LILLY ELI & CO
Form 10-K
February 24, 2012

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, 2011

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 $38,414,000,000

Number of shares of common stock outstanding as of February 15, 2012: 1,160,406,840

Portions of the Registrant s Proxy Statement to be filed on or about March 5, 2012 have been incorporated by reference into Part III of this report.

Part I

Item 1. Business

Eli Lilly and Company (the company or registrant) 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 sell products in one significant business segment pharmaceutical products. We also have an animal health business segment, whose operations are not material to our financial statements.

Our mission 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.

We manufacture and distribute our products through facilities in the United States, Puerto Rico, and 15 other countries. Our products are sold in approximately 130 countries.

Products

Our products include:

Neuroscience products, our largest-selling product group, including:

- *Zyprexa®*, for the treatment of schizophrenia, acute mixed or manic episodes associated with bipolar I disorder, and bipolar maintenance
- *Zyprexa Relprevv* (*Zypadhera®* in the European Union), a long-acting intramuscular injection formulation of Zyprexa
- *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
- *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.

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®, approved in Europe in 2011 and in the U.S. in January 2012 for the treatment of type 2 diabetes (see Pharmaceutical Marketing Collaborations below for information about the termination of our collaboration with Amylin Pharmaceuticals for Byetta and Bydureon)

Actos®, for the treatment of type 2 diabetes (marketed by us only in certain countries outside the U.S.)

Tradjenta , approved and launched in 2011 for the treatment of type 2 diabetes

Evista®, for the prevention and treatment of osteoporosis in postmenopausal women and for the reduction of the risk of invasive breast cancer in postmenopausal women with osteoporosis and postmenopausal women at high risk for invasive breast cancer

Forteo®, for the treatment of osteoporosis in postmenopausal women and men at high risk for fracture and for glucocorticoid-induced osteoporosis in men and postmenopausal women

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 (launched in 2011).

Oncology products, including:

Alimta®, for the first-line treatment, in combination with another agent, of non-small cell lung cancer for patients with non-squamous cell histology; for the second-line treatment of non-small cell lung cancer; in the European Union as monotherapy for the maintenance treatment of locally advanced or metastatic non-small cell lung cancer in patients with non-squamous cell histology whose disease has not progressed immediately following platinum-based chemotherapy; 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 European Union 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 approved in the U.S. for the treatment of 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®, a statin medication for use as an adjunct to diet in the treatment of high cholesterol (primary hyperlipidemia or mixed dyslipidemia).

Animal health products, including:

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

Comfortis®, a chewable tablet that kills fleas and prevents flea infestations on dogs

Trifexis®, a monthly chewable tablet for dogs that kills fleas, prevents flea infestations, prevents heartworm disease, and controls intestinal parasite infections

Reconcile®, for treatment of canine separation anxiety in conjunction with behavior modification training.

Other pharmaceuticals, including:

Vancocin® HCl, used primarily to treat staphylococcal infections

Ceclor™, for the treatment of a wide range of bacterial infections.

Marketing

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

Pharmaceuticals United States

In the United States, we distribute pharmaceutical products principally through independent wholesale distributors, with some sales directly to pharmacies. In 2011, 2010, and 2009, three wholesale distributors in the U.S. AmerisourceBergen Corporation, McKesson Corporation, and Cardinal Health, Inc. each accounted for between 11 percent and 17 percent of our worldwide 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 United States 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 web sites 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. In response to competitive pressures, we have entered into arrangements with some of these organizations providing for discounts or rebates on Lilly products.

Pharmaceuticals Outside the United States

Outside the United States, we promote our pharmaceutical products primarily through sales representatives. While the products marketed vary from country to country, neuroscience 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.

Pharmaceutical Marketing Collaborations

Certain of our 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. We co-market Evista in Japan with Chugai Pharmaceutical Co., Ltd.

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 and resolve all outstanding litigation between the companies. The parties are transitioning full responsibility for the worldwide development and commercialization of both products to Amylin, starting in the U.S. on November 30, 2011, and progressing to all markets not earlier than mid-2012 and not later than the end 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 several other Asian countries. Daiichi Sankyo retains sole marketing rights in Japan, and we retain sole marketing rights in Canada, Australia, Russia, and certain other countries.

Tradjenta is 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 United States. Elanco also has an extensive sales force outside the U.S. Elanco sells its products primarily to wholesale distributors.

Competition

Our pharmaceutical products compete with products manufactured by many other companies in highly competitive markets throughout the world. 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 products 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 therefore 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.

We believe our long-term competitive success depends upon discovering and developing (either alone or in collaboration with others) or acquiring innovative, cost-effective medicines that provide improved outcomes to individual patients 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 FDA. A single patent for a 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 often 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 European Union 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 pharmaceuticals varies widely. Under the Trade-Related Aspects of Intellectual Property Agreement (TRIPs) administered by the World Trade Organization (WTO), over 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.

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 concomitant nutritional supplement use patent (2021), as extended by pediatric exclusivity (2022).

Cialis is protected by compound and use patents (2017).

Cymbalta is protected by a compound patent (June 2013). We are seeking pediatric exclusivity which, if granted, would extend protection to December 2013.

Effient is protected by a compound patent (2017).

Evista is protected by patents on the treatment and prevention of osteoporosis (2014). Evista for use in breast cancer risk reduction is protected by orphan drug exclusivity (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 is protected by a compound patent (2023), and Boehringer Ingelheim has applied for a patent extension to 2025 under the patent restoration laws.

U.S. patent protection or data package protection for our new molecular entities that have been submitted for regulatory review is as follows. Additional information about these molecules is provided in Item 7, Management s Discussion and Analysis under Late Stage Pipeline. The dates below do not include any potential patent extensions or adjustments as described above:

Florbetapir is covered by a compound patent (2025).

Liprotamase is expected to 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 Glaxo SmithKline 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 Hatch-Waxman, made a complex set of changes to both patent and new-drug-approval laws. Before Hatch-Waxman, no drug could be approved without providing the FDA complete safety and efficacy studies, *i.e.*, a complete New Drug Application (NDA). Hatch-Waxman authorizes the FDA to approve generic versions of innovative 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 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 7, Management s Discussion and Analysis Legal and Regulatory Matters.

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.

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 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. 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 products and administers requirements covering the testing, safety, effectiveness, manufacturing, quality control, distribution, labeling, marketing, advertising, dissemination of information, and post-marketing surveillance of our pharmaceutical products. The FDA, along with the U.S. Department of Agriculture (USDA), also regulates our animal health products. The U.S. Environmental Protection Agency also regulates some animal health products.

The FDA extensively regulates all aspects of manufacturing quality 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 European Union 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 federal and state laws, including the federal anti-kickback statute and the False Claims Act and state laws governing kickbacks, false claims, unfair trade practices, and consumer protection. These laws are administered by, among others, the Department of Justice, 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 Department of Justice, 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 (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 pharmaceuticals are employed by the government and the purchasers of pharmaceuticals are government entities; therefore, our interactions with these prescribers and purchasers are subject to regulation under the FCPA. Recently the U.S. Securities and Exchange Commission (SEC) and the Department of Justice (DOJ)

have increased their FCPA enforcement activities with respect to pharmaceutical companies. See Item 3, Legal Proceedings, for information about a currently pending 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 Pharmaceutical Pricing, Reimbursement, and Access

In the United States, we are required to provide rebates to state governments on their purchases of our products 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 enactment of the Patient Protection and Affordable Care Act and The Health Care and Education Reconciliation Act of 2010 in March 2010 has brought significant changes to U.S. health care. Increases in the minimum statutory rebate for branded prescription drugs sold to Medicaid beneficiaries from 15.1 percent to 23.1 percent were generally effective in 2010. 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. Beginning in 2011, 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). The doughnut hole is being phased out by the federal government between 2011 and 2020. Additionally, beginning in 2011, 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 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 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 2011, we employed approximately 7,500 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 $5.02 billion in 2011, $4.88 billion in 2010, and $4.33 billion in 2009.

Our pharmaceutical research and development focuses on five therapeutic categories: cancer; endocrine diseases, including diabetes, obesity, 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 nearly

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 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.

Drug 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 sick 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 now rigorously 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 two to four years.

Submission Phase

Once a molecule 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 65 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, rheumatoid arthritis, lupus, psoriasis, schizophrenia, depression, and pancreatic exocrine insufficiency, as well as an imaging agent for detecting beta-amyloid plaques (which are associated with Alzheimer s disease) in the brain. We are studying many other drug candidates in the earlier stages of development, including molecules targeting various cancers, diabetes, obesity, Alzheimer s disease, depression, bipolar disorder,

migraine, atherosclerosis, anemia, rheumatoid arthritis, musculoskeletal disorders, and renal diseases. We are also developing new uses, formulations, or delivery methods for many of these molecules as well as several currently marketed products, including Alimta, Cialis, Effient, Erbitux, Forteo, 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 primary bulk 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 labeling and packaging, take place at a number of sites throughout the world. In January 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 will manufacture final and intermediate-step active pharmaceutical ingredients for certain Lilly human 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 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. We have implemented quality systems relating to the quality and integrity of scientific information and production processes.

Control of production processes involves rigid specifications for 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 our 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 monitors existing 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 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 April 16, 2012, 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.	58	Chairman (since January 2009), President (since October 2005), Chief Executive Officer (since April 2008) and a Director (since October 2005)
Robert A. Armitage	63	Senior Vice President and General Counsel (since January 2003)
Bryce D. Carmine	60	Executive Vice President and President, Lilly Bio-Medicines (since November 2009) (retired December 2011)

Enrique A. Conterno	45	Senior Vice President and President, Lilly Diabetes (since November 2009)
Maria A. Crowe	52	President, Manufacturing Operations (since January 2012)
Frank M. Deane, Ph.D.	62	President, Manufacturing Operations (since June 2007) (retired December 2011)
Stephen F. Fry	46	Senior Vice President, Human Resources and Diversity (since February 2011)
Jan M. Lundberg, Ph.D.	58	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.

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Name	Age	Offices and Business Experience
Susan Mahony, Ph.D.	47	Senior Vice President and President, Lilly Oncology (since February 2011)
Anne Nobles	55	Senior Vice President, Enterprise Risk Management (since April 2009) and Chief Ethics and Compliance Officer (since June 2007)
Barton R. Peterson	53	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	47	Executive Vice President, Global Services (since January 2010) and Chief Financial Officer (since May 2006)
David A. Ricks	44	Senior Vice President and President, Lilly Bio-Medicines (since January 2012)
Jeffrey N. Simmons	44	Senior Vice President and President, Elanco Animal Health (since January 2008)
Jacques Tapiero	53	Senior Vice President and President, Emerging Markets (since January 2010)
Fionnuala M. Walsh	52	Senior Vice President, Global Quality (since July 2007)

Employees

At the end of 2011, we employed approximately 38,080 people, including approximately 20,800 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 of this Form 10-K, 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. In addition, margins vary for our different products due to various factors, including differences in the cost to manufacture and market the products, the value of the products to the marketplace, and government restrictions on pricing and reimbursement. 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, 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 Web Site

We make available through our company web site, 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 web site link to our SEC filings is **http://investor.lilly.com/sec.cfm**.

In addition, the Corporate Governance portion of our web site 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; Cautionary Statement Regarding Forward Looking Statements

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.

We make certain forward-looking statements in this Form 10-K, and company spokespersons may make such statements in the future. Where possible, we try to identify forward-looking statements by using such words as expect, plan, will, estimate, forecast, project, believe, a anticipate . Forward-looking statements do not relate strictly to historical or current facts. They are likely to address our growth strategy, sales of current and anticipated products, financial results, our research and development programs, the status of product approvals, legislative and regulatory developments, and the outcome of contingencies such as litigation and investigations. All forward-looking statements are based on our expectations at the time we make them. They are subject to risks and uncertainties, including those summarized below.

Pharmaceutical research and development is very costly and highly uncertain. 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 costs over $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. 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. 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. 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 patents; as a result, we expect that our U.S. patents on major 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 comprised 71 percent of our worldwide revenue in 2011, have lost or will lose 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 U.S., in the next several years:

Product	Worldwide Revenues (2011)	Percent of Total 2011 Revenues	Loss of Relevant U.S. Exclusivity
Zyprexa	$4.62 billion	19	October 2011
Cymbalta	$4.16 billion	17	2013
Alimta	$2.46 billion	10	2017 (compound patent plus pediatric exclusivity); 2022 (concomitant nutritional supplement use patent plus

			pediatric exclusivity)
Humalog	$2.37 billion	10	2013
Cialis	$1.88 billion	8	2017
Evista	$1.07 billion	4	2014
Strattera	$620.1 million	3	2017

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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 business is subject to increasing government price controls and other health care cost-containment measures. Government health care cost-containment measures can significantly affect our revenue and profitability. In many countries outside the U.S., government agencies strictly control, directly or indirectly, the prices at which our products are sold. In the U.S., we are subject to substantial pricing 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 the recently-enacted U.S. health care reform legislation is increasing these pricing pressures. In addition, many state legislative proposals would further negatively affect our pricing and/or reimbursement for our products. We expect pricing 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 today, and future claims will be largely self-insured. We are subject to a substantial number of product liability claims involving primarily Byetta, Zyprexa, diethylstilbestrol (DES), and Darvon®, and 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. See Item 7, Management s Discussion and Analysis Legal and Regulatory Matters, and Item 3, Legal Proceedings, for more information on our current product liability litigation. Due to a very restrictive market for product liability insurance, we have been and will continue to be largely self-insured for future 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 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. 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, a prolonged economic downturn coupled with rising unemployment (and a corresponding increase in the uninsured and underinsured population) could lead to decreased utilization of drugs, affecting our sales volume. Declining tax revenues attributable to the downturn are increasing 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 that they purchase. We have experienced delays in repayment from national health care systems in certain countries, including but not limited to 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. We rely to a large 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 trade secrets, personal information, or other sensitive data may be exposed to unauthorized persons

or to the public. 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 affect our business.

We face other risks to our business and operating results. Our business is subject to a number of other risks and uncertainties, including:

- Economic factors over which we have no control, including changes in inflation, interest rates, and foreign currency exchange rates, can affect our results of operations.
- 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 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.
- Changes in accounting standards promulgated by the Financial Accounting Standards Board and the Securities and Exchange Commission can affect our financial statements.
- Our financial statements can also be affected by internal factors, such as changes in business strategies and the impact of restructurings, asset impairments, technology acquisition and disposition transactions, and business combinations.

We undertake no duty to update forward-looking statements.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our principal domestic and international executive offices are located in Indianapolis. At December 31, 2011, we owned 12 production and distribution sites in the U.S. and Puerto Rico. Together with the corporate administrative offices, these facilities contain an aggregate of approximately 13.4 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, Ireland, the United Kingdom, Spain, Italy, Mexico, and Brazil.

Our U.S. research and development facilities consist of approximately 3.5 million square feet and are located primarily in Indianapolis, with smaller sites in San Diego and New York City. We also have smaller research and development facilities in the United Kingdom, Canada, and Spain.

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 7, Management s Discussion and Analysis Legal and Regulatory Matters. 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 7, 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 Management s Discussion and Analysis

See Item 7, Management s Discussion and Analysis Legal and Regulatory Matters, for information on various legal proceedings, including but not limited to:

- The U.S. patent litigation involving Alimta and Strattera
- The Zyprexa product liability and related litigation, including claims brought on behalf of state Medicaid agencies and private healthcare payers
- The Byetta product liability litigation.

That information is incorporated into this Item by reference.

