LILLY ELI & CO
Form 10-K
February 21, 2013

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, 2012
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 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 Act: None

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes þ No ¨

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the 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 Securities Exchange Act of 1934 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.¨

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 of 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 of the 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 $42,793,000,000

Number of shares of common stock outstanding as of February 15, 2013: 1,134,411,762

Portions of the Registrant's Proxy Statement to be filed on or about March 25, 2013 have been incorporated by reference into Part III of this report.

1

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 many risks and uncertainties associated with pharmaceutical research and development;
- the possibility that pipeline products may not receive the necessary clinical and manufacturing regulatory approvals or be commercially successful;
- unexpected safety or efficacy concerns associated with our products;
- competitive developments affecting current products;
- market uptake of recently launched products;
- the timing of anticipated regulatory approvals and launches of new products;
- regulatory actions regarding currently marketed products;
- issues with product supply;
- regulatory changes or other developments;
- regulatory compliance problems or government investigations;
- our ability to protect and enforce patents and other intellectual property;
- changes in patent law or regulations related to data-package exclusivity;
- litigation involving current or future products;
- the impact of governmental actions regarding pricing, importation, and reimbursement for pharmaceuticals, including U.S. health care reform;
- 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 the Elanco Animal Health division, develops, manufactures, and markets products for both food 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 130 countries.

Human Pharmaceutical Products

Our human pharmaceutical products include:

Neuroscience products, our largest-selling product group, 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 in children, adolescents, and in the U.S., in adults
- Prozac®, for the treatment of major depressive disorder, obsessive-compulsive disorder, bulimia nervosa, and panic disorder
- Symbyax®, for the treatment of bipolar depression and treatment-resistant depression
- 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.

Endocrinology products, including:

- Humalog®, Humalog Mix 75/25,™ and Humalog Mix 50/50,™ for the treatment of diabetes
- Humulin®, for the treatment of diabetes
- Byetta®, for the treatment of type 2 diabetes
- Bydureon®, for the treatment of type 2 diabetes (see “Human Pharmaceutical Marketing Collaborations” below for information about the termination of our collaboration with Amylin Pharmaceuticals for Byetta and Bydureon)
- Tradjenta®, for the treatment of type 2 diabetes
- Jentadueto®, a combination tablet of Tradjenta 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.

Oncology products, including:

- Alimta®, for the first-line treatment, in combination with another agent, of advanced non-small cell lung cancer for patients with non-squamous cell histology; for the second-line treatment of advanced non-squamous non-small cell lung cancer; as monotherapy for the maintenance treatment of advanced non-squamous non-small cell lung cancer in patients whose disease has not progressed immediately following chemotherapy treatment; and in combination with another agent, for the treatment of malignant pleural mesothelioma
- Gemzar®, for the treatment of pancreatic cancer; in combination with other agents, for the treatment of metastatic breast cancer, non-small cell lung cancer, and advanced or recurrent ovarian cancer; and in the EU for the treatment of bladder cancer
- 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.

Cardiovascular products, including:

- Cialis®, for the treatment of erectile dysfunction and benign prostatic hyperplasia
- Effient®, for the reduction of thrombotic cardiovascular events (including stent thrombosis) in patients with acute coronary syndrome who are managed with an artery-opening procedure known as percutaneous coronary intervention (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
- Livalo®, for use as an adjunct to diet in the treatment of high cholesterol (primary hyperlipidemia or mixed dyslipidemia).

Other pharmaceuticals, including:

- Vancocin® HCl, used primarily to treat staphylococcal infections
- Ceclor,™ for the treatment of a wide range of bacterial infections.

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
- 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
- Paylean® and Optaflexx,™ leanness and performance enhancers for swine and cattle, respectively
- Posilac®, a protein supplement to improve milk productivity in dairy cows

- Coban®, Monteban®, and Maxiban®, anticoccidial agents for use in poultry
- Apralan,™ an antibiotic used to control enteric infections in calves and swine
- 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
- Reconcile®, for treatment of canine separation anxiety in conjunction with behavior modification training.

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 2012, 2011, and 2010, three wholesale distributors in the U.S.—AmerisourceBergen Corporation, McKesson Corporation, and Cardinal Health, Inc.—each accounted for between 10 percent and 16 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 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, government and long-term care institutions, hospitals, and certain retail pharmacies. We have entered into arrangements with many of 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 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). In a collaboration that ended in December 2012, we co-marketed Evista in Japan with Chugai Pharmaceutical Co., Ltd. We now market Evista in Japan without a collaboration partner.
- Byetta and Bydureon have been the subject of a collaboration with Amylin Pharmaceuticals, Inc., under which we co-promoted Byetta in the U.S. and Puerto Rico and have exclusive marketing rights to both products in other territories. In November 2011, we entered into agreement with Amylin to

terminate the collaboration. Commercial operations were transferred to Amylin in the U.S. at the end of November 2011. Outside the U.S., we anticipate transferring responsibility for commercialization of exenatide to Amylin in substantially all markets by the end of the first quarter of 2013. See Item 8, "Financial Statements and Supplementary Data—Note 4, Collaborations," for more information on the November 2011 agreement.

- Erbitux is marketed in North America by Bristol-Myers Squibb. We have the option to co-promote Erbitux in North America. Outside North America, 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 in the U.S., major European markets, Brazil, Mexico, China, 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.
- Tradjenta and Jentadueto are being jointly developed and commercialized with us by Boehringer Ingelheim pursuant to a collaboration agreement reached in 2011 under which both parties contributed certain mid- and late-stage development potential diabetes treatments 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 include safety, effectiveness, and ease of use of our products; 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 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 progressive price reductions, decreased sales volume, or both. Increasingly, to obtain favorable reimbursement and formulary positioning with government payers, managed care organizations, and pharmacy benefits managers, we must demonstrate that our human pharmaceuticals offer not only medical benefits but also more value as compared with other forms of care.

Manufacturers of generic pharmaceuticals invest far less than we do in research and development and typically have lower manufacturing cost structures; therefore, they can price their products much lower than our branded products. Accordingly, when our branded 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.

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 pharmaceuticals 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.

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.

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 an additional five years.

Loss of 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 expiry of the product 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 based on the innovator company's regulatory submission data for the drug. For small molecule new molecular entities, the base period of data package protection is five years in the U.S., 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.
- Some of our current products, including Erbitux and ReoPro, and many of the new molecular entities in our research pipeline are biological products (biologics). Based on 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 biologic products. 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. Regulators in the EU and other countries also have been given the authority to approve biosimilars. The specific requirements of these new approval processes, and 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, are not

yet entirely clear, and will depend on a number of regulatory and marketplace factors that are still developing.

- 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.
- The FDA also has authority to grant "orphan" status to a specific use of a drug. Under the U.S. orphan drug law, 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 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, and substantive limitations, 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 product patent.

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

- Alimta is protected by a compound patent (2016), as extended by pediatric exclusivity (2017), and a vitamin dosage regimen patent (2021), as extended by pediatric exclusivity (2022).
- Cialis is protected by compound and use patents (2017).
- Cymbalta is protected by a compound patent, as extended by pediatric exclusivity (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 is protected by a compound patent (May 2013).

- Strattera is protected by a patent covering its use in treating attention deficit-hyperactivity disorder (2016), as extended by pediatric exclusivity (2017).
- Tradjenta 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 or data package protection includes:

- Alimta in most major European countries (compound patent 2015, vitamin dosage regimen patent 2021)
- Cialis in major European countries (compound patent 2017)
- Cymbalta in major European countries (data package protection August 2014)
- Zyprexa in Japan (compound patent 2015).

U.S. patent protection or data package protection for our new molecular entity that has been submitted for regulatory review is as follows (Additional information about this molecule is provided in Item 7, "Management's Discussion and Analysis—Late-Stage Pipeline"):

- Liprotamase, if approved, would be protected for at least the five-year data package protection period following U.S. regulatory approval.

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 larger 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 compound and process 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 a wide array of 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 on Alimta. For more information on this litigation, see Item 8, "Financial Statements and Supplementary Data —Note 15, 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 challenges to our Alimta patent protection in Europe, see Item 8, "Financial Statements and Supplementary Data—Note 15, 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.

The FDA extensively regulates all aspects of manufacturing quality for human pharmaceuticals under its current Good Manufacturing Practices (cGMP) regulations. 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 cGMP compliance. However, in the event we fail to adhere to cGMP requirements in the future, we could be subject to interruptions in production, fines and penalties, and delays in new product approvals.

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.

The marketing, promotional, and pricing practices of 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

10

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. Over this period, 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. Recently 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 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 have enhanced their laws and regulations in this area, increased their enforcement activities, and 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 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, we are required to provide rebates to state governments on their purchases of our human pharmaceuticals under state Medicaid programs and to private payers who cover patients in certain types of health care facilities that serve low-income and uninsured patients (known as 340B facilities). We also give rebates to private payers who provide prescription drug benefits to seniors covered by Medicare. Additional cost-containment measures have been adopted or proposed by federal, state, and local government entities that provide or pay for health care. In most international markets, we operate in an environment of government-mandated cost-containment programs, which may include price controls, reference pricing, discounts and rebates, restrictions on physician prescription levels, restrictions on reimbursement, compulsory licenses, health economic assessments, and generic substitution.

The 2010 enactment of the Patient Protection and Affordable Care Act and The Health Care and Education Reconciliation Act brought significant changes to U.S. health care. The minimum statutory rebate for branded prescription drugs sold to Medicaid beneficiaries increased from 15.1 percent to 23.1 percent. This rebate has been expanded to managed-Medicaid, a program that provides for the delivery of Medicaid benefits via managed care organizations, under arrangements between those organizations and state Medicaid agencies. Additionally, a prescription drug discount program for outpatient drugs in 340B facilities has been expanded. 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. See Item 7, “Management’s Discussion and Analysis—Executive Overview—Legal, Regulatory, and Other Matters,” for more discussion of U.S. health

11

care reform. At the state level, budget pressures are causing various states to impose cost-control measures such as higher rebates and more restrictive formularies.

International operations are also generally subject to extensive price and market regulations, and there are many proposals for additional cost-containment measures, 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. Recently, several governments have implemented across-the-board price cuts of branded human pharmaceuticals as part of austerity measures in the face of the global financial crisis and severe national budget deficits.

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 negatively affect our pricing and rebates.

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 2012, we employed approximately 7,700 people in 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 $5.28 billion in 2012, $5.02 billion in 2011, and $4.88 billion in 2010.

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 educational 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 investments in external research and technologies that hold the promise to complement and strengthen our own research efforts. These investments can take many forms, including licensing arrangements, co-development and co-marketing agreements, co-promotion arrangements, joint ventures, and acquisitions.

Our Elanco animal health innovation strategy is focused on identifying and developing promising technologies and potential products from internal and external sources to meet unmet veterinary needs. Our animal health scientists 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 clinical studies to collect and understand the benefits and potential risks of medicines as they are used as therapeutics. The following describes the new drug research and development process in more detail:

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 go on to the next phase of development. The probability of any one such lead molecule completing the rest of the drug development process and becoming a 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, 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 in the product

phase of development or awaiting regulatory approval are potential therapies for diabetes, various cancers, Alzheimer's disease, high-risk vascular disease, rheumatoid arthritis, lupus, psoriasis, depression, and exocrine pancreatic insufficiency. We are studying many other drug candidates in the earlier stages of development, including molecules targeting various cancers, diabetes, Alzheimer's disease, depression, migraine, anemia, cardiovascular disease, musculoskeletal disorders, renal diseases, osteoarthritis pain, and bipolar disorder. We are also developing new uses, formulations, or delivery methods for many of these molecules as well as several currently marketed products, including Alimta, Axiron, Cialis, Effient, Erbitux, and Humalog.

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.

Our 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, and packaging, take place at a number of sites throughout the world. In 2010, we sold our Tippecanoe Laboratories manufacturing site in West Lafayette, Indiana, to an affiliate of Evonik Industries AG, and entered into a nine-year supply and services agreement whereby Evonik manufactures final and intermediate-step active pharmaceutical ingredients for certain Lilly human pharmaceutical and animal health products.

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. However, pharmaceutical production processes are complex, highly regulated, and vary widely from product to product. Shifting or adding manufacturing capacity can be a very lengthy process requiring significant capital expenditures, process modifications, and regulatory approvals. Accordingly, if we were to experience 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 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 6, 2013, 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.	59	Chairman (since January 2009), President (since October 2005), Chief Executive Officer (since April 2008), and a Director (since October 2005)
Robert A. Armitage	64	Senior Vice President and General Counsel (since January 2003) (retired December 2012)
Melissa S. Barnes	44	Senior Vice President, Enterprise Risk Management and Chief Ethics and Compliance Officer (since January 2013)
Enrique A. Conterno	46	Senior Vice President and President, Lilly Diabetes (since November 2009)
Maria A. Crowe	53	President, Manufacturing Operations (since January 2012)
Stephen F. Fry	47	Senior Vice President, Human Resources and Diversity (since February 2011)
Michael J. Harrington	50	Senior Vice President and General Counsel (since January 2013)
Jan M. Lundberg, Ph.D.	59	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.	48	Senior Vice President and President, Lilly Oncology (since February 2011)
Anne Nobles	56	Senior Vice President, Enterprise Risk Management (since April 2009) and Chief Ethics and Compliance Officer (since June 2007) (retired December 2012)
Barton R. Peterson	54	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	48	Executive Vice President, Global Services (since January 2010) and Chief Financial Officer (since May 2006)
David A. Ricks	45	Senior Vice President and President, Lilly Bio-Medicines (since January 2012)
Jeffrey N. Simmons	45	Senior Vice President and President, Elanco Animal Health (since January 2008)
Jacques Tapiero	54	Senior Vice President and President, Emerging Markets (since January 2010)
Fionnuala M. Walsh	53	Senior Vice President, Global Quality (since July 2007)

Employees

At the end of 2012, we employed approximately 38,350 people, including approximately 21,200 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—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—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://investor.lilly.com/governance.cfm.

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 patent protection. There are many difficulties and uncertainties inherent in 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 of efficacy and safety for new product approvals; 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 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 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.
- 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. See Item 1, “Business—Patents, Trademarks, and Other Intellectual Property Rights,” for more details. We face generic manufacturer challenges to our patents outside the U.S. as well. 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,” for more details.

- We depend on patent-protected products for most of our revenues, cash flows, and earnings, and we will lose effective intellectual property protection for many of them in the next several years. Seven significant patent-protected products, which together composed 68 percent of our worldwide revenue in 2012, recently have lost, or will lose in the next several years, their most significant remaining U.S. patent protection and data-based protection, as well as their intellectual property-based exclusivity in most countries outside the United States:

Product	Worldwide Revenues (2012)	Percent of Total 2012 Revenues	Loss of Relevant U.S. Exclusivity
Cymbalta	$4.99 billion	22	December 2013 (compound patent plus pediatric exclusivity)
Alimta	$2.59 billion	11	2017 (compound patent plus pediatric exclusivity); 2022 (vitamin dosage regimen patent plus pediatric exclusivity)
Humalog	$2.40 billion	11	May 2013
Cialis	$1.93 billion	9	2017
Zyprexa	$1.70 billion	8	2011
Evista	$1.01 billion	4	March 2014
Strattera	$621.4 million	3	2017

Outside the U.S., important patent or data package protection includes Cymbalta in major European countries (data package protection until August 2014); Alimta in major European countries (compound patent 2015; vitamin dosage regimen patent 2021); Cialis in major European countries (compound patent 2017); and Zyprexa in Japan (compound patent 2015).

Loss of exclusivity, whether by expiration or as a consequence of litigation, typically results in a rapid and severe decline in sales. See Item 7, “Management’s Discussion and Analysis—Financial Condition,” and Item 1, “Business—Patents, Trademarks, and Other Intellectual Property Rights,” 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. Globally, governments are becoming increasingly aggressive in imposing health care cost-containment measures in response to budget deficit challenges. These measures can significantly affect our revenue and profitability. In many countries outside the U.S., government agencies strictly control, directly or indirectly, pricing, reimbursement, and patient access to our human pharmaceuticals. In the U.S., we are subject to substantial pricing, reimbursement, and access pressures from state Medicaid programs and private insurance programs and pharmacy benefit managers, including those operating under the Medicare Part D pharmaceutical benefit, and implementation of U.S. health care reform legislation is increasing these pricing pressures. In addition, many state legislative proposals would further negatively affect our pricing and reimbursement for, or access to, our products. Globally, public and private payers are increasingly restricting access to human pharmaceuticals based on the payers' assessments of comparative effectiveness and value. 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 Pharmaceutical Pricing, Reimbursement, and Access,” for more details.

- Pharmaceutical products can develop unexpected safety or efficacy concerns. Unexpected safety or efficacy concerns can arise with respect to marketed products, leading to product recalls, withdrawals, or declining revenue, as well as costly product liability claims.
- Regulatory compliance problems could be damaging to the company. The marketing, promotional, and pricing practices of pharmaceutical manufacturers, as well as the manner in which manufacturers interact with purchasers, prescribers, and patients, are subject to extensive regulation. Many companies, including 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 nonmonetary remedies, including exclusion from U.S. federal health care programs. In addition, regulatory issues concerning compliance with current Good Manufacturing Practice (cGMP) 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 cGMP 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.
- We face many product liability claims and are largely 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, Zyprexa, diethylstilbestrol (DES), Darvon®, and Prozac. See Item 8, “Financial Statements and Supplementary Data—Note 15, Contingencies,” and Item 3, “Legal Proceedings,” for more information on our current product liability litigation. Because of the nature of pharmaceutical products, it is possible that 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 have been and will continue to be largely self-insured for product liability losses for substantially all our currently marketed products. In addition, there is no assurance that we will be able to fully collect from our insurance carriers on past claims.
- 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. See Item 1, “Business—Raw Materials and Product Supply,” for more details.
- Worsening economic conditions could adversely affect our business and operating results. While 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. We have experienced delays in repayment from national health care systems in certain countries, including but not limited to Greece and regions within Spain and Italy. The ongoing euro area financial crisis has heightened our sensitivity to such trends, and we continue to monitor the countries’ and regions’ creditworthiness. A prolonged economic downturn could also adversely affect our investment portfolio, which could lead to the recognition of losses on our corporate investments and increased benefit expense related to our pension obligations. 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.
- We are increasingly dependent on information technology systems and infrastructure; system inadequacies, operating failures, or security breaches could harm our business. We rely to a large

18

extent on sophisticated information technology systems and infrastructure. The size and complexity of these systems make them potentially vulnerable to breakdown, malicious intrusion, and random attack. Likewise, confidentiality or data privacy breaches by employees or others with permitted access to our systems may pose a risk that valuable trade secrets, personal information, or other sensitive data may be exposed to unauthorized persons or to the public. Such information security breaches may be very difficult to detect. To date, system breakdowns and, to the extent we have been made aware of them, security breaches, have been infrequent in occurrence and their aggregate impact on our operations and expenses has not been material. While we have invested heavily in the protection of data and information technology, there can be no assurance that our efforts will prevent breakdowns or breaches in our systems that could adversely and materially affect 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. Failure of these third parties to meet their contractual, regulatory, or other obligations to us could adversely affect our business.
- 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 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, 2012, we owned 13 production and distribution sites in the U.S. and Puerto Rico. Together with the corporate administrative offices, these facilities contain an aggregate of approximately 10.0 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, Canada, 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 15, Contingencies." While it is not possible to determine the outcome of the legal actions, investigations and proceedings brought against us, we believe that, except as otherwise specifically noted in Item 8—Note 15, the resolution of all such matters will not have a material adverse effect on our consolidated financial position or liquidity, but could be material to our consolidated results of operations in any one accounting period.

