected industry trends. The estimated future net cash flows are then discounted to the present value using an appropriate discount rate. This analysis is performed for each project independently. These assets are treated as indefinite-lived intangible assets until completion or abandonment of the projects, at which time the assets are tested for impairment and amortized over the remaining useful life or written off, as appropriate. For transactions other than a business combination, we also capitalize milestone payments incurred at or after the product has

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obtained regulatory approval for marketing and amortize those amounts over the remaining estimated useful life of the underlying asset.

Goodwill and indefinite-lived intangible assets are reviewed for impairment at least annually and when impairment indicators are present. When required, a comparison of fair value to the carrying amount of assets is performed to determine the amount of any impairment. When determining the fair value of indefinite-lived IPR&D assets for impairment testing purposes, we utilize the "income method" discussed in the previous paragraph. Finite-lived intangible assets are reviewed for impairment when an indicator of impairment is present.

Property and equipment

Property and equipment is stated on the basis of cost. Provisions for depreciation of buildings and equipment are computed generally by the straight-line method at rates based on their estimated useful lives (12 to 50 years for buildings and 3 to 18 years for equipment). We review the carrying value of long-lived assets for potential impairment on a periodic basis and whenever events or changes in circumstances indicate the carrying value of an asset may not be recoverable. Impairment is determined by comparing projected undiscounted cash flows to be generated by the asset to its carrying value. If an impairment is identified, a loss is recorded equal to the excess of the asset’s net book value over its fair value, and the cost basis is adjusted.

Litigation and environmental liabilities

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

Revenue recognition

We recognize revenue from sales of products at the time title of goods passes to the buyer and the buyer assumes the risks and rewards of ownership. Provisions for returns, discounts, and rebates are established in the same period the related sales are recognized.

We also generate income as a result of collaboration agreements. Revenue from co-promotion arrangements is based upon gross margins reported to us by our co-promotion partners. Initial fees we receive from the partnering of our compounds under development where we have continuing involvement are generally amortized through the expected product approval date. For out-licensing agreements that include both the sale of marketing rights to our commercialized products and a related commitment to supply the products, the initial fees received are generally recognized in net product sales over the term of the supply agreement when we have determined that the marketing rights do not have value on a standalone basis. We immediately recognize the full amount of developmental milestone payments due to us upon the achievement of the milestone event if the event is objectively determinable and the milestone is substantive in its entirety. A milestone is considered substantive if the consideration earned 1) relates solely to past performance, 2) is commensurate with the enhancement in the pharmaceutical product's value associated with the achievement of the important event in its development life cycle, and 3) is reasonable relative to all of the deliverables and payment terms within the arrangement. Milestone payments earned by us are generally recorded in other–net, (income) expense. If the payment to us is a commercialization payment that is part of a multiple-element collaborative commercialization arrangement and is a result of the initiation of the commercialization period (e.g., payments triggered by regulatory approval for marketing or launch of the product), we amortize the payment to income as we perform under the terms of the arrangement. See Note 4 for specific agreement details.

Royalty revenue from licensees, which is based on third-party sales of licensed products and technology, is recorded as earned in accordance with the contract terms when third-party sales can be reasonably

measured and collection of the funds is reasonably assured. This royalty revenue is included in collaboration and other revenue.

Research and development expenses and acquired IPR&D

Research and development expenses include the following:

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

Acquired IPR&D expense includes the initial costs of IPR&D projects acquired directly in asset acquisitions, unless they have an alternative future use.

Income taxes

Deferred taxes are recognized for the future tax effects of temporary differences between financial and income tax reporting based on enacted tax laws and rates. Federal income taxes are provided on the portion of the income of foreign subsidiaries that is expected to be remitted to the U.S. and be taxable. When foreign earnings are expected to be indefinitely reinvested outside the U.S., no accrual for U.S. income taxes is provided.

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

Earnings per share

We calculate basic earnings per share based on the weighted-average number of common shares outstanding and incremental shares. We calculate diluted earnings per share based on the weighted-average number of common shares outstanding, including incremental shares and dilutive stock options. See Note 13 for further discussion.

Stock-based compensation

We recognize the fair value of stock-based compensation as expense over the requisite service period of the individual grantees, which generally equals the vesting period. Under our policy, all stock-based awards are approved prior to the date of grant. The compensation committee of the board of directors approves the value of the award and date of grant. Stock-based compensation that is awarded as part of our annual equity grant is made on a specific grant date scheduled in advance.

Reclassifications

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

Note 2: Implementation of New Financial Accounting Pronouncements

In July 2013, the Financial Accounting Standards Board issued a clarification regarding the presentation of an unrecognized tax benefit related to a net operating loss carryforward, a similar tax loss, or a tax credit carryforward. Under this new standard, the liability related to an unrecognized tax benefit, or a portion thereof, should be presented in the financial statements as a reduction to a deferred tax asset if available under the tax law of the applicable jurisdiction to settle any additional income taxes that would result from the disallowance of a tax position. Otherwise, the unrecognized tax benefit should be presented in the financial statements as a separate liability. The assessment is based on the unrecognized tax benefit and deferred tax asset that exist at the reporting date. The provisions of the new standard are effective on a prospective basis beginning in 2014 for annual and interim reporting periods, with earlier adoption permitted. While we are still finalizing our determination of the impact of this standard on both our deferred tax assets and income taxes payable, we do not currently anticipate that the implementation of this standard will have a material impact on our consolidated balance sheets, and it will have no impact on our consolidated statements of operations.