Other Product Liability Litigation

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

In approximately 15 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 DES during pregnancy in the 1950s and 1960s. Approximately 65 of these claimants allege that they were indirectly exposed in utero to the medicine and later developed breast cancer as a consequence. In December 2009, a lawsuit was filed in U.S. District Court in Washington, D.C. against Lilly and other manufacturers (*Michele Fecho, et al v. Eli Lilly and Company, et al*) seeking to assert product liability claims on behalf of a putative class of men and women allegedly exposed to the medicine who claim to have later developed breast cancer. In January 2012, the judge in this case ordered the parties to proceed to mediation. 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 165 cases in the U.S. involving approximately 755 claimants related to the analgesic Darvon and related formulations of propoxyphene. These cases generally allege various cardiac injuries. In November 2011, a lawsuit was filed in the U.S. District Court for the Eastern District of Louisiana (*Ballard, et al. v. Eli Lilly and Company et al.)* against Lilly and other manufacturers as a putative class action seeking to assert product liability claims on behalf of U.S. residents who ingested propoxyphene and allegedly sustained personal injuries. 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. Under our agreement with Takeda, we will be indemnified by Takeda for our losses and expenses in accordance with the terms of the agreement.

Other Marketing Practices Investigations

In August 2003, we received notice that the staff of the SEC is conducting an investigation into the compliance by Polish subsidiaries of certain pharmaceutical companies, including Lilly, with the U.S. Foreign Corrupt Practices Act of 1977. The staff has issued subpoenas to us requesting production of documents related to the investigation. In connection with that matter, staffs of the SEC and the Department of Justice (DOJ) have asked us to voluntarily provide additional information related to certain activities of Lilly affiliates in a number of other countries. The SEC staff has also issued subpoenas related to activities in these countries. We are cooperating with the SEC and the DOJ in this investigation and are in advanced discussions with the SEC to resolve their investigation.

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 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.

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 Office of the Inspector General of the U.S. Department of Health and Human Services 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.

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. Other pharmaceutical industry participants face similar lawsuits. 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 this time. Plaintiffs appeal of the summary judgment ruling was heard in October 2011, and we are waiting for a ruling. 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 May 2011, Amylin Pharmaceuticals, Inc., our collaboration partner with respect to Byetta and Bydureon, filed a lawsuit against us in the U.S. District Court for the Southern District of California alleging various antitrust and unfair competition law violations and breach of contract. In November 2011, we entered into an agreement that ended this litigation and provides for the transition of full responsibility for the worldwide development and commercialization of Byetta and Bydureon to Amylin, starting in the U.S. on November 30, 2011, and progressing to all markets by the end of 2013. See Item 8, Financial Statements and Supplementary Data Note 4, Collaborations , for more information on the November 2011 agreement.

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 pharmaceuticals and an injunction against the allegedly violative conduct. Summary judgment was granted to us and the other defendants and in July 2008, the California Court of Appeal affirmed that decision. In July 2010, the California Supreme Court overturned the lower court decision and remanded the case to the state court. In March 2011, the state court again granted summary judgment for us and the other defendants. Plaintiffs have appealed this decision to the California Court of Appeal. We believe the lawsuit has no merit and are prepared to defend against it vigorously.

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 under 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, 2011:

Period	Total Number of Shares Purchased (in thousands) (a)	Average Price Paid per Share (b)	Total Number of Shares Purchased as Part of Publicly Announced	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs

			Plans or Programs	(dollars in millions)
			(c)	(d)
October 2011	0	$ 0.00	0.0	$ 419.2
November 2011	0	0.00	0.0	419.2
December 2011	0	0.00	0.0	419.2
Total	0		0.0	

The amounts presented in columns (a) and (b) above represent purchases of common stock related to our stock-based compensation programs. The amounts presented in columns (c) and (d) in the above table represent activity related to our $3.00 billion share repurchase program announced in March 2000. As of December 31, 2011, we have purchased $2.58 billion related to this program. During 2011, no shares were repurchased under this program, and we do not anticipate any such purchases in 2012.

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.

Financial Results

We achieved revenue growth of 5 percent in 2011, which was primarily driven by the collective growth of Cymbalta, insulin products, animal health products, Alimta, Effient, and Cialis, 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 earnings per share decreased 15 percent to $3.90 per share, in 2011 as compared to $5.07 billion, or $4.58 per share, in 2010.

2011

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 $.29 per share. Also, marketing, selling, and administrative expenses increased by $178.0 million (pretax), or $.16 per share, as a result of the mandatory pharmaceutical manufacturers fee.

Collaborations (Note 4)

We incurred acquired in-process research and development (IPR&D) charges associated with the diabetes collaboration with Boehringer Ingelheim of $388.0 million (pretax), which decreased earnings per share by $.23.

Asset Impairments and Related Restructuring and Other Special Charges (Note 5)

We recognized restructuring charges of $316.4 million (pretax), or $.24 per share, primarily related to severance costs from previously announced strategic actions that we are taking to reduce our cost structure and global workforce.

We incurred a charge of $85.0 million (pretax), or approximately $.05 per share, in 2011 primarily for returned product and contractual commitments related to the withdrawal of Xigris.

2010

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 $.16 per share. We also recorded a one-time non-cash deferred income tax charge in the first quarter of $85.1 million, or $.08 per share, associated with the imposition of tax on the prescription drug subsidy of our U.S. retiree health plan.

Acquisitions (Note 3)

We incurred acquired IPR&D charges associated with the in-licensing arrangement with Acrux Limited (Acrux) of $50.0 million (pretax), which decreased earnings per share by $.03.

Asset Impairments and Related Restructuring and Other Special Charges (Note 5)

We recognized asset impairments, restructuring, and other special charges of $192.0 million (pretax), or $.13 per share, primarily related to severance costs from previously announced strategic actions.

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 65 potential new drugs in human testing and a larger number of projects in preclinical research.

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 because of efficacy or safety concerns, inability to obtain necessary regulatory approvals, limited scope of approved uses, difficulty or excessive costs to manufacture, or infringement of the patents or intellectual property rights of others. Delays and uncertainties in the U.S. Food and Drug Administration (FDA) approval process and the approval processes in other countries can result in delays in product launches and lost market opportunity. 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.

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:

Dulaglutide* (Q3 2008) a glucagon-like peptide 1 analog for the treatment of type 2 diabetes

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

Empagliflozin-BI10773 (Q3 2010) a sodium glucose co-transporter (SGLT-2) inhibitor for the treatment of type 2 diabetes (in collaboration with Boehringer Ingelheim)

Enzastaurin (Q1 2006) a small molecule for the treatment of diffuse large B-cell lymphoma

Ixekizumab formerly IL-17 MAb* (Q4 2011) a monoclonal antibody for the treatment of psoriasis

Necitumumab* (Q4 2009) a fully human monoclonal antibody for the treatment of squamous non-small cell lung cancer (NSCLC) (in collaboration with Bristol Myers Squibb)

New insulin glargine product formerly LY2963016 (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 (in collaboration with Boehringer Ingelheim)

Pomaglumetad Methionil (Q1 2011) a metabotropic glutamate 2/3 (mGlu 2/3) receptor agonist for the treatment of schizophrenia

Ramucirumab* (Q4 2009) a monoclonal antibody for the treatment of metastatic breast, gastric, liver, NSCLC, and colorectal cancers

Solanezumab* (Q2 2009) an amyloid beta (Aß) antibody for the treatment of Alzheimer s disease.

Tabalumab formerly BAFF MAb* (Q4 2010) an anti-BAFF monoclonal antibody for the treatment of lupus and rheumatoid arthritis

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

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

Florbetapir (Q3 2010) a molecular imaging tool for the detection of beta-amyloid plaque in the brain

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, 2011:

Arxxant In December, we completed and evaluated the final clinical trial for Arxxant, the EYES study, which did not meet the primary study endpoint. We have opted not to re-submit Arxxant to the FDA for diabetic retinopathy.

Bydureon In June, the European Commission granted marketing authorization for Bydureon, the first once-weekly treatment for type 2 diabetes in combination with certain oral therapies. European launches began in the third quarter of 2011, starting with the United Kingdom and Germany. In January 2012, the FDA approved Bydureon as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes. We and Amylin terminated the collaboration in November 2011; refer to Note 4 of the Financial Statements for additional information.

Florbetapir In March, we received a complete response letter from the FDA for the New Drug Application (NDA) for Amyvid (florbetapir) that was primarily focused on the need to establish a reader training program for market implementation that helps to ensure reader accuracy and consistency of interpretations of existing Amyvid scans. We submitted our response to the FDA s complete response letter.

Ixekizumab In November, we began the first Phase III clinical trial for ixekizumab.

Linagliptin and Empagliflozin In January 2011, we announced a global agreement with Boehringer Ingelheim (Boehringer) to jointly develop and commercialize a portfolio of diabetes compounds currently in mid- and late-stage development, including Boehringer s two investigational oral diabetes agents, linagliptin and empagliflozin. 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. In January 2012, the FDA approved Jentadueto , a combination of linagliptin and metformin for the treatment of adults with type 2 diabetes.

Liprotamase In April, we received a complete response letter from the FDA for the NDA for liprotamase that communicated the need for us to conduct an additional clinical trial prior to a re-submission. We are currently finalizing the study design and anticipate starting a clinical study in 2012.

Necitumumab In February 2011, we and Bristol-Myers Squibb Company stopped enrollment in one of the two global Phase III studies. The decision to stop enrollment in the Phase III non-squamous NSCLC INSPIRE trial (combination treatment with Alimta) followed an independent Data Monitoring Committee recommendation that no new or recently enrolled patients continue treatment in the trial because of safety concerns related to thromboembolism (blood clots) in the experimental arm of the study. The second Phase III study in squamous NSCLC looking at the combination use of necitumumab with Gemzar is continuing.

New insulin glargine product In September, we began the first Phase III clinical trial for our new insulin glargine product.

Novel basal insulin analog In November, we began the first Phase III clinical trial for our novel basal insulin analog.

Pomaglumetad Methionil In February 2011, we began the first Phase III clinical trial for pomaglumetad methionil.

Solanezumab In January 2012, an independent Data Monitoring Committee (DMC) recommended that we continue the two ongoing Phase III randomized pivotal trials for solanezumab without modifications, based on pre-planned interim safety and futility analyses. The DMC also recommended that we make a protocol modification to EXPEDITION-XT, the open-label extension study of the two Phase III trials, making the protocol for the open-label extension more consistent with the current protocol for the pivotal studies.

Acquisition

In February 2012, we acquired ChemGen Corp., 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. The transaction is not material to our consolidated financial statements.

Legal, Regulatory, and Other Matters

In October 2011, we announced the withdrawal of our Xigris [drotrecogin alfa (activated)] product in all markets following results of the PROWESS-SHOCK study, which did not meet the primary endpoint of a statistically significant reduction in 28-day all-cause mortality in patients with septic shock. We incurred a charge of $85.0 million (pretax), or approximately $.05 per share, for product returns and contractual commitments related to Xigris. Revenue related to Xigris has not been material to our consolidated financial statements.

The enactment of the Patient Protection and Affordable Care Act (PPACA) and The Health Care and Education Reconciliation Act of 2010 in March 2010 brought significant changes to U.S. health care. These changes began to affect our financial results in the first quarter of 2010 and will continue to have significant impact on our results in the future. The U.S. Supreme Court has agreed to decide the constitutionality of the PPACA. Oral arguments will take place in March 2012 and a decision is expected in the summer of 2012.

Changes to the rebates for prescription drugs sold to Medicaid beneficiaries, which increase the minimum statutory rebate for branded drugs from 15.1 percent to 23.1 percent, became effective in the first quarter of 2010. 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 certain types of health care facilities that serve low-income and uninsured patients (known as 340B facilities) has been expanded.

Beginning in 2011, 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). The doughnut hole will be phased out by the federal government between 2011 and 2020. 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. In 2011, we recorded $178.0 million related to this fee, which is included in marketing, selling, and administrative expense in our consolidated statement of operations.

Also, there are changes to the tax treatment of subsidies paid by the government to employers, such as us, who provide their retirees with a drug benefit at least equivalent to the Medicare Part D drug benefit. Beginning in 2013, the federal government will tax the subsidy it provides to such employers. While this tax will not take effect for two more years, accounting rules dictated that we adjust our deferred tax asset through a one-time non-cash charge of $85.1 million upon enactment of the tax law change, which we recorded in the first quarter of 2010.

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

expenses may be enacted. Certain other federal and state health care proposals continue to be debated, and could place downward pressure on pharmaceutical industry sales or prices. We also expect pricing pressures at state levels could become more severe. These federal and state proposals, or state price pressures, could have a material adverse effect on our consolidated 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 also have been tax proposals under discussion or introduced in the U.S. Congress that could change the manner in which, and the rate at which, income of U.S. companies would be taxed. While it is uncertain how the U.S. Congress may address U.S. tax policy matters in the future, reform of U.S. taxation, including taxation of international income, will continue to be a topic of discussion for Congress and the Obama Administration. A significant change to the U.S. tax system, including changes to the taxation of international income, could have a material adverse effect on our consolidated results of operations. In October 2010, Puerto Rico enacted income and excise tax legislation affecting our operations. This tax is included in costs of sales in our consolidated statement of operations. We believe this tax should be creditable against our U.S. income taxes.

International operations also are generally subject to extensive price and market regulations, and several European countries have recently required either price decreases or rebate increases in response to economic pressures. We also anticipate an adverse effect from biennial pricing actions in Japan. There are proposals for cost-containment measures pending in a number of additional 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.

OPERATING RESULTS 2011

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, 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. In 2011, total revenue was reduced by $408.8 million due to the impact of U.S. health care reform.

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

	Year Ended December 31, 2011			Year Ended December 31, 2010	Percent Change
Product	U.S.[1]	Outside U.S.	Total[2]	Total	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
Animal health products	896.8	781.8	1,678.6	1,391.4	21
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
Total net product sales	12,424.4	11,180.4	23,604.8	22,442.2	5
Collaboration and other revenue[3]	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] Numbers may not add due to rounding.
[3] Collaboration and other revenue is primarily composed of Erbitux royalties and 50 percent of Byetta s gross margin in the U.S.

Zyprexa is a treatment for schizophrenia, acute mixed or manic episodes associated with bipolar I disorder, and bipolar maintenance. Zyprexa sales in the U.S. decreased 13 percent in 2011 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. In the five major European countries, which in the aggregate had approximately $900 million in sales in 2011, we lost exclusivity in Spain in April 2011 and in France, Germany, Italy, and the United Kingdom in September 2011. Globally, upon loss of exclusivity, we are experiencing generic competition which is causing rapid and severe declines on our Zyprexa sales. In Japan, our second-largest market with approximately $540 million in sales in 2011, our patent expires in December 2015. We anticipate worldwide sales of Zyprexa to decline by at least $3 billion in 2012.

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 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, a treatment for various cancers, 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. We expect 2012 sales outside the U.S. to be negatively affected by significant government price reductions in Japan, which is our second largest market for Alimta, and the introduction of generic competition in certain markets.

Sales of Humalog, our injectable human insulin analog for the treatment of diabetes, 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, a treatment for erectile dysfunction (also approved in October 2011 for benign prostatic hyperplasia in the U.S.), 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, an injectable human insulin for the treatment of diabetes, 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, a product for the prevention and treatment of osteoporosis in postmenopausal women and for reduction of risk of invasive breast cancer in postmenopausal women with osteoporosis and postmenopausal women at high risk for invasive breast cancer, increased 4 percent in the U.S., due to higher prices partially offset by lower 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, 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, 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 the increased demand in Japan.

Sales of Strattera, a treatment for attention-deficit hyperactivity disorder in children, adolescents, and in the U.S. in adults, 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. We expect sales to continue to decline in 2012.

We report as revenue for Erbitux, a product approved to treat various cancers, the net royalties received from our collaboration partners and our product sales. Our revenues increased 6 percent to $409.2 million in 2011.

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 U.S. In December 2011, we recognized a pro rata portion of revenue resulting from the termination arrangement. We will continue to recognize 100 percent of Byetta and Bydureon sales outside the U.S. until those markets transition to Amylin on a market-by-market basis over a period beginning no earlier than the second half of 2012 and that will not extend beyond December 31, 2013. We also recognize our sales of Byetta pen delivery devices to Amylin which will continue until no later than the end of 2013. 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 during 2011, 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 previously announced strategic actions that we are taking 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 a net expense of $179.0 million in 2011, due primarily to the partial impairment of the acquired IPR&D assets related to liprotamase and Amyvid in 2011 and damages recovered in 2010 from generic pharmaceutical companies related to Zyprexa patent litigation in Germany.