Legal Proceedings Described in Note 15 to the Consolidated Financial Statements

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

- The U.S. patent litigation involving Alimta
- The U.S. product liability litigation involving Byetta, DES, and Zyprexa.

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 Prozac, Darvon, Actos®, and Cymbalta.

We have been named as a defendant in seven U.S. lawsuits involving claimants alleging that the antidepressant Prozac caused or contributed to birth defects in the children of women who ingested the drug during pregnancy. We are aware of approximately 340 additional claims related to birth defects, which have not yet been filed. We believe these claims are without merit and are prepared to defend against them vigorously.

Along with several other manufacturers, we have been named as a defendant in approximately 125 cases in the U.S. involving approximately 1,890 claimants related to the analgesic Darvon and related formulations of propoxyphene. These cases generally allege various cardiac injuries. Almost all of these cases have been consolidated in a federal multi-district litigation in the Eastern District of Kentucky or are pending in state and federal courts in California. Two lawsuits have been filed as putative class actions in the U.S. District Court for the Eastern District of Louisiana (Ballard, et al. v. Eli Lilly and Company et al. and Lewis v. Eli Lilly and Company and Xanodyne Pharmaceuticals, Inc.) 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. In Lewis, Lilly was voluntarily dismissed with prejudice and the dismissal cannot be appealed. In Ballard, Lilly was dismissed with prejudice following a dispositive motion; however, the case remains open as other defendants have not been dismissed and there is currently no final appealable order. We transferred the U.S. regulatory approvals and all marketing rights to our propoxyphene products in 2002 to AAi Pharma, 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 four purported product liability class actions in Canada related to Actos, including two in Ontario (Casseres et al. v. Takeda Pharmaceutical North America, Inc., et al. and Brewer et al. v. Takeda Canada et al.), one in Quebec (Whyte et al. v. Eli Lilly et al.), and one in Alberta (Epp v. Takeda Canada et al.). We have also been named along with Takeda in an individual action for damages in Ontario, Canada (Antonacci v. Takeda Pharmaceutical Company Ltd, 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

we will indemnify Takeda for their losses and expenses with respect to the Canadian litigation. 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.

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 November 2008, we received a subpoena from the U.S. Department of Health and Human Services Office of Inspector General in coordination with the U.S. Attorney for the Western District of New York seeking production of a wide range of documents and information relating to reimbursement of Alimta. We are cooperating in this investigation.

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.

In December 2010, we received a civil investigative demand from the Attorney General of Texas seeking production of a wide range of documents and information related to Actos. We are cooperating in this investigation.

Employee Litigation

We have been named as a defendant in a lawsuit filed in the U.S. District Court for the Northern District of New York (Schaefer-LaRose, et al. v. Eli Lilly and Company, filed November 14, 2006) claiming that our pharmaceutical sales representatives should have been categorized as “non-exempt” rather than “exempt” employees, and claiming that the company owes them back wages for overtime worked, as well as penalties, interest, and attorneys’ fees. The case was transferred to the U.S. District Court for the Southern District of Indiana and involves approximately 400 plaintiffs. In September 2009, the District Court granted our motion for summary judgment with regard to Ms. Schaefer-LaRose’s claims and ordered the plaintiffs to demonstrate why the entire collective action should not be decertified within 30 days. Plaintiffs filed a motion for reconsideration of the summary judgment decision and also opposed decertification, and in October 2010, the court denied plaintiffs' motion for reconsideration but decided not to decertify the collective action at that time. In May 2012, the U.S. Court of Appeals for the Seventh Circuit affirmed the District Court's summary judgment ruling. In June 2012, the Supreme Court of the United States ruled, in a case against another pharmaceutical company, that sales representatives employed by that company were exempt from the overtime requirements of the Fair Labor Standards Act. We are waiting for the district court to rule on the status of the remaining plaintiffs in the Schaefer-LaRose case. We believe this lawsuit is without merit and are prepared to defend against it vigorously.

We have been named in a lawsuit brought by the Labor Attorney for 15th Region in the Labor Court of Paulinia, State of Sao Paulo, Brazil, alleging possible harm to employees and former employees caused by

exposure to heavy metals. We have also been named in approximately 50 lawsuits filed in the same court by individual former employees making similar claims. We believe these lawsuits are without merit and are prepared to defend against them vigorously.

Other Matters

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. We are seeking leave to file a petition for review of the Court of Appeal's decision before the Supreme Court of Canada. Absent a reversal by the Supreme Court of Canada, we will be exposed to damages to the defendant generic companies arising from our market exclusivity for Zyprexa. The total amount of damages cannot be determined until after a separate damages trial, which has not yet been scheduled.

In 2004 we, along with several other pharmaceutical companies, were named in a lawsuit in California state court brought by approximately 20 California pharmacies alleging that pharmaceutical companies prevented commercial importation of prescription drugs from outside the U.S. and used Canadian pharmaceutical prices as an agreed floor for prices in the U.S. in violation of antitrust laws. The case sought restitution for alleged overpayments for human pharmaceuticals and an injunction against the allegedly violative conduct. In March 2011, the trial court granted summary judgment for us and the other defendants. In August 2012, the California Court of Appeal affirmed the trial court, and in November 2012, the Supreme Court of California denied plaintiffs' petition for review, bringing this matter to a close.

In June 2009, we received a civil investigative demand from the office of the Attorney General of Texas requesting documents related to nominal pricing of Axid®; we divested the marketing rights for Axid in 2000. We are cooperating in this matter.

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 8, "Financial Statements and Supplementary Information—Selected Quarterly Data (unaudited)" and "Selected Financial 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, 2012:

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 2012	—	$—	—	$419.2
November 2012	8,772	47.77	8,772	—
December 2012	8,146	49.09	8,146	1,100.0
Total	16,918	48.40	16,918	

In March 2000, we announced a $3.00 billion share repurchase program. During November 2012, we completed the $3.00 billion share repurchase program with the share purchase of $419.2 million. In December 2012, we announced a $1.50 billion share repurchase program. During December 2012, we repurchased $400.0 million of shares, and, as a result, $1.10 billion remains to be purchased under this program.

Item 6. Selected Financial Data

You can find selected financial data for each of our five most recent fiscal years in Item 8 under "Selected Financial Data (unaudited)." That information is incorporated here by reference.

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 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 Pharmaceuticals, Inc. (Amylin). The following highlighted items affect comparisons of our 2012 and 2011 financial results:

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

- We recognized asset impairments, 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™.

2011

Collaborations (Note 4 to the consolidated financial statements)

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

Asset Impairments, 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.

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 compounds 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) 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 inflammatory and autoimmune diseases (in collaboration with Incyte Corporation)

Dulaglutide* (Q4 2008)—a long-acting analog of glucagon-like peptide 1 for the treatment of type 2 diabetes

Edivoxetine (Q4 2010)—a norepinepherine reuptake inhibitor for the treatment of major depression

Empagliflozin (Q3 2010)—a sodium glucose co-transporter-2 (SGLT-2) inhibitor for the treatment of type 2 diabetes (in collaboration with Boehringer Ingelheim)

Enzastaurin (Q1 2006)—a serine-threonine kinase inhibitor that inhibits signaling within the protein kinase C beta (PKCß) and PI3K/AKT pathways for the treatment of diffuse large B-cell lymphoma (DLBCL)
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 non-small cell lung cancer (NSCLC)
New insulin glargine product (Q3 2011)—a new insulin glargine product for the treatment of type 1 and type 2 diabetes (in collaboration with Boehringer Ingelheim)
Novel basal insulin analog* (Q4 2011)—a novel basal insulin for the treatment of type 1 and type 2 diabetes
Ramucirumab* (Q4 2009)—an anti-vascular endothelial growth factor receptor-2 (VEGFR-2) monoclonal antibody for the treatment of metastatic breast, gastric, liver, NSCLC, and colorectal cancers
Solanezumab* (Q2 2009)—an anti-amyloid beta (Aß) monoclonal antibody for the treatment of Alzheimer’s disease
Tabalumab* (Q4 2010)—an anti-B-cell activating factor (BAFF) monoclonal antibody for the treatment of systemic lupus erythematosus (lupus).
* Biologic molecule subject to the U.S. Biologics Price Competition and Innovation Act
The following NME has 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 parenthesis:
Liprotamase (Q1 2010)—a non-porcine pancreatic enzyme replacement therapy for the treatment of exocrine pancreatic insufficiency.
The following late-stage pipeline developments have occurred since January 1, 2012:
Baricitinib—In November 2012, we initiated Phase III clinical trial testing.
Dulaglutide—In October 2012, we announced positive top-line results of three completed Phase III AWARD trials (AWARD-1, AWARD-3, and AWARD-5) studying dulaglutide as a once-weekly treatment for type 2 diabetes. The primary efficacy endpoints, as measured by reduction in hemoglobin A1c (HbA1c) at the 1.5 mg dose, were met in all three studies. Having met the primary endpoints, superiority for HbA1c lowering was examined, and both doses of dulaglutide (0.75 mg and 1.5 mg) demonstrated statistically superior reduction in HbA1c from baseline compared to exenatide twice-daily injection at 26 weeks (AWARD-1); metformin at 26 weeks (AWARD-3); and sitagliptin at 52 weeks (AWARD-5). We anticipate filing for regulatory review in the U.S. and Europe in 2013.
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 completed in 2012, and we and Boehringer Ingelheim anticipate filing for regulatory review in the U.S., Europe, and Japan in 2013.
Evacetrapib—In October 2012, we initiated Phase III clinical trial testing.
Florbetapir—On April 6, 2012, the FDA approved Amyvid (florbetapir), a radioactive diagnostic agent indicated for brain imaging of beta-amyloid plaques in patients with cognitive impairment who are being evaluated for Alzheimer's disease and other causes of cognitive decline. In June 2012, Amyvid became available to a limited number of imaging centers. In January 2013, Amyvid was also approved by the European Commission, which has the authority to approve medicines for the European Union.

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

Liprotamase—We continue to engage in discussions with the FDA regarding future clinical trial requirements for liprotamase. See Note 7 to the consolidated financial statements for additional information.

Necitumumab—We will assume sole worldwide development and commercialization rights to necitumumab following notice in the fourth quarter of 2012 from BMS to terminate the collaboration for necitumumab in North America and Japan.

Novel basal insulin analog—In January 2013, we announced that we and Boehringer Ingelheim adjusted the scope of our collaboration, resulting in our reassuming the sole worldwide development and commercialization rights for the novel basal insulin analog. We also 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.

Pomaglumetad Methionil—In August 2012, we announced the decision to stop ongoing Phase III clinical studies investigating pomaglumetad methionil for the treatment of patients suffering from schizophrenia. The decision was based on a lack of efficacy in two registration trials. The decision was not based on any safety signals.

Ramucirumab—In October 2012, we announced that the REGARD trial, a Phase III study of ramucirumab as a second-line treatment in patients with metastatic gastric cancer, met its primary endpoint of improved overall survival and its secondary endpoint of increased progression-free survival. We anticipate filing for regulatory review in the U.S. and Europe in 2013.

Solanezumab—In August 2012, we announced that the primary endpoints, both cognitive and functional, were not met in either of the two Phase III, double-blind, placebo-controlled EXPEDITION trials in patients with mild-to-moderate Alzheimer's disease. However, a pre-specified secondary analysis of pooled data across both trials showed a 34 percent reduction of cognitive decline in patients with mild Alzheimer's disease. We plan to conduct an additional Phase III study of solanezumab in patients with mild Alzheimer's disease. Enrollment is expected to begin no later than the third quarter of 2013.

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 ongoing and will continue as planned.

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 FDA approval process and the approval processes in 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.

26

Legal, Regulatory, and Other Matters

We will lose U.S. patent protection for Cymbalta in December 2013 and for Evista in March 2014. See "Financial Condition" for additional information.

The enactment of the Patient Protection and Affordable Care Act and The Health Care and Education Reconciliation Act of 2010 brought significant changes to U.S. health care. These changes began to affect our financial results in 2010 and will continue to have significant impact on our results in the future. Beginning in 2011, pharmaceutical drug manufacturers provided 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, beginning in 2011, a non-tax-deductible annual fee is imposed on pharmaceutical manufacturers and importers that sell branded prescription drugs to specified government programs. This fee is allocated to companies based on their prior-calendar-year market share for branded prescription drug sales into these government programs. We recognized $170.7 million and $178.0 million as marketing, selling, and administrative expense related to this fee, for the years ended December 31, 2012 and 2011, respectively.

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 other 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 austerity measures being pursued in a number of countries.

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.

Operating Results—2012

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:

	Year Ended December 31, 2012			Year Ended December 31, 2011	Percent Change from 2011
Product	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, 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 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. We will lose effective exclusivity for Cymbalta in the U.S. in December 2013. Several manufacturers have received tentative approvals to market generic duloxetine, and we expect generic duloxetine to be introduced in the market immediately following the loss of exclusivity. While it is difficult to predict the precise impact on Cymbalta sales, we expect the introduction of generics to result in a rapid and severe decline in our Cymbalta sales, which will have a material adverse effect on results of operations and cash flows.

Sales of Alimta, a treatment for various cancers, 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, our injectable human insulin analog for the treatment of diabetes, 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, a treatment for erectile dysfunction and benign prostatic hyperplasia (BPH), 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, a treatment for schizophrenia, acute mixed or manic episodes associated with bipolar I disorder, and bipolar maintenance, 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.

28

Sales of Humulin, an injectable human insulin for the treatment of diabetes, 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, an injectable treatment for osteoporosis in postmenopausal women and men at high risk for fracture and for glucocorticoid-induced osteoporosis in postmenopausal women and men, 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, 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, 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, a treatment for attention-deficit hyperactivity disorder in children, adolescents, and in the U.S. in adults, 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, 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 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 impairments, 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 product delivery device platform, and $20.0 million related to the withdrawal of Xigris. In 2011, we recognized asset impairments, 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 17 to the consolidated financial statements for additional information.

29

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 13 to the consolidated financial statements for additional information.

Operating Results—2011

Financial Results

We achieved revenue growth of 5 percent to $24.29 billion in 2011, primarily driven by the collective growth of Cymbalta, insulin products, animal health products, Alimta, Effient, and Cialis, partially offset by the decline in Gemzar and Zyprexa revenue due to the loss of patent exclusivity. This revenue growth, as well as a lower effective tax rate, was more than offset by lower gross margin percentage; increased marketing, selling, and administrative costs; higher other expense; and the increased impact in 2011 of the items noted below. As a result, net income decreased 14 percent to $4.35 billion, and EPS decreased 15 percent to $3.90 per share, in 2011 as compared to $5.07 billion, or $4.58 per share, in 2010. In addition to the highlighted items summarized in the "Executive Overview," 2011 results also included the following items that affect comparisons:

U.S. Health Care Reform

- As a result of higher rebates and subsidies included in health care reform enacted in the U.S. during 2010, total revenue in 2011 was reduced by $408.8 million (pretax), or $0.29 per share. Also, marketing, selling, and administrative expenses increased by $178.0 million (pretax), or $0.16 per share, as a result of the mandatory pharmaceutical manufacturers’ fee.

The 2010 highlighted items are summarized as follows:

U.S. Health Care Reform

- As a result of higher rebates included in health care reform enacted in the U.S. during 2010, total revenue in 2010 was reduced by $229.0 million (pretax), or $0.16 per share. We also recorded a one-time non-cash deferred income tax charge of $85.1 million, or $0.08 per share, associated with the imposition of tax on the prescription drug subsidy of our U.S. retiree health plan.

Acquisitions (Note 3 to the consolidated financial statements)

- We incurred acquired IPR&D charges associated with the in-licensing arrangement with Acrux Limited (Acrux) of $50.0 million (pretax), which decreased EPS by $0.03.

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

- We recognized asset impairments, restructuring, and other special charges of $192.0 million (pretax), or $0.13 per share, primarily related to severance costs.

Revenue

Our worldwide revenue for 2011 increased 5 percent, to $24.29 billion, driven by the collective growth of Cymbalta, insulin products, animal health products, Alimta, Effient, and Cialis, partially offset by the decline in Gemzar and Zyprexa revenue due to the loss of patent exclusivity. Worldwide sales volume increased 6 percent, and the favorable impact of foreign exchange rates contributed 2 percent of revenue growth, partially offset by a 3 percent decrease due to lower prices. The increase in volume and reduction in price were partially driven by the loss of U.S. patent exclusivity for Zyprexa and Gemzar and the agreements to supply authorized versions of olanzapine and gemcitabine. Revenue in the U.S. increased 1 percent, to $12.98 billion, due to higher volume, partially offset by lower prices. Revenue outside the U.S. increased 11 percent, to $11.31 billion, due to increased demand and the positive impact of foreign exchange rates, partially offset by lower prices. Total revenue was reduced by $408.8 million in 2011 due to the impact of U.S. health care reform, compared to a reduction of $229.0 million in 2010.

The following table summarizes our revenue activity in 2011 compared with 2010:

Product	Year Ended December 31, 2011 U.S.[1]	Outside U.S.	Total	Year Ended December 31, 2010 Total	Percent Change from 2010
	(Dollars in millions)				
Zyprexa	$2,165.3	$2,456.7	$4,622.0	$5,026.4	(8)
Cymbalta	3,173.4	988.4	4,161.8	3,459.2	20
Alimta	994.6	1,466.5	2,461.1	2,208.6	11
Humalog	1,398.9	968.7	2,367.6	2,054.2	15
Cialis	704.5	1,171.1	1,875.6	1,699.4	10
Humulin	588.1	660.7	1,248.8	1,088.9	15
Evista	707.5	359.4	1,066.9	1,024.4	4
Forteo	453.1	496.7	949.8	830.1	14
Strattera	392.2	227.9	620.1	576.7	8
Gemzar	70.6	381.5	452.1	1,149.4	(61)
Other pharmaceutical products	879.4	1,221.0	2,100.4	1,933.5	9
Animal health products	896.8	781.8	1,678.6	1,391.4	21
Total net product sales	12,424.4	11,180.4	23,604.8	22,442.2	5
Collaboration and other revenue[2]	552.8	128.9	681.7	633.8	8
Total revenue	$12,977.2	$11,309.3	$24,286.5	$23,076.0	5

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 Zyprexa decreased 13 percent in the U.S., due to the loss of patent exclusivity in the U.S. on October 23, 2011. Despite a decline in demand for branded Zyprexa, U.S. volume increased in 2011 primarily as a result of sales of authorized olanzapine in connection with our six-month agreement with Prasco Laboratories. This volume increase was more than offset by significant price reductions attributable both to branded Zyprexa and authorized olanzapine.