Note 3: Acquisitions

During 2012 and 2011, we completed the acquisitions of ChemGen Corporation (ChemGen) and the animal health business of Janssen Pharmaceuticia NV (Janssen), respectively. These acquisitions were accounted for as business combinations under the acquisition method of accounting. The assets acquired and liabilities assumed were recorded at their respective fair values as of the acquisition date in our consolidated financial statements. The determination of estimated fair value required management to make significant estimates and assumptions. The excess of the purchase price over the fair value of the acquired net assets, where applicable, has been recorded as goodwill. The results of operations of these acquisitions are included in our consolidated financial statements from the date of acquisition. None of these acquisitions were material to our consolidated financial statements.

In addition to the acquisitions of businesses, we also acquired assets in development in 2013 and 2011 which are further discussed below in Product Acquisitions and in Note 4, respectively. Upon acquisition, the acquired IPR&D related to these products was immediately written off as an expense because the products had no alternative future use. For the years ended December 31, 2013 and 2011, we recorded acquired IPR&D charges of $57.1 million and $388.0 million, respectively, associated with these transactions. There were no acquired IPR&D charges in 2012.

In connection with the arrangements described below, our partners may be entitled to future milestones and royalties based on sales should these products be approved for commercialization.

Acquisition of Businesses

ChemGen

On February 17, 2012, we acquired all of the outstanding stock of ChemGen Corporation, a privately-held bioscience company specializing in the development and commercialization of innovative feed-enzyme products that improve the efficiency of poultry, egg, and meat production, for total purchase consideration of $206.9 million in cash. In connection with this acquisition, we recorded $151.5 million of marketed product assets and $55.4 million of other net assets.

Janssen

On July 7, 2011, we acquired the animal health business of Janssen, a Johnson & Johnson company, for total purchase consideration of $307.8 million in cash. We obtained a portfolio of more than 50 marketed animal health products. In connection with this acquisition, we recorded $234.4 million of marketed product assets, $29.6 million of acquired IPR&D assets, and $43.8 million of other net assets.

Product Acquisitions

In December 2013, we acquired all development and commercial rights for a calcitonin gene-related peptide (CGRP) antibody currently being studied as a potential treatment for the prevention of frequent, recurrent migraine headaches for $57.1 million in cash. At the time of the purchase, the product had completed a successful Phase II proof-of-concept study and had no alternative future use. The related $57.1 million charge for acquired IPR&D was included as expense in the fourth quarter of 2013 and is deductible for tax purposes.

Note 4: Collaborations

We often enter into collaborative arrangements to develop and commercialize drug candidates. Collaborative activities may include research and development, marketing and selling (including promotional activities and physician detailing), manufacturing, and distribution. These collaborations often require milestone and royalty or profit-share payments, contingent upon the occurrence of certain future events linked to the success of the asset in development, as well as expense reimbursements or payments to the third party. Revenues related to products we sell pursuant to these arrangements are included in net product sales, while other sources of revenue (e.g., royalties and profit-share payments) are included in collaboration and other revenue. For the years ended December 31, 2013, 2012, and 2011, we recognized collaboration and other revenue of $707.5 million, $633.0 million, and $681.7 million, respectively. Operating expenses for costs incurred pursuant to these arrangements are reported in their respective expense line item, net of any payments made

to or reimbursements received from our collaboration partners. Each collaboration is unique in nature, and our more significant arrangements are discussed below.

Exenatide

In November 2011, we agreed with Amylin Pharmaceuticals, Inc. (Amylin) to terminate our collaborative arrangement for the joint development, marketing, and selling of Byetta® (exenatide injection) and other forms of exenatide such as Bydureon® (exenatide extended-release for injectable suspension). Under the terms of the termination agreement, Amylin made a one-time, upfront payment to us of $250.0 million. Amylin also agreed to make future revenue-sharing payments to us in an amount equal to 15.0 percent of its global net sales of exenatide products until Amylin made aggregate payments to us of $1.20 billion plus interest, which would accrue at 9.5 percent. Upon completion of the acquisition of Amylin by Bristol-Myers Squibb Company in August 2012, Amylin's obligation of $1.26 billion, including accrued interest, was paid in full, with $1.21 billion representing a prepayment of the obligation. We would also receive a $150.0 million milestone payment contingent upon U.S. Food and Drug Administration (FDA) approval of a once-monthly suspension version of exenatide.

Commercial operations were transferred to Amylin in the U.S. in late-2011. Outside the U.S., we transferred to Amylin exenatide commercial rights and control in all markets during the first quarter of 2013.

Payments received from Amylin were allocated 65 percent to the U.S., which was treated as a contract termination, and 35 percent to the business outside the U.S., which was treated as the disposition of a business. The allocation was based upon relative fair values. The revenue-sharing income allocated to the U.S. was recognized as collaboration and other revenue, consistent with our policy for royalty revenue, while the income related to the prepayment of Amylin's obligation allocated to the U.S. was recognized in other-net, (income) expense. All income allocated to the business outside the U.S. that was transferred during the first quarter of 2013 was recognized as a gain on the disposition of a business in other–net, (income) expense, net of the goodwill allocated to the business transferred.

Prior to termination of the collaboration, we and Amylin were co-promoting Byetta in the United States. Amylin was responsible for manufacturing and primarily utilized third-party contract manufacturers to supply Byetta. We supplied Byetta pen delivery devices for Amylin and will continue to do so for a period that will not extend beyond the first quarter of 2014. We were responsible for certain development costs related to certain clinical trials outside the U.S. that we were conducting as of the date of the termination agreement as well as commercialization costs outside the U.S. until the commercial rights were transferred to Amylin.