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 of $85.3 million primarily 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 of $85.1 million associated with the imposition of tax on the prescription drug subsidy of our retiree health plan as part of U.S. health care reform.

OPERATING RESULTS 2010

Financial Results

We achieved revenue growth of 6 percent to $23.08 billion in 2010, which was primarily driven by the collective growth of Alimta, Cymbalta, animal health products, insulin products, Cialis, and Zyprexa, offset by a decline in Gemzar revenue. Cost of sales and marketing, selling, and administrative expenses grew at a slower rate than revenue, while our investment in research and development grew at a greater rate than revenue and our effective tax rate increased. Net income increased 17 percent to $5.07 billion, and earnings per share increased 16 percent to $4.58 per share, in 2010, as compared to $4.33 billion, or $3.94 per share, in 2009. Net income comparisons between 2010 and 2009 are affected by the impact of several highlighted items. The highlighted items for 2010 are summarized in the Executive Overview. The 2009 highlighted items are summarized as follows:

Acquisitions (Note 3)

We incurred acquired IPR&D charges associated with an in-licensing arrangement with Incyte Corporation (Incyte) of $90.0 million (pretax), which decreased earnings per share by $.05.

Asset Impairments and Related Restructuring and Other Special Charges (Notes 5 and 15)

We recognized asset impairments, restructuring, and other special charges of $462.7 million (pretax), which decreased earnings per share by $.29, for asset impairments and restructuring primarily related to the sale of our Tippecanoe Laboratories manufacturing site.

We incurred pretax charges of $230.0 million in connection with the claims of several states related to Zyprexa, which decreased earnings per share by $.13.

Revenue

Our worldwide revenue for 2010 increased 6 percent, to $23.08 billion, driven by the collective growth of Alimta, Cymbalta, animal health products, insulin products, Cialis, and Zyprexa, offset by a decline in Gemzar revenue. Worldwide sales volume increased 3 percent, while selling prices contributed 2 percent of revenue growth, and the impact of foreign exchange rates was negligible. Revenue in the U.S. increased 5 percent, to $12.87 billion, due to higher prices. Revenue outside the U.S. increased 7 percent, to $10.21 billion, due to increased demand, partially offset by lower prices. In 2010, total revenue was reduced by $229.0 million due to the impact of U.S. health care reform.

The following table summarizes our revenue activity in 2010 compared with 2009:

Product	Year Ended December 31, 2010 U.S.[1]	Outside U.S.	Total[2]	Year Ended December 31, 2009 Total	Percent Change from 2010
	(Dollars in millions)				
Zyprexa	$ 2,495.5	$ 2,530.9	$ 5,026.4	$ 4,915.7	2
Cymbalta	2,772.0	687.2	3,459.2	3,074.7	13
Alimta	957.1	1,251.5	2,208.6	1,706.0	29
Humalog	1,222.4	831.8	2,054.2	1,959.0	5
Cialis	658.1	1,041.4	1,699.4	1,559.1	9
Animal health products	775.1	616.3	1,391.4	1,207.2	15
Gemzar	723.3	426.1	1,149.4	1,363.2	(16)
Humulin	470.8	618.0	1,088.9	1,022.0	7
Evista	681.8	342.6	1,024.4	1,030.4	(1)
Forteo	499.0	331.0	830.1	816.7	2
Strattera	389.8	186.9	576.7	609.4	(5)
Other pharmaceutical products	737.4	1,196.3	1,933.5	1,908.1	1
Total net product sales	12,382.3	10,060.0	22,442.2	21,171.5	6
Collaboration and other revenue[3]	483.3	150.4	633.8	664.5	(5)
Total revenue	$ 12,865.6	$ 10,210.4	$ 23,076.0	$ 21,836.0	6

[1] U.S. revenue includes revenue in Puerto Rico.
[2] Numbers may not add due to rounding.
[3] Collaboration and other revenue is primarily composed of Erbitux royalties and 50 percent of Byetta s gross margin in the U.S.

Zyprexa sales in the U.S. increased 7 percent in 2010, driven by higher prices, partially offset by lower demand. Sales outside the U.S. decreased 2 percent driven by lower prices and decreased demand in Europe and Canada, partially offset by the favorable impact of foreign exchange rates and increased demand in Japan.

Sales of Cymbalta increased 9 percent in the U.S., driven primarily by higher prices. Sales outside the U.S. increased 31 percent, driven primarily by increased demand in Japan, Europe, and Canada.

Sales of Alimta increased 17 percent in the U.S., due primarily to increased demand. Sales outside the U.S. increased 41 percent, due to increased demand. Demand outside the U.S. was favorably affected by continued strong growth in Japan.

Sales of Humalog increased 1 percent in the U.S., due to higher prices, partially offset by the impact of wholesaler buying patterns. Sales outside the U.S. increased 11 percent, driven by increased demand primarily in Japan and China.

Sales of Cialis increased 6 percent in the U.S., due to higher prices. Sales outside the U.S. increased 11 percent, due primarily to increased demand and, to a lesser extent, higher prices.

Sales of Gemzar decreased 3 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 31 percent, due primarily to generic competition in most major markets.

Sales of Humulin increased 17 percent in the U.S., driven primarily by higher prices and increased demand. Sales outside the U.S. remained essentially flat when compared to 2009, due to lower prices offset by increased demand and the favorable impact of foreign exchange rates.

Sales of Evista remained essentially flat in the U.S., due to decreased demand offset by increased prices. Sales outside the U.S. decreased 2 percent, driven by lower prices and lower demand, partially offset by a favorable impact of foreign exchange rates.

Sales of Forteo decreased 4 percent in the U.S., driven by lower demand, partially offset by higher prices. Sales outside the U.S. increased 11 percent, due to increased demand and, to a lesser extent, higher prices.

Sales of Strattera decreased 13 percent in the U.S., due primarily to lower demand, and to a lesser extent, lower net effective selling prices. Sales outside the U.S. increased 14 percent, driven by increased demand, partially offset by lower prices.

Worldwide sales of Byetta decreased 11 percent to $710.2 million during 2010 due to competitive pressures in the U.S. and European markets. Our revenues decreased 4 percent to $430.6 million in 2010.

Erbitux revenues were $386.1 million in 2010, compared with $390.8 million in 2009.

Animal health product sales in the U.S. and outside the U.S. increased 15 percent, due primarily to increased demand for our companion animal and feed additive products.

Gross Margin, Costs, and Expenses

Gross margin as a percent of total revenue increased by 0.5 percentage points in 2010 to 81.1 percent. This increase was due to lower manufacturing costs and higher selling prices, partially offset by the negative effect of foreign exchange rates on international inventories sold.

Marketing, selling, and administrative expenses increased 2 percent in 2010 to $7.05 billion. The increase was driven by higher marketing and selling expenses outside the U.S., partially offset by lower administrative and litigation expenses and company-wide cost containment efforts. Investment in research and development increased 13 percent, to $4.88 billion, due primarily to charges related to pipeline molecules, including charges related to business development activities and termination of clinical trials.

We incurred an IPR&D charge of $50.0 million in 2010, associated with the in-licensing agreement with Acrux, compared with $90.0 million in 2009 resulting from the in-licensing agreement with Incyte. We recognized asset impairments, restructuring, and other special charges of $192.0 million in 2010, primarily related to severance and other related costs from previously announced strategic actions we are taking to reduce our cost structure and global workforce. In 2009, we recognized charges totaling $692.7 million for asset impairments, restructuring, and other special charges. See Notes 3, 5, and 15 to the consolidated financial statements for additional information.

Other net, expense improved $224.5 million to a net expense of $5.0 million in 2010, due primarily to net gains on equity investments, lower net interest expense, damages recovered from generic pharmaceutical companies following Zyprexa patent litigation in Germany, and an insurance recovery associated with the theft of product at our Enfield, Connecticut, distribution center.

The effective tax rate was 22.3 percent for 2010, compared with 19.2 percent for 2009. The 2010 increase was driven by $85.1 million in additional tax expense in the first quarter related to U.S. health care reform. The 2009 effective tax rate was reduced due to the tax benefit of asset impairment and restructuring charges associated with the sale of the Tippecanoe Laboratories manufacturing site.

FINANCIAL CONDITION

As of December 31, 2011, cash, cash equivalents, and short-term investments totaled $6.90 billion compared with $6.73 billion at December 31, 2010. The increase in cash was driven by cash from operations of $7.23 billion, partially offset by net noncurrent investment activity (as cash was invested with maturities greater than one year) of $2.32 billion, dividends paid of $2.18 billion, business and product acquisitions of $1.33 billion, and purchases of property and equipment of $672.0 million.

Capital expenditures of $672.0 million during 2011 were $22.3 million less than in 2010. We expect 2012 capital expenditures to be approximately $800 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.

Total debt at December 31, 2011, was $6.99 billion, an increase of $60.5 million from December 31, 2010, which was due primarily to the $252.4 million increase in the fair value of hedged debt offset by the full repayment in 2011 of $125.0 million of short-term floating rate debt and $63.7 million in Employee Stock Ownership Plan debentures. In 2012, we plan to retire $1.51 billion of our debt as it matures. 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 2011 and 2010. 2011 was the 127th consecutive year in which we made dividend payments. In the fourth quarter of 2011, effective for the dividend to be paid in the first quarter of 2012, the quarterly dividend was maintained at $.49 per share, resulting in an indicated annual rate for 2012 of $1.96 per share.

As of the fourth quarter of 2011, the U.S. economy continues to recover while concerns have grown regarding the health of the European economy. Worries in Europe have spread beyond the peripheral nations to encompass the entirety of the euro area, with many economists believing a recession in the euro area to be probable. Meanwhile, U.S. economic data in the fourth quarter generally exceeded expectations, with housing and employment indicators signaling a strengthening recovery. Still, given the fragility of the economic recovery and the heightened anxiety regarding Europe, the Federal Reserve has maintained its view that accommodative policy is likely to be warranted through 2014. Both domestically and abroad, high sovereign debt levels, sluggish growth, rating downgrades, and ongoing fiscal deficits have spurred efforts at fiscal austerity, notably in Spain, Italy, and Greece. 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. 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 debt service, capital expenditures, and dividends in 2012. We believe that amounts accessible through existing commercial

paper markets should be adequate to fund short-term borrowings. Because of the high credit quality of our short- and long-term debt, our access to credit markets has not been adversely affected. We currently have $1.24 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 Item 1A, Risk Factors, and the Financial Expectations for 2012 section, 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 (June 2013) and Evista (March 2014) . Cymbalta could receive an additional six months of exclusivity, based on completion of pediatric studies.

Zyprexa and Gemzar have already lost exclusivity in the U.S. and Europe. In the U.S., Gemzar lost exclusivity in November 2010 and Zyprexa lost exclusivity in October 2011. In addition, we face U.S. patent litigation over Alimta, and it is possible we could lose our exclusivity prior to the expiration of the relevant patents. Refer to the Hatch-Waxman patent litigation discussion in Note 15 and in the Legal and Regulatory Matters section below. The loss of exclusivity for Alimta, Cymbalta, or Evista would likely result in generic competition, generally causing a rapid and severe decline in revenue from the affected product, which would have 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 company has received approval to market a biosimilar version of Humalog; however, it is difficult to predict the likelihood 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 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 new products in these markets.

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

Our primary interest rate risk exposure results from changes in short-term U.S. dollar interest rates. In an effort to manage interest rate exposures, we strive to achieve an acceptable balance between fixed and floating rate debt positions and may enter into interest rate derivatives to help maintain that balance. Based on our overall interest rate exposure at December 31, 2011 and 2010, 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, 2011 and 2010, respectively, would have no 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, 2011 and 2010, a hypothetical 10 percent change in exchange rates (primarily against the U.S. dollar) as of December 31, 2011 and 2010, respectively, would have no 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.

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]	$ 9,127.8	$ 1,672.0	$ 1,323.5	$ 519.5	$ 5,612.8
Capital lease obligations	60.8	8.0	12.5	11.5	28.8
Operating leases	514.9	111.7	155.1	100.3	147.8
Purchase obligations[2]	12,694.3	10,791.8	1,258.2	496.5	147.8
Other long-term liabilities reflected on our balance sheet[3]	1,679.7	0.0	549.0	233.0	897.7
Other[4]	180.5	180.5	0.0	0.0	0.0
Total	$ 24,258.0	$ 12,764.0	$ 3,298.3	$ 1,360.8	$ 6,834.9

[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, 2011, to compute the amount of the contractual obligation for interest on the variable rate debt instruments and swaps.

[2] We have included the following:
Purchase obligations, consisting primarily of all open purchase orders at our significant operating locations as of December 31, 2011. 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 liabilities for unrecognized tax benefits of $1.09 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.

The contractual obligations table is current as of December 31, 2011. 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 POLICIES

In preparing our financial statements in accordance with generally accepted accounting principles (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 policies have been discussed with our audit committee and are described below.

Revenue Recognition and Sales Return, Rebate, and Discount Accruals

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

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

Consistent with revenue recognition accounting guidance, 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 one 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 government 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. U.S. sales returns, federally mandated Medicaid rebate and state pharmaceutical assistance programs (Medicaid), and Medicare rebates reduced sales by $2.46 billion, $1.66 billion, and $1.20 billion in 2011, 2010, and 2009, respectively. A 5 percent change in the sales return, Medicaid, and Medicare rebate amounts we recognized in 2011 would lead to an approximate $123 million effect on our income before income taxes. As of December 31, 2011, our sales returns, Medicaid, and Medicare rebate liability was $1.23 billion.

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. Approximately 82 percent and 83 percent of our global sales return, rebate, and discount liability resulted from sales of our products in the U.S. as of December 31, 2011 and 2010, respectively. The following represents a roll-forward of our most significant U.S. returns, rebate, and discount liability balances, including Medicaid (in millions):

	2011	2010
Sales return, rebate, and discount liabilities, beginning of year	$ 1,155.3	$ 963.6
Reduction of net sales due to sales returns, discounts, and rebates[1]	4,016.9	2,876.1
Cash payments of discounts and rebates	(3,574.3)	(2,684.4)
Sales return, rebate, and discount liabilities, end of year	$ 1,597.9	$ 1,155.3

[1] Adjustments of the estimates for these returns, rebates, and discounts to actual results were less than 0.3 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 future 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. In evaluating these assumptions, we consider many factors, including an evaluation of the discount rates, expected return on plan assets, and health-care-cost trend rates of other companies; our historical assumptions compared with actual results; an analysis of current market conditions and asset allocations (approximately 81 percent of which are growth investments); and the views of leading financial advisers and economists. We use an actuarially determined, company-specific yield curve to determine the discount rate. 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 each future year, the aggregate of the service cost and interest cost components of the 2011 annual expense would increase by $15.1 million. A one-percentage-point decrease would decrease the aggregate of the 2011 service cost and interest cost by $12.3 million. If the 2011 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 $28.4 million. If the 2011 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 $19.2 million. If our assumption regarding the 2011 expected age of future retirees for U.S. plans were adjusted by one year, our income before income taxes would be affected by $35.3 million. The U.S. plans, including Puerto Rico, represent approximately 82 percent of the total accumulated postretirement benefit obligation and approximately 81 percent of total plan assets at December 31, 2011.

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.

There are several methods that can 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 at some time 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 and the issuance of regulations or interpretations by the taxing authorities, new information obtained during a tax examination, or resolution of an examination. We believe that our estimates for uncertain tax positions are appropriate and sufficient to pay assessments that may result from examinations of our tax returns. We recognize both accrued interest and penalties related to unrecognized tax

benefits in income tax expense.

We have recorded valuation allowances against certain of our deferred tax assets, primarily those that have been generated from net operating losses and tax credit carryforwards in certain taxing jurisdictions. In evaluating whether we would more likely than not recover these deferred tax assets, we have not assumed any future taxable

income or tax planning strategies in the jurisdictions associated with these carryforwards where history does not support such an assumption. Implementation of tax planning strategies to recover these deferred tax assets or future income generation in these jurisdictions could lead to the reversal of these valuation allowances and a reduction of income tax expense.