Sales outside the U.S. decreased 3 percent, driven primarily by the loss of patent exclusivity throughout most major markets outside of Japan during 2011, partially offset by the favorable impact of foreign exchange rates and increased demand in Japan.

Sales of Cymbalta increased 14 percent in the U.S., driven primarily by increased demand and higher prices. Sales outside the U.S. increased 44 percent, driven primarily by increased demand and, to a lesser extent, the favorable impact of foreign exchange rates.

Sales of Alimta increased 4 percent in the U.S., due primarily to higher prices and increased demand. Sales outside the U.S. increased 17 percent, due to increased demand and, to a lesser extent, the favorable impact of foreign exchange rates.

Sales of Humalog increased 14 percent in the U.S., due to increased demand and, to a lesser extent, higher prices. Sales outside the U.S. increased 16 percent, driven by increased demand and, to a lesser extent, the favorable impact of foreign exchange rates.

Sales of Cialis increased 7 percent in the U.S., primarily due to higher prices. Sales outside the U.S. increased 12 percent, driven by increased demand, the favorable impact of foreign exchange rates, and higher prices.

Sales of Humulin increased 25 percent in the U.S., driven primarily by higher prices for Humulin and increased demand attributable to Humulin ReliOn. Sales outside the U.S. increased 7 percent, due to increased demand and the favorable impact of foreign exchange rates, partially offset by lower prices.

Sales of Evista increased 4 percent in the U.S., due to higher prices, partially offset by decreased demand. Sales outside the U.S. increased 5 percent, driven by the favorable impact of foreign exchange rates and, to a lesser extent, increased demand, partially offset by lower prices.

Sales of Forteo decreased 9 percent in the U.S., driven by lower demand, partially offset by higher prices. Sales outside the U.S. increased 50 percent, primarily due to increased demand in Japan.

Sales of Strattera increased 1 percent in the U.S., due primarily to higher prices, partially offset by lower demand. Sales outside the U.S. increased 22 percent, driven primarily by increased demand and, to a lesser extent, the favorable impact of foreign exchange rates, partially offset by lower prices.

Sales of Gemzar, a product approved to treat various cancers, decreased 90 percent in the U.S., due to a rapid and severe decline in sales as a result of generic competition, which began in November 2010, following the expiration of the compound patent. Sales outside the U.S. decreased 10 percent, due to generic competition in most major markets.

Prior to the termination of our exenatide collaboration with Amylin in November 2011, we recognized in revenue our 50 percent share of Byetta's gross margin in the United States. In December 2011, we recognized a pro rata portion of revenue resulting from the termination agreement. In 2011, we recognized total exenatide revenue of $422.7 million, a decrease of 2 percent.

Animal health product sales in the U.S. increased 16 percent, due primarily to increased demand. Sales outside the U.S. increased 27 percent, driven primarily by the impact of the acquisition of certain Janssen and Pfizer animal health assets in Europe and, to a lesser extent, increased demand for other products and the favorable impact of foreign exchange rates.

Gross Margin, Costs, and Expenses

Gross margin as a percent of total revenue decreased by 2.0 percentage points in 2011 to 79.1 percent. This decrease was due primarily to the effect of foreign exchange rates on international inventories sold, which significantly increased cost of sales in 2011, but led to a modest reduction to cost of sales in 2010. Patent expirations for Zyprexa and Gemzar also drove the reduction in gross margin percent.

Marketing, selling, and administrative expenses increased 12 percent in 2011 to $7.88 billion. The increase was driven by the diabetes collaboration with Boehringer Ingelheim, as well as the effect of foreign exchange rates. In addition, higher administrative expenses in the U.S. included $178.0 million related to the mandatory pharmaceutical manufacturers' fee associated with U.S. health care reform. Investment in research and development increased 3 percent, to $5.02 billion, due primarily to increased late-stage clinical trial costs, including costs related to the diabetes collaboration with Boehringer Ingelheim.

We incurred an IPR&D charge of $388.0 million in 2011, associated with our diabetes collaboration with Boehringer Ingelheim, compared with $50.0 million in 2010 associated with the in-licensing agreement with Acrux. We recognized asset impairments, restructuring, and other special charges of $401.4 million in 2011, including charges of $316.4 million primarily related to severance costs from strategic actions to reduce our cost structure and global workforce, and a special charge of $85.0 million related to the withdrawal of Xigris. In 2010, we recognized charges totaling $192.0 million for asset impairments, restructuring, and other special charges. See Notes 3 and 5 to the consolidated financial statements for additional information.

Other—net, expense increased $174.0 million to an expense of $179.0 million in 2011, due primarily to impairments of acquired IPR&D assets in 2011 and damages recovered in 2010 from generic pharmaceutical companies related to Zyprexa patent litigation in Germany. See Note 17 to the consolidated financial statements for additional information.

Our effective tax rate was 18.7 percent in 2011, compared with 22.3 percent in 2010. The decrease was due to the tax benefit on the IPR&D charge associated with the Boehringer Ingelheim diabetes collaboration, 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. Additionally, the tax rate for 2010 was increased by a one-time charge associated with the imposition of tax on the prescription drug subsidy of our retiree health plan as part of U.S. health care reform. See Note 13 to the consolidated financial statements for additional information.

FINANCIAL CONDITION

As of December 31, 2012, cash and cash equivalents totaled $4.02 billion compared with $5.92 billion at December 31, 2011. The decrease was driven by net purchases of $3.26 billion in investment securities with maturities extending beyond one year, dividends paid of $2.19 billion, the maturity and repayment of long-term debt of $1.50 billion, purchases of property and equipment of $905.4 million, and common stock repurchases of $721.1 million, partially offset by cash from operations of $5.30 billion, and $1.38 billion in proceeds from the early payment of Amylin's revenue-sharing obligations and loan.

Capital expenditures of $905.4 million during 2012 were $233.4 million more than in 2011. We expect 2013 capital expenditures to be approximately $900 million 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.

As of December 31, 2012, total debt was $5.53 billion, a decrease of $1.46 billion compared with $6.99 billion at December 31, 2011. The decrease is due primarily to the previously mentioned long-term debt maturity and payment of $1.50 billion. Our current debt ratings from Standard & Poor’s and Moody’s remain AA- and A2, respectively. Our ratings outlook from both Moody’s and Standard & Poor’s is stable.

Dividends of $1.96 per share were paid in 2012 and 2011. 2012 was the 128th consecutive year in which we made dividend payments. In the fourth quarter of 2012, effective for the dividend to be paid in the first quarter of 2013, the quarterly dividend was maintained at $0.49 per share, resulting in an indicated annual rate for 2013 of $1.96 per share.

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; the federal government's involvement in the U.S. economy; and various international government funding levels. We continue to focus specifically on the economic health of the European economy, as heightened economic concerns persist. Currently, we believe economic conditions in Europe will not have a material impact on our liquidity.

We believe that cash generated from operations, along with available cash and cash equivalents, will be sufficient to fund our normal operating needs, including dividends, share repurchases, capital expenditures, and contractual maturities due on debt in 2013. We believe that amounts accessible through existing commercial paper markets should be adequate to fund short-term borrowings. We currently have $1.36 billion of unused committed bank credit facilities, $1.20 billion of which backs our commercial paper program. 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.

We depend on patents or other forms of intellectual-property protection for most of our revenues, cash flows, and earnings. Through 2014, we expect to lose U.S. patent protection for Cymbalta (December 2013) and Evista (March 2014). The loss of exclusivity for Cymbalta and Evista will likely result in generic competition, generally causing a rapid and severe decline in revenue from the affected product, and having a material adverse effect on our results of operations. The U.S. patent for Humalog expires in May 2013. Humalog is currently protected in Europe only by formulation patents. We do not currently expect the loss of patent protection for Humalog to result 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. Our goal is to mitigate the effect of these exclusivity losses on our operations, liquidity, and financial position through growth in our patent-protected products that do not lose exclusivity during this period, in the emerging markets, in Japan, and in our animal health business. Our expected growth in the emerging markets and Japan is attributable to both the growth of these markets and launches of patent-protected products.

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.

33

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, 2012 and 2011, 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, 2012 and 2011, 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, 2012 and 2011, a hypothetical 10 percent change in exchange rates (primarily against the U.S. dollar) as of December 31, 2012 and 2011, 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 assets 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 of the product 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. 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]	$7,425.6	$156.5	$1,277.5	$1,474.0	$4,517.6
Capital lease obligations	42.0	14.9	22.3	4.8	—
Operating leases	647.3	145.3	231.6	134.0	136.4
Purchase obligations[2]	13,629.5	12,158.5	674.9	460.0	336.1
Other long-term liabilities reflected on our balance sheet[3]	1,796.9	—	537.2	262.6	997.1
Other[4]	371.3	371.3	—	—	—
Total	$23,912.6	$12,846.5	$2,743.5	$2,335.4	$5,987.2

[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, 2012, 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, 2012. 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 $1.33 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 $75.4 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, 2012. 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

35

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 primarily based on historical return rates as well as specifically identified anticipated returns due to known business conditions and product expiry dates. 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 percent of sales.

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 sales return, rebate, and discount liability at December 31, 2012 would lead to an approximate $108 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 83 percent and 82 percent as of December 31, 2012 and 2011, respectively.

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

	2012	2011
Sales return, rebate, and discount liabilities, beginning of year	$1,597.9	$1,155.3
Reduction of net sales due to sales returns, discounts, and rebates[(1)]	3,563.5	4,016.9
Cash payments of discounts and rebates	(3,576.9)	(3,574.3)
Sales return, rebate, and discount liabilities, end of year	$1,584.5	$1,597.9

[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.

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 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 have been and will continue to be largely self-insured for product liability losses for substantially all our currently marketed products. In addition, there is no assurance that we will be able to fully collect from our insurance carriers on past claims.

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 14 to the consolidated financial statements for additional information regarding our retirement benefits.

Annually, we evaluate the discount rate and the expected return on plan assets in our defined benefit pension and retiree health benefit plans. We use an actuarially determined, plan-specific yield curve of high quality, fixed income debt instruments to determine the discount rates. In evaluating the expected 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.

If the health-care-cost trend rates were to be increased by one percentage point, the aggregate of the service cost and interest cost components of the 2012 annual expense would increase by $15.6 million. A one-

percentage-point decrease would decrease the aggregate of the 2012 service cost and interest cost by $12.6 million. If the 2012 discount rate for the U.S. defined benefit pension and retiree health benefit plans (U.S. plans) were to be changed by a quarter percentage point, income before income taxes would change by $35.2 million. If the 2012 expected return on plan assets for U.S. plans were to be changed by a quarter percentage point, income before income taxes would change by $19.7 million. If our assumption regarding the 2012 expected age of future retirees for U.S. plans were adjusted by one year, our income before income taxes would be affected by $43.6 million. The U.S. plans, including Puerto Rico, represent approximately 80 percent of the total projected benefit obligation and approximately 81 percent of total plan assets at December 31, 2012.

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.

The estimated 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 evaluating whether we would more likely than not recover these deferred tax assets, we have not assumed

38

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, 2012, 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 $46.4 million and $33.8 million, respectively.

LEGAL AND REGULATORY MATTERS

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

FINANCIAL EXPECTATIONS FOR 2013

Our 2013 financial guidance includes an estimated one-time benefit of $0.07 per share associated with the research and development tax credit for 2012 that will be recorded in the first quarter of 2013, resulting from the delay in the enactment of the American Taxpayer Relief Act of 2012. For the full year of 2013, we expect EPS to be in the range of $4.10 to $4.25. We anticipate that total revenue will be between $22.6 billion and $23.4 billion. Despite the initial impact of the U.S. Cymbalta patent expiration in the fourth quarter of 2013 and the loss of the anticipated 15 percent revenue-sharing obligation on worldwide exenatide sales, we expect overall revenue growth, driven by a portfolio of products including Humalog, Humulin, Cialis, Strattera, Forteo, Alimta, Cymbalta outside the U.S., Effient, Tradjenta, and Axiron, as well as animal health products. In addition, significant revenue growth is expected in Japan and the emerging markets, particularly China.

We anticipate that gross margin as a percent of revenue will be approximately 78 percent. Marketing, selling, and administrative expenses are expected to be in the range of $7.1 billion to $7.4 billion. Research and development expense is expected to be in the range of $5.2 billion to $5.5 billion. Other—net, (income) expense is expected to be in a range between $340 million and $490 million of income. Operating cash flows are expected to be more than sufficient to pay our dividend, complete our previously announced $1.5 billion share repurchase program, allow for capital expenditures of approximately $900 million, and fund potential business development activity.

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)	2012	2011	2010
Revenue	$22,603.4	$24,286.5	$23,076.0
Cost of sales	4,796.5	5,067.9	4,366.2
Research and development	5,278.1	5,020.8	4,884.2
Marketing, selling, and administrative	7,513.5	7,879.9	7,053.4
Acquired in-process research and development (Notes 3 and 4)	—	388.0	50.0
Asset impairments, restructuring, and other special charges (Note 5)	281.1	401.4	192.0
Other—net, (income) expense (Note 17)	(674.0)	179.0	5.0
	17,195.2	18,937.0	16,550.8
Income before income taxes	5,408.2	5,349.5	6,525.2
Income taxes (Note 13)	1,319.6	1,001.8	1,455.7
Net income	$4,088.6	$4,347.7	$5,069.5
Earnings per share—basic (Note 12)	$3.67	$3.90	$4.58
Earnings per share—diluted (Note 12)	$3.66	$3.90	$4.58

See notes to consolidated financial statements.

Consolidated Statements of Comprehensive Income

ELI LILLY AND COMPANY AND SUBSIDIARIES (Dollars in millions) Year Ended December 31	2012	2011	2010
Net income	$4,088.6	$4,347.7	$5,069.5
Other comprehensive income (loss)			
Foreign currency translation gains (losses)	160.9	(244.8)	(325.1)
Net unrealized gains (losses) on securities	88.5	(178.5)	80.8
Defined benefit pension and retiree health benefit plans (Note 14)	(128.6)	(1,240.2)	148.9
Effective portion of cash flow hedges	8.7	44.8	(26.6)
Other comprehensive income (loss) before income taxes	129.5	(1,618.7)	(122.0)
Provision for income taxes related to other comprehensive income (loss) items	(68.0)	430.2	(76.2)
Other comprehensive income (loss) (Note 16)	61.5	(1,188.5)	(198.2)
Comprehensive income	$4,150.1	$3,159.2	$4,871.3

See notes to consolidated financial statements.

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

December 31	2012	2011
Assets		
Current Assets		
Cash and cash equivalents (Note 6)	$4,018.8	$5,922.5
Short-term investments (Note 6)	1,665.5	974.6
Accounts receivable, net of allowances of $108.5 (2012) and $110.1 (2011)	3,336.3	3,597.7
Other receivables (Note 10)	552.0	640.2
Inventories	2,643.8	2,299.8
Prepaid expenses and other (Note 10)	822.3	813.4
Total current assets	13,038.7	14,248.2
Other Assets		
Investments (Note 6)	6,313.3	4,029.8
Goodwill and other intangibles—net (Note 7)	4,752.7	5,128.1
Sundry (Note 10)	2,534.0	2,493.4
Total other assets	13,600.0	11,651.3
Property and equipment, net	7,760.2	7,760.3
Total assets	$34,398.9	$33,659.8
Liabilities and Shareholders’ Equity		
Current Liabilities		
Short-term borrowings and current maturities of long-term debt (Note 8)	$11.9	$1,522.3
Accounts payable	1,188.3	1,125.2
Employee compensation	940.3	804.7
Sales rebates and discounts	1,777.2	1,771.3
Dividends payable	541.4	542.3
Income taxes payable (Note 13)	143.5	261.6
Deferred income taxes (Note 13)	1,048.0	422.3
Other current liabilities (Note 10)	2,738.9	2,481.2
Total current liabilities	8,389.5	8,930.9
Other Liabilities		
Long-term debt (Note 8)	5,519.4	5,464.7
Accrued retirement benefits (Note 14)	3,012.4	3,068.5
Long-term income taxes payable (Note 13)	1,334.3	1,086.3
Other noncurrent liabilities (Note 10)	1,369.4	1,573.8
Total other liabilities	11,235.5	11,193.3
Commitments and contingencies (Note 15)		
Shareholders' Equity (Notes 9 and 11)		
Common stock—no par value		
Authorized shares: 3,200,000	716.6	724.1
Issued shares: 1,146,493 (2012) and 1,158,644 (2011)		
Additional paid-in capital	4,963.1	4,886.8
Retained earnings	16,088.2	14,897.8
Employee benefit trust	(3,013.2)	(3,013.1)
Accumulated other comprehensive loss (Note 16)	(3,797.1)	(3,858.6)
Noncontrolling interests	8.7	(6.1)
Cost of common stock in treasury, 2,850 shares (2012) and 853 shares (2011)	(192.4)	(95.3)
Total shareholders’ equity	14,773.9	13,535.6
Total liabilities and shareholders’ equity	$34,398.9	$33,659.8

See notes to consolidated financial statements.