Under the terms of our prior arrangement, we reported as collaboration and other revenue our 50 percent share of gross margin on Amylin’s net product sales in the United States. We reported as net product sales 100 percent of sales outside the U.S. and our sales of Byetta pen delivery devices to Amylin. We paid Amylin a percentage of the gross margin of exenatide sales outside of the U.S., and these costs were recorded in cost of sales. This arrangement for the commercial operations outside the U.S. continued until those rights were transferred to Amylin during the first quarter of 2013. Prior to termination of the agreement, under the 50/50 profit-sharing arrangement for the U.S., in addition to recording as revenue our 50 percent share of exenatide’s gross margin, we also recorded approximately 50 percent of U.S. related research and development costs and marketing and selling costs in the respective line items on the consolidated statements of operations.

In accordance with the prior arrangement and pursuant to Amylin’s request, we loaned Amylin $165.0 million in the second quarter of 2011. This loan and related accrued interest were paid in full in August 2012.

The following table summarizes the revenue and other income recognized with respect to exenatide:

	2013	2012	2011
Net product sales	$133.1	$207.8	$179.6
Collaboration and other revenue	—	70.1	243.1
Total revenue	$133.1	$277.9	$422.7
Income related to termination of the exenatide collaboration with Amylin[1]	$495.4	$787.8	$—

[1] Presented in other-net, (income) expense

Effient®

We are in a collaborative arrangement with Daiichi Sankyo Co., Ltd. (Daiichi Sankyo) to develop, market, and promote Effient. We and Daiichi Sankyo co-promote Effient in certain territories (including the U.S. and five major European markets), while we have exclusive marketing rights in certain other territories. Daiichi Sankyo has exclusive marketing rights in Japan and certain other territories. The parties share approximately 50/50 in the profits, as well as in the costs of development and marketing in the co-promotion territories. A third party manufactures bulk product, and we produce the finished product for our exclusive and co-promotion territories. We record product sales in our exclusive and co-promotion territories. In our exclusive territories, we pay Daiichi Sankyo a royalty specific to these territories. Profit-share payments made to Daiichi Sankyo are recorded as marketing, selling, and administrative expenses. All royalties paid to Daiichi Sankyo and the third-party manufacturer are recorded in cost of sales. Effient sales were $508.7 million, $457.2 million, and $302.5 million for the years ended December 31, 2013, 2012, and 2011, respectively.

Erbitux®

We have several collaborations with respect to Erbitux. The most significant collaborations are in the U.S., Canada, and Japan (Bristol-Myers Squibb Company); and worldwide except the U.S. and Canada (Merck KGaA). Upon expiration of the agreements, all of the rights to Erbitux in the U.S. and Canada return to us and certain rights to Erbitux outside the U.S. and Canada will remain with Merck KGaA (Merck).

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

	2013	2012	2011
Net product sales	$58.5	$76.4	$87.6
Collaboration and other revenue	315.2	320.6	321.6
Total revenue	$373.7	$397.0	$409.2

Bristol-Myers Squibb Company

Pursuant to commercial agreements with Bristol-Myers Squibb Company and E.R. Squibb (collectively, BMS), we are co-developing Erbitux in the U.S. and Canada with BMS through September 2018, exclusively, and in Japan with BMS and Merck through 2032. Under these arrangements, Erbitux research and development and other costs are shared by both companies according to a predetermined ratio.

Responsibilities associated with clinical and other ongoing studies are apportioned between the parties under the agreements. Collaborative reimbursements received by us for supply of clinical trial materials; for research and development; and for a portion of marketing, selling, and administrative expenses are recorded as a reduction to the respective expense line items on the consolidated statement of operations. We receive a distribution fee in the form of a royalty from BMS, based on a percentage of net sales in the U.S. and Canada, which is recorded in collaboration and other revenue. Royalty expense paid to third parties, net of any reimbursements received, is recorded as a reduction of collaboration and other revenue.

We are responsible for the manufacture and supply of all requirements of Erbitux in bulk-form active pharmaceutical ingredient (API) for clinical and commercial use in the U.S. and Canada, and BMS will purchase all of its requirements of API for commercial use from us, subject to certain stipulations per the agreement. Sales of Erbitux to BMS for commercial use are reported in net product sales.

Merck KGaA

A development and license agreement grants Merck exclusive rights to market Erbitux outside of the U.S. and Canada, and expires in December 2018. A separate agreement grants co-exclusive rights among Merck, BMS and us in Japan and expires in 2032.

Merck manufactures Erbitux for supply in its territory as well as for Japan. We receive a royalty on the sales of Erbitux outside of the U.S. and Canada, which is included in collaboration and other revenue as earned. Collaborative reimbursements received for research and development and for marketing, selling, and administrative expenses are recorded as a reduction to the respective expense line items on the consolidated statement of operations. Royalty expense paid to third parties, net of any royalty reimbursements received, is recorded as a reduction of collaboration and other revenue.