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 $40.6 million and $30.6 million, respectively.

FINANCIAL EXPECTATIONS FOR 2012

For the full year of 2012, we expect earnings per share to be in the range of $3.10 to $3.20. We anticipate that total revenue will be between $21.8 billion and $22.8 billion. This includes an expected decline of more than $3 billion in Zyprexa sales due to patent expirations in most markets outside of Japan. The reduction in revenue due to Zyprexa patent expirations is expected to be partially offset by growth in key franchises including Cymbalta, Cialis, Humalog, Humulin, and Forteo, as well as continued growth of newer products such as Effient, Axiron, and Tradjenta. We also anticipate continued strong, double-digit revenue growth from our Elanco Animal Health business. Both Japan and emerging markets are expected to post continued strong underlying volume growth; however, overall revenue growth in these markets in 2012 will be adversely affected by anticipated pricing actions in Japan and by the expected impact of patent expirations, including Zyprexa, in some emerging market countries.

We anticipate that gross margin as a percent of revenue will be approximately 77 percent. Marketing, selling, and administrative expenses are expected to decline and be in the range of $7.4 billion to $7.8 billion. Research and development expense is expected to be flat to increasing and in the range of $5.0 billion to $5.3 billion. Other net, expense is expected to be in a range between net expense of $50 million and net income of $100 million. Operating cash flows are expected to be more than sufficient to fund capital expenditures of approximately $800 million, as well as anticipated business development activity and our current dividend.

PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995

A CAUTION CONCERNING FORWARD-LOOKING STATEMENTS

Under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, we caution investors that any forward-looking statements or projections made by us, including those above, are based on management s belief at the time they are made. However, they are subject to risks and uncertainties. Actual results could differ materially and will depend on, among other things, the continuing growth of our currently marketed products; developments with competitive products; the implementation of U.S. health care reform; the timing and scope of regulatory approvals and the success of our new product launches; asset impairments, restructurings, and acquisitions of compounds under development resulting in acquired IPR&D charges; foreign exchange rates and global macroeconomic conditions; changes in effective tax rates; wholesaler inventory changes; other regulatory developments, litigation, patent disputes, and government investigations; the impact of governmental actions regarding pricing, importation, and reimbursement for pharmaceuticals; and other factors that may affect our operations and prospects, which are discussed earlier in this section and in Item 1A, Risk Factors. We undertake no duty to update these forward-looking statements.

LEGAL AND REGULATORY MATTERS

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 brought pursuant to procedures set out in the Hatch-Waxman Act (the Drug Price Competition and Patent Term Restoration Act of 1984):

Alimta: 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, concomitant nutritional supplement use 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. The generic manufacturers have appealed this decision. 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 concomitant nutritional supplement use patent is valid and infringed. No trial date has yet been set. In January 2012, we filed a similar lawsuit against Accord Healthcare Inc.

We believe the Hatch-Waxman challenges to Alimta 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.

Strattera: Actavis Elizabeth LLC (Actavis), Apotex Inc. (Apotex), Aurobindo Pharma Ltd. (Aurobindo), Mylan Pharmaceuticals Inc. (Mylan), Sandoz Inc. (Sandoz), Sun Pharmaceutical Industries Limited (Sun Ltd.), and Teva Pharmaceuticals USA, Inc. (Teva USA) each submitted an ANDA seeking permission to market generic versions of Strattera prior to the expiration of our relevant U.S. patent and data-based pediatric exclusivity period (expiring in 2017), and alleging that this patent is invalid. In 2007, we brought a lawsuit against Actavis, Apotex, Aurobindo, Mylan, Sandoz, Sun Ltd., and Teva USA in the U.S. District Court for the District of New Jersey. In August 2010, the court ruled that our patent was invalid; however, in July 2011, the Court of Appeals for the Federal Circuit overturned that decision, upholding the patent. The Federal Circuit Court of Appeals denied the generic manufacturers petition for rehearing en banc in October 2011, and the deadline for any further appeal has passed. Zydus Pharmaceuticals (Zydus) filed an action in the New Jersey district court in October 2010 seeking a declaratory judgment that it has the right to launch a generic atomoxetine product, based on the district court ruling. We believe that Zydus is subject to the injunction issued by the court of appeals in the Actavis case.

Zyprexa Litigation

We are a defendant in approximately 40 Zyprexa product liability lawsuits in the U.S. covering approximately 120 plaintiffs. The lawsuits allege a variety of injuries from the use of Zyprexa, with the majority alleging that the product caused or contributed to diabetes or high blood-glucose levels. 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. Approximately 25 of the lawsuits, covering about 30 plaintiffs, are part of a Multi-District Litigation (MDL) proceeding before The Honorable Jack Weinstein in the Federal District Court for the Eastern District of New York (EDNY) (MDL No. 1596). In October 2011, a jury trial in a California state court was decided in our favor. We are prepared to continue our vigorous defense of Zyprexa in all these lawsuits and claims.

We were served with lawsuits filed by 13 states alleging that Zyprexa caused or contributed to diabetes or high blood-glucose levels, and that we improperly promoted the drug. We settled the Zyprexa-related claims of all of these states, incurring pretax charges of $230.0 million in 2009 and $15.0 million in 2008.

In 2005 and 2006, four lawsuits were filed in the EDNY purporting to be nationwide class actions on behalf of all consumers and third-party payors, excluding governmental entities, which made or will make payments for their members or insured patients being prescribed Zyprexa. These actions were consolidated into a single lawsuit, brought under certain state consumer-protection statutes, the federal civil Racketeer Influenced and Corrupt Organizations Act, and common law theories, seeking a refund of the cost of Zyprexa, treble damages, punitive damages, and attorneys fees. As with the product liability suits, these lawsuits allege that we inadequately tested for and warned about side effects of Zyprexa and improperly promoted the drug. In September 2008, Judge Weinstein certified a class consisting of third-party payors, excluding governmental entities and individual consumers, and denied our motion for summary judgment. In September 2010, both decisions were reversed by the Second Circuit Court of Appeals, which found that the case cannot proceed as a class action and entered a judgment in our favor on plaintiffs overpricing claim. The U.S. Supreme Court denied plaintiffs petition for certiorari. All remaining claims at issue in these cases have now been resolved.

Byetta Litigation

We have been named as a defendant in approximately 120 lawsuits involving approximately 480 plaintiffs, primarily seeking to recover damages for pancreatitis experienced by patients prescribed Byetta. We are aware of approximately 530 additional claimants who have not yet filed suit. Approximately 100 of these lawsuits are filed in California and coordinated in a Los Angeles Superior Court.

Other Product Liability Litigation

We have been named as a defendant in numerous other product liability lawsuits involving primarily diethylstilbestrol. These claims are covered by insurance, subject to deductibles and coverage limits.

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 for other products 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 future product liability losses. In addition, there is no assurance that we will be able to fully collect from our insurance carriers in the future.

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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

(Dollars in millions, except per-share data)	**Year Ended December 31**	**2011**	**2010**	**2009**
Revenue		$ 24,286.5	$ 23,076.0	$ 21,836.0
Cost of sales		5,067.9	4,366.2	4,247.0
Research and development		5,020.8	4,884.2	4,326.5
Marketing, selling, and administrative		7,879.9	7,053.4	6,892.5
Acquired in-process research and development (Notes 3 and 4)		388.0	50.0	90.0
Asset impairments, restructuring, and other special charges (Note 5)		401.4	192.0	692.7
Other net, expense (Note 17)		179.0	5.0	229.5
		18,937.0	16,550.8	16,478.2
Income before income taxes		5,349.5	6,525.2	5,357.8
Income taxes (Note 13)		1,001.8	1,455.7	1,029.0
Net income		$ 4,347.7	$ 5,069.5	$ 4,328.8
Earnings per share basic and diluted (Note 12)		$ 3.90	$ 4.58	$ 3.94

See notes to consolidated financial statements.

Consolidated Statements of Comprehensive Income

ELI LILLY AND COMPANY AND SUBSIDIARIES

(Dollars in millions) Year Ended December 31	2011	2010	2009
Net income	$ 4,347.7	$ 5,069.5	$ 4,328.8
Other comprehensive income (loss)			
Foreign currency translation gains (losses)	(244.8)	(325.1)	284.9
Net unrealized gains (losses) on securities	(178.5)	80.8	289.8
Defined benefit pension and retiree health benefit plans (Note 14)	(1,240.2)	148.9	(280.3)
Effective portion of cash flow hedges	44.8	(26.6)	48.2
Other comprehensive income (loss) before income taxes	(1,618.7)	(122.0)	342.6
Provision for income taxes related to other comprehensive income (loss) items	430.2	(76.2)	(27.7)
Other comprehensive income (loss) (Note 16)	(1,188.5)	(198.2)	314.9
Comprehensive income	$ 3,159.2	$ 4,871.3	$ 4,643.7

See notes to consolidated financial statements.

Consolidated Balance Sheets

ELI LILLY AND COMPANY AND SUBSIDIARIES

(Dollars in millions, shares in thousands) December 31	2011	2010
Assets		
Current Assets		
Cash and cash equivalents (Note 6)	$ 5,922.5	$ 5,993.2
Short-term investments (Note 6)	974.6	733.8
Accounts receivable, net of allowances of $110.1 (2011) and $79.9 (2010)	3,597.7	3,493.8
Other receivables (Note 10)	640.2	664.3
Inventories	2,299.8	2,517.7
Prepaid taxes	158.5	828.3
Prepaid expenses and other (Note 10)	654.9	608.9
Total current assets	14,248.2	14,840.0
Other Assets		
Investments (Note 6)	4,029.8	1,779.5
Goodwill and other intangibles net (Note 7)	5,128.1	4,818.8
Sundry (Note 10)	2,493.4	1,622.4
Total other assets	11,651.3	8,220.7
Property and Equipment, net	7,760.3	7,940.7
Total assets	$ 33,659.8	$ 31,001.4
Liabilities and Shareholders Equity		
Current Liabilities		
Short-term borrowings and current maturities of long-term debt (Note 8)	$ 1,522.3	$ 156.0
Accounts payable	1,125.2	1,072.2
Employee compensation	804.7	851.8
Sales rebates and discounts	1,771.3	1,372.6
Dividends payable	542.3	540.0
Income taxes payable (Note 13)	261.6	457.5
Other current liabilities (Note 10)	2,903.5	2,476.8
Total current liabilities	8,930.9	6,926.9
Other Liabilities		
Long-term debt (Note 8)	5,464.7	6,770.5
Accrued retirement benefits (Note 14)	3,068.5	1,887.4
Long-term income taxes payable (Note 13)	1,086.3	1,234.8
Other noncurrent liabilities (Note 10)	1,573.8	1,769.0
Total other liabilities	11,193.3	11,661.7
Commitments and contingencies (Note 15)		
Shareholders' Equity (Notes 9 and 11)		
Common stock no par value		
Authorized shares: 3,200,000		
Issued shares: 1,158,644 (2011) and 1,154,018 (2010)	724.1	721.3
Additional paid-in capital	4,886.8	4,798.5
Retained earnings	14,897.8	12,732.6
Employee benefit trust	(3,013.1)	(3,013.2)
Deferred costs ESOP		(52.4)
Accumulated other comprehensive loss (Note 16)	(3,858.6)	(2,670.1)
Noncontrolling interests	(6.1)	(7.5)
Cost of common stock in treasury, 853 shares (2011) and 864 shares (2010)	(95.3)	(96.4)
Total shareholders equity	13,535.6	12,412.8
Total liabilities and shareholders equity	$ 33,659.8	$ 31,001.4

See notes to consolidated financial statements.

Consolidated Statements of Cash Flows

ELI LILLY AND COMPANY AND SUBSIDIARIES

(Dollars in millions) Year Ended December 31	2011	2010	2009
Cash Flows from Operating Activities			
Net income	$ 4,347.7	$ 5,069.5	$ 4,328.8
Adjustments to Reconcile Net Income to Cash Flows from Operating Activities			
Depreciation and amortization	1,373.6	1,328.2	1,297.8
Change in deferred income taxes	(268.5)	559.7	189.9
Stock-based compensation expense	147.4	231.0	368.5
Impairment charges, indefinite lived intangibles	151.5		
Acquired in-process research and development, net of tax	252.2	32.5	58.5
Net marketing investigation charges paid (Note 15)		(112.3)	(1,313.6)
Other operating activities, net	(17.8)	(66.3)	362.5
Changes in operating assets and liabilities, net of acquisitions			
Receivables increase	(188.8)	(319.1)	(492.9)
Inventories decrease (increase)	203.1	157.0	(179.0)
Other assets decrease (increase)	642.7	340.5	(84.9)
Accounts payable and other liabilities increase (decrease)	591.4	(363.9)	(200.1)
Net Cash Provided by Operating Activities	7,234.5	6,856.8	4,335.5
Cash Flows from Investing Activities			
Purchases of property and equipment	(672.0)	(694.3)	(765.0)
Disposals of property and equipment	25.3	24.6	17.7
Net change in short-term investments	(250.9)	(686.5)	399.1
Proceeds from sales and maturities of noncurrent investments	2,138.5	584.7	1,107.8
Purchases of noncurrent investments	(4,459.4)	(1,067.2)	(432.3)
Purchase of product rights	(632.9)	(442.4)	
Purchases of in-process research and development	(388.0)	(50.0)	(90.0)
Cash paid for acquisitions, net of cash acquired	(307.8)	(609.4)	
Loan to collaboration partner	(165.0)		
Other investing activities, net	(112.2)	(219.3)	(94.5)
Net Cash (Used for) Provided by Investing Activities	(4,824.4)	(3,159.8)	142.8
Cash Flows from Financing Activities			
Dividends paid	(2,180.1)	(2,165.3)	(2,152.1)
Net change in short-term borrowings	(141.2)	123.9	(5,824.2)
Proceeds from issuance of long-term debt		1.2	2,400.0
Repayments of long-term debt	(54.6)	(1.1)	
Other financing activities, net	6.0	19.4	42.6
Net Cash Used for Financing Activities	(2,369.9)	(2,021.9)	(5,533.7)
Effect of exchange rate changes on cash and cash equivalents	(110.9)	(144.8)	21.6
Net (decrease) increase in cash and cash equivalents	(70.7)	1,530.3	(1,033.8)
Cash and cash equivalents at beginning of year	5,993.2	4,462.9	5,496.7
Cash and Cash Equivalents at End of Year	$ 5,922.5	$ 5,993.2	$ 4,462.9

See notes to consolidated financial statements.

Segment Information

We operate in one significant business segment human pharmaceutical products. Operations of the animal health business segment are not material and share many of the same economic and operating characteristics as human pharmaceutical products. Therefore, they are included with pharmaceutical products for purposes of segment reporting.

ELI LILLY AND COMPANY AND SUBSIDIARIES

(Dollars in millions) Year Ended December 31	2011	2010	2009
Revenue to unaffiliated customers			
Neuroscience	$ 9,723.8	$ 9,419.0	$ 8,976.4
Endocrinology	6,806.7	6,135.4	6,015.0
Oncology	3,322.2	3,744.5	3,460.0
Cardiovascular	2,486.4	2,171.3	1,971.1
Animal health	1,678.6	1,391.4	1,207.2
Other pharmaceuticals	268.8	214.4	206.3
Revenue	$ 24,286.5	$ 23,076.0	$ 21,836.0
Geographic Information			
Revenue to unaffiliated customers[1]			
United States	$ 12,977.2	$ 12,865.6	$ 12,294.4
Europe	5,290.9	5,106.4	5,227.2
Japan	2,104.1	1,616.6	1,224.8
Other foreign countries	3,914.3	3,487.4	3,089.6
Revenue	$ 24,286.5	$ 23,076.0	$ 21,836.0
Long-lived assets			
United States	$ 5,485.3	$ 5,333.9	$ 5,310.0
Europe	2,220.2	2,250.7	2,313.3
Japan	102.9	101.2	90.9
Other foreign countries	1,564.0	1,588.4	1,632.4
Long-lived assets	$ 9,372.4	$ 9,274.2	$ 9,346.6

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

Our neuroscience group of products includes Zyprexa, Cymbalta, Strattera, and Prozac. Endocrinology products consist primarily of Humalog, Humulin, Evista, Forteo, Humatrope, Byetta, and Actos. Oncology products consist primarily of Alimta, Gemzar, and Erbitux. Cardiovascular products consist primarily of Cialis, Effient, and ReoPro. 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. The other pharmaceuticals category includes anti-infectives, primarily Vancocin and Ceclor, and other miscellaneous pharmaceutical products and services.