Consolidated Statements of Cash Flows

ELI LILLY AND COMPANY AND SUBSIDIARIES (Dollars in millions)	Year Ended December 31 2012	2011	2010
Cash Flows from Operating Activities			
Net income	$4,088.6	$4,347.7	$5,069.5
Adjustments to Reconcile Net Income to Cash Flows from Operating Activities			
Depreciation and amortization	1,462.2	1,373.6	1,328.2
Change in deferred income taxes	126.0	(268.5)	559.7
Stock-based compensation expense	141.5	147.4	231.0
Impairment charges, indefinite lived intangibles	205.0	151.5	—
Acquired in-process research and development, net of tax	—	252.2	32.5
Income related to prepayment of revenue-sharing obligation (Note 4)	(787.8)	—	—
Other operating activities, net	120.5	(17.8)	(178.6)
Changes in operating assets and liabilities, net of acquisitions			
Receivables—(increase) decrease	361.8	(188.8)	(319.1)
Inventories—(increase) decrease	(307.9)	203.1	157.0
Other assets—(increase) decrease	231.0	642.7	340.5
Accounts payable and other liabilities—increase (decrease)	(336.1)	591.4	(363.9)
Net Cash Provided by Operating Activities	5,304.8	7,234.5	6,856.8
Cash Flows from Investing Activities			
Purchases of property and equipment	(905.4)	(672.0)	(694.3)
Disposals of property and equipment	22.0	25.3	24.6
Net change in short-term investments	375.1	(250.9)	(686.5)
Proceeds from sales and maturities of noncurrent investments	4,355.7	2,138.5	584.7
Purchases of noncurrent investments	(7,618.6)	(4,459.4)	(1,067.2)
Purchase of product rights	(138.8)	(632.9)	(442.4)
Purchases of in-process research and development	—	(388.0)	(50.0)
Cash paid for acquisitions, net of cash acquired	(199.3)	(307.8)	(609.4)
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	(100.6)	(112.2)	(219.3)
Net Cash Used for Investing Activities	(2,832.8)	(4,824.4)	(3,159.8)
Cash Flows from Financing Activities			
Dividends paid	(2,187.4)	(2,180.1)	(2,165.3)
Net change in short-term borrowings	(10.5)	(141.2)	125.1
Repayments of long-term debt	(1,500.6)	(54.6)	(1.1)
Purchases of common stock	(721.1)	—	—
Other financing activities, net	—	6.0	19.4
Net Cash Used for Financing Activities	(4,419.6)	(2,369.9)	(2,021.9)
Effect of exchange rate changes on cash and cash equivalents	43.9	(110.9)	(144.8)
Net increase (decrease) in cash and cash equivalents	(1,903.7)	(70.7)	1,530.3
Cash and cash equivalents at beginning of year	5,922.5	5,993.2	4,462.9
Cash and Cash Equivalents at End of Year	$4,018.8	$5,922.5	$5,993.2

See notes to consolidated financial statements.

Segment Information

We operate in two business segments—human pharmaceutical products and animal health. Our business segments are distinguished by the ultimate end user of the product—humans or animals. Performance is evaluated based on profit or loss from operations before income taxes. The accounting policies of the individual segments are the same as those described in the summary of significant accounting policies in Note 1 to the consolidated financial statements.

Our human pharmaceutical products segment includes the discovery, development, manufacturing, marketing, and sales of human pharmaceutical products worldwide in the following therapeutic areas: neuroscience, endocrinology, oncology, cardiovascular, and other. Our neuroscience group of products includes Cymbalta, Zyprexa, Strattera, and Prozac. Endocrinology products consist primarily of Humalog, Humulin, Forteo, Evista, Humatrope, Byetta, and Actos. Oncology products consist primarily of Alimta, Erbitux, and Gemzar. Cardiovascular products consist primarily of Cialis, Effient, and ReoPro. The other pharmaceuticals category includes anti-infectives, primarily Vancocin and Ceclor, and other miscellaneous pharmaceutical products and services.

Our animal health segment, operating through our Elanco animal health division, includes the development, manufacturing, marketing, and sales of animal health products worldwide for both food and companion animals. Animal health products include Rumensin, Tylan, Posilac, Paylean, and other products for livestock and poultry, as well as Trifexis, Comfortis, and other products for companion animals.

Most of our pharmaceutical products are distributed through wholesalers that serve pharmacies, physicians and other health care professionals, and hospitals. For the years ended December 31, 2012, 2011, and 2010, our three largest wholesalers each accounted for between 10 percent and 16 percent of consolidated total revenue. Further, they each accounted for between 9 percent and 14 percent of accounts receivable as of December 31, 2012 and 2011. Animal health products are sold primarily to wholesale distributors.

We manage our assets on a total company basis, not by operating segment, as the assets of the animal health business are intermixed with those of the pharmaceutical products business. Therefore, our chief operating decision maker does not review any asset information by operating segment and, accordingly, we do not report asset information by operating segment.

We are exposed to the risk of changes in social, political, and economic conditions inherent in foreign operations, and our results of operations and the value of our foreign assets are affected by fluctuations in foreign currency exchange rates.

ELI LILLY AND COMPANY AND SUBSIDIARIES (Dollars in millions)	Year Ended December 31	2012	2011	2010
Segment revenue—to unaffiliated customers				
Human pharmaceutical products				
Neuroscience		$7,575.1	$9,723.8	$9,419.0
Endocrinology		6,810.9	6,806.7	6,135.4
Oncology		3,281.6	3,322.2	3,744.5
Cardiovascular		2,632.5	2,486.4	2,171.3
Other pharmaceuticals		266.8	268.8	214.4
Total human pharmaceutical products		20,566.9	22,607.9	21,684.6
Animal health		2,036.5	1,678.6	1,391.4
Total segment revenue		$22,603.4	$24,286.5	$23,076.0
Segment profits				
Human pharmaceutical products		$4,393.4	$5,837.9	$6,516.3
Animal health		508.1	301.0	250.9
Total segment profits		$4,901.5	$6,138.9	$6,767.2
Reconciliation of total segment profits to consolidated income before taxes				
Segment profits		$4,901.5	$6,138.9	$6,767.2
Other profits (losses)				
Income related to prepayment of Amylin's obligation (Note 4)		787.8	—	—
Acquired in-process research and development (Notes 3 and 4)		—	(388.0)	(50.0)
Asset impairments, restructuring, and other special charges (Note 5)		(281.1)	(401.4)	(192.0)
Total consolidated income before taxes		$5,408.2	$5,349.5	$6,525.2

For internal management reporting presented to the chief operating decision maker, certain costs are fully allocated to our human pharmaceutical products segment and therefore are not reflected in the animal health segment's profit. Such items include costs associated with treasury-related financing, global service centers, certain acquisition-related transaction costs, and inventory valuation adjustments.

(Dollars in millions)	Year Ended December 31	2012	2011	2010
Geographic Information				
Revenue—to unaffiliated customers[1]				
United States		$12,313.1	$12,977.2	$12,865.6
Europe		4,259.7	5,290.9	5,106.4
Japan		2,246.2	2,104.1	1,616.6
Other foreign countries		3,784.4	3,914.3	3,487.4
Revenue		$22,603.4	$24,286.5	$23,076.0
Long-lived assets[2]				
United States		$5,064.7	$5,485.3	$5,333.9
Europe		2,281.1	2,220.2	2,250.7
Japan		101.5	102.9	101.2
Other foreign countries		1,543.2	1,564.0	1,588.4
Long-lived assets		$8,990.5	$9,372.4	$9,274.2

[1] Revenue is attributed to the countries based on the location of the customer.

[2] Long-lived assets consist of property and equipment and certain sundry assets.

45

Selected Quarterly Data (unaudited)

ELI LILLY AND COMPANY AND SUBSIDIARIES (Dollars in millions, except per-share data)	2012	Fourth	Third	Second	First
Revenue		$5,957.3	$5,443.3	$5,600.7	$5,602.0
Cost of sales		1,248.3	1,203.6	1,146.7	1,197.9
Operating expenses		3,440.6	3,100.2	3,251.8	2,999.0
Acquired in-process research and development		—	—	—	—
Asset impairments, restructuring, and other special charges		204.0	53.3	—	23.8
Other—net, (income) expense		52.0	(788.5)	16.5	46.0
Income before income taxes		1,012.4	1,874.7	1,185.7	1,335.3
Net income		827.2	1,326.6	923.6	1,011.1
Earnings per share—basic		0.75	1.18	0.83	0.91
Earnings per share—diluted		0.74	1.18	0.83	0.91
Dividends paid per share		0.49	0.49	0.49	0.49
Common stock closing prices					
High		53.81	47.64	42.91	41.80
Low		45.91	41.98	39.18	38.49

	2011	Fourth	Third	Second	First
Revenue		$6,046.6	$6,147.9	$6,252.8	$5,839.2
Cost of sales		1,321.7	1,338.1	1,228.0	1,180.1
Operating expenses		3,488.7	3,198.7	3,303.6	2,909.7
Acquired in-process research and development		—	—	—	388.0
Asset impairments, restructuring, and other special charges		167.6	25.2	132.3	76.3
Other—net, expense		26.8	83.4	57.6	11.2
Income before income taxes		1,041.8	1,502.5	1,531.3	1,273.9
Net income		858.2	1,236.3	1,197.3	1,055.9
Earnings per share—basic and diluted		0.77	1.11	1.07	0.95
Dividends paid per share		0.49	0.49	0.49	0.49
Common stock closing prices					
High		41.75	39.32	39.15	35.84
Low		35.58	34.49	34.99	33.63

Our common stock is listed on the New York, London, and Swiss stock exchanges.

Selected Financial Data (unaudited)
ELI LILLY AND COMPANY AND SUBSIDIARIES

(Dollars in millions, except revenue per employee and per-share data)	2012	2011	2010	2009	2008
Operations					
Revenue	$22,603.4	$24,286.5	$23,076.0	$21,836.0	$20,371.9
Cost of sales	4,796.5	5,067.9	4,366.2	4,247.0	4,376.7
Research and development	5,278.1	5,020.8	4,884.2	4,326.5	3,840.9
Marketing, selling, and administrative	7,513.5	7,879.9	7,053.4	6,892.5	6,626.4
Other[1]	(392.9)	968.4	247.0	1,012.2	6,835.5
Income (loss) before income taxes	5,408.2	5,349.5	6,525.2	5,357.8	(1,307.6)
Income taxes[2]	1,319.6	1,001.8	1,455.7	1,029.0	764.3
Net income (loss)	4,088.6	4,347.7	5,069.5	4,328.8	(2,071.9)
Net income (loss) as a percent of revenue	18.1%	17.9%	22.0%	19.8%	NM
Net income (loss) per share—diluted	3.66	3.90	4.58	3.94	(1.89)
Dividends declared per share	1.96	1.96	1.96	1.96	1.90
Weighted-average number of shares outstanding—diluted (thousands)	1,117,294	1,113,967	1,105,813	1,098,367	1,094,499
Financial Position					
Current assets	$13,038.7	$14,248.2	$14,840.0	$12,486.5	$12,453.3
Current liabilities	8,389.5	8,930.9	6,926.9	6,568.1	13,109.7
Property and equipment—net	7,760.2	7,760.3	7,940.7	8,197.4	8,626.3
Total assets	34,398.9	33,659.8	31,001.4	27,460.9	29,212.6
Long-term debt	5,519.4	5,464.7	6,770.5	6,634.7	4,615.7
Shareholders' equity	14,773.9	13,535.6	12,412.8	9,525.3	6,737.7
Supplementary Data					
Return on shareholders' equity	27.8%	31.4%	46.1%	51.0%	(16.3)%
Return on assets	12.3%	13.4%	17.7%	15.8%	(7.5)%
Capital expenditures	$905.4	$672.0	$694.3	$765.0	$947.2
Depreciation and amortization	1,462.2	1,373.6	1,328.2	1,297.8	1,122.6
Effective tax rate[2]	24.4%	18.7%	22.3%	19.2%	NM
Revenue per employee	$590,000	$638,000	$602,000	$540,000	$504,000
Number of employees	38,350	38,080	38,350	40,360	40,450
Number of shareholders of record	33,638	35,200	36,700	38,400	39,800

NM—Not Meaningful

[1] The year ended December 31, 2008 reflects the in-process research and development (IPR&D) expense of $4.69 billion associated with the ImClone acquisition and $1.48 billion associated with the Zyprexa investigation settlements.

2 We incurred tax expense of $764.3 million in 2008, despite having a loss before income taxes of $1.31 billion. Our net loss was driven by the $4.69 billion acquired IPR&D charge for ImClone and the $1.48 billion Zyprexa investigation settlements. The IPR&D charge was not tax deductible, and only a portion of the Zyprexa investigation settlements was deductible. In addition, we recorded tax expense associated with the ImClone acquisition, as well as a discrete income tax benefit of $210.3 million for the resolution of a substantial portion of the 2001–2004 IRS audit.

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 2008 through 2012. The graph assumes that, on December 31, 2007, a person invested $100 each in Lilly stock, the S&P 500 Stock Index, and the peer group's 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 2007

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

	Lilly	Peer Group	S&P 500
Dec-07	$100.00	$100.00	$100.00
Dec-08	$78.62	$86.09	$63.06
Dec-09	$73.80	$97.05	$79.69
Dec-10	$76.52	$97.52	$91.68
Dec-11	$95.58	$111.40	$93.31
Dec-12	$118.48	$135.73	$108.53

1 We constructed the peer group as the industry index for this graph. It comprises the companies in the pharmaceutical industry that we used to benchmark the compensation of executive officers for 2012: Abbott Laboratories; Amgen Inc.; AstraZeneca PLC; Baxter International Inc.; Bristol-Myers Squibb Company; GlaxoSmithKline plc; Johnson & Johnson; Merck & Co., Inc.; Novartis AG.; Pfizer Inc.; Sanofi-Aventis; and Takeda Pharmaceuticals Company.

Notes to Consolidated Financial Statements
ELI LILLY AND COMPANY AND SUBSIDIARIES
(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 in shareholders' 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, or approximately 40 percent of our total inventories. Other inventories are valued by the first-in, first-out (FIFO) method. FIFO cost approximates current replacement cost. Inventories at December 31 consisted of the following:

	2012	2011
Finished products	$834.4	$786.4
Work in process	1,735.8	1,518.2
Raw materials and supplies	256.1	205.8
	2,826.3	2,510.4
Reduction to LIFO cost	(182.5)	(210.6)
Inventories	$2,643.8	$2,299.8

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 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 income (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. 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 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 or investments to a floating rate are designated as fair value hedges of the underlying instruments. Interest rate swaps or collars that convert floating-rate debt or investments 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.

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 over their estimated useful lives, ranging from 3 to 20 years.

The cost of in-process research and development (IPR&D) projects acquired directly in a transaction other than a business combination is 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 amortized over the remaining useful life or written off, as appropriate. We also capitalize milestone payments incurred at or after the product has 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 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. 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.

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

	2012	2011
Land	$201.4	$202.5
Buildings	6,373.8	6,135.7
Equipment	7,542.9	7,219.9
Construction in progress	799.9	1,036.0
	14,918.0	14,594.1
Less accumulated depreciation	(7,157.8)	(6,833.8)
Property and equipment, net	$7,760.2	$7,760.3

Depreciation expense for the years ended December 31, 2012, 2011, and 2010 was $754.0 million, $732.4 million, and $749.1 million, respectively. Interest costs of $21.0 million, $25.7 million, and $26.0 million were capitalized as part of property and equipment for the years ended December 31, 2012, 2011, and 2010, respectively. Total rental expense for all leases, including contingent rentals (not material), amounted to $285.8 million, $267.4 million, and $255.7 million for the years ended December 31, 2012, 2011, and 2010, respectively. Assets under capital leases included in property and equipment in the consolidated balance sheets, capital lease obligations entered into, and future minimum rental commitments are not material.

Litigation and environmental liabilities

Litigation accruals and 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 probable and reasonably estimable. A portion of the costs associated with defending and disposing of these suits is covered by insurance. We record receivables for insurance-related recoveries when it is probable they will be realized. These receivables are classified as a reduction of the litigation charges on the statement of operations. We estimate insurance

recoverables based on existing deductibles, coverage limits, our assessment of any defenses to coverage that might be raised by the carriers, the financial condition of the insurers, and the possibility of and length of time for collection. 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 recorded.

We also generate income as a result of collaboration agreements. Revenue from co-promotion services is based upon net sales reported by our co-promotion partners and, if applicable, the number of sales calls we perform. 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. Initial fees received from out-licensing agreements that include both the sale of marketing rights to our commercialized products and a related commitment to supply the products are generally recognized in net product sales over the term of the supply agreement. We immediately recognize the full amount of developmental milestone payments due to us upon the achievement of the milestone event if the event is substantive, is objectively determinable, and represents an important point in the development life cycle of the pharmaceutical product. 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.

Following is the composition of revenue:

	2012	2011	2010
Net product sales	$21,970.4	$23,604.8	$22,442.2
Collaboration and other revenue (Note 4)	633.0	681.7	633.8
Total revenue	$22,603.4	$24,286.5	$23,076.0

Research and development expenses and acquired research and development

Research and development expenses include the following:

- Research and development costs, which are expensed as incurred.
- Milestone payments 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 United States and be taxable.

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 stock options. See Note 12 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 2010, the Financial Accounting Standards Board (FASB) issued an Accounting Standards Update (ASU) that applies to the annual fee imposed on pharmaceutical manufacturers and importers that sell branded prescription drugs to specified government programs as part of U.S. health care reform. This fee is allocated to companies based on their prior-calendar-year market share for branded prescription drug sales into these government programs. In accordance with the ASU, we record this fee as marketing, selling, and administrative expense in our consolidated results of operations and amortize it on a straight-line basis for the year. This guidance was effective for us January 1, 2011. For the years ended December 31, 2012 and 2011, we recorded $170.7 million and $178.0 million, respectively, related to this fee, which is not deductible for tax purposes.

Note 3: Acquisitions

From 2010 to 2012, we completed the acquisitions of ChemGen Corporation (ChemGen), the animal health business of Janssen Pharmaceuticia NV (Janssen), Avid Radiopharmaceuticals, Inc. (Avid), Alnara Pharmaceuticals, Inc. (Alnara), and a group of animal health product lines. 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.

These acquisitions included IPR&D, which represented compounds, new indications, or line extensions under development that had not yet achieved regulatory approval for marketing. As discussed in Note 1, the fair values of IPR&D assets acquired as part of the acquisition of a business are capitalized as intangible assets. We capitalized $1.6 million, $29.6 million, and $598.0 million of IPR&D assets that were acquired in business combinations during the years ended December 31, 2012, 2011, and 2010, respectively. The ongoing expenses with respect to each of these assets in development are not material to our total research and development expense currently and are not expected to be material to our total research and development expense on an annual basis in the future.

Some of these acquisitions included contingent consideration, which is recorded at fair value in other liabilities as of the acquisition date. The fair value of the contingent consideration was determined by utilizing a probability weighted estimated cash flow stream discounted for the expected timing of each payment.

In addition to the acquisitions of businesses, we also acquired several assets in development during 2011 and 2010, which are discussed below in Product Acquisitions and in Note 4. The acquired IPR&D related to these

products of $388.0 million and $50.0 million for the years ended December 31, 2011, and 2010, respectively, was written off by a charge to income immediately upon acquisition because the products had no alternative future use. 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 preliminarily recorded $151.5 million of marketed product assets, with $55.4 million of other net assets. The final determination may result in asset and liability fair values that differ from the preliminary estimates, but it is not expected that these differences will be material to our consolidated financial statements.