Diabetes Collaboration

In January 2011, we and Boehringer Ingelheim entered into a global agreement to jointly develop and commercialize a portfolio of diabetes compounds. Currently, the compounds included in the collaboration are Boehringer Ingelheim's two oral diabetes agents, linagliptin and empagliflozin, and our new insulin glargine product. Additionally, Boehringer Ingelheim may elect to opt in to the Phase III development and potential commercialization of our anti-TGF-beta monoclonal antibody. Under the terms of the global agreement, we made an initial one-time payment to Boehringer Ingelheim of $388.0 million and recorded an acquired IPR&D charge, which was included as expense in the first quarter of 2011 and was deductible for tax purposes.

Linagliptin was subsequently approved in 2011 and launched in the U.S. (trade name Tradjenta®), Japan (trade name Trazenta™), certain countries in Europe (trade name Trajenta®), and other countries. Currently, empagliflozin and the new insulin glargine product are both under regulatory review in the U.S., Europe, and Japan, and the anti-TGF-beta monoclonal antibody is in Phase II clinical testing.

In connection with the approval of linagliptin in the U.S., Japan, and Europe, in 2011 we paid $478.7 million in success-based regulatory milestones, all of which were capitalized as intangible assets and are being amortized to cost of sales. We incurred milestone-related expenses of $97.2 million in connection with regulatory submissions for empagliflozin in the U.S., Europe, and Japan during 2013. These regulatory submission milestones were recorded as research and development expenses. We may also pay up to 225.0 million euro in additional success-based regulatory milestones for empagliflozin.

During 2013, we earned $50.0 million in milestones for the regulatory submissions of our new insulin glargine product in the U.S., Europe, and Japan. These submission milestones were recorded as income in other–net, (income) expense. In the future, we will be eligible to receive up to $250.0 million in success-based regulatory milestones on our new insulin glargine product.

Should Boehringer Ingelheim elect to opt in to the Phase III development and potential commercialization of the anti-TGF-beta monoclonal antibody, we would be eligible for up to $525.0 million in opt-in and success-based regulatory milestone payments.

The companies share ongoing development costs equally. The companies also share in the commercialization costs and gross margin for any product resulting from the collaboration that receives regulatory approval. We record our portion of the gross margin as collaboration and other revenue, and we record our portion of the commercialization costs as marketing, selling, and administrative expense. Each company will also be entitled to potential performance payments on sales of the molecules they contribute to the collaboration. Our revenue related to this collaboration (which is, to-date, entirely related to Trajenta) was $249.2 million, $88.6 million, and $15.1 million for the years ended December 31, 2013, 2012, and 2011, respectively.

Solanezumab

We have an agreement with an affiliate of TPG-Axon Capital (TPG) whereby TPG funded a portion of the Phase III development of solanezumab. Under the agreement, TPG’s obligation to fund solanezumab costs was not material and ended in the first half of 2011. In exchange for their funding, TPG may receive success-based sales milestones totaling approximately $70 million and mid-single digit royalties contingent upon the successful development of solanezumab. The royalties would be paid for approximately ten years after launch of a product.

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Baricitinib

In December 2009, we entered into a worldwide license and collaboration agreement with Incyte Corporation (Incyte) to acquire development and commercialization rights to its Janus tyrosine kinase (JAK) inhibitor compound, now known as baricitinib, and certain follow-on compounds, for the treatment of inflammatory and autoimmune diseases. Incyte has the right to receive tiered, double-digit royalty payments on future global sales with rates ranging up to 20 percent if the product is successfully commercialized. The agreement provides Incyte with options to co-develop these compounds on an indication-by-indication basis by funding 30 percent of the associated development costs from the initiation of a Phase IIb trial through regulatory approval in exchange for increased tiered royalties ranging up to percentages in the high twenties. In 2010, Incyte exercised its option to co-develop baricitinib in rheumatoid arthritis. The agreement also provides Incyte with an option to co-promote in the U.S. and calls for payments associated with certain development, success-based regulatory, and sales-based milestones. Upon initiation of Phase III trials for the treatment of rheumatoid arthritis in the fourth quarter of 2012, we incurred a milestone-related expense of $50.0 million which was recorded as research and development expense. As of December 31, 2013, Incyte is eligible to receive up to $415.0 million of additional payments from us contingent upon certain development and success-based regulatory milestones as well as an additional $150.0 million of potential sales-based milestones.

Tanezumab

In October 2013, we entered into a collaboration agreement with Pfizer Inc. (Pfizer) to jointly develop and globally commercialize tanezumab for the potential treatment of osteoarthritis pain, chronic low back pain and cancer pain. Tanezumab is currently in Phase III development and is subject to a partial clinical hold by the FDA pending submission of nonclinical data to the FDA. Under the agreement, the companies share equally the ongoing development costs and, if successful, in gross margins and commercialization expenses. Contingent upon the parties continuing in the collaboration after receipt of the FDA's response to the submission of the nonclinical data, we will be obligated to pay an upfront fee of $200.0 million. This payment would be immediately expensed. In addition to this fee, we may pay up to $350.0 million in success-based regulatory milestones and up to $1.23 billion in a series of sales-based milestones, contingent upon the commercial success of tanezumab. Both parties have the right to terminate the agreement under certain circumstances.

Summary of Collaboration-Related Commission and Profit-Share Payments

The aggregate amount of commission and profit-share payments included in marketing, selling, and administrative expense pursuant to the collaborations described above was $203.7 million, $188.5 million, and $125.4 million for the years ended December 31, 2013, 2012, and 2011, respectively.

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

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

	2013	2012	2011
Severance	$90.6	$74.5	$251.8
Asset impairment and other special charges	30.0	206.6	149.6
Asset impairment, restructuring, and other special charges	$120.6	$281.1	$401.4

Severance costs listed above for all years relate to initiatives to reduce our cost structure and global workforce.