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, 2011, 2010, and 2009, our three largest wholesalers each accounted for between 11 percent and 17 percent of consolidated total revenue. Further, they each accounted for between 9 percent and 15 percent of accounts receivable as of December 31, 2011 and 2010. Animal health products are sold primarily to wholesale distributors.

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 substantially the same as those described in the summary of significant accounting policies in Note 1 to the consolidated financial statements. Income before income taxes for the animal health business was approximately $301 million, $251 million, and $217 million for the years ended December 31, 2011, 2010, and 2009, respectively.

The assets of the animal health business are intermixed with those of the pharmaceutical products business. Long-lived assets disclosed above consist of property and equipment and certain sundry assets.

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.

Selected Quarterly Data (unaudited)

ELI LILLY AND COMPANY AND SUBSIDIARIES

(Dollars in millions, except per-share data)	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	.95
Dividends paid per share		.49	.49	.49	.49
Common stock closing prices					
High		41.75	39.32	39.15	35.84
Low		35.58	34.49	34.99	33.63

	2010	Fourth	Third	Second	First
Revenue		$ 6,187.0	$ 5,654.8	$ 5,748.7	$ 5,485.5
Cost of sales		1,232.2	987.6	1,023.9	1,122.5
Operating expenses		3,426.8	2,914.7	2,942.6	2,653.5
Acquired in-process research and development					50.0
Asset impairments, restructuring, and other special charges		79.0	59.5	27.3	26.2
Other net, expense (income)		39.4	21.7	18.4	(74.5)
Income before income taxes		1,409.6	1,671.3	1,736.5	1,707.8
Net income		1,169.6	1,302.9	1,348.9	1,248.1
Earnings per share basic and diluted		1.05	1.18	1.22	1.13
Dividends paid per share		.49	.49	.49	.49
Common stock closing prices					
High		38.06	37.77	36.92	37.41
Low		33.66	33.12	32.25	33.95

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)	2011	2010	2009	2008	2007
Operations					
Revenue	**$ 24,286.5**	$ 23,076.0	$ 21,836.0	$ 20,371.9	$ 18,633.5
Cost of sales	**5,067.9**	4,366.2	4,247.0	4,376.7	4,248.8
Research and development	**5,020.8**	4,884.2	4,326.5	3,840.9	3,486.7
Marketing, selling, and administrative	**7,879.9**	7,053.4	6,892.5	6,626.4	6,095.1
Other	**968.4**	247.0	1,012.2	6,835.5[1]	926.1
Income (loss) before income taxes	**5,349.5**	6,525.2	5,357.8	(1,307.6)	3,876.8
Income taxes	**1,001.8**	1,455.7	1,029.0	764.3	923.8
Net income (loss)	**4,347.7**	5,069.5	4,328.8	(2,071.9)	2,953.0
Net income as a percent of revenue	**17.9%**	22.0%	19.8%	NM	15.8%
Net income (loss) per share diluted	**3.90**	4.58	3.94	(1.89)	2.71
Dividends declared per share	**1.96**	1.96	1.96	1.90	1.75
Weighted-average number of shares outstanding diluted (thousands)	**1,113,967**	1,105,813	1,098,367	1,094,499	1,090,750
Financial Position					
Current assets	**$ 14,248.2**	$ 14,840.0	$ 12,486.5	$ 12,453.3	$ 12,316.1
Current liabilities	**8,930.9**	6,926.9	6,568.1	13,109.7	5,436.8
Property and equipment net	**7,760.3**	7,940.7	8,197.4	8,626.3	8,575.1
Total assets	**33,659.8**	31,001.4	27,460.9	29,212.6	26,874.8
Long-term debt	**5,464.7**	6,770.5	6,634.7	4,615.7	4,593.5
Shareholders' equity	**13,535.6**	12,412.8	9,525.3	6,737.7	13,510.3
Supplementary Data					
Return on shareholders' equity	**31.4%**	46.1%	51.0%	(16.3)%	24.3%
Return on assets	**13.4%**	17.7%	15.8%	(7.5)%	12.1%
Capital expenditures	**$ 672.0**	$ 694.3	$ 765.0	$ 947.2	$ 1,082.4
Depreciation and amortization	**1,373.6**	1,328.2	1,297.8	1,122.6	1,047.9
Effective tax rate	**18.7%**	22.3%	19.2%	NM [2]	23.8%
Revenue per employee	**$ 638,000**	$ 602,000	$ 540,000	$ 504,000	$ 459,000
Number of employees	**38,080**	38,350	40,360	40,450	40,600
Number of shareholders of record	**35,200**	36,700	38,400	39,800	41,700

NM Not Meaningful

[1] The increase 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 2007 through 2011. The graph assumes that, on December 31, 2006, 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 2006

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

			Peer Group	
	Lilly	Peer Group	(Previous)	S&P 500
Dec-06	$100.00	$100.00	$100.00	$100.00
Dec-07	$105.68	$100.43	$100.12	$105.48
Dec-08	$ 83.08	$ 86.51	$ 85.77	$ 66.52
Dec-09	$ 77.99	$ 96.90	$ 97.75	$ 84.07
Dec-10	$ 80.87	$ 97.81	$ 97.91	$ 96.71
Dec-11	$101.01	$109.47	$112.59	$ 98.76

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 2011: Abbott Laboratories; Amgen Inc.; AstraZeneca PLC; Baxter International Inc.; Bristol-Myers Squibb Company; Genzyme Corporation (prior to the company s acquisition by Sanofi-Aventis); GlaxoSmithKline plc; Johnson & Johnson; Merck & Co., Inc.; Novartis AG.; Pfizer Inc.; Sanofi-Aventis; and Takeda Pharmaceuticals Company.

2 Due to changes in the pharmaceutical industry, we revised our peer group for 2011 by adding Baxter International Inc., Genzyme Corporation (prior to the company s acquisition by 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 45 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:

	2011	2010
Finished products	$ 786.4	$ 800.8
Work in process	1,518.2	1,714.2
Raw materials and supplies	205.8	220.8
	2,510.4	2,735.8
Reduction to LIFO cost	(210.6)	(218.1)
Inventories	$ 2,299.8	$ 2,517.7

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, 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, 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. There are several methods that can be used to determine the estimated fair value of the IPR&D acquired in a business combination. We utilized 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 will be 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. 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:

	2011	2010
Land	$ 202.5	$ 207.8
Buildings	6,135.7	6,029.3
Equipment	7,219.9	7,355.7
Construction in progress	1,036.0	893.8
	14,594.1	14,486.6
Less accumulated depreciation	(6,833.8)	(6,545.9)
Property and equipment, net	$ 7,760.3	$ 7,940.7

Depreciation expense for the years ended December 31, 2011, 2010, and 2009 was $732.4 million, $749.1 million, and $813.5 million, respectively. Interest costs of $25.7 million, $26.0 million, and $30.2 million were capitalized as part of property and equipment for the years

ended December 31, 2011, 2010, and 2009, respectively. Total rental expense for all leases, including contingent rentals (not material), amounted to $353.4 million, $339.3 million, and

$337.8 million for the years ended December 31, 2011, 2010, and 2009, 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, and the existing and projected future level of insolvencies among the insurance carriers. However, for substantially all of our currently marketed products, we are completely self-insured for future 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, 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:

	2011	2010	2009
Net product sales	$ 23,604.8	$ 22,442.2	$ 21,171.5
Collaboration and other revenue (Note 4)	681.7	633.8	664.5
Total revenue	$ 24,286.5	$ 23,076.0	$ 21,836.0

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 outstanding common shares and incremental shares. We calculate diluted earnings per share based on the weighted-average number of outstanding common shares plus the effect of dilutive stock options and other incremental shares. 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 the December 31, 2010 and 2009 consolidated financial statements and accompanying notes to conform with the December 31, 2011 presentation.

Note 2: Implementation of New Financial Accounting Pronouncements

In 2010, the Financial Accounting Standards Board (FASB) issued an Accounting Standard 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. This guidance clarifies how pharmaceutical manufacturers should recognize and classify in their income statements fees mandated by U.S. health care reform. This fee is recorded as selling, general, and administrative expense in our consolidated results of operations and is amortized on a straight-line basis for the year. This guidance was effective for us January 1, 2011. In accordance with this guidance, for the year ended December 31, 2011 we recorded $178.0 million related to this fee, which is not deductible for tax purposes.

In 2009, the FASB issued an ASU related to Revenue Recognition that amends the previous guidance on arrangements with multiple deliverables. This guidance provides principles and application guidance on whether multiple deliverables exist, how the arrangements should be separated, and how the consideration should be allocated. It also clarifies the method to allocate revenue in an arrangement using the estimated selling price. This guidance was effective for us January 1, 2011, and did not have a material impact on our consolidated financial position or results of operations.

Note 3: Acquisitions

During 2011 and 2010, we completed the acquisitions of 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.

Most of 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. Accordingly, we capitalized IPR&D assets acquired in business combinations totaling $30.9 million and $598.0 million for the years ended December 31, 2011 and 2010, respectively. Once the Avid and Alnara products are launched, the amortization of the respective acquired IPR&D assets will not be deductible for tax purposes. 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. Subsequent to the acquisition date, on a quarterly basis we remeasure the contingent consideration at current fair value with changes recorded in other net, expense in the statement of operations.

In addition to the acquisitions of businesses, we also acquired several assets in development which are discussed below in Product Acquisitions and in Note 4. The acquired IPR&D related to these products of $388.0 million, $50.0 million, and $90.0 million for the years ended December 31, 2011, 2010, and 2009, respectively, was written off by a charge to income immediately upon acquisition because the products had no alternative future use.

Acquisition of Businesses

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 preliminarily

recorded $223.5 million of marketed product assets and $30.9 million of acquired IPR&D assets, with $53.4 million of other net assets. Although the final determination may result in asset and liability fair values that are different than the preliminary estimates of these amounts, it is not expected that those differences will be material to our financial results.

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 topography (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 under development, florbetapir, 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. The New Drug Application (NDA) was submitted to the U.S. Food and Drug Administration (FDA) in the third quarter of 2010. In March 2011, we received a complete response letter that was primarily focused on the need to establish a reader training program for market implementation that helps to ensure reader accuracy and consistency of interpretations of existing Amyvid scans. During the year ended December 31, 2011 we recorded impairment charges related to the partial impairment of the IPR&D asset related to Amyvid, as discussed further in Note 7. We submitted our response to the complete response letter in 2011.

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 NDA was submitted to the 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 re-submission. During the year ended December 31, 2011 we recorded impairment charges related to the partial impairment of the IPR&D asset related to liprotamase, as discussed further in Note 7. We are currently finalizing the study design and anticipate starting a clinical study in 2012.

Animal Health Product Lines

On May 28, 2010, we acquired the European marketing rights to several animal health product lines divested by Pfizer Inc. as part of its acquisition of Wyeth, 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 U.S.

In December 2009, we entered into a licensing and collaboration agreement with Incyte Corporation (Incyte) to acquire rights to its compound, and certain follow-on compounds, for the treatment of inflammatory and autoimmune diseases. The lead compound was in the development stage (Phase II clinical trials for rheumatoid arthritis) and had no alternative future use. The charge of $90.0 million for acquired IPR&D related to this arrangement was included in expense in the fourth quarter of 2009 and is deductible for tax purposes. As part of this agreement, Incyte has the option to co-develop these compounds and the option to co-promote in the U.S.

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

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.

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:

	2011	2010	2009
Net product sales	$ 87.6	$ 71.9	$ 92.5
Collaboration and other revenue	321.6	314.2	298.3
Total revenue	$ 409.2	$ 386.1	$ 390.8

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 also 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. We and BMS share the cost of developing and potentially commercializing necitumumab in the U.S., Canada, and Japan. We maintain exclusive rights to necitumumab in all other markets. We will fund 45 percent of the development costs for studies that will be used only in the U.S., and 72.5 percent for global studies. We will be responsible for the manufacturing of API, and BMS will be responsible for manufacturing the finished product. We could receive a payment of $250.0 million upon approval in the U.S. In the U.S. and Canada, BMS will record sales and we will receive 45 percent of the profits for necitumumab, while we will provide 50 percent of the selling effort. In Japan, we and BMS will share costs and profits evenly.

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 percent of their global net sales of exenatide products until Amylin has made aggregate payments to us of $1.20 billion plus interest, which will accrue at 9.5 percent. Amylin issued a secured note in the amount of $1.20 billion to us under which any revenue-sharing payments made to us will reduce amounts outstanding under

the note. In general, Amylin s obligation for the revenue-sharing payments and the secured note will terminate if all exenatide products are withdrawn from the market due to safety or efficacy issues and are not sold for a period of four years. 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, although we will continue to provide certain transition services. Outside the U.S., we will transfer responsibility for commercialization of exenatide to Amylin on a market-by-market basis over a period beginning no earlier than the second half of 2012 and that will not extend beyond December 31, 2013.

Payments received from Amylin are allocated 65 percent to the U.S., which is 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 is based upon relative fair values. Revenue-sharing payments will be recognized as income as Amylin records sales. The income allocated to the U.S. is recognized as collaboration and other revenue and the income allocated to the business outside the U.S. will be recognized as proceeds from the disposition of a business in other-net, expense in our consolidated income statement beginning at the time control of the business transfers to Amylin. The amounts we may receive pursuant to the revenue-sharing arrangement represent contingent consideration and, therefore, do not qualify for recognition as income until the contingency is resolved and the amount becomes fixed or determinable. As a consequence, the note has not been recognized in our consolidated balance sheet. The income recognized from this transaction was not material for the year ended December 31, 2011, as the income recognized from the upfront payment was substantially offset by the derecognition of amounts previously capitalized related to certain supply arrangements and approval milestones.

Prior to termination of the collaboration, we and Amylin were co-promoting Byetta in the U.S. 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, unless we and Amylin agree otherwise. 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.

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 U.S. 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 June 2011, the European Commission granted marketing authorization to Bydureon for the once-weekly treatment of type 2 diabetes in combination with certain oral therapies. European launches began in the third quarter of 2011, starting with the United Kingdom and Germany. Net product sales of Bydureon were not material for the year ended December 31, 2011. In January 2012, the FDA approved Bydureon for marketing in the U.S.

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

	2011	2010	2009
Net product sales	$ 179.6	$ 168.1	$ 147.7
Collaboration and other revenue	243.1	262.5	300.8
Total revenue	$ 422.7	$ 430.6	$ 448.5

In accordance with the prior arrangement and pursuant to Amylin s request, in the second quarter of 2011 we loaned Amylin $165.0 million. Interest on this loan is to be received quarterly and all outstanding principal and interest is due five years from the date of the advance.

Cymbalta

We were in a collaborative arrangement with Boehringer Ingelheim (Boehringer) 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 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 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 approximately $400 million and will also pay to Boehringer a

percentage of our sales of duloxetine in these countries through 2012 as consideration for the rights acquired. We record these costs as intangible assets, which will be amortized to marketing, selling, and administrative expenses using the straight-line method over the life of the original agreement, which is through 2015.

Effient

We are in a collaborative arrangement with Daiichi Sankyo Company, Limited (D-S) to develop, market, and promote Effient. We and D-S have agreed to co-promote in certain territories (including the U.S. and five major European markets), while we have exclusive marketing rights in certain other territories. D-S has exclusive marketing rights in Japan. 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 D-S a royalty specific to these territories. Profit share payments made to D-S are recorded as marketing, selling, and administrative expenses. All royalties paid to D-S and the third-party manufacturer are recorded in cost of sales. Worldwide Effient sales were $302.5 million, $115.0 million, and $27.0 million for the years ended December 31, 2011, 2010, and 2009, respectively.