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 and $29.6 million of acquired IPR&D assets, with $43.8 million of other net assets.

Avid

On December 20, 2010, we acquired all of the outstanding stock of Avid, a company focusing on developing molecular radiopharmaceutical tracers in positron emission tomography (PET) scan imaging, for total purchase consideration of $346.1 million, which included an upfront payment of $286.3 million and up to $550 million in additional payments contingent upon potential future regulatory and commercial milestones. The fair value of the contingent consideration at the acquisition date was $59.8 million. In connection with this acquisition, we recorded $334.0 million of acquired IPR&D assets, $119.6 million of goodwill, and $116.9 million of deferred tax liability, with $9.4 million of other net assets. Avid’s lead product, Amyvid, is a PET agent indicated for imaging amyloid plaque pathology in the brain to aid the evaluation of patients with signs or symptoms of cognitive impairment. During the year ended December 31, 2011, we recorded impairment charges for the IPR&D asset related to Amyvid, as discussed further in Note 7. Amyvid received regulatory approval in the U.S. in 2012 and European Union in 2013, and is available to a limited number of imaging centers.

Alnara

On July 20, 2010, we acquired all of the outstanding stock of Alnara, a privately-held company developing protein therapeutics for the treatment of metabolic diseases, for total purchase consideration of $291.7 million, which included an upfront payment of $188.7 million and up to $200 million in additional payments contingent upon potential future regulatory and commercial milestones. The fair value of the contingent consideration at the acquisition date was $103.0 million. In connection with this acquisition, we recorded $264.0 million of acquired IPR&D assets, $100.5 million of goodwill, and $92.4 million of deferred tax liability, with $19.6 million of other net assets. Alnara's lead product in development is liprotamase, a non-porcine pancreatic enzyme replacement therapy. The New Drug Application (NDA) was submitted to the U.S. Food and Drug Administration (FDA) in the first quarter of 2010. In April 2011, we received a complete response letter that communicated the need for us to conduct an additional clinical trial prior to a resubmission. During the years ended December 31, 2012 and 2011, we recorded impairment charges for the IPR&D asset related to liprotamase, as discussed further in Note 7.

Animal Health Product Lines

On May 28, 2010, we acquired the European marketing rights to several animal health product lines divested by Pfizer Inc., for total purchase consideration of $148.4 million paid in cash. These products, including vaccines, parasiticides, and feed additives, serve both the production animal and companion animal markets.

We also acquired a manufacturing facility in Sligo, Ireland, currently used in the production of animal vaccines. In connection with this acquisition, we recorded $76.2 million of marketed product intangible assets, with $72.2 million of other net assets.

Product Acquisitions

In March 2010, we entered into a license agreement with Acrux Limited to acquire the exclusive rights to commercialize its proprietary testosterone solution Axiron. At the time of the licensing, the product had not been approved and had no alternative future use. The charge of $50.0 million for acquired IPR&D related to this arrangement was included as expense in the first quarter of 2010 and is deductible for tax purposes. In the fourth quarter of 2010, Axiron was approved by the FDA for the treatment of testosterone deficiency in men. In the first quarter of 2011, the product was available in pharmacies in the United States.

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 sold by us 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. 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 their 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 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. Amylin will also pay a $150.0 million milestone to us contingent upon FDA approval of a once-monthly suspension version of exenatide that is currently in Phase II clinical trials.

Commercial operations were transferred to Amylin in the U.S. at the end of November 2011. Outside the U.S., we anticipate transferring responsibility for commercialization of exenatide to Amylin in substantially all markets at the end of 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 will be 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 as other-net, (income) expense. All income allocated to the business outside the U.S. will be recognized on a pro rata basis as a gain on the disposition of a business in other–net, (income) expense as control of the business transfers to Amylin during 2013. We expect to recognize a net gain of approximately $490 million in 2013 contingent upon the transfer of the commercial rights outside the United States.

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 December 31, 2013. We are 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 operations are transferred to Amylin.

55

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. will continue until those operations transfer to Amylin. Prior to its termination, 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 also paid in full in August 2012.

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

	2012	2011	2010
Net product sales	$207.8	$179.6	$168.1
Collaboration and other revenue	70.1	243.1	262.5
Total revenue	$277.9	$422.7	$430.6
Income related to prepayment of Amylin's obligation[1]	$787.8	$—	$—

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

Erbitux

We have several collaborations with respect to Erbitux. The most significant collaborations are in the U.S., Japan, and Canada (Bristol-Myers Squibb Company); and worldwide except the U.S. and Canada (Merck KGaA). The agreements are expected to expire in 2018, upon which all of the rights with respect to Erbitux in the U.S. and Canada return to us and certain rights with respect to Erbitux outside the U.S. and Canada (excluding Japan) remain with Merck KGaA (Merck). The following table summarizes the revenue recognized with respect to Erbitux:

	2012	2011	2010
Net product sales	$76.4	$87.6	$71.9
Collaboration and other revenue	320.6	321.6	314.2
Total revenue	$397.0	$409.2	$386.1

Bristol-Myers Squibb Company

Pursuant to a commercial agreement with Bristol-Myers Squibb Company and E.R. Squibb (collectively, BMS), relating to Erbitux, we are co-developing Erbitux in the U.S. and Canada with BMS, exclusively, and in Japan with BMS and Merck. The companies have jointly agreed to expand the investment in the ongoing clinical development plan for Erbitux to further explore its use in additional tumor types. Under this arrangement, 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 agreement. 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 territory, 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 with Merck with respect to Erbitux granted Merck exclusive rights to market Erbitux outside of the U.S. and Canada, and co-exclusive rights with BMS and us in Japan. Merck also has rights to manufacture Erbitux for supply in its territory. 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 for development; and 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.

Necitumumab

The commercial agreement with BMS described above includes the co-development and co-commercialization of necitumumab, which is currently in Phase III clinical testing for squamous non-small cell lung cancer. Under the agreement, we and BMS have shared in the costs of developing and potentially commercializing necitumumab; however, in the fourth quarter of 2012, BMS provided notice of termination of its involvement with necitumumab. Under the terms of the agreement, BMS will continue to fund a portion of the costs over the following 18-month period, at which point BMS's involvement with necitumumab will terminate and we will hold exclusive rights to necitumumab in all markets.

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 $457.2 million, $302.5 million, and $115.0 million for the years ended December 31, 2012, 2011, and 2010, respectively.

Diabetes Collaboration

In January 2011, we and Boehringer Ingelheim entered into a global agreement to jointly develop and commercialize a portfolio of diabetes compounds. Included are Boehringer Ingelheim's two oral diabetes agents, linagliptin and empagliflozin. Subsequently in 2011, linagliptin was approved and launched in the U.S. (trade name Tradjenta), Japan (trade name Trazenta™), Europe (trade name Trajenta®), and other countries. Empagliflozin is currently in Phase III clinical testing. Also included in the agreement were our new insulin glargine product and our novel basal insulin analog, both of which began Phase III clinical testing in the second half of 2011; and an option granted to Boehringer Ingelheim to co-develop and co-commercialize our anti-TGF-beta monoclonal antibody, which is currently in Phase II clinical testing. Subsequently in 2013, Boehringer Ingelheim elected to terminate our collaboration with respect to the novel basal insulin analog. 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 is deductible for tax purposes.

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 may pay up to 300.0 million euro in additional success-based regulatory milestones for empagliflozin. We will be eligible to receive up to a total of $300.0 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

57

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. Revenue related to this collaboration was not material during the years ended December 31, 2012 and 2011.

Cymbalta

Boehringer Ingelheim

We were in a collaborative arrangement with Boehringer Ingelheim to jointly develop, market, and promote Cymbalta (duloxetine) outside the U.S. and Japan. Pursuant to the terms of the agreement, we generally shared equally in development, marketing, and selling expenses, and paid Boehringer Ingelheim a commission on sales in the co-promotion territories. We manufactured the product for all territories. Reimbursements or payments for the cost sharing of marketing, selling, and administrative expenses were recorded in the respective expense line items in the consolidated statements of operations. The commission paid to Boehringer Ingelheim was recorded in marketing, selling, and administrative expenses. In March 2010, the parties agreed to terminate this agreement, and we reacquired the exclusive rights to develop and market duloxetine for all indications in countries outside the U.S. and Japan. In connection with the termination, we paid Boehringer Ingelheim approximately $400 million and will also pay to Boehringer Ingelheim a percentage of our sales of duloxetine in these countries through the end of 2012 as consideration for the rights acquired. We record these costs as intangible assets that are amortized to marketing, selling, and administrative expenses using the straight-line method over the life of the original agreement, which is through the third quarter of 2015.

Quintiles

We were in a collaborative arrangement with Quintiles Transnational Corp. (Quintiles) to jointly market and promote Cymbalta in the United States. Pursuant to the terms of the agreement, Quintiles shared in the costs to co-promote Cymbalta with us and received a commission based upon net product sales. Quintiles' obligation to promote Cymbalta expired during 2009, and we incurred a lower commission for three years after completion of their promotion efforts. The commissions paid to Quintiles were recorded as marketing, selling, and administrative expenses.

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 that are contingent upon the successful development of solanezumab. The royalties relating to solanezumab would be paid for approximately eight years after launch of a product.

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 JAK inhibitor compound, now known as baricitinib, and certain follow-on compounds, for the treatment of inflammatory and autoimmune diseases. The agreement calls for payments of up to $515.0 million associated with certain development and regulatory milestones as well as an additional $150.0 million of potential sales-based milestones. Incyte also 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. The agreement also provides Incyte with an option to co-promote in the United States. In 2010, Incyte exercised its option to co-develop baricitinib in rheumatoid arthritis. We made development milestone payments of $49.0 million in 2010 related to Phase II trials of baricitinib. Upon initiation of Phase III trials for the treatment of rheumatoid arthritis in the fourth quarter of 2012, we incurred an additional milestone-related expense of $50.0 million. These milestone payments were recorded as research and development expenses.

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 $261.5 million, $219.2 million, and $174.5 million for the years ended December 31, 2012, 2011, and 2010, respectively.

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

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

	2012	2011	2010
Severance	$74.5	$251.8	$142.0
Asset impairments and other special charges	206.6	149.6	50.0
Asset impairments, restructuring, and other special charges	$281.1	$401.4	$192.0

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

For the year ended December 31, 2012, we incurred $206.6 million of asset impairments and other special charges consisting of $122.6 million related to an intangible asset impairment for liprotamase (see Note 7) net of the reduction of the related contingent consideration liability (see Note 6), $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, a decision that was as a result of our initiative to reorganize global operations, streamline various functions of the business, and reduce the total number of employees.

For the year ended December 31, 2010, we incurred $50.0 million of asset impairments and other special charges primarily consisting of lease termination costs and asset impairments outside the United States.

Note 6: 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, 2012, we had outstanding foreign currency forward commitments to purchase 273.8 million U.S. dollars and sell 210.0 million euro, and commitments to purchase 212.0 million euro and sell 277.4 million U.S. dollars, which will all settle within 45 days.

At December 31, 2012, approximately 100 percent of our total debt is at a fixed rate. We have converted approximately 60 percent of our fixed-rate debt to floating rates through the use of interest rate swaps.

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:

	2012	2011	2010
Fair value hedges			
Effect from hedged fixed-rate debt	$51.5	$259.6	$149.6
Effect from interest rate contracts	(51.5)	(259.6)	(149.6)
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	(35.8)	97.4	12.0

The effective portion of net gains (losses) on equity contracts in designated cash flow hedging relationships recorded in other comprehensive income (loss) was $0.0 million, $35.6 million, and $(35.6) million for the years ended December 31, 2012, 2011, and 2010, respectively. There have been no equity contracts in designated cash flow hedging relationships in 2012.

During the next 12 months, we expect to reclassify from accumulated other comprehensive loss to earnings $9.0 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, 2012, 2011, and 2010, 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, 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]	233.1	233.1				
Noncurrent investments	$6,313.3	$6,203.8				
December 31, 2011						
Cash and cash equivalents	$5,922.5	$5,922.5	$5,264.6	$657.9	$	$5,922.5
Short-term investments						
U.S. government and agencies	$362.3	$362.3	$351.3	$11.0	$	$362.3
Corporate debt securities	600.7	601.1		600.7		600.7
Other securities	11.6	11.6		11.6		11.6
Short-term investments	$974.6	$975.0				
Noncurrent investments						
U.S. government and agencies	$908.8	$901.3	$673.5	$235.3	$	$908.8
Corporate debt securities	2,081.3	2,093.3		2,081.3		2,081.3
Mortgage-backed	443.8	479.1		443.8		443.8
Asset-backed	245.0	253.2		245.0		245.0
Other securities	10.0	11.9		8.7	1.3	10.0
Marketable equity	180.8	107.5	180.8			180.8
Equity method and other investments[1]	160.1	160.1				
Noncurrent investments	$4,029.8	$4,006.4				

[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, 2012	$(5,531.3)	$	$(5,996.6)	$	$(5,996.6)
December 31, 2011	(6,981.5)		(7,451.5)		(7,451.5)

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, 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)
December 31, 2011					
Risk-management instruments					
Interest rate contracts designated as hedging instruments					
Other receivables	$6.1	$	$6.1	$	$6.1
Sundry	531.7		531.7		531.7
Foreign exchange contracts not designated as hedging instruments					
Other receivables	16.2		16.2		16.2
Other current liabilities	(25.9)		(25.9)		(25.9)

The fair value of the contingent consideration liability related to prior acquisitions, a Level 3 measurement in the fair value hierarchy, was $0.0 million and $121.6 million as of December 31, 2012 and 2011, respectively. The decrease in the fair value of the contingent consideration to zero as of December 31, 2012 was due to our expectations for the applicable products (see Note 5) and a $50.0 million approval milestone that was paid for Amyvid in the second quarter of 2012.

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, 2012:

	Maturities by Period				
	Total	Less Than 1 Year	1-5 Years	6-10 Years	More Than 10 Years
Fair value of debt securities	$7,569.9	$1,665.5	$4,776.5	$373.9	$754.0

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:

	2012	2011
Unrealized gross gains	$140.5	$103.0
Unrealized gross losses	29.0	80.0
Fair value of securities in an unrealized gain position	5,246.0	2,498.9
Fair value of securities in an unrealized loss position	2,102.0	2,164.4

Other-than-temporary impairment losses on fixed income securities of $12.2 million, $26.8 million, and $12.0 million were recognized in the consolidated statements of operations for the years ended December 31, 2012, 2011, and 2010, respectively. 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, 2012.

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

	2012	2011	2010
Proceeds from sales	$6,529.8	$2,268.3	$760.3
Realized gross gains on sales	82.3	140.0	110.7
Realized gross losses on sales	10.9	9.9	4.8

Note 7: Goodwill and Other Intangibles

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

	2012	2011
Indefinite-lived intangible assets		
Goodwill	$1,501.3	$1,434.7
In-process research and development	65.0	474.9
Total indefinite-lived intangible assets	$1,566.3	$1,909.6

Substantially all of our goodwill balance is attributable to the human pharmaceutical business segment. No impairments occurred with respect to the carrying value of goodwill for the years ended December 31, 2012, 2011, or 2010.

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. 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.

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. The remaining reduction of IPR&D in 2012 was primarily due to the reclassification of the $190.0 million Amyvid intangible asset from indefinite to finite-lived upon receiving FDA approval for marketing.

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 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. No material impairments occurred with respect to the carrying value of indefinite-lived intangible assets for the year ended December 31, 2010.

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

Description	2012 Carrying Amount—Gross	Accumulated Amortization	2012 Carrying Amount—Net	2011 Carrying Amount—Gross	Accumulated Amortization	2011 Carrying Amount—Net
Finite-lived intangible assets						
Marketed products	$5,107.9	$(1,987.0)	$3,120.9	$4,624.9	$(1,481.2)	$3,143.7
Other	129.5	(64.0)	65.5	117.3	(42.5)	74.8
Total finite-lived intangible assets	$5,237.4	$(2,051.0)	$3,186.4	$4,742.2	$(1,523.7)	$3,218.5

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, 2012, 2011 and 2010.

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

As of December 31, 2012, the remaining weighted-average amortization period for finite-lived intangible assets is approximately 9 years. Amortization expense was $563.0 million, $469.0 million, and $385.7 million for 2012, 2011, and 2010, respectively. The estimated amortization expense associated with our current finite-lived intangible assets for each of the next five years approximates $540 million in 2013, $530 million in 2014, $480 million in 2015, $380 million in 2016, and $200 million in 2017. 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 8: Borrowings

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

	2012	2011
3.55 to 7.13 percent notes (due 2012-2037)	$4,887.3	$6,387.4
Other, including capitalized leases	37.4	37.6
Fair value adjustment	606.6	556.5
	5,531.3	6,981.5
Less current portion	(11.9)	(1,516.8)
Long-term debt	$5,519.4	$5,464.7

Current maturities of long-term debt of $1.50 billion were repaid during the year ended December 31, 2012.

The 6.55 percent Employee Stock Ownership Plan (ESOP) debentures of $63.7 million were repaid in full during the year ended December 31, 2011.

The aggregate amounts of maturities on long-term debt for the next five years are $11.9 million in 2013, $1.01 billion in 2014, $9.0 million in 2015, $203.9 million in 2016, and $1.00 billion in 2017.

At December 31, 2012 and 2011, short-term borrowings included $0.0 million and $5.5 million, respectively, of notes payable to banks. At December 31, 2012, 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, 2012. Compensating balances and commitment fees are not material, and there are no conditions that are probable of occurring under which the lines may be withdrawn.

In 2010, we borrowed $125.0 million of short-term floating-rate debt, which was repaid in full during the year ended December 31, 2011.

We have converted approximately 60 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, 2012 and 2011, including the effects of interest rate swaps for hedged debt obligations, were 3.20 percent and 3.00 percent, respectively.