For the year ended December 31, 2013, we incurred $30.0 million of asset impairment and other special charges related primarily to costs associated with the anticipated closure of a packaging and distribution facility in Germany.

For the year ended December 31, 2012, we incurred $206.6 million of asset impairment and other special charges consisting of $122.6 million related to an intangible asset impairment for liprotamase (see Note 8) net of the reduction of the related contingent consideration liability, $64.0 million related to the recognition of an

asset impairment associated with the decision to stop development of a delivery device platform, and $20.0 million resulting from a change in our estimates of returned product related to the withdrawal of Xigris™ from the market during the fourth quarter of 2011.

For the year ended December 31, 2011, we incurred $149.6 million of asset impairments and other special charges primarily consisting of $85.0 million for returned product and contractual commitments related to the withdrawal of Xigris from the market and $56.1 million related to our decision to vacate certain leased premises.

Note 6: Inventories

Inventories at December 31 consisted of the following:

	2013	2012
Finished products	$968.1	$834.4
Work in process	1,868.3	1,735.8
Raw materials and supplies	259.0	256.1
	3,095.4	2,826.3
Reduction to LIFO cost	(166.6)	(182.5)
Inventories	$2,928.8	$2,643.8

Inventories valued under the LIFO method comprised $1.02 billion and $994.3 million of total inventories at December 31, 2013 and 2012, respectively.

Note 7: Financial Instruments

Financial instruments that potentially subject us to credit risk consist principally of trade receivables and interest-bearing investments. Wholesale distributors of life-sciences products account for a substantial portion of trade receivables; collateral is generally not required. The risk associated with this concentration is mitigated by our ongoing credit-review procedures and insurance. A large portion of our cash is held by a few major financial institutions. We monitor our exposures with these institutions and do not expect any of these institutions to fail to meet their obligations. Major financial institutions represent the largest component of our investments in corporate debt securities. In accordance with documented corporate policies, we monitor the amount of credit exposure to any one financial institution or corporate issuer. We are exposed to credit-related losses in the event of nonperformance by counterparties to risk-management instruments but do not expect any counterparties to fail to meet their obligations given their high credit ratings.

At December 31, 2013, we had outstanding foreign currency forward commitments to purchase 462.6 million U.S. dollars and sell 337.6 million euro; commitments to purchase 520.7 million euro and sell 716.8 million U.S. dollars; commitments to purchase 180.7 million British pounds and sell 216.0 million euro; and commitments to purchase 234.4 million U.S. dollars and sell 24.35 billion Japanese yen, which will all settle within 30 days.

At December 31, 2013, substantially all of our total debt is at a fixed rate. We have converted approximately 65 percent of our fixed-rate debt to floating rates through the use of interest rate swaps.

During 2013 we entered into forward-starting interest rate swaps with a notional amount of $500.0 million and maturities not exceeding 30 years to hedge a portion of the cash flows associated with the planned refinancing of our $1.00 billion March 2014 debt maturity.

The Effect of Risk Management Instruments on the Statement of Operations

The following effects of risk-management instruments were recognized in other—net, (income) expense:

	2013	2012	2011
Fair value hedges:			
Effect from hedged fixed-rate debt	$(308.2)	$51.5	$259.6
Effect from interest rate contracts	308.2	(51.5)	(259.6)
Cash flow hedges:			
Effective portion of losses on interest rate contracts reclassified from accumulated other comprehensive loss	9.0	9.0	9.0
Net (gains) losses on foreign currency exchange contracts not designated as hedging instruments	15.4	(35.8)	97.4

The effective portion of net gains (losses) on equity contracts in designated cash flow hedging relationships recorded in other comprehensive income (loss) was $(149.6) million, $0.0 million, and $35.6 million for the years ended December 31, 2013, 2012, and 2011, respectively. There were no equity contracts in designated cash flow hedging relationships in 2012. During the next 12 months, we expect to sell the underlying equity securities in designated cash flow hedging relationships that were outstanding at December 31, 2013, and will reclassify to earnings the accumulated other comprehensive loss related to the cash flow hedges and the unrealized gains on the underlying equity securities. The unrealized gains are in excess of the losses on the cash flow hedges.

For forward-starting interest rate swaps in designated cash flow hedging relationships associated with an anticipated debt issuance, the effective portion of net gains recorded in other comprehensive income (loss) was $16.7 million for the year ended December 31, 2013. There were no forward-starting interest rate swaps in designated cash flow hedging relationships in 2012 and 2011.

During the next 12 months, we expect to reclassify from accumulated other comprehensive loss to earnings $8.8 million of pretax net losses on cash flow hedges of the variability in expected future interest payments on our floating rate debt.

During the years ended December 31, 2013, 2012, and 2011, net losses related to ineffectiveness, as well as net losses related to the portion of our risk-management hedging instruments, fair value hedges, and cash flow hedges that were excluded from the assessment of effectiveness, were not material.