Diabetes Collaboration

In January 2011, we and Boehringer entered into a global agreement to jointly develop and commercialize a portfolio of diabetes compounds. Included are Boehringer 's two oral diabetes agents, linagliptin and empagliflozin (BI 10773). Subsequently in 2011, linagliptin was approved and launched in the U.S. (tradename Tradjenta), Japan (tradename Trazenta), Europe (tradename Trajenta), and other countries. Empagliflozin is currently in Phase III clinical testing. Also included in the agreement is 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 to co-develop and co- commercialize our anti-TGF-beta monoclonal antibody, which is currently in Phase II clinical testing. Under the terms of the agreement, we made an initial one-time payment to Boehringer 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 approximately 300 million in additional success-based regulatory milestones for empagliflozin. We will be eligible to receive up to a total of $650.0 million in success-based regulatory milestones on our two insulin products. Should Boehringer elect to opt in to the Phase III development and potential commercialization of the anti-TGF-beta monoclonal antibody, we would be eligible for up to $525.0 million in opt-in and success-based regulatory milestone payments. The companies share ongoing development costs equally. The companies also share in the commercialization costs and gross margin for any product resulting from the collaboration that receives regulatory approval. We record our portion of the gross margin as collaboration and other revenue, and we record our portion of the commercialization costs as marketing, selling, and administrative expense. Each company will also be entitled to potential performance payments on sales of the molecules they contribute to the collaboration. Revenue related to this collaboration has not been significant to date.

Solanezumab

We have an agreement with an affiliate of TPG-Axon Capital (TPG) whereby both we and TPG were obligated to fund the Phase III development of solanezumab. Under the agreement, TPG s obligation to fund solanezumab costs are not material and ended in the first half of 2011. In exchange for their funding, TPG may receive success-based sales milestones totaling approximately $70.0 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. Reimbursements received from TPG for its portion of research and development costs incurred were recorded as a reduction to the research and development expense line item on the consolidated statements of operations. The reimbursement from TPG was not material in any period.

Summary of Collaboration-Related Commission and Profit Share Payments

The aggregate amounts of commissions and profit share payments included in marketing, selling, and administrative expense pursuant to the collaborations described above were $219.2 million, $174.5 million, and $319.2 million for the years ended December 31, 2011, 2010, and 2009, 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.

	2011	2010	2009
Severance	$ 251.8	$ 142.0	$ 99.0
Asset impairments and other special charges	149.6	50.0	363.7
Product liability and other special charges legal settlement			230.0
Asset impairments, restructuring, and other special charges	$ 401.4	$ 192.0	$ 692.7

Severance

Severance costs listed above, substantially all of which have been paid, are primarily the result of the 2009 initiative to reorganize global operations, streamline various functions of the business, and reduce total employees, as well as other previously announced strategic actions to reduce our cost structure and global workforce. Included in the 2009 severance charges is $61.1 million related to the sale of our Tippecanoe Laboratories manufacturing site, which is further described below.

Asset Impairments and Other Special Charges

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 2009 initiative to reorganize global operations, streamline various functions of the business, and reduce total 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.

In 2009, we recognized non-cash asset impairments and other special charges of $363.7 million primarily due to the sale of our Tippecanoe Laboratories manufacturing site to an affiliate of Evonik Industries AG (Evonik) in early 2010. In connection with the sale of the site, we entered into a nine-year supply and services agreement, whereby Evonik will manufacture final and intermediate step API for certain of our human and animal health products. The fair value of assets used in determining impairment charges was based on contracted sales prices.

Product Liability and Other Special Charges

In 2009, we incurred other special charges of $230.0 million related to advanced discussions with the attorneys general for several states, seeking to resolve their Zyprexa-related claims. The charges represented the then-current probable and estimable exposures in connection with the states claims. Refer to Note 15 for additional information.

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. Major financial institutions represent the largest component of our investments in corporate debt securities. In accordance with documented corporate policies, we limit 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, 2011, we had outstanding foreign currency forward commitments to purchase 494.3 million British pounds and sell 583.4 million euro, and commitments to purchase 1.61 billion euro and sell 2.11 billion U.S. dollars, which will all settle within 30 days.

At December 31, 2011, approximately 90 percent of our total debt is at a fixed rate. We have converted approximately 70 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, expense:

	2011	2010	2009
Fair value hedges			
Effect from hedged fixed-rate debt	$ 259.6	$ 149.6	$ (369.5)
Effect from interest rate contracts	(259.6)	(149.6)	369.5
Cash flow hedges			
Effective portion of losses on interest rate contracts reclassified from accumulated other comprehensive loss	9.0	9.0	10.2

Net losses on foreign currency exchange contracts not designated as hedging instruments	97.4	12.0	82.6

The effective portion of net gains (losses) on equity contracts in designated cash flow hedging relationships recorded in other comprehensive income (loss) was $35.6 million, $(35.6) million, and $0.0 million for the years ended December 31, 2011, 2010, and 2009, respectively. The effective portion of net gains on interest rate contracts in designated cash flow hedging relationships recorded in other comprehensive income (loss) was $0.0 million, $0.0 million, and $38.0 million for the years ended December 31, 2011, 2010, and 2009 respectively.

We expect to reclassify $9.0 million of pretax net losses on cash flow hedges of the variability in expected future interest payments on floating rate debt from accumulated other comprehensive loss to earnings during the next 12 months.

During the years ended December 31, 2011, 2010, and 2009, 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:

			Fair Value Measurements Using			
Description	Carrying Amount	Amortized Cost	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, 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	$ 362.3	$	$	$ 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	$ 908.8	$	$	$ 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				
Investments	$ 4,029.8	$ 4,006.4				
December 31, 2010						
Cash and cash equivalents	$ 5,993.2	$ 5,993.2	$ 2,138.6	$ 3,854.6	$	$ 5,993.2
Short-term investments						
Commercial paper	$ 540.8	$ 540.8	$	$ 540.8	$	$ 540.8
U.S. government and agencies	128.9	128.9	128.9			128.9
Corporate debt securities	63.4	63.9		63.4		63.4
Other securities	0.7	0.7		0.7		0.7
Short-term investments	$ 733.8	$ 734.3				
Noncurrent investments						
U.S. government and agencies	$ 359.2	$ 361.8	$ 359.2	$	$	$ 359.2
Corporate debt securities	367.9	368.9		367.9		367.9
Mortgage-backed	315.5	350.7		315.5		315.5
Asset-backed	132.4	140.8		132.4		132.4
Other securities	6.4	8.3		3.3	3.1	6.4
Marketable equity	433.7	182.6	433.7			433.7
Equity method and other investments[1]	164.4	164.4				
Investments	$ 1,779.5	$ 1,577.5				

[1] Fair value not applicable

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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, 2011	$ (6,981.5)	$	$ (7,451.5)	$	$ (7,451.5)
December 31, 2010	(6,788.7)		(7,030.0)		(7,030.0)

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, 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)
December 31, 2010					
Risk-management instruments					
Interest rate contracts designated as hedging instruments					
Sundry	$ 278.3	$	$ 278.3	$	$ 278.3
Foreign exchange contracts not designated as hedging instruments					
Other receivables	13.7		13.7		13.7
Other current liabilities	(31.6)		(31.6)		(31.6)
Equity contracts designed as hedging instruments					
Other current liabilities	(35.6)		(35.6)		(35.6)

The fair value of the contingent consideration liability related to the Avid and Alnara acquisitions (Note 3), a Level 3 measurement in the fair value hierarchy, was $121.6 million and $163.5 million as of December 31, 2011 and 2010, respectively.

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.

Approximately $4.03 billion of our investments in debt securities, measured at fair value, will mature within five years.

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:

	2011	2010
Unrealized gross gains	$ 103.0	$ 262.6
Unrealized gross losses	80.0	61.1
Fair value of securities in an unrealized gain position	2,498.9	1,031.8
Fair value of securities in an unrealized loss position	2,164.4	758.1

Other-than-temporary impairment losses on fixed income securities of $26.8 million, $12.0 million, and $22.4 million were recognized in the statement of operations for the years ended December 31, 2011, 2010, and 2009, respectively. These losses primarily relate to credit losses on other securities for the year ended December 31, 2011 and on certain mortgage-backed securities for the years ended December 31, 2010 and 2009. 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, 2011.

The net adjustment to unrealized gains and losses (net of tax) on available-for-sale securities decreased other comprehensive income (loss) by $114.1 million for the year ended December 31, 2011 and increased other comprehensive income (loss) by $53.5 million and $186.6 million for the years ended December 31, 2010 and 2009, respectively. Activity related to our available-for-sale investment portfolio was as follows:

	2011	2010	2009
Proceeds from sales	**$ 2,268.3**	$ 760.3	$ 1,227.4
Realized gross gains on sales	**140.0**	110.7	68.9
Realized gross losses on sales	**9.9**	4.8	6.8

Note 7: Goodwill and Other Intangibles

Goodwill at December 31 was as follows:

	2011	2010
Goodwill	$ 1,434.7	$ 1,423.9

Substantially all of our goodwill balance is attributable to the human pharmaceutical business segment. See Note 3 for a further discussion of goodwill resulting from recent business combinations. No impairments occurred with respect to the carrying value of goodwill for the years ended December 31, 2011, 2010, or 2009.

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

	2011			2010		
Description	Carrying Amount Gross	Accumulated Amortization	Carrying Amount Net	Carrying Amount Gross	Accumulated Amortization	Carrying Amount Net
Finite-lived intangible assets						
Marketed products	**$ 4,624.9**	**$ (1,481.2)**	**$ 3,143.7**	$ 3,789.1	$ (1,023.4)	$ 2,765.7
Other	**117.3**	**(42.5)**	**74.8**	62.5	(31.3)	31.2
Total finite-lived intangible assets	**4,742.2**	**(1,523.7)**	**3,218.5**	3,851.6	(1,054.7)	2,796.9
Indefinite-lived intangible assets						
In-process research and development	**474.9**	**0.0**	**474.9**	598.0	0.0	598.0
Total other intangible assets	**$ 5,217.1**	**$ (1,523.7)**	**$ 3,693.4**	$ 4,449.6	$ (1,054.7)	$ 3,394.9

Marketed products consists 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. IPR&D consists of the acquisition date fair value of intangible assets acquired in business

combinations that have not yet achieved regulatory approval for marketing. See Note 3 for a further discussion of indefinite-lived intangible assets acquired in recent business combinations.

The remaining weighted-average amortization period for finite-lived intangible assets is approximately 9 years. Amortization expense for 2011, 2010, and 2009 was $469.0 million, $385.7 million, and $277.0 million, respectively. The estimated amortization expense for our current finite-lived intangible assets for each of the five succeeding years approximates $530 million in 2012, $460 million in 2013, $410 million in 2014, $380 million in 2015, and $330 million in 2016. Amortization expense is included in either cost of sales or marketing, selling, and administrative depending on the nature of the intangible asset being amortized.

During 2011, we recorded impairment charges of $151.5 million due primarily to the partial 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 re-submission, resulting in an impairment of liprotamase.

No impairments occurred with respect to the carrying value of other intangible assets for the years ended December 31, 2010 and 2009.

Note 8: Borrowings

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

	2011	2010
3.55 to 7.13 percent notes (due 2012-2037)	**$ 6,387.4**	$ 6,387.4
Other, including capitalized leases	**37.6**	97.2
Fair value adjustment	**556.5**	304.1
	6,981.5	6,788.7
Less current portion	**(1,516.8)**	(18.2)
Long-term debt	**$ 5,464.7**	$ 6,770.5

In March 2009, we issued $2.40 billion of fixed-rate notes with interest to be paid semi-annually.

The 6.55 percent Employee Stock Ownership Plan (ESOP) debentures were repaid in full during the year ended December 31, 2011. The balance was $63.7 million at December 31, 2010, and is included in Other in the table above.

The aggregate amounts of maturities on long-term debt for the next five years are as follows: 2012, $1.51 billion; 2013, $10.2 million; 2014, $1.01 billion; 2015, $5.3 million; and 2016, $201.2 million.

At December 31, 2011 and 2010, short-term borrowings included $5.5 million and $137.8 million, respectively, of notes payable to banks. At December 31, 2011, we have $1.24 billion of unused committed bank credit facilities, $1.20 billion of which backs our commercial paper program and matures in April 2015. There were no amounts outstanding under the facility as of or during the year ended December 31, 2011. Compensating balances and commitment fees are not material, and there are no conditions that are probable of occurring under which the lines may be withdrawn.

In September 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 70 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, 2011 and 2010, including the effects of interest rate swaps for hedged debt obligations, were 3.00 percent and 2.87 percent, respectively.

For the years ended December 31, 2011, 2010, and 2009, cash payments of interest on borrowings totaled $167.4 million, $176.3 million, and $205.9 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 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 $147.4 million, $231.0 million, and $368.5 million was recognized for the years ended December 31, 2011, 2010, and 2009, respectively, as well as related tax benefits of $51.6 million, $80.8 million, and $128.9 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, 2011, additional stock-based compensation awards may be granted under the 2002 Lilly Stock Plan for not more than 93.0 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. In 2009, we granted both a one-year and a two-year award to all global management

as a transition to a two-year performance period for all PAs granted beginning in 2010. 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, 2011 and 2010 were $31.90 and $30.88, respectively. The fair values of PAs granted in 2009 were $36.17 for the one-year award and $34.12 for the two-year award. 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 3.9 million shares, 3.8 million shares, and 2.8 million shares were issued during the years ended December 31, 2011, 2010, and 2009, respectively. Approximately 1.6 million shares are expected to be issued in 2012. As of December 31, 2011, the total remaining unrecognized compensation cost related to nonvested PAs amounted to $16.7 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, 2011, 2010, and 2009 were $28.33, $25.97, and $33.97, respectively, determined using the following assumptions:

(Percents)	**2011**	**2010**	**2009**
Expected dividend yield	**4.90**	4.50	4.00
Risk-free interest rate	**.20 1.36**	.10 1.36	.44 1.48
Range of volatilities	**27.61 29.10**	28.00 28.69	24.34 24.92

A summary of the SVA activity is presented below:

	Units Attributable to SVAs (in thousands)
Outstanding at January 1, 2009	1,903
Granted	1,416
Forfeited or expired	(559)
Outstanding at December 31, 2009	2,760
Granted	1,987
Issued	(365)
Forfeited or expired	(745)
Outstanding at December 31, 2010	3,637
Granted	1,830
Issued	(428)
Forfeited or expired	(740)
Outstanding at December 31, 2011	4,299

The maximum number of shares that could ultimately be issued upon vesting of the SVA units outstanding at December 31, 2011, is 5.6 million. Approximately 1.0 million shares are expected to be issued in 2012. As of December 31, 2011, the total remaining unrecognized compensation cost related to nonvested SVAs amounted to $45.9 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 three years. The fair values of RSU awards granted during the years ended December 31, 2011, 2010, and 2009 were $35.80, $34.78, and $38.12, respectively. The

number of shares ultimately issued for the RSU program remains constant with the exception of forfeitures. Pursuant to this plan, 1.5 million, 1.5 million and 0.5 million shares were granted during the years ended December 31, 2011, 2010, and 2009, respectively, and approximately 0.2 million and 0.2 million shares were issued during the years ended December 31, 2011 and 2010, respectively. Approximately 0.3 million shares are expected to be issued in 2012. As of December 31, 2011, the total remaining unrecognized compensation cost related to nonvested RSUs amounted to $52.0 million, which will be amortized over the weighted-average remaining requisite service period of 21 months.

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 vest three years from the grant date and have a term of 10 years.

Stock option activity during the year ended December 31, 2011 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, 2011	55,507	$ 69.04		
Exercised	(18)	24.33		
Forfeited or expired	(18,933)	74.56		
Outstanding at December 31, 2011	36,556	66.22	1.8	$1.2
Exercisable at December 31, 2011	36,556	66.22	1.8	1.2

All options were vested as of December 31, 2011.