For the years ended December 31, 2012, 2011, and 2010, cash payments for interest on borrowings totaled $171.9 million, $167.4 million, and $176.3 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 9: Stock-Based Compensation

Stock-based compensation expense in the amount of $141.5 million, $147.4 million, and $231.0 million was recognized for the years ended December 31, 2012, 2011, and 2010, respectively, as well as related tax benefits of $49.5 million, $51.6 million, and $80.8 million, respectively. Our stock-based compensation expense consists primarily of performance awards (PAs), shareholder value awards (SVAs), and restricted stock units (RSUs). We recognize the stock-based compensation expense over the requisite service period of the individual grantees, which generally 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, 2012, additional stock-based compensation awards may be granted under the 2002 Lilly Stock Plan for not more than 92.0 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, 2012, 2011, and 2010 were $35.74, $31.90, and $30.88, 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 1.6 million shares, 3.9 million shares, and 3.8 million shares were issued during the years ended December 31, 2012, 2011, and 2010, respectively. Approximately 0.7 million shares are expected to be issued in 2013. As of December 31, 2012, the total remaining unrecognized compensation cost related to nonvested PAs amounted to $17.2 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 common stock at the end of a three-year period. The number of shares actually issued 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 Monte Carlo simulation 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, 2012, 2011, and 2010 were $30.35, $28.33, and $25.97, respectively, determined using the following assumptions:

(Percents)	2012	2011	2010
Expected dividend yield	4.50	4.90	4.50
Risk-free interest rate	.10-.36	.20-1.36	.10-1.36
Range of volatilities	22.40-25.64	27.61-29.10	28.00-28.69

A summary of the SVA activity is presented below:

	Units Attributable to SVAs (in thousands)
Outstanding at January 1, 2010	2,760
Granted	1,987
Issued	(365)
Forfeited or expired	(745)
December 31, 2010	3,637
Granted	1,830
Issued	(428)
Forfeited or expired	(740)
December 31, 2011	4,299
Granted	1,742
Issued	(973)
Forfeited or expired	(165)
December 31, 2012	4,903

The maximum number of shares that could ultimately be issued upon vesting of the SVA units outstanding at December 31, 2012, is 6.9 million. Approximately 2.4 million shares are expected to be issued in 2013. As of December 31, 2012, the total remaining unrecognized compensation cost related to nonvested SVAs amounted to $48.2 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, 2012, 2011, and 2010 were $39.65, $35.80, and $34.78, respectively. The number of shares ultimately issued for the RSU program remains constant with the exception of forfeitures. Pursuant to this plan, 1.4 million, 1.5 million, and 1.5 million shares were granted during the years ended December 31, 2012, 2011, and 2010, respectively, and approximately 0.3 million, 0.2 million, and 0.2 million shares were issued during the years ended December 31, 2012, 2011, and 2010, respectively. Approximately 0.9 million shares are expected to be issued in 2013. As of December 31, 2012, the total remaining unrecognized compensation cost related to nonvested RSUs amounted to $54.6 million, which will be amortized over the weighted-average remaining requisite service period of 21 months.

66

Stock Option Program

Stock options were granted prior to 2007 to officers, management, and board members at exercise prices equal to the fair market value of our stock price at the date of grant. Options fully vested 3 years from the grant date and have a term of 10 years.

Stock option activity during the year ended December 31, 2012 is summarized below:

	Shares of Common Stock Attributable to Options (in thousands)	Weighted-Average Exercise Price of Options	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at January 1, 2012	36,556	$ 66.22		
Exercised	(50)	20.37		
Forfeited or expired	(9,274)	73.28		
Outstanding at December 31, 2012	27,232	63.89	1.2	$0.4
Exercisable at December 31, 2012	27,232	63.89	1.2	0.4

For options exercised during the years ended December 31, 2012, 2011, and 2010, the related intrinsic value, cash received, and tax benefits were not material.

Note 10: Other Assets and Other Liabilities

Other receivables include tax receivables, receivables from our collaboration partners, interest receivable on the interest rate swaps, and a variety of other items.

Prepaid expenses and other includes global prepaid operating expenses and deferred taxes (Note 13).

Sundry assets primarily include deferred tax assets (Note 13), the fair value of interest rate swaps, capitalized computer software, and prepaid retirement plan outside the United States.

Other current liabilities include deferred income from our collaboration arrangements, other taxes payable, the current portion of our estimated product return liabilities, and a variety of other items.

Other noncurrent liabilities include deferred income from our collaboration and out-licensing arrangements, the long-term portion of our estimated product return liabilities, deferred tax liabilities (Note 13), product litigation, and a variety of other items.

Note 11: Shareholders' Equity

Changes in certain components of shareholders' equity were as follows:

	Additional Paid-in Capital	Retained Earnings	Deferred Costs - ESOP	Common Stock in Treasury Shares (in thousands)	Amount
Balance at January 1, 2010	$4,635.6	$9,830.4	$(77.4)	882	$98.5
Net income		5,069.5			
Cash dividends declared per share: $1.96		(2,167.3)			
Retirement of treasury shares	(1.0)			(28)	(1.0)
Issuance of stock under employee stock plans-net	(87.6)			10	(1.1)
Stock-based compensation	231.0				
ESOP transactions	20.5		25.0		
Balance at December 31, 2010	4,798.5	12,732.6	(52.4)	864	96.4
Net income		4,347.7			
Cash dividends declared per share: $1.96		(2,182.5)			
Retirement of treasury shares	(0.1)			(1)	(0.1)
Issuance of stock under employee stock plans-net	(108.7)			(10)	(1.0)
Stock-based compensation	147.4				
ESOP transactions	49.7		52.4		
Balance at December 31, 2011	4,886.8	14,897.8	—	853	95.3
Net income		4,088.6			
Cash dividends declared per share: $1.96		(2,186.5)			
Retirement of treasury shares		(711.7)		(14,912)	(721.1)
Purchase for treasury				16,918	819.2
Issuance of stock under employee stock plans-net	(65.2)			(9)	(1.0)
Stock-based compensation	141.5				
Balance at December 31, 2012	$4,963.1	$16,088.2	$—	2,850	$192.4

During 2012, we repurchased $819.2 million of shares, including $419.2 million remaining under the $3.00 billion share repurchase program announced in 2000 and $400.0 million under the $1.50 billion program announced in 2012. No shares were repurchased during the years ended December 31, 2011 and 2010.

We have 5 million authorized shares of preferred stock. As of December 31, 2012 and 2011, no preferred stock has been issued.

We have an employee benefit trust that held 50.0 million and 50.0 million shares of our common stock at December 31, 2012 and 2011, respectively, to provide a source of funds to assist us in meeting our obligations under various employee benefit plans. The cost basis of the shares held in the trust was $3.01 billion and $3.01 billion at December 31, 2012 and 2011, respectively, and is shown as a reduction in shareholders’ equity. Any dividend transactions between us and the trust are eliminated. Stock held by the trust is not considered outstanding in the computation of earnings per share. The assets of the trust were not used to fund any of our obligations under these employee benefit plans during the years ended December 31, 2012, 2011, and 2010.

We have an ESOP as a funding vehicle for the existing employee savings plan. The ESOP used the proceeds of a loan from us to purchase shares of common stock from the treasury. The ESOP issued third-party debt, which was repaid in 2011 (Note 8). The proceeds were used to purchase shares of our common stock on the open market. As of December 31, 2012, all shares of common stock held by the ESOP were allocated to participating employees as part of our savings plan contribution. The fair value of shares allocated each period was recognized as compensation expense.

68

Note 12: Earnings Per Share

Following is a reconciliation of the denominators used in computing earnings per share:

	2012	2011	2010
	(Shares in thousands)		
Income available to common shareholders	$4,088.6	$4,347.7	$5,069.5
Basic earnings per share			
Weighted-average number of common shares outstanding, including incremental shares	1,113,178	1,113,923	1,105,788
Basic earnings per share	$3.67	$3.90	$4.58
Diluted earnings per share			
Weighted-average number of common shares outstanding, including incremental shares and stock options	1,117,294	1,113,967	1,105,813
Diluted earnings per share	$3.66	$3.90	$4.58

Note 13: Income Taxes

Following is the composition of income tax expense:

	2012	2011	2010
Current			
Federal	$596.8	$671.4	$376.2
Foreign	540.6	759.5	513.9
State	56.2	(22.9)	23.3
Total current tax expense	1,193.6	1,408.0	913.4
Deferred			
Federal	87.0	(398.5)	624.4
Foreign	29.9	(34.7)	(55.2)
State	9.1	27.0	(26.9)
Total deferred tax expense (benefit)	126.0	(406.2)	542.3
Income taxes	$1,319.6	$1,001.8	$1,455.7

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

	2012	2011
Deferred tax assets		
Compensation and benefits	$1,081.8	$1,286.5
Tax credit carryforwards and carrybacks	703.2	695.3
Tax loss carryforwards and carrybacks	370.1	406.1
Asset purchases	366.8	386.2
Sale of intangibles	278.6	207.1
Debt	232.8	214.9
Intercompany profit in inventories	159.6	277.2
Product return reserves	153.8	146.2
Contingencies	113.2	94.5
Other	361.5	292.8
Total gross deferred tax assets	3,821.4	4,006.8
Valuation allowances	(675.8)	(611.9)
Total deferred tax assets	3,145.6	3,394.9
Deferred tax liabilities		
Unremitted earnings	(920.4)	(940.2)
Intangibles	(708.8)	(797.6)
Inventories	(573.4)	(489.2)
Property and equipment	(407.1)	(451.0)
Financial instruments	(257.0)	(196.9)
Total deferred tax liabilities	(2,866.7)	(2,874.9)
Deferred tax assets - net	$278.9	$520.0

At December 31, 2012 and 2011, no individually significant items were classified as “Other” deferred tax assets.

The deferred tax asset and related valuation allowance amounts for U.S. federal and state net operating losses and tax credits shown above have been reduced for differences between financial reporting and tax return filings.

Based on filed tax returns, we have tax credit carryforwards and carrybacks of $973.2 million available to reduce future income taxes; $433.4 million will be carried back; $0.7 million of the tax credit carryforwards will expire between 10 and 20 years; and $3.7 million of the tax credit carryforwards will never expire. The remaining portion of the tax credit carryforwards is related to federal tax credits of $80.3 million, international tax credits of $93.6 million, and state tax credits of $361.5 million, all of which are substantially reserved.

At December 31, 2012, based on filed tax returns we had net operating losses and other carryforwards for international and U.S. income tax purposes of $737.5 million: $309.7 million will expire within 5 years; $394.5 million will expire between 5 and 20 years; and $33.4 million of the carryforwards will never expire. Deferred tax assets related to state net operating losses of $100.7 million and $16.4 million of other state carryforwards are substantially reserved.

Domestic and Puerto Rican companies contributed approximately 54 percent, 24 percent, and 45 percent for the years ended December 31, 2012, 2011, and 2010, respectively, to consolidated income before income taxes. We have a subsidiary operating in Puerto Rico under a tax incentive grant. The current tax incentive grant will not expire prior to 2017.

At December 31, 2012, we had an aggregate of $20.98 billion of unremitted earnings of foreign subsidiaries that have been or are intended to be permanently reinvested for continued use in foreign operations and that, if distributed, would result in additional income tax expense at approximately the U.S. statutory rate.

Cash payments of income taxes totaled $992.0 million, $943.0 million, and $861.0 million, for the years ended December 31, 2012, 2011, and 2010, respectively.

Following is a reconciliation of the income tax expense applying the U.S. federal statutory rate to income before income taxes to reported income tax expense:

	2012	2011	2010
Income tax at the U.S. federal statutory tax rate	$1,892.9	$1,872.3	$2,283.8
Add (deduct)			
International operations, including Puerto Rico	(593.8)	(796.7)	(823.3)
U.S. health care reform	59.8	62.9	85.1
General business credits	(11.2)	(80.8)	(83.2)
IRS audit conclusion	—	(85.3)	—
Other	(28.1)	29.4	(6.7)
Income taxes	$1,319.6	$1,001.8	$1,455.7

The American Taxpayer Relief Act of 2012, which included the reinstatement of the research tax credit for the year 2012, was enacted in early 2013. While we expect to claim a research tax credit for 2012, we are required to record the tax benefit, which is presented with other general business credits, in the year it is enacted.

In October 2010, Puerto Rico enacted excise tax legislation that affected our operations beginning with the year ended December 31, 2011. The excise tax is imposed on the purchase of goods and services from a related manufacturer in Puerto Rico, and is therefore included in costs of sales in our consolidated statement of operations rather than income taxes. The Internal Revenue Service (IRS) has stated it would not challenge a taxpayer's position that this excise tax is creditable for U.S. income tax purposes, pending the resolution of numerous legal and factual issues. As a result, the benefit in 2012 and 2011 on international operations reported in the effective tax rate reconciliation above includes the foreign tax credit related to the excise tax.

The U.S. health care legislation (both the primary Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act) eliminated the tax-free nature of the subsidy we receive for sponsoring retiree drug coverage that is "actuarially equivalent" to Medicare Part D. This provision is effective January 1, 2013. While this change has a future impact on our net tax deductions related to retiree health benefits, we were required to record a one-time charge to adjust our deferred tax asset for this change in the law in the quarter of enactment. Accordingly, we recorded a non-cash charge of $85.1 million in the first quarter of 2010. In addition, U.S. health care reform mandated an annual industry fee effective beginning January 1, 2011, which is not deductible for tax purposes.

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

	2012	2011	2010
Beginning balance at January 1	$1,274.8	$1,619.6	$1,351.2
Additions based on tax positions related to the current year	141.5	89.4	186.2
Additions for tax positions of prior years	70.1	390.0	117.0
Reductions for tax positions of prior years	(38.5)	(492.3)	(30.2)
Settlements	(9.2)	(326.3)	(0.1)
Lapses of statutes of limitation	(4.6)	(2.6)	(7.0)
Changes related to the impact of foreign currency translation	(0.3)	(3.0)	2.5
Balance at December 31	$1,433.8	$1,274.8	$1,619.6

The total amount of unrecognized tax benefits that, if recognized, would affect our effective tax rate was $928.1 million and $812.3 million at December 31, 2012 and 2011, respectively.

We file income tax returns in the U.S. federal jurisdiction and various state, local, and non-U.S. jurisdictions. We are no longer subject to U.S. federal, state and local, or non-U.S. income tax examinations in major taxing jurisdictions for years before 2007.

During 2011, we settled the U.S. examinations of tax years 2005-2007, along with certain matters related to tax years 2008-2009. The examination of the remainder of 2008-2009 commenced in the fourth quarter of 2011. Considering this current examination cycle, as well as the settlement of 2005-2007 and certain matters related to 2008-2009, our consolidated results of operations benefited from a reduction in tax expense of $85.3 million in 2011. We made cash payments totaling approximately $300 million for tax years 2005-2007.

71

The U.S. examination of certain matters related to tax years 2008-2009 that were not settled as part of previous examinations remains in progress. Management believes it is reasonably possible the remaining 2008-2009 tax matters could be concluded within the next 12 months. However, resolution of these matters is still dependent upon a number of factors, including the potential for formal administrative and legal proceedings. As a result, it is not possible to estimate the range of the reasonably possible changes in unrecognized tax benefits that could occur within the next 12 months related to these years, nor is it possible to estimate reliably the total future cash flows related to these unrecognized tax benefits.

We recognize both accrued interest and penalties related to unrecognized tax benefits in income tax expense. During the years ended December 31, 2012, 2011, and 2010, we recognized income tax expense (benefit) of $42.3 million, $(47.3) million, and $38.3 million, respectively, related to interest and penalties. At December 31, 2012 and 2011, our accruals for the payment of interest and penalties totaled $187.5 million and $134.6 million, respectively. Substantially all of the expense (benefit) and accruals relate to interest.

Note 14: Retirement Benefits

We use a measurement date of December 31 to develop the change in benefit obligation, change in plan assets, funded status, and amounts recognized in the consolidated balance sheets at December 31 for our defined benefit pension and retiree health benefit plans, which were as follows:

	Defined Benefit Pension Plans		Retiree Health Benefit Plans	
	2012	2011	2012	2011
Change in benefit obligation				
Benefit obligation at beginning of year	$9,191.2	$8,115.0	$2,308.6	$2,088.5
Service cost	253.1	236.3	63.3	72.4
Interest cost	455.1	447.9	114.9	118.0
Actuarial (gain) loss	834.0	794.7	(57.0)	110.2
Benefits paid	(404.2)	(400.1)	(67.2)	(77.9)
Plan amendments	(0.6)	10.0	(28.4)	1.1
Foreign currency exchange rate changes and other adjustments	95.2	(12.6)	3.5	(3.7)
Benefit obligation at end of year	10,423.8	9,191.2	2,337.7	2,308.6
Change in plan assets				
Fair value of plan assets at beginning of year	7,186.3	6,983.0	1,339.0	1,327.7
Actual return on plan assets	922.7	209.2	183.4	16.6
Employer contribution	469.7	402.4	62.8	72.6
Benefits paid	(404.2)	(400.1)	(67.2)	(77.9)
Foreign currency exchange rate changes and other adjustments	112.1	(8.2)	—	—
Fair value of plan assets at end of year	8,286.6	7,186.3	1,518.0	1,339.0
Funded status	(2,137.2)	(2,004.9)	(819.7)	(969.6)
Unrecognized net actuarial loss	5,187.5	4,857.5	1,156.7	1,367.4
Unrecognized prior service (benefit) cost	54.9	57.3	(203.4)	(215.1)
Net amount recognized	$3,105.2	$2,909.9	$133.6	$182.7
Amounts recognized in the consolidated balance sheet consisted of:				
Prepaid expenses and other	$125.5	$160.8	$—	$—
Other current liabilities	(61.2)	(57.5)	(8.9)	(9.3)
Accrued retirement benefit	(2,201.6)	(2,108.2)	(810.8)	(960.3)
Accumulated other comprehensive loss before income taxes	5,242.5	4,914.8	953.3	1,152.3
Net amount recognized	$3,105.2	$2,909.9	$133.6	$182.7

The unrecognized net actuarial loss and unrecognized prior service cost (benefit) have not yet been recognized in net periodic pension costs and are included in accumulated other comprehensive loss at December 31, 2012.

For the year ended December 31, 2013, we expect to recognize from accumulated other comprehensive loss as components of net periodic benefit cost, $395.4 million of unrecognized net actuarial loss and $3.1 million of unrecognized prior service cost related to our defined benefit pension plans, and $96.2 million of unrecognized net actuarial loss and $29.3 million of unrecognized prior service benefit related to our retiree health benefit plans. We do not expect any plan assets to be returned to us in 2013.

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

	Defined Benefit Pension Plans			Retiree Health Benefit Plans		
(Percents)	2012	2011	2010	2012	2011	2010
Weighted-average assumptions as of December 31						
Discount rate for benefit obligation	4.3	5.0	5.6	4.3	5.1	5.8
Discount rate for net benefit costs	5.0	5.6	5.9	5.1	5.8	6.0
Rate of compensation increase for benefit obligation	3.4	3.7	3.7			
Rate of compensation increase for net benefit costs	3.7	3.7	3.7			
Expected return on plan assets for net benefit costs	8.4	8.5	8.8	8.8	8.8	9.0

We annually evaluate the expected return on plan assets in our defined benefit pension and retiree health benefit plans. In evaluating the expected rate of return, we consider many factors, with a primary analysis of current and projected market conditions; asset returns and asset allocations; and the views of leading financial advisers and economists. We may also review our historical assumptions compared with actual results, as well as the assumptions and trend rates utilized by similar plans, where applicable. Health-care-cost trend rates are assumed to increase at an annual rate of 7.1 percent for the year ended December 31, 2013, decreasing by approximately 0.3 percent per year to an ultimate rate of 5.0 percent by 2020.