Fair Value of Financial Instruments

The following tables summarize certain fair value information at December 31 for assets and liabilities measured at fair value on a recurring basis, as well as the carrying amount and amortized cost of certain other investments:

Description	Carrying Amount	Amortized Cost	Fair Value Measurements Using Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Fair Value
December 31, 2013						
Cash and cash equivalents	$3,830.2	$3,830.2	$3,772.6	$57.6	$	$3,830.2
Short-term investments:						
U.S. government and agencies	$276.4	$276.6	$276.4	$	$	$276.4
Corporate debt securities	931.7	929.8		931.7		931.7
Other securities	2.7	2.7		2.7		2.7
Marketable equity	356.3	75.0	356.3			356.3
Short-term investments	$1,567.1	$1,284.1				
Noncurrent investments:						
U.S. government and agencies	$1,115.6	$1,126.1	$1,035.6	$80.0	$	$1,115.6
Corporate debt securities	4,940.5	4,933.7		4,940.5		4,940.5
Mortgage-backed	636.0	652.4		636.0		636.0
Asset-backed	490.0	494.5		490.0		490.0
Other securities	7.3	8.3		7.3		7.3
Marketable equity	81.2	22.8	81.2			81.2
Equity method and other investments[1]	354.3	354.3				
Noncurrent investments	$7,624.9	$7,592.1				
December 31, 2012						
Cash and cash equivalents	$4,018.8	$4,018.8	$3,964.4	$54.4	$	$4,018.8
Short-term investments:						
U.S. government and agencies	$150.2	$150.2	$150.2	$	$	$150.2
Corporate debt securities	1,503.5	1,501.5		1,503.5		1,503.5
Other securities	11.8	11.8		11.8		11.8
Short-term investments	$1,665.5	$1,663.5				
Noncurrent investments:						
U.S. government and agencies	$1,362.7	$1,360.3	$1,122.4	$240.3	$	$1,362.7
Corporate debt securities	3,351.3	3,322.9		3,351.3		3,351.3
Mortgage-backed	668.1	677.7		668.1		668.1
Asset-backed	519.0	523.5		519.0		519.0
Other securities	3.3	3.3		3.3		3.3
Marketable equity	175.8	83.0	175.8			175.8
Equity method and other investments[1]	233.7	233.7				
Noncurrent investments	$6,313.9	$6,204.4				

[1] Fair value not applicable

Description	Carrying Amount	Fair Value Measurements Using Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Fair Value
Long-term debt, including current portion					
December 31, 2013	$(5,212.9)	$	$(5,490.9)	$	$(5,490.9)
December 31, 2012	(5,531.3)		(5,996.6)		(5,996.6)

Description	Carrying Amount	Fair Value Measurements Using Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Fair Value
December 31, 2013					
Risk-management instruments					
Interest rate contracts designated as hedging instruments:					
Other receivables	$20.1	$	$20.1	$	$20.1
Sundry	278.7		278.7		278.7
Other noncurrent liabilities	(0.9)		(0.9)		(0.9)
Foreign exchange contracts not designated as hedging instruments:					
Other receivables	6.7		6.7		6.7
Other current liabilities	(7.1)		(7.1)		(7.1)
Equity contracts designated as hedging instruments:					
Other current liabilities	(149.6)		(149.6)		(149.6)
December 31, 2012					
Risk-management instruments					
Interest rate contracts designated as hedging instruments:					
Sundry	589.4		589.4		589.4
Foreign exchange contracts not designated as hedging instruments:					
Other receivables	11.0		11.0		11.0
Other current liabilities	(17.5)		(17.5)		(17.5)

Risk-management instruments above are disclosed on a gross basis. There are various rights of setoff associated with certain of the risk-management instruments above that are subject to an enforceable master netting arrangement or similar agreements. Although various rights of setoff and master netting arrangements or similar agreements may exist with the individual counterparties to the risk-management instruments above, individually, these financial rights are not material.

We determine fair values based on a market approach using quoted market values, significant other observable inputs for identical or comparable assets or liabilities, or discounted cash flow analyses. The fair value of equity method investments and other investments is not readily available.

The table below summarizes the contractual maturities of our investments in debt securities measured at fair value as of December 31, 2013:

	Maturities by Period				
	Total	Less Than 1 Year	1-5 Years	6-10 Years	More Than 10 Years
Fair value of debt securities	$8,400.2	$1,210.8	$5,977.4	$471.3	$740.7

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

	2013	2012
Unrealized gross gains	$375.6	$140.5
Unrealized gross losses	59.8	29.0
Fair value of securities in an unrealized gain position	4,982.7	5,246.0
Fair value of securities in an unrealized loss position	3,664.7	2,102.0

Other-than-temporary impairment losses on investment securities of $11.3 million, $22.6 million, and $31.1 million were recognized in the consolidated statements of operations for the years ended December 31, 2013, 2012, and 2011, respectively. For fixed-income securities, the amount of credit losses represents the difference between the present value of cash flows expected to be collected on these securities and the amortized cost. Factors considered in assessing the credit loss were the position in the capital structure, vintage and amount of collateral, delinquency rates, current credit support, and geographic concentration.

The securities in an unrealized loss position include fixed-rate debt securities of varying maturities. The value of fixed-income securities is sensitive to changes in the yield curve and other market conditions. Approximately 90 percent of the securities in a loss position are investment-grade debt securities. At this time, there is no indication of default on interest or principal payments for debt securities other than those for which an other-than-temporary impairment charge has been recorded. We do not intend to sell and it is not more likely than not we will be required to sell the securities in a loss position before the market values recover or the underlying cash flows have been received, and we have concluded that no additional other-than-temporary loss is required to be charged to earnings as of December 31, 2013.