The intrinsic value of options exercised during the years ended December 31, 2011, 2010, and 2009 amounted to $0.2 million, $0.1 million, and $0.3 million, respectively. The total grant date fair value of options vested during the year ended December 31, 2009 amounted to $68.5 million. We received cash of $0.4 million, $0.1 million, and $0.2 million from exercises of stock options during the years ended December 31, 2011, 2010, and 2009, respectively. The recognized related tax benefits for all three years were not material.

Note 10: Other Assets and Other Liabilities

Other receivables include receivables from our collaboration partners, tax receivables, 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), capitalized computer software, receivables from our collaboration partners, the fair value of the interest rate swaps, and prepaid retirement plan outside the U.S. The increase in sundry asset is attributable to the increase in deferred tax assets, the increase in the fair value of the interest rate swaps, the increase in the prepayment of a retirement plan outside the U.S. (Note 14), and the increase relating to the loan made to Amylin in the second quarter of 2011 (Note 4).

Other current liabilities include product litigation, other taxes payable, deferred tax liabilities (Note 13), deferred income and liabilities from our collaboration arrangements, the current portion of our estimated product return liabilities, and a variety of other items. The increase in other current liabilities is primarily attributable to the increase in deferred income relating to the termination of the collaboration agreement with Amylin (Note 4) and, to a lesser extent, an increase in liabilities from our collaboration arrangements, product liabilities, and deferred taxes.

Other noncurrent liabilities include deferred income from our collaboration and out-licensing arrangements, deferred tax liabilities (Note 13), the fair value of contingent consideration from business combinations (Note 3), the long-term portion of our estimated product return liabilities, product litigation, and a variety of other items. The decrease in other noncurrent liabilities was primarily due to the decrease in deferred tax liabilities and, to a lesser extent, the decrease in contingent consideration, and the decrease in deferred income. The decreases were offset by the increase in the long-term portion of the estimated product return liabilities.

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)	Common Stock in Treasury Amount
Balance at January 1, 2009	$ 3,976.6	$ 7,654.9	$ (86.3)	889	$ 99.2
Net income		4,328.8			
Cash dividends declared per share: $1.96		(2,153.3)			
Retirement of treasury shares	(3.3)			(132)	(3.3)
Issuance of stock under employee stock plans-net	(85.0)			125	2.6
Stock-based compensation	368.5				
ESOP transactions	6.9		8.9		
Employee benefit trust contribution	371.9				
Balance at December 31, 2009	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	$ 0.0	853	$ 95.3

As of December 31, 2011, we have purchased $2.58 billion of our announced $3.00 billion share repurchase program. No shares were repurchased during the years ended December 31, 2011, 2010, or 2009.

We have 5 million authorized shares of preferred stock. As of December 31, 2011 and 2010, 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, 2011 and 2010, 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, 2011 and 2010, 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, 2011, 2010, or 2009.

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, repayment of which was guaranteed by us (Note 8). The proceeds were used to purchase shares of our common stock on the open market. As of December 31, 2011, 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.

Note 12: Earnings Per Share

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

	2011	2010	2009
		(Shares in thousands)	
Income available to common shareholders	**$ 4,347.7**	$ 5,069.5	$ 4,328.8
Basic earnings per share			
Weighted-average number of common shares outstanding, including incremental shares	**1,113,923**	1,105,788	1,098,338
Basic earnings per share	**$ 3.90**	$ 4.58	$ 3.94
Diluted earnings per share			
Weighted-average number of common shares outstanding	**1,107,112**	1,099,310	1,094,623
Stock options and other incremental shares	**6,855**	6,503	3,744
Weighted-average number of common shares outstanding diluted	**1,113,967**	1,105,813	1,098,367
Diluted earnings per share	**$ 3.90**	$ 4.58	$ 3.94

Note 13: Income Taxes

Following is the composition of income tax expense:

	2011	2010	2009
Current			
Federal	**$ 671.4**	$ 376.2	$ 45.7
Foreign	**759.5**	513.9	772.2
State	**(22.9)**	23.3	49.2
Total current tax expense	**1,408.0**	913.4	867.1
Deferred			
Federal	**(398.5)**	624.4	82.5
Foreign	**(34.7)**	(55.2)	79.8
State	**27.0**	(26.9)	(0.4)
Total deferred tax expense (benefit)	**(406.2)**	542.3	161.9
Income taxes	**$ 1,001.8**	$ 1,455.7	$ 1,029.0

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

	2011	2010
Deferred tax assets		
Compensation and benefits	**$ 1,286.5**	$ 890.4
Tax credit carryforwards and carrybacks	**695.3**	503.1
Asset purchases	**428.5**	275.1
Tax loss carryforwards and carrybacks	**406.1**	414.0
Intercompany profit in inventories	**277.2**	316.7
Debt	**214.9**	114.6
Sale of intangibles	**207.1**	112.8
Product return reserves	**146.2**	84.0
Contingencies	**94.5**	106.6
Other	**301.3**	363.4
Total gross deferred tax assets	**4,057.6**	3,180.7
Valuation allowances	**(611.9)**	(473.1)
Total deferred tax assets	**3,445.7**	2,707.6
Deferred tax liabilities		
Unremitted earnings	**(940.2)**	(741.8)
Intangibles	**(839.9)**	(954.9)
Inventories	**(489.2)**	(525.6)
Property and equipment	**(451.0)**	(505.2)
Financial instruments	**(196.9)**	(160.9)
Other	**(8.5)**	(19.1)
Total deferred tax liabilities	**(2,925.7)**	(2,907.5)
Deferred tax assets (liabilities) net	**$ 520.0**	$ (199.9)

At December 31, 2011 and 2010, no individually significant items were classified as Other deferred tax assets or liabilities.

The deferred tax asset and related valuation allowance amounts for U.S. and state net operating losses and tax credits shown above have been reduced for differences between financial reporting and tax return filings. At December 31, 2011, based on filed tax returns we had net operating losses and other carryforwards for international and U.S. income tax purposes of $780.8 million: $335.5 million will expire within 5 years; $404.8 million will expire between 5 and 20 years; and $40.5 million of the carryforwards will never expire. The remaining balance of the deferred tax asset for tax loss carryforwards and carrybacks is related to net operating losses for state income tax purposes that are substantially reserved.

Based on filed tax returns, we also have tax credit carryforwards and carrybacks of $1.01 billion available to reduce future income taxes; $514.4 million will be carried back; $53.0 million of the tax credit carryforwards will expire between 10 and 20 years; and $1.3 million of the tax credit carryforwards will never expire. The remaining portion of the tax credit carryforwards is related to federal tax credits of $93.8 million and state tax credits of $349.4 million, both of which are fully reserved.

Domestic and Puerto Rican companies contributed approximately 24 percent, 45 percent, and 39 percent for the years ended December 31, 2011, 2010, and 2009, 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, 2011, we had an aggregate of $20.60 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 $943.0 million, $861.0 million, and $1.14 billion, for the years ended December 31, 2011, 2010, and 2009, 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:

	2011	2010	2009
Income tax at the U.S. federal statutory tax rate	**$ 1,872.3**	$ 2,283.8	$ 1,875.2
Add (deduct)			
International operations, including Puerto Rico	**(796.7)**	(823.3)	(741.1)
U.S. health care reform	**62.9**	85.1	0.0
General business credits	**(80.8)**	(83.2)	(79.4)
IRS audit conclusion	**(85.3)**	0.0	(54.4)
Other	**29.4**	(6.7)	28.7
Income taxes	**$ 1,001.8**	$ 1,455.7	$ 1,029.0

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 2011 benefit on international operations reported in the effective tax rate reconciliation above includes the benefit from 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 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:

	2011	2010	2009
Beginning balance at January 1	**$ 1,619.6**	$ 1,351.2	$ 1,223.2
Additions based on tax positions related to the current year	**89.4**	186.2	179.1
Additions for tax positions of prior years	**390.0**	117.0	170.4
Reductions for tax positions of prior years	**(492.3)**	(30.2)	(128.9)
Lapses of statutes of limitation	**(2.6)**	(7.0)	(3.3)
Settlements	**(326.3)**	(0.1)	(95.0)
Changes related to the impact of foreign currency translation	**(3.0)**	2.5	5.7
Balance at December 31	**$ 1,274.8**	$ 1,619.6	$ 1,351.2

The total amount of unrecognized tax benefits that, if recognized, would affect our effective tax rate was $812.3 million and $1.07 billion at December 31, 2011 and 2010, 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. Because the examination of the remainder of 2008-2009 is still in the early stages, the resolution of all issues in this audit period will likely extend beyond the next 12 months.

During 2009, we settled an IRS administrative appeals matter from the 2001-2004 IRS audit. Considering the status of the 2005-2007 IRS examination at that time and the settlement of the IRS administrative appeals matter from the 2001-2004 audit, our income tax expense was reduced by $54.4 million, and a cash payment of approximately $50 million was paid, after utilization of applicable tax credit carryovers.

We recognize both accrued interest and penalties related to unrecognized tax benefits in income tax expense. During the years ended December 31, 2011, 2010, and 2009, we recognized income tax expense (benefit) of $(47.3) million, $38.3 million, and $(1.9) million, respectively, related to interest and penalties. At December 31, 2011 and 2010, our accruals for the payment of interest and penalties totaled $145.1 million and $221.0 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	
	2011	**2010**	**2011**	**2010**
Change in benefit obligation				
Benefit obligation at beginning of year	**$ 8,115.0**	$ 7,553.9	**$ 2,088.5**	$ 2,032.8
Service cost	**236.3**	219.2	**72.4**	56.5
Interest cost	**447.9**	431.6	**118.0**	121.4
Actuarial loss	**794.7**	342.2	**110.2**	10.0
Benefits paid	**(400.1)**	(387.8)	**(77.9)**	(98.0)
Plan amendments	**10.0**	0.3	**1.1**	(64.2)
Foreign currency exchange rate changes and other adjustments	**(12.6)**	(44.4)	**(3.7)**	30.0
Benefit obligation at end of year	9,191.2	8,115.0	2,308.6	2,088.5
Change in plan assets				
Fair value of plan assets at beginning of year	**6,983.0**	6,008.5	**1,327.7**	1,180.7
Actual return on plan assets	**209.2**	818.3	**16.6**	152.2
Employer contribution	**402.4**	563.5	**72.6**	92.8
Benefits paid	**(400.1)**	(387.8)	**(77.9)**	(98.0)
Foreign currency exchange rate changes and other adjustments	**(8.2)**	(19.5)	**0.0**	0.0
Fair value of plan assets at end of year	**7,186.3**	6,983.0	**1,339.0**	1,327.7
Funded status	**(2,004.9)**	(1,132.0)	**(969.6)**	(760.8)
Unrecognized net actuarial loss	**4,857.5**	3,796.6	**1,367.4**	1,235.3
Unrecognized prior service cost (benefit)	**57.3**	56.1	**(215.1)**	(261.1)
Net amount recognized	**$ 2,909.9**	$ 2,720.7	**$ 182.7**	$ 213.4
Amounts recognized in the consolidated balance sheet consisted of				
Prepaid expenses and other	**$ 160.8**	$ 58.5	**$ 0.0**	$ 0.0
Other current liabilities	**(57.5)**	(54.7)	**(9.3)**	(9.2)
Accrued retirement benefit	**(2,108.2)**	(1,135.8)	**(960.3)**	(751.6)
Accumulated other comprehensive loss before income taxes	**4,914.8**	3,852.7	**1,152.3**	974.2
Net amount recognized	**$ 2,909.9**	$ 2,720.7	**$ 182.7**	$ 213.4

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, 2011.

For the year ended December 31, 2012, we expect to recognize from accumulated other comprehensive loss as components of net periodic benefit cost, $285.3 million of unrecognized net actuarial loss and $3.3 million of unrecognized prior service loss related to our defined benefit pension plans, and $95.7 million of unrecognized net actuarial loss and $35.1 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 2012.

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

	Defined Benefit Pension Plans			Retiree Health Benefit Plans		
(Percents)	**2011**	**2010**	**2009**	**2011**	**2010**	**2009**
Weighted-average assumptions as of December 31						
Discount rate for benefit obligation	**5.0**	5.6	5.9	**5.1**	5.8	6.0

Discount rate for net benefit costs	**5.6**	5.9	6.7	**5.8**	6.0	6.9
Rate of compensation increase for benefit obligation	**3.7**	3.7	3.7			
Rate of compensation increase for net benefit costs	**3.7**	3.7	4.1			
Expected return on plan assets for net benefit costs	**8.5**	8.8	8.8	**8.8**	9.0	9.0

In evaluating the expected return on plan assets annually we consider numerous factors, including our historical assumptions compared with actual results, an analysis of current and future market conditions, our current and expected asset allocations, historical returns, and the views of leading financial advisers and economists for future asset class returns. As noted, historical returns are just one of several factors considered and are not the starting point for determining the expected return. Health-care-cost trend rates are assumed to increase at an annual rate of 7.4 percent for the year ended December 31, 2012, 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:

	2012	2013	2014	2015	2016	2017-2021
Defined benefit pension plans	$ 416.1	$ 424.2	$ 437.2	$ 449.9	$ 464.2	$ 2,609.2
Retiree health benefit plans-gross	$ 118.7	$ 119.1	$ 123.6	$ 127.3	$ 135.2	$ 790.8
Medicare rebates	(11.7)	(9.9)	(11.0)	(12.4)	(13.5)	(91.7)
Retiree health benefit plans-net	$ 107.0	$ 109.2	$ 112.6	$ 114.9	$ 121.7	$ 699.1

The total accumulated benefit obligation for our defined benefit pension plans was $8.20 billion and $7.23 billion at December 31, 2011 and 2010, 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 $8.12 billion and $5.96 billion, respectively, as of December 31, 2011, and $7.12 billion and $5.93 billion, respectively, as of December 31, 2010. 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 $7.03 billion and $5.75 billion, respectively, as of December 31, 2011, and $1.10 billion and $136.3 million, respectively, as of December 31, 2010.

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

	Defined Benefit Pension Plans			Retiree Health Benefit Plans		
	2011	2010	2009	2011	2010	2009
Components of net periodic benefit cost						
Service cost	**$ 236.3**	$ 219.2	$ 242.1	**$ 72.4**	$ 56.5	$ 53.7
Interest cost	**447.9**	431.6	417.5	**118.0**	121.4	119.6
Expected return on plan assets	**(685.9)**	(638.2)	(584.9)	**(129.4)**	(122.6)	(117.9)
Amortization of prior service cost (benefit)	**8.6**	8.8	8.0	**(42.9)**	(37.2)	(36.0)
Recognized actuarial loss	**200.4**	163.0	84.5	**88.7**	85.0	71.8
Net periodic benefit cost	**$ 207.3**	$ 184.4	$ 167.2	**$ 106.8**	$ 103.1	$ 91.2

If the health-care-cost trend rates were to be increased by one percentage point each future year, the December 31, 2011, accumulated postretirement benefit obligation would increase by $209.4 million and the aggregate of the service cost and interest cost components of the 2011 annual expense would increase by $15.1 million. A one percentage point decrease in these rates would decrease the December 31, 2011, accumulated postretirement benefit obligation by $187.1 million and the aggregate of the 2011 service cost and interest cost by $12.3 million.

The following represents the amounts recognized in other comprehensive income (loss) for the year ended December 31, 2011:

	Defined Benefit Pension Plans	Retiree Health Benefit Plans
Actuarial loss arising during period	$ 1,266.0	$ 221.3
Plan amendments during period	10.0	1.1
Amortization of prior service cost (benefit) included in net income	(8.6)	42.9
Amortization of net actuarial loss included in net income	(200.4)	(88.7)
Foreign currency exchange rate changes	(4.9)	1.5
Total other comprehensive loss during period	$ 1,062.1	$ 178.1

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 $117.6 million, $119.8 million, and

$127.6 million for the years ended December 31, 2011, 2010, and 2009, 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, 2011, 2010, and 2009 were not significant.