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

	2013	2014	2015	2016	2017	2018-2022
Defined benefit pension plans	$427.1	$434.0	$445.3	$459.1	$473.8	$2,646.0
Retiree health benefit plans-gross	$111.6	$114.5	$119.4	$124.6	$129.9	$729.7
Medicare rebates	(6.3)	(9.5)	(10.2)	(10.6)	(10.9)	(49.5)
Retiree health benefit plans-net	$105.3	$105.0	$109.2	$114.0	$119.0	$680.2

The total accumulated benefit obligation for our defined benefit pension plans was $9.46 billion and $8.20 billion at December 31, 2012 and 2011, respectively. The projected benefit obligation and fair value of the plan assets for the defined benefit pension plans with projected benefit obligations in excess of plan assets were $9.15 billion and $6.89 billion, respectively, as of December 31, 2012, and $8.12 billion and $5.96 billion, respectively, as of December 31, 2011. The accumulated benefit obligation and fair value of the plan assets for the defined benefit pension plans with accumulated benefit obligations in excess of plan assets were $8.02 billion and $6.58 billion, respectively, as of December 31, 2012, and $7.03 billion and $5.75 billion, respectively, as of December 31, 2011.

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

	Defined Benefit Pension Plans			Retiree Health Benefit Plans		
	2012	2011	2010	2012	2011	2010
Components of net periodic benefit cost						
Service cost	$253.1	$236.3	$219.2	$63.3	$72.4	$56.5
Interest cost	455.1	447.9	431.6	114.9	118.0	121.4
Expected return on plan assets	(684.8)	(685.9)	(638.2)	(127.2)	(129.4)	(122.6)
Amortization of prior service (benefit) cost	4.2	8.6	8.8	(39.8)	(42.9)	(37.2)
Recognized actuarial loss	285.7	200.4	163.0	98.4	88.7	85.0
Net periodic benefit cost	$313.3	$207.3	$184.4	$109.6	$106.8	$103.1

If the health-care-cost trend rates were to be increased by one percentage point, the December 31, 2012, accumulated postretirement benefit obligation would increase by $218.2 million and the aggregate of the service cost and interest cost components of the 2012 annual expense would increase by $15.6 million. A one percentage point decrease in these rates would decrease the December 31, 2012, accumulated postretirement benefit obligation by $193.6 million, and the aggregate of the 2012 service cost and interest cost by $12.6 million.

The following represents the amounts recognized in other comprehensive income (loss) for the year ended December 31, 2012:

	Defined Benefit Pension Plans	Retiree Health Benefit Plans
Actuarial (gain) loss arising during period	$598.9	$(113.2)
Plan amendments during period	(0.6)	(28.4)
Amortization of prior service (benefit) cost included in net income	(4.2)	39.8
Amortization of net actuarial loss included in net income	(285.7)	(98.4)
Foreign currency exchange rate changes	19.3	1.1
Total other comprehensive (income) loss during period	$327.7	$(199.1)

We have defined contribution savings plans that cover our eligible employees worldwide. The purpose of these defined contribution plans is generally to provide additional financial security during retirement by providing employees with an incentive to save. Our contributions to the plan are based on employee contributions and the level of our match. Expenses under the plans totaled $127.3 million, $117.6 million, and $119.8 million for the years ended December 31, 2012, 2011, and 2010, respectively.

We provide certain other postemployment benefits primarily related to disability benefits and accrue for the related cost over the service lives of employees. Expenses associated with these benefit plans for the years ended December 31, 2012, 2011, and 2010 were not material.

Benefit Plan Investments

Our benefit plan investment policies are set with specific consideration of return and risk requirements in relationship to the respective liabilities. U.S. and Puerto Rico plans represent 81 percent of our global investments. Given the long-term nature of our liabilities, these plans have the flexibility to manage an above-average degree of risk in the asset portfolios. At the investment-policy level, there are no specifically prohibited investments. However, within individual investment manager mandates, restrictions and limitations are contractually set to align with our investment objectives, ensure risk control, and limit concentrations.

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

Our global benefit plans may enter into contractual arrangements (derivatives) to implement the local investment policy or manage particular portfolio risks. Derivatives are principally used to increase or decrease exposure to a particular public equity, fixed income, commodity, or currency market more rapidly or

74

less expensively than could be accomplished through the use of the cash markets. The plans utilize both exchange-traded and over-the-counter instruments. The maximum exposure to either a market or counterparty credit loss is limited to the carrying value of the receivable, and is managed within contractual limits. We expect all of our counterparties to meet their obligations. The gross values of these derivative receivables and payables are not material to the global asset portfolio, and their values are reflected within the tables below.

The defined benefit pension and retiree health benefit plan allocation for the U.S. and Puerto Rico currently comprises approximately 80 percent growth investments and 20 percent fixed-income investments. The growth investment allocation encompasses U.S. and international public equity securities, hedge funds, private equity-like investments, and real estate. These portfolio allocations are intended to reduce overall risk by providing diversification, while seeking moderate to high returns over the long term.

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

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

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

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

Real estate is composed of both public and private holdings. Real estate investments in registered investment companies that trade on an exchange are classified as Level 1 on the fair value hierarchy. Real estate investments in funds measured at fair value on the basis of NAV provided by the fund manager are classified as Level 3. These NAVs are developed with inputs including discounted cash flow, independent appraisal, and market comparable analyses.

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

75

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

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

The fair values of our defined benefit pension plan and retiree health plan assets as of December 31, 2012 by asset category are as follows:

		Fair Value Measurements Using		
Asset Class	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Defined Benefit Pension Plans				
Public equity securities				
U.S.	$457.7	$307.9	$ 149.8	$
International	1,905.3	673.3	1,232.0	
Fixed income				
Developed markets	1,075.4	156.4	915.3	3.7
Emerging markets	402.3		402.3	
Private alternative investments				
Hedge funds	2,555.5		1,337.4	1,218.1
Equity-like funds	991.2	17.4	63.3	910.5
Real estate	504.3	353.5	8.2	142.6
Other	394.9	140.1	254.8	
Total	$8,286.6	$1,648.6	$ 4,363.1	$2,274.9
Retiree Health Benefit Plans				
Public equity securities				
U.S.	$45.4	$30.4	$ 15.0	$
International	127.7	33.9	93.8	
Fixed income				
Developed markets	59.4		59.0	0.4
Emerging markets	40.3		40.3	
Private alternative investments				
Hedge funds	234.0		134.1	99.9
Equity-like funds	81.9			81.9
Cash value of trust owned insurance contract	869.1		869.1	
Real estate	35.4	35.4		
Other	24.8	6.2	18.6	
Total	$1,518.0	$105.9	$ 1,229.9	$182.2

No material transfers between Level 1, Level 2, or Level 3 occurred during the year ended December 31, 2012.

The activity in the Level 3 investments during the year ended December 31, 2012 was as follows:

	Fixed Income: Developed Markets	Hedge Funds	Equity-like Funds	Real Estate	Total
Defined Benefit Pension Plans					
Beginning balance at January 1, 2012	$—	$1,248.4	$870.2	$138.0	$2,256.6
Actual return on plan assets, including changes in foreign exchange rates:					
Relating to assets still held at the reporting date	0.3	18.3	10.1	3.3	32.0
Relating to assets sold during the period	—	(0.2)	—	—	(0.2)
Purchases, sales, and settlements, net	2.3	(48.4)	30.2	1.3	(14.6)
Transfers into (out of) Level 3	1.1	—	—	—	1.1
Ending balance at December 31, 2012	$3.7	$1,218.1	$910.5	$142.6	$2,274.9
Retiree Health Benefit Plans					
Beginning balance at January 1, 2012	$—	$105.3	$79.9		$185.2
Actual return on plan assets, including changes in foreign exchange rates:					
Relating to assets still held at the reporting date	—	(0.9)	—		(0.9)
Relating to assets sold during the period	—	—	—		—
Purchases, sales, and settlements, net	0.3	(4.5)	2.0		(2.2)
Transfers into (out of) Level 3	0.1	—	—		0.1
Ending balance at December 31, 2012	$0.4	$99.9	$81.9		$182.2

The fair values of our defined benefit pension plan and retiree health plan assets as of December 31, 2011 by asset category are as follows:

Asset Class	Total	Fair Value Measurements Using Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Defined Benefit Pension Plans				
Public equity securities				
U.S.	$454.5	$317.2	$137.3	$
International	1,462.4	505.9	956.5	
Fixed income				
Developed markets	929.1	100.9	828.2	
Emerging markets	341.5	0.1	341.4	
Private alternative investments				
Hedge funds	2,312.6		1,064.2	1,248.4
Equity-like funds	870.2			870.2
Real estate	409.2	271.2		138.0
Other	406.8	177.7	229.1	
Total	$7,186.3	$1,373.0	$3,556.7	$2,256.6
Retiree Health Benefit Plans				
Public equity securities				
U.S.	$40.9	$28.0	$12.9	$
International	97.1	27.5	69.6	
Fixed income				
Developed markets	55.3		55.3	
Emerging markets	34.6		34.6	
Private alternative investments				
Hedge funds	213.1		107.8	105.3
Equity-like funds	79.9			79.9
Cash value of trust owned insurance contract	767.9		767.9	
Real estate	27.5	27.5		
Other	22.7	8.6	14.1	
Total	$1,339.0	$91.6	$1,062.2	$185.2

No material transfers between Level 1, Level 2, or Level 3 occurred during the year ended December 31, 2011.

The activity in the Level 3 investments during the year ended December 31, 2011 was as follows:

	Hedge Funds	Equity-like Funds	Real Estate	Total
Defined Benefit Pension Plans				
Beginning balance at January 1, 2011	$1,241.9	$802.9	$126.5	$2,171.3
Actual return on plan assets, including changes in foreign exchange rates:				
Relating to assets still held at the reporting date	(8.1)	34.4	3.9	30.2
Relating to assets sold during the period	(18.1)	—	—	(18.1)
Purchases, sales, and settlements, net	32.7	32.9	7.6	73.2
Ending balance at December 31, 2011	$1,248.4	$870.2	$138.0	$2,256.6
Retiree Health Benefit Plans				
Beginning balance at January 1, 2011	$106.6	$74.5		$181.1
Actual return on plan assets, including changes in foreign exchange rates:				
Relating to assets still held at the reporting date	0.5	3.3		3.8
Relating to assets sold during the period	(1.8)	—		(1.8)
Purchases, sales, and settlements, net	—	2.1		2.1
Ending balance at December 31, 2011	$105.3	$79.9		$185.2

For the year ended December 31, 2013, we expect to contribute approximately $60 million to our defined benefit pension plans to satisfy minimum funding requirements for the year. In addition, we expect to contribute approximately $300 million of additional discretionary funding in the aggregate during the year ended December 31, 2013 to several of our global defined benefit pension and post-retirement health benefit plans.

Note 15: Contingencies

We are a party to various legal actions and government investigations. The most significant of these are described below. It is not possible to determine the outcome of these matters, and we cannot reasonably estimate the maximum potential exposure or the range of possible loss in excess of amounts accrued for any of these matters; however, we believe that, except as specifically noted below with respect to the Alimta Hatch-Waxman Act patent challenges, the resolution of all such matters will not have a material adverse effect on our consolidated financial position or liquidity, but could possibly be material to our consolidated results of operations in any one accounting period.

Patent Litigation

We are engaged in the following U.S. patent litigation matters involving Alimta brought pursuant to procedures set out in the Hatch-Waxman Act (the Drug Price Competition and Patent Term Restoration Act of 1984). Teva Parenteral Medicines, Inc. (Teva); APP Pharmaceuticals, LLC (APP); and Barr Laboratories, Inc. (Barr) each submitted ANDAs seeking approval to market generic versions of Alimta prior to the expiration of the relevant U.S. patents and data-based pediatric exclusivity period (compound patent licensed from the Trustees of Princeton University and expiring in 2017, vitamin dosage regimen patent expiring in 2022) and alleging the patents are invalid. We, along with Princeton, filed lawsuits in the U.S. District Court for the District of Delaware against Teva, APP, and Barr seeking rulings that the compound patent is valid and infringed. In July 2011, the district court entered judgment in our favor, upholding that patent’s validity. In August 2012, the U.S. Court of Appeals for the Federal Circuit (CAFC) affirmed the district court's judgment in our favor. Teva and APP filed a petition for en banc review of the CAFC's panel decision, which was denied in November 2012. It is possible that Teva and APP may seek review by the U.S. Supreme Court.

In October 2010, we filed a lawsuit in the U.S. District Court for the Southern District of Indiana against Teva, APP, Pliva Hrvatska D.O.O., and Barr seeking rulings that our vitamin dosage regimen patent is valid and infringed. Trial in this case is scheduled to begin in August 2013. In January 2012 and April 2012, we filed similar lawsuits against Accord Healthcare Inc. and Apotex Inc., respectively. In addition, generic

79

manufacturers have opposed the European Patent Office's decision to grant a vitamin dosage regimen patent, and are seeking revocation of that patent.

We believe the challenges to the Alimta patents are without merit and expect to prevail in this litigation. However, it is not possible to determine the outcome of this litigation, and accordingly, we can provide no assurance that we will prevail. An unfavorable outcome could have a material adverse impact on our future consolidated results of operations, liquidity, and financial position. We expect a loss of exclusivity for Alimta would result in a rapid and severe decline in future revenues in the relevant market.

Byetta Product Liability Litigation

We have been named as a defendant in approximately 140 Byetta product liability lawsuits involving approximately 520 plaintiffs. Approximately 100 of these lawsuits, covering about 485 plaintiffs, are filed in California and coordinated in a Los Angeles Superior Court. We are aware of approximately 465 additional claimants who have not yet filed suit. The majority of the claims allege damages for pancreatitis. A smaller number of claimants allege that Byetta caused or contributed to their pancreatic cancer. We believe these claims are without merit and are prepared to defend against them vigorously.

Diethylstilbestrol Product Liability Litigation

In approximately 90 U.S. lawsuits against us involving approximately 90 claimants, plaintiffs seek to recover damages on behalf of children or grandchildren of women who were prescribed diethylstilbestrol (DES) during pregnancy in the 1950s and 1960s. Approximately 80 of these claimants allege that they were indirectly exposed in utero to the medicine and later developed breast cancer as a consequence. We believe these claims are without merit and are prepared to defend against them vigorously.

Zyprexa Product Liability Litigation

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.

Product Liability Insurance

Because of the nature of pharmaceutical products, it is possible that we could become subject to large numbers of product liability and related claims in the future. In the past several years, we have been unable to obtain product liability insurance due to a very restrictive insurance market. Therefore, for substantially all of our currently marketed products, we have been and expect that we will continue to be completely self-insured for product liability losses. The DES claims are covered by insurance, subject to deductibles and coverage limits. There is no assurance that we will be able to fully collect from our insurance carriers in the future.

Note 16: Other Comprehensive Income (Loss)

The accumulated balances related to each component of other comprehensive income (loss) were as follows:

(Amounts presented net of taxes)	Foreign Currency Translation Gains (Losses)	Unrealized Net Gains (Losses) on Securities	Defined Benefit Pension and Retiree Health Benefit Plans	Effective Portion of Cash Flow Hedges	Accumulated Other Comprehensive Loss
Beginning balance at January 1, 2010	$ 835.8	$75.4	$ (3,264.3)	$(118.8)	$ (2,471.9)
Unrealized gain (loss)		81.1		(9.3)	
Net amount reclassed to net income		(27.6)		(5.8)	
Other comprehensive income (loss)	(325.1)	53.5	88.5	(15.1)	(198.2)
Balance at December 31, 2010	510.7	128.9	(3,175.8)	(133.9)	(2,670.1)
Unrealized gain (loss)		(59.4)		32.6	
Net amount reclassed to net income		(54.7)		(5.8)	
Other comprehensive income (loss)	(244.8)	(114.1)	(856.4)	26.8	(1,188.5)
Balance at December 31, 2011	265.9	14.8	(4,032.2)	(107.1)	(3,858.6)
Unrealized gain (loss)		104.1			
Net amount reclassed to net income		(46.4)		5.9	
Other comprehensive income (loss)	160.9	57.7	(163.0)	5.9	61.5
Balance at December 31, 2012	$ 426.8	$72.5	$ (4,195.2)	$(101.2)	$ (3,797.1)

The tax effect on the unrealized net gains (losses) on securities was an expense of $30.8 million in 2012, a benefit of $64.4 million in 2011, and an expense of $27.3 million in 2010. The tax effect related to our defined benefit pension and retiree health benefit plans (Note 14) was an expense of $34.4 million in 2012, a benefit of $383.8 million in 2011, and an expense of $60.4 million in 2010. The tax effect on the effective portion of cash flow hedges was not significant for the years ended December 31, 2012, 2011, and 2010. Income taxes were not provided for foreign currency translation.

Generally, the assets and liabilities of foreign operations are translated into U.S. dollars using the current exchange rate. For those operations, changes in exchange rates generally do not affect cash flows; therefore, resulting translation adjustments are made in shareholders' equity rather than in income.

Note 17: Other—Net, (Income) Expense:

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

	2012	2011	2010
Income related to prepayment of Amylin's obligation (Note 4)	$(787.8)	$—	$—
Interest expense	177.8	186.0	185.5
Interest income	(105.0)	(79.9)	(51.9)
Other (income) expense	41.0	72.9	(128.6)
Other—net, (income) expense	$(674.0)	$179.0	$5.0

The most significant component of other—net, (income) expense for the year ended December 31, 2012 was the income recognized from the early payment of the exenatide revenue-sharing obligation by Amylin. See Note 4 for additional information. For the year ended December 31, 2011, other—net, (income) expense primarily consists of the impairment on acquired IPR&D assets related to liprotamase and Amyvid (Note 7) partially offset by gains on the disposal of investment securities. For the year ended December 31, 2010, other—net, (income) expense primarily consists of damages recovered from generic pharmaceutical companies related to Zyprexa patent litigation in Germany and gains on the disposal of investment securities.

Management’s Reports

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

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

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

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

Our audit committee includes five nonemployee members of the board of directors, all of whom are independent from our company. The committee charter, which is available on our website, outlines the members’ roles and responsibilities and is consistent with enacted corporate reform laws and regulations. It is the audit committee’s responsibility to appoint an independent registered public accounting firm subject to shareholder ratification, approve both audit and non-audit services performed by the independent registered public accounting firm, and review the reports submitted by the firm. The audit committee meets several times during the year with management, the internal auditors, and the independent public accounting firm to discuss audit activities, internal controls, and financial reporting matters, including reviews of our externally published financial results. The internal auditors and the independent registered public accounting firm have full and free access to the committee.