Activity related to our investment portfolio, substantially all of which related to available-for-sale securities, was as follows:

	2013	2012	2011
Proceeds from sales	$13,753.5	$6,529.8	$2,268.3
Realized gross gains on sales	49.5	82.3	140.0
Realized gross losses on sales	15.4	10.9	9.9

Note 8: Goodwill and Other Intangibles

Goodwill and other indefinite-lived intangible assets at December 31 were as follows:

	2013	2012
Goodwill (by segment):		
Human pharmaceutical products	$1,354.7	$1,364.2
Animal health	162.1	137.1
Total goodwill	1,516.8	1,501.3
In-process research and development	33.6	65.0
Total indefinite-lived intangible assets	$1,550.4	$1,566.3

No impairments occurred with respect to the carrying value of goodwill for the years ended December 31, 2013, 2012, and 2011.

IPR&D consists of the acquisition date fair value of products under development acquired in business combinations that have not yet achieved regulatory approval for marketing adjusted for subsequent impairments. Examples of such products acquired in business combinations include liprotamase and Amyvid®, which are discussed further below. As discussed in Note 1, we use the "income method" to calculate the fair value of the IPR&D assets, which is a Level 3 fair value measurement.

No material impairments occurred with respect to the carrying value of IPR&D for the year ended December 31, 2013.

In 2012, we recorded impairment charges of $205.0 million related to liprotamase as a result of changes in key assumptions used in the valuation, based upon additional communications with the FDA regarding the clinical trial that would be required for resubmission, and our expectations for the product.

In 2011, we recorded impairment charges of $151.5 million due primarily to the impairment of the IPR&D assets related to Amyvid and liprotamase. The impairment of Amyvid was due to a delay in product launch and lower sales projections during the early part of the product's expected life cycle. In April 2011, we received a complete response letter from the FDA for the New Drug Application (NDA) for liprotamase, which communicated the need for us to conduct an additional clinical trial prior to a resubmission, resulting in an impairment of liprotamase.

The components of finite-lived intangible assets at December 31 were as follows:

	2013			2012		
Description	Carrying Amount—Gross	Accumulated Amortization	Carrying Amount—Net	Carrying Amount—Gross	Accumulated Amortization	Carrying Amount—Net
Marketed products	$5,136.1	$(2,447.2)	$2,688.9	$5,107.9	$(1,987.0)	$3,120.9
Other	164.8	(73.0)	91.8	129.5	(64.0)	65.5
Total finite-lived intangible assets	$5,300.9	$(2,520.2)	$2,780.7	$5,237.4	$(2,051.0)	$3,186.4

Marketed products consist of the amortized cost of the rights to assets acquired in business combinations and approved for marketing in a significant global jurisdiction (U.S., Europe, and Japan) and capitalized milestone payments. Other intangibles consist primarily of the amortized cost of licensed platform technologies that have alternative future uses in research and development, manufacturing technologies, and customer relationships from business combinations. No material impairments occurred with respect to the carrying value of finite-lived intangible assets for the years ended December 31, 2013, 2012 and 2011.

See Note 3 for further discussion of intangible assets acquired in recent business combinations.

As of December 31, 2013, the remaining weighted-average amortization period for finite-lived intangible assets is approximately 8 years. Amortization expense was $555.0 million, $563.0 million, and $469.0 million for 2013, 2012, and 2011, respectively. The estimated amortization expense associated with our current finite-lived intangible assets for each of the next five years approximates $530 million in 2014, $490 million in 2015, $380 million in 2016, $200 million in 2017, and $180 million in 2018. Amortization expense is included in either cost of sales, marketing, selling, and administrative or research and development depending on the nature of the intangible asset being amortized.

Note 9: Property and Equipment

At December 31, property and equipment consisted of the following:

	2013	2012
Land	$198.7	$201.4
Buildings	6,489.9	6,373.8
Equipment	7,752.7	7,542.9
Construction in progress	1,205.4	799.9
	15,646.7	14,918.0
Less accumulated depreciation	(7,671.2)	(7,157.8)
Property and equipment, net	$7,975.5	$7,760.2

Depreciation expense for the years ended December 31, 2013, 2012, and 2011 was $774.8 million, $754.0 million, and $732.4 million, respectively. Interest costs of $24.1 million, $21.0 million, and $25.7 million were capitalized as part of property and equipment for the years ended December 31, 2013, 2012, and 2011, respectively. Total rental expense for all leases, including contingent rentals (not material), amounted to $227.2 million, $262.2 million, and $267.4 million for the years ended December 31, 2013, 2012, and 2011, respectively. Assets under capital leases included in property and equipment, net on the consolidated balance sheets, capital lease obligations entered into, and future minimum rental commitments are not material.

Note 10: Borrowings

Long-term debt at December 31 consisted of the following:

	2013	2012
4.20 to 7.13 percent notes (due 2014-2037)	$4,887.3	$4,887.3
Other, including capitalized leases	27.1	37.4
Fair value adjustment	298.5	606.6
	5,212.9	5,531.3
Less current portion	(1,012.6)	(11.9)
Long-term debt	$4,200.3	$5,519.4

Current maturities of long-term debt of $1.51 billion were repaid during the year ended December 31, 2012.

The aggregate amounts of maturities on long-term debt for the next five years are $1.01 billion in 2014, $9.5 million in 2015, $205.6 million in 2016, $1.00 billion in 2017, and $200.3 million in 2018.

At December 31, 2013, we have $1.36 billion of unused committed bank credit facilities, $1.20 billion of which is a revolving credit facility that backs our commercial paper program and matures in April 2015. There were no amounts outstanding under the revolving credit facility during the year ended December 31, 2013. Compensating balances and commitment fees are not material, and there are no conditions that are probable of occurring under which the lines may be withdrawn.