We are dedicated to ensuring that we maintain the high standards of financial accounting and reporting that we have established. We are committed to providing financial information that is transparent, timely, complete, relevant, and accurate. Our culture demands integrity and an unyielding commitment to strong internal practices and policies. Finally, we have the highest confidence in our financial reporting, our underlying system of internal controls, and our people, who are objective in their responsibilities and operate under a code of conduct and the highest level of ethical standards.

Management’s Report on Internal Control Over Financial Reporting—Eli Lilly and Company and Subsidiaries

Management of Eli Lilly and Company and subsidiaries is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934. We have global financial policies that govern critical areas, including internal controls, financial accounting and reporting, fiduciary accountability, and safeguarding of corporate assets. Our internal accounting control systems are designed to provide reasonable assurance that assets are safeguarded, that transactions are executed in accordance with management’s authorization and are properly recorded, and that accounting records are adequate for preparation of financial statements and other financial information. A staff of internal auditors regularly monitors, on a worldwide basis, the adequacy and effectiveness of internal accounting controls. The general auditor reports directly to the audit committee of the board of directors.

We conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in "Internal Control—Integrated Framework" issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under this framework, we concluded that our internal control over financial reporting was effective as of December 31, 2012. However, because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

The internal control over financial reporting has been assessed by Ernst & Young LLP as of December 31, 2012. Their responsibility is to evaluate whether internal control over financial reporting was designed and operating effectively.

John C. Lechleiter, Ph.D.

Chairman, President, and Chief Executive Officer

Derica W. Rice

Executive Vice President, Global Services and Chief Financial Officer

February 21, 2013

Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders of Eli Lilly and Company

We have audited the accompanying consolidated balance sheets of Eli Lilly and Company and subsidiaries as of December 31, 2012 and 2011, and the related consolidated statements of operations, cash flows, and comprehensive income for each of the three years in the period ended December 31, 2012. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Eli Lilly and Company and subsidiaries at December 31, 2012 and 2011, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2012, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Eli Lilly and Company and subsidiaries' internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 21, 2013 expressed an unqualified opinion thereon.

Indianapolis, Indiana
February 21, 2013

Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders of Eli Lilly and Company

We have audited Eli Lilly and Company and subsidiaries' internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Eli Lilly and Company and subsidiaries' management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Eli Lilly and Company and subsidiaries maintained, in all material respects, effective internal control over financial reporting as of December 31, 2012, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the 2012 consolidated financial statements of Eli Lilly and Company and subsidiaries and our report dated February 21, 2013 expressed an unqualified opinion thereon.

Indianapolis, Indiana
February 21, 2013

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

Under applicable SEC regulations, management of a reporting company, with the participation of the principal executive officer and principal financial officer, must periodically evaluate the company's "disclosure controls and procedures," which are defined generally as controls and other procedures of a reporting company designed to ensure that information required to be disclosed by the reporting company in its periodic reports filed with the SEC (such as this Form 10-K) is recorded, processed, summarized, and reported on a timely basis.

Our management, with the participation of John C. Lechleiter, Ph.D., chairman, president, and chief executive officer, and Derica W. Rice, executive vice president, global services and chief financial officer, evaluated our disclosure controls and procedures as of December 31, 2012, and concluded that they are effective.

Internal Control over Financial Reporting

Dr. Lechleiter and Mr. Rice provided a report on behalf of management on our internal control over financial reporting, in which management concluded that the company's internal control over financial reporting is effective at December 31, 2012. In addition, Ernst & Young LLP as of December 31, 2012, the company's independent registered public accounting firm, provided an attestation report on the company's internal control over financial reporting. You can find the full text of management's report and Ernst & Young's attestation report in Item 8, and both reports are incorporated by reference in this Item.

Changes in Internal Controls

During the fourth quarter of 2012, there were no changes in our internal control over financial reporting that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

Not applicable.

Part III

Item 10. Directors, Executive Officers, and Corporate Governance

Directors and Executive Officers

Information relating to our Board of Directors is found in our Proxy Statement to be dated on or about March 25, 2013 (the Proxy Statement) under “Board of Directors” and is incorporated in this report by reference.

Information relating to our executive officers is found at Item 1, "Business—Executive Officers of the Company.”

Code of Ethics

We have adopted a code of ethics that complies with the applicable SEC and New York Stock Exchange requirements. The code is set forth in:

- The Red Book, a comprehensive code of ethical and legal business conduct applicable to all employees worldwide and to our Board of Directors; and
- Code of Ethical Conduct for Lilly Financial Management, a supplemental code for our chief executive officer and all members of financial management that focuses on accounting, financial reporting, internal controls, and financial stewardship.

Both documents are online on our website at http://www.lilly.com/about/compliance/conduct. In the event of any amendments to, or waivers from, a provision of the code affecting the chief executive officer, chief financial officer, chief accounting officer, controller, or persons performing similar functions, we intend to post on the above website within four business days after the event a description of the amendment or waiver as required under applicable SEC rules. We will maintain that information on our website for at least 12 months. Paper copies of these documents are available free of charge upon request to the company’s secretary at the address on the front of this Form 10-K.

Corporate Governance

In our proxy statements, we describe the procedures by which shareholders can recommend nominees to our board of directors. There have been no changes in those procedures since they were last published in our proxy statement of March 5, 2012.

The board has appointed an audit committee consisting entirely of independent directors in accordance with applicable SEC and New York Stock Exchange rules for audit committees. The members of the committee are Michael L. Eskew (chair), Katherine Baicker, R. David Hoover, Douglas R. Oberhelman, and Kathi P. Seifert. The board has determined that Messrs. Eskew, Hoover, and Oberhelman are audit committee financial experts as defined in the SEC rules.

Item 11. Executive Compensation

Information on director compensation, executive compensation, and compensation committee matters can be found in the Proxy Statement under “Directors’ Compensation,” “Compensation Committee Interlocks and Insider Participation,” "Compensation Discussion and Analysis," and “Executive Compensation.” That information is incorporated in this report by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

Security Ownership of Certain Beneficial Owners and Management

Information relating to ownership of the company's common stock by management and by persons known by the company to be the beneficial owners of more than five percent of the outstanding shares of common stock is found in the Proxy Statement under "Ownership of Company Stock." That information is incorporated in this report by reference.

Securities Authorized for Issuance Under Equity Compensation Plans

Information on securities authorized for issuance under our equity compensation plans is found in the Proxy Statement under "Item 4, Reapproval of Material Terms of Performance Goals for 2002 Lilly Stock Plan." That information is incorporated in this report by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence

Related Person Transactions

Information relating to two related person transactions and the board's policies and procedures for approval of related person transactions can be found in the Proxy Statement under "Highlights of the Company's Corporate Governance Guidelines—Review and Approval of Transactions with Related Persons." That information is incorporated in this report by reference.

Director Independence

Information relating to director independence can be found in the Proxy Statement under "Highlights of the Company's Corporate Governance Guidelines—Independence Determinations" and is incorporated in this report by reference.

Item 14. Principal Accountant Fees and Services

Information related to the fees and services of our principal independent accountants, Ernst & Young LLP, can be found in the Proxy Statement under "Services Performed by the Independent Auditor" and "Independent Auditor Fees." That information is incorporated in this report by reference.

Item 15. Exhibits and Financial Statement Schedules

(a)1. Financial Statements

The following consolidated financial statements of the company and its subsidiaries are found at Item 8:

- Consolidated Statements of Operations—Years Ended December 31, 2012, 2011, and 2010
- Consolidated Statements of Comprehensive Income—Years Ended December 31, 2012, 2011, and 2010
- Consolidated Balance Sheets—December 31, 2012 and 2011
- Consolidated Statements of Cash Flows—Years Ended December 31, 2012, 2011, and 2010
- Segment Information
- Notes to Consolidated Financial Statements

(a)2. Financial Statement Schedules

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

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

(a)3. Exhibits

3.1	Amended Articles of Incorporation
3.2	By-laws, as amended
4.1	Form of Indenture with respect to Debt Securities dated as of February 1, 1991, between Eli Lilly and Company and Citibank, N.A., as Trustee
4.2	Agreement dated September 13, 2007 appointing Deutsche Bank Trust Company Americas as Successor Trustee under the Indenture listed above
4.3	Form of Standard Multiple-Series Indenture Provisions dated, and filed with the Securities and Exchange Commission on February 1, 1991
4.4	Form of Fiscal Agency Agreement dated May 30, 2001, between Eli Lilly and Company and Citibank, N.A., Fiscal Agent, relating to Resetable Floating Rate Debt Security due 2037[1]
4.5	Form of Resetable Floating Rate Debt Security due 2037[1]
10.1	2002 Lilly Stock Plan, as amended[2]
10.2	Form of two-year Performance Award under the 2002 Lilly Stock Plan[2]
10.3	Form of Shareholder Value Award under the 2002 Lilly Stock Plan[2]
10.4	Form of Restricted Stock Unit under the 2002 Lilly Stock Plan[2]
10.5	The Lilly Deferred Compensation Plan, as amended[2]
10.6	The Lilly Directors' Deferral Plan, as amended[2]
10.7	The Eli Lilly and Company Bonus Plan, as amended[2]
10.8	The Eli Lilly and Company Executive Officer Incentive Plan[2]
10.9	2007 Change in Control Severance Pay Plan for Select Employees, as amended effective October 20, 2010[2]
10.10	2007 Change in Control Severance Pay Plan for Select Employees, as amended effective October 18, 2012[2]
10.11	Arrangement regarding retirement benefits for Robert A. Armitage[2]
10.12	Arrangement regarding severance for Dr. Jan Lundberg[2]

10.13	Guilty Plea Agreement in The United States District Court for the Eastern District of Pennsylvania, United States of America v. Eli Lilly and Company
10.14	Settlement Agreement among the company and the United States of America, acting through the United States Department of Justice, Civil Division, and the United States Attorney's Office of the Eastern District of Pennsylvania, the Office of the Inspector General of the Department of Health and Human Services, TRICARE Management Activity, and the United States Office of Personnel Management, and certain individual relators
10.15	Corporate Integrity Agreement between the company and the Office of Inspector General of the Department of Health and Human Services
12	Statement re: Computation of Ratio of Earnings (Loss) to Fixed Charges

21	List of Subsidiaries
23	Consent of Independent Registered Public Accounting Firm
31.1	Rule 13a-14(a) Certification of John C. Lechleiter, Ph.D., Chairman of the Board, President, and Chief Executive Officer
31.2	Rule 13a-14(a) Certification of Derica W. Rice, Executive Vice President, Global Services and Chief Financial Officer
32	Section 1350 Certification
101	Interactive Data File

[1] This exhibit is not filed with this report. Copies will be furnished to the Securities and Exchange Commission upon request.

[2] Indicates management contract or compensatory plan.

Signatures

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

Eli Lilly and Company

By /s/ John C. Lechleiter

John C. Lechleiter, Ph.D.,

Chairman of the Board, President, and Chief Executive Officer

February 21, 2013

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below on February 21, 2013 by the following persons on behalf of the Registrant and in the capacities indicated.

Signature	Title
/s/ John C. Lechleiter, Ph.D. JOHN C. LECHLEITER, Ph.D.	Chairman of the Board, President, and Chief Executive Officer, and a Director (principal executive officer)
/s/ Derica W. Rice DERICA W. RICE	Executive Vice President, Global Services and Chief Financial Officer (principal financial officer)
/s/ Donald A. Zakrowski DONALD A. ZAKROWSKI	Vice President, Finance and Chief Accounting Officer (principal accounting officer)
/s/ Ralph Alvarez RALPH ALVAREZ	Director
/s/ Katherine Baicker, Ph.D. KATHERINE BAICKER, Ph.D.	Director
/s/ Sir Winfried Bischoff SIR WINFRIED BISCHOFF	Director
/s/ Michael L. Eskew MICHAEL L. ESKEW	Director
/s/ J. Erik Fyrwald J. ERIK FYRWALD	Director
/s/ Alfred G. Gilman, M.D., Ph.D. ALFRED G. GILMAN, M.D., Ph.D.	Director
/s/ R. David Hoover R. DAVID HOOVER	Director
/s/ Karen N. Horn, Ph.D. KAREN N. HORN, Ph.D.	Director
/s/ William G. Kaelin, Jr., M.D., Ph.D. WILLIAM G. KAELIN, JR., M.D., Ph.D.	Director
/s/ Ellen R. Marram ELLEN R. MARRAM	Director
/s/ Douglas R. Oberhelman DOUGLAS R. OBERHELMAN	Director
/s/ Franklyn G. Prendergast, M.D., Ph.D. FRANKLYN G. PRENDERGAST, M.D., Ph.D.	Director

/s/ Kathi P. Seifert KATHI P. SEIFERT	Director

Trademarks Used In This Report

Trademarks or service marks owned by Eli Lilly and Company or its subsidiaries or affiliates, when first used in this report, appear with an initial capital and are followed by the symbol ® or ™, as applicable. In subsequent uses of the marks in the report, the symbols are omitted.

Actos® is a trademark of Takeda Chemical Industries, Ltd.

Axid® is a trademark of Reliant Pharmaceuticals, LLC.

Bydureon® and Byetta® are trademarks of Amylin Pharmaceuticals, Inc.

Darvon® is a trademark of Xanodyne Pharmaceuticals, Inc.

Livalo® is a trademark of Kowa Company Ltd.

Jentadueto®, Tradjenta®, Trazenta™, and Trajenta® are trademarks of Boehringer Ingelheim GmbH.

Vancocin® is a trademark of ViroPharma Incorporated.

Xigris™ is a trademark of Biocritica, Inc.

Index to Exhibits

The following documents are filed as part of this report:

Exhibit		Location
3.1	Amended Articles of Incorporation	Incorporated by reference from Exhibit 3.1 to the Company's Report on Form 10-Q for the quarter ended March 31, 2008
3.2	By-laws, as amended	Incorporated by reference from Exhibit 99 to the Company's Report on Form 8-K filed February 27, 2012
4.1	Form of Indenture with respect to Debt Securities dated as of February 1, 1991, between Eli Lilly and Company and Citibank, N.A., as Trustee	Incorporated by reference from Exhibit 4.1 to the Company's Registration Statement on Form S-3, Amendment No. 1, Registration No. 333-106478
4.2	Agreement dated September 13, 2007 appointing Deutsche Bank Trust Company Americas as Successor Trustee under the Indenture listed above	Incorporated by reference from Exhibit 4.2 to the Company's Report on Form 10-K for the year ended December 31, 2008
4.3	Form of Standard Multiple-Series Indenture Provisions dated, and filed with the Securities and Exchange Commission on February 1, 1991	Incorporated by reference from Exhibit 4.2 to the Company's Registration Statement on Form S-3, Amendment No. 1, Registration No. 333-106478
4.4	Form of Fiscal Agency Agreement dated May 30, 2001, between Eli Lilly and Company and Citibank, N.A., Fiscal Agent, relating to Resettable Floating Rate Debt Security due 2037	*
4.5	Form of Resettable Floating Rate Debt Security due 2037	*
10.1	2002 Lilly Stock Plan, as amended	Incorporated by reference from Exhibit 10 to the Company's Report on Form 10-Q for the quarter ended September 30, 2012
10.2	Form of two-year Performance Award under 2002 Lilly Stock Plan	Incorporated by reference from Exhibit 10.3 to the Company's Report on Form 10-K for the year ended December 31, 2009
10.3	Form of Shareholder Value Award under 2002 Lilly Stock Plan	Incorporated by reference from Exhibit 10.4 to the Company's Report on Form 10-K for the year ended December 31, 2009

* Not filed with this report. Copies will be furnished to the Securities and Exchange Commission upon request.

Exhibit		Location
10.4	Form of Restricted Stock Unit under 2002 Lilly Stock Plan	Incorporated by reference from Exhibit 10.5 to the Company’s Report on Form 10-K for the year ended December 31, 2009
10.5	The Lilly Deferred Compensation Plan, as amended	Incorporated by reference from Exhibit 10.3 to the Company’s Report on Form 10-Q for the quarter ended September 30, 2008
10.6	The Lilly Directors’ Deferral Plan, as amended	Incorporated by reference from Exhibit 10.2 to the Company’s Report on Form 10-Q for the quarter ended September 30, 2009
10.7	The Eli Lilly and Company Bonus Plan, as amended	Incorporated by reference from Exhibit 10.8 to the Company’s Report on Form 10-K for the year ended December 31, 2010
10.8	The Eli Lilly and Company Executive Officer Incentive Plan	Incorporate by reference from Appendix B to the Company’s proxy statement on Schedule 14A filed March 7, 2011
10.9	2007 Change in Control Severance Pay Plan for Select Employees, as amended effective October 20, 2010	Incorporated by reference from Exhibit 10.5 to the Company’s Report on Form 10-Q for the quarter ended September 30, 2008
10.10	2007 Change in Control Severance Pay Plan for Select Employees, as amended effective October 18, 2012	Incorporated by reference from Exhibit 10 to the Company’s Report on Form 10-Q for the quarter ended September 30, 2010
10.11	Arrangement regarding retirement benefits for Robert A. Armitage	Attached
10.12	Arrangement regarding severance for Dr. Jan Lundberg	Incorporated by reference from Exhibit 10.13 to the Company's Report on Form 10-K for the year ended December 31, 2012
10.13	Guilty Plea Agreement in The United States District Court for the Eastern District of Pennsylvania, United States of America v. Eli Lilly and Company	Incorporated by reference from Exhibit 10.15 to the Company’s Report on Form 10-K for the year ended December 31, 2008
10.14	Settlement Agreement among the company and the United States of America, acting through the U. S. Department of Justice, Civil Division, and the U. S. Attorney’s Office of the Eastern District of Pennsylvania, the Office of the Inspector General of the Department of Health and Human Services, TRICARE Management Activity, and the U. S. Office of Personnel Management, and certain individual relators	Incorporated by reference from Exhibit 10.16 to the Company’s Report on Form 10-K for the year ended December 31, 2008

10.15	Corporate Integrity Agreement between the company and the Office of Inspector General of the Department of Health and Human Services	Incorporated by reference from Exhibit 10.17 to the Company's Report on Form 10-K for the year ended December 31, 2008
12	Statement re: Computation of Ratio of Earnings (Loss) to Fixed Charges	Attached
21	List of Subsidiaries	Attached
23	Consent of Registered Independent Public Accounting Firm	Attached
31.1	Rule 13a-14(a) Certification of John C. Lechleiter, Ph.D., Chairman of the Board, President, and Chief Executive Officer	Attached

Exhibit		Location
31.2	Rule 13a-14(a) Certification of Derica W. Rice, Executive Vice President, Global Services and Chief Financial Officer	Attached
32	Section 1350 Certification	Attached
101	Interactive Data File	Attached

95