We have converted approximately 65 percent of all fixed-rate debt to floating rates through the use of interest rate swaps. The weighted-average effective borrowing rates based on debt obligations and interest rates at December 31, 2013 and 2012, including the effects of interest rate swaps for hedged debt obligations, were 3.10 percent and 3.20 percent, respectively.

For the years ended December 31, 2013, 2012, and 2011, cash payments for interest on borrowings totaled $139.7 million, $171.9 million, and $167.4 million, respectively, net of capitalized interest.

In accordance with the requirements of derivatives and hedging guidance, the portion of our fixed-rate debt obligations that is hedged, as a fair value hedge, is reflected in the consolidated balance sheets as an amount equal to the sum of the debt’s carrying value plus the fair value adjustment representing changes in fair value of the hedged debt attributable to movements in market interest rates subsequent to the inception of the hedge.

Note 11: Stock-Based Compensation

Stock-based compensation expense of $144.9 million, $141.5 million, and $147.4 million was recognized for the years ended December 31, 2013, 2012, and 2011, respectively, as well as related tax benefits of $50.7 million, $49.5 million, and $51.6 million, respectively. Our stock-based compensation expense consists of performance awards (PAs), shareholder value awards (SVAs), and restricted stock units (RSUs). We recognize stock-based compensation expense over the requisite service period of the individual grantees, which equals the vesting period. We provide newly issued shares and treasury stock to satisfy stock option exercises and for the issuance of PA, SVA, and RSU shares. We classify tax benefits resulting from tax deductions in excess of the compensation cost recognized for exercised stock options as a financing cash flow in the consolidated statements of cash flows.

At December 31, 2013, additional stock-based compensation awards may be granted under the 2002 Lilly Stock Plan for not more than 100.0 million shares.

Performance Award Program

PAs are granted to officers and management and are payable in shares of our common stock. The number of PA shares actually issued, if any, varies depending on the achievement of certain pre-established earnings-per-share targets over a two-year period. PA shares are accounted for at fair value based upon the closing stock price on the date of grant and fully vest at the end of the measurement periods. The fair values of PAs granted for the years ended December 31, 2013, 2012, and 2011 were $50.19, $35.74, and $31.90, respectively. The number of shares ultimately issued for the PA program is dependent upon the earnings achieved during the vesting period. Pursuant to this plan, approximately 0.7 million shares, 1.6 million shares, and 3.9 million shares were issued during the years ended December 31, 2013, 2012, and 2011, respectively. Approximately 0.6 million shares are expected to be issued in 2014. As of December 31, 2013, the total remaining unrecognized compensation cost related to nonvested PAs was $18.9 million, which will be amortized over the weighted-average remaining requisite service period of 12 months.

Shareholder Value Award Program

SVAs are granted to officers and management and are payable in shares of our common stock at the end of a three-year period. The number of shares actually issued, if any, varies depending on our stock price at the end of the three-year vesting period compared to pre-established target stock prices. We measure the fair value of the SVA unit on the grant date using a Monte Carlo simulation model. The model utilizes multiple input variables that determine the probability of satisfying the market condition stipulated in the award grant and calculates the fair value of the award. Expected volatilities utilized in the model are based on implied volatilities from traded options on our stock, historical volatility of our stock price, and other factors. Similarly, the dividend yield is based on historical experience and our estimate of future dividend yields. The risk-free interest rate is derived from the U.S. Treasury yield curve in effect at the time of grant. The weighted-average fair values of the SVA units granted during the years ended December 31, 2013, 2012, and 2011 were $45.17, $30.35, and $28.33, respectively, determined using the following assumptions:

(Percents)	2013	2012	2011
Expected dividend yield	3.50 %	4.50 %	4.90 %
Risk-free interest rate	.08-.43	.10-.36	.20-1.36
Range of volatilities	18.95-22.37	22.40-25.64	27.61-29.10

A summary of the SVA activity is presented below:

Units Attributable to SVAs (in thousands)	2013	2012	2011
Outstanding at January 1	7,539	7,036	6,381
Granted	1,795	2,439	2,561
Issued	(2,397)	(973)	(428)
Forfeited or expired	(301)	(963)	(1,478)
Outstanding at December 31	6,636	7,539	7,036

Approximately 2.2 million shares are expected to be issued in 2014. As of December 31, 2013, the total remaining unrecognized compensation cost related to nonvested SVAs was $51.6 million, which will be amortized over the weighted-average remaining requisite service period of 20 months.

Restricted Stock Units

RSUs are granted to certain employees and are payable in shares of our common stock. RSU shares are accounted for at fair value based upon the closing stock price on the date of grant. The corresponding expense is amortized over the vesting period, typically 3 years. The fair values of RSU awards granted during the years ended December 31, 2013, 2012, and 2011 were $54.10, $39.65, and $35.80, respectively. The number of shares ultimately issued for the RSU program remains constant with the exception of forfeitures. Pursuant to this plan, 1.1 million, 1.4 million, and 1.5 million shares were granted during the years ended December 31, 2013, 2012, and 2011, respectively, and approximately 0.8 million, 0.3 million, and 0.2 million shares were issued during the years ended December 31, 2013, 2012, and 2011, respectively. Approximately 0.8 million shares are expected to be issued in 2014. As of December 31, 2013, the total remaining unrec