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 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 strategy for the U.S. and Puerto Rico currently comprises approximately 81 percent growth investments and 19 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.

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, 2011 by asset category are as follows:

		Fair Value Measurements Using		
		Quoted Prices in Active Markets for Identical Assets	Significant Observable Inputs	Significant Unobservable Inputs
Asset Class	**Total**	**(Level 1)**	**(Level 2)**	**(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)	0.0	0.0	(18.1)
Purchases	217.7	159.1	11.5	388.3
Sales	(25.2)	0.0	(3.9)	(29.1)
Settlements	(159.8)	(126.2)	0.0	(286.0)
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)	0.0		(1.8)
Purchases	18.2	14.4		32.6
Sales	(2.0)	0.0		(2.0)
Settlements	(16.2)	(12.3)		(28.5)
Ending balance at December 31, 2011	$ 105.3	$ 79.9		$ 185.2

The fair values of our defined benefit pension plan and retiree health plan assets as of December 31, 2010 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.	$ 589.4	$421.4	$168.0	$
International	1,868.3	907.1	961.2	
Fixed income				
Developed markets	791.6	77.6	714.0	
Emerging markets	336.2		336.2	
Private alternative investments				
Hedge funds	2,020.3		778.4	1,241.9
Equity-like funds	812.9	10.0		802.9
Real estate	126.5			126.5
Other	437.8	195.9	241.9	
Total	$6,983.0	$1,612.0	$3,199.7	$2,171.3
Retiree Health Benefit Plans				
Public equity securities				
U.S.	$ 56.0	$ 39.7	$ 16.3	$
International	131.6	67.8	63.8	
Fixed income				
Developed markets	50.5		50.5	
Emerging markets	33.9		33.9	
Private alternative investments				
Hedge funds	185.2		78.6	106.6
Equity-like funds	74.5			74.5
Cash value of trust owned insurance contract	761.7		761.7	

Other	34.3	12.6	21.7	
Total	$1,327.7	$ 120.1	$ 1,026.5	$ 181.1

The activity in the Level 3 investments during the year ended December 31, 2010 was as follows:

	Hedge Funds	Equity-like Funds	Inter-national Equity	Fixed Income-Developed Markets	Real Estate	Total
Defined Benefit Pension Plans						
Beginning balance at January 1, 2010	$ 1,381.5	$ 658.2	$ 3.9	$ 3.5	$ 85.4	$ 2,132.5
Actual return on plan assets, including changes in foreign exchange rates:						
Relating to assets still held at the reporting date	106.1	66.2	0.1	0.1	4.2	176.7
Relating to assets sold during the period	0.0	11.3	(0.4)	(0.1)	(5.3)	5.5
Purchases	215.8	131.4	0.1	0.0	41.4	388.7
Sales	(21.4)	0.0	(3.1)	(3.4)	0.0	(27.9)
Settlements	(18.1)	(64.2)	0.0	(0.1)	0.0	(82.4)
Transfers in and/or out of Level 3	(422.0)	0.0	(0.6)	0.0	0.8	(421.8)
Ending balance at December 31, 2010	$ 1,241.9	$ 802.9	$ 0.0	$ 0.0	$ 126.5	$ 2,171.3
Retiree Health Benefit Plans						
Beginning balance at January 1, 2010	$ 140.9	$ 63.6	$ 0.4	$ 0.4	$ 0.0	$ 205.3
Actual return on plan assets, including changes in foreign exchange rates:						
Relating to assets still held at the reporting date	5.4	4.6	0.0	0.0	0.0	10.0
Relating to assets sold during the period	0.0	0.6	0.0	0.0	0.0	0.6
Purchases	5.3	11.9	0.0	0.0	0.0	17.2
Sales	(0.6)	0.0	(0.4)	(0.4)	0.0	(1.4)
Settlements	(1.8)	(6.2)	0.0	0.0	0.0	(8.0)
Transfers in and/or out of Level 3	(42.6)	0.0	0.0	0.0	0.0	(42.6)
Ending balance at December 31, 2010	$ 106.6	$ 74.5	$ 0.0	$ 0.0	$ 0.0	$ 181.1

Substantially all of the Level 3 transfers are associated with assets that can be redeemed at their NAV per share within a reasonable period of time. This reclassification is in accordance with current accounting guidance.

For the year ended December 31, 2012, we expect to contribute approximately $75 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, 2012 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 brought pursuant to procedures set out in the Hatch-Waxman Act (the Drug Price Competition and Patent Term Restoration Act of 1984):

Alimta: 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, concomitant nutritional

supplement use 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. The generic manufacturers have appealed this decision. 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 concomitant nutritional supplement use patent is valid and infringed. No trial date has yet been set. In January 2012, we filed a similar lawsuit against Accord Healthcare Inc.

We believe the Hatch-Waxman challenges to Alimta 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.

Strattera: Actavis Elizabeth LLC (Actavis), Apotex Inc. (Apotex), Aurobindo Pharma Ltd. (Aurobindo), Mylan Pharmaceuticals Inc. (Mylan), Sandoz Inc. (Sandoz), Sun Pharmaceutical Industries Limited (Sun Ltd.), and Teva Pharmaceuticals USA, Inc. (Teva USA) each submitted an ANDA seeking permission to market generic versions of Strattera prior to the expiration of our relevant U.S. patent and data-based pediatric exclusivity period (expiring in 2017), and alleging that this patent is invalid. In 2007, we brought a lawsuit against Actavis, Apotex, Aurobindo, Mylan, Sandoz, Sun Ltd., and Teva USA in the U.S. District Court for the District of New Jersey. In August 2010, the court ruled that our patent was invalid; however, in July 2011, the Court of Appeals for the Federal Circuit overturned that decision, upholding the patent. The Federal Circuit Court of Appeals denied the generic manufacturers petition for rehearing en banc in October 2011, and the deadline for any further appeal has passed. Zydus Pharmaceuticals (Zydus) filed an action in the New Jersey district court in October 2010 seeking a declaratory judgment that it has the right to launch a generic atomoxetine product, based on the district court ruling. We believe that Zydus is subject to the injunction issued by the court of appeals in the Actavis case.

Zyprexa Litigation

We are a defendant in approximately 40 Zyprexa product liability lawsuits in the U.S. covering approximately 120 plaintiffs. The lawsuits allege a variety of injuries from the use of Zyprexa, with the majority alleging that the product caused or contributed to diabetes or high blood-glucose levels. 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. Approximately 25 of the lawsuits, covering about 30 plaintiffs, are part of a Multi-District Litigation (MDL) proceeding before The Honorable Jack Weinstein in the Federal District Court for the Eastern District of New York (EDNY) (MDL No. 1596). In October 2011, a jury trial in a California state court was decided in our favor. We are prepared to continue our vigorous defense of Zyprexa in all these lawsuits and claims.

We were served with lawsuits filed by 13 states alleging that Zyprexa caused or contributed to diabetes or high blood-glucose levels, and that we improperly promoted the drug. We settled the Zyprexa-related claims of all of these states, incurring pretax charges of $230.0 million in 2009 and $15.0 million in 2008.

In 2005 and 2006, four lawsuits were filed in the EDNY purporting to be nationwide class actions on behalf of all consumers and third-party payors, excluding governmental entities, which made or will make payments for their members or insured patients being prescribed Zyprexa. These actions were consolidated into a single lawsuit, brought under certain state consumer-protection statutes, the federal civil Racketeer Influenced and Corrupt Organizations Act, and common law theories, seeking a refund of the cost of Zyprexa, treble damages, punitive damages, and attorneys fees. As with the product liability suits, these lawsuits allege that we inadequately tested for and warned about side effects of Zyprexa and improperly promoted the drug. In September 2008, Judge Weinstein certified a class consisting of third-party payors, excluding governmental entities and individual consumers, and denied our motion for summary judgment. In September 2010, both decisions were reversed by the Second Circuit Court of Appeals, which found that the case cannot proceed as a class action and entered a judgment in our favor on plaintiffs overpricing claim. The U.S. Supreme Court denied plaintiffs petition for certiorari. All remaining claims at issue in these cases have now been resolved.

Byetta Litigation

We have been named as a defendant in approximately 120 lawsuits involving approximately 480 plaintiffs, primarily seeking to recover damages for pancreatitis experienced by patients prescribed Byetta. We are aware of approximately 530 additional claimants who have not yet filed suit. Approximately 100 of these lawsuits are filed in California and coordinated in a Los Angeles Superior Court.

Other Product Liability Litigation

We have been named as a defendant in numerous other product liability lawsuits involving primarily diethylstilbestrol. These claims are covered by insurance, subject to deductibles and coverage limits.

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 for other products 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 future product liability losses. In addition, 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:

	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, 2011	$ 510.7	$ 128.9	$(3,175.8)	$(133.9)	$(2,670.1)
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)

The amounts above are net of income taxes. The income taxes associated with the unrecognized net actuarial losses and prior service costs on our defined benefit pension and retiree health benefit plans (Note 14) were a benefit of $383.8 million for the year ended December 31, 2011. The income taxes associated with the net unrealized losses on securities were a benefit of $64.4 million for the year ended December 31, 2011. The income taxes related to the other components of comprehensive income (loss) were not significant, as income taxes were not provided for foreign currency translation.

The unrealized gains (losses) on securities is net of reclassification adjustments of net gains (losses) of $54.7 million, $27.6 million, and $19.0 million, net of tax, for the years ended December 31, 2011, 2010, and 2009, respectively, for net realized gains (losses) on sales of securities included in net income. The effective portion of cash flow hedges is net of reclassification adjustments of $5.8 million, $5.8 million, and $6.7 million, net of tax, for the years ended December 31, 2011, 2010, and 2009, respectively, for interest expense on interest rate swaps designated as cash flow hedges.

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, Expense:

Other net, expense consisted of the following:

	2011	2010	2009
Interest expense	$ 186.0	$ 185.5	$ 261.3
Interest income	(79.9)	(51.9)	(75.2)
Other (income) expense	72.9	(128.6)	43.4
Other net, expense	$ 179.0	$ 5.0	$ 229.5

Other expense for the year ended December 31, 2011 primarily consists of the partial 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 (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 web site, 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, 2011. 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, 2011. 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
February 24, 2012

Derica W. Rice
Executive Vice President, Global Services and Chief Financial Officer

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, 2011 and 2010, and the related consolidated statements of operations, cash flows, and comprehensive income for each of the three years in the period ended December 31, 2011. 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, 2011 and 2010, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2011, 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, 2011, 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 24, 2012 expressed an unqualified opinion thereon.

Indianapolis, Indiana

February 24, 2012

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, 2011, 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, 2011, based on the COSO criteria**.**

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the 2011 consolidated financial statements of Eli Lilly and Company and subsidiaries and our report dated February 24, 2012 expressed an unqualified opinion thereon.

Indianapolis, Indiana

February 24, 2012

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 Securities and Exchange Commission (SEC) regulations, management of a reporting company, with the participation of the principal executive officer and principal financial officer, must periodically evaluate the company s disclosure controls and procedures, which are defined generally as controls and other procedures 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, 2011, 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, 2011. In addition, Ernst & Young LLP as of December 31, 2011, 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 2011, 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. We are pursuing a multi-year initiative to outsource some accounting transaction-processing activities, migrating to a consistent enterprise financial system across the organization, and moving certain activities to newly-established captive shared services centers. In addition, we are in the process of reducing financial human resources at various locations around the world. None of these initiatives is in response to any identified deficiency or weakness in our internal control over financial reporting. These initiatives are expected to continue to enhance our internal control over financial reporting, but in the short term may increase our risk.

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 5, 2012 (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 of this Form 10-K under 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 web site 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 web site 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 web site 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 7, 2011.

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), Martin S. Feldstein, 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 , Executive Compensation , and Compensation Committee Interlocks and Insider Participation. 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

The following table presents information as of December 31, 2011, about our compensation plans under which shares of Lilly stock have been authorized for issuance.

Plan Category	(a) Number of securities to be issued upon exercise of outstanding options, warrants, and rights	(b) Weighted-average exercise price of outstanding options, warrants, and rights	(c) Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in (a))
Equity compensation plans approved by security holders	35,951,135	$ 66.07	93,041,299
Equity compensation plans not approved by security holders[1]	604,825	74.89	0

Total	36,555,960	66.22	93,041,299

[1] Represents shares in the Lilly GlobalShares Stock Plan, which permitted the company to grant stock options to non-management employees worldwide. The plan was administered by the senior vice president responsible for human resources. The stock options are nonqualified for U.S. tax purposes. The option price cannot be less than the fair market value at the time of grant. The options shall not exceed 11 years in duration and shall be subject to vesting schedules established by the plan administrator. There are provisions for early vesting and early termination of the options in the event of retirement, disability, and death. In the event of stock splits or other recapitalizations, the administrator may adjust the number of shares available for grant, the number of shares subject to outstanding grants, and the exercise price of outstanding grants.

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, 2011, 2010, and 2009

Consolidated Statements of Comprehensive Income Years Ended December 31, 2011, 2010, and 2009

Consolidated Balance Sheets December 31, 2011 and 2010

Consolidated Statements of Cash Flows Years Ended December 31, 2011, 2010, and 2009

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

2	Agreement and Plan of Merger dated October 6, 2008, among Eli Lilly and Company, Alaska Acquisition Corporation and ImClone Systems Incorporated
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	1998 Lilly Stock Plan, as amended[2]
10.2	2002 Lilly Stock Plan, as amended[2]
10.3	Form of two-year Performance Award under the 2002 Lilly Stock Plan[2]
10.4	Form of Shareholder Value Award under the 2002 Lilly Stock Plan[2]
10.5	Form of Restricted Stock Unit under the 2002 Lilly Stock Plan[2]
10.6	The Lilly Deferred Compensation Plan, as amended[2]
10.7	The Lilly Directors Deferral Plan, as amended[2]
10.8	The Eli Lilly and Company Bonus Plan, as amended[2]
10.9	The Eli Lilly and Company Executive Officer Incentive Plan[2]
10.10	2007 Change in Control Severance Pay Plan for Select Employees, as amended effective October 20, 2010[2]
10.11	2007 Change in Control Severance Pay Plan for Select Employees, as amended effective October 18, 2012[2]

10.12	Arrangement regarding retirement benefits for Robert A. Armitage[2]
10.13	Arrangement regarding severance for Dr. Jan Lundberg[2]
10.14	Guilty Plea Agreement in *The United States District Court for the Eastern District of Pennsylvania, United States of America v. Eli Lilly and Company*
10.15	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
10.16	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 24, 2012

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below on February 24, 2012 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/ Arnold C. Hanish ARNOLD C. HANISH	Vice President, Finance and Chief Accounting Officer (principal accounting officer)
/s/ Ralph Alvarez RALPH ALVAREZ	Director
/s/ Katherine Baicker KATHERINE BAICKER	Director
/s/ Sir Winfried Bischoff SIR WINFRIED BISCHOFF	Director
/s/ Michael L. Eskew MICHAEL L. ESKEW	Director
/s/ Martin S. Feldstein, Ph.D. MARTIN S. FELDSTEIN, Ph.D.	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/ 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.

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

Vancocin® is a trademark of ViroPharma Incorporated

Index to Exhibits

The following documents are filed as part of this report:

Exhibit		Location
2	Agreement and Plan of Merger, dated as of October 6, 2008, among Eli Lilly and Company, Alaska Acquisition Corporation and ImClone Systems Incorporated	Incorporated by reference from Exhibit 2.1 to the Company s Report on Form 8-K filed October 10, 2008
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 3 to the Company s Report on Form 8-K filed July 14, 2009
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	1998 Lilly Stock Plan, as amended	Incorporated by reference from Exhibit 10.1 to the Company s Report on Form 10-K for the year ended December 31, 2006
10.2	2002 Lilly Stock Plan, as amended	Incorporated by reference from Exhibit 10.1 to the Company s Report on Form 10-Q for the quarter ended September 30, 2008
10.3	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
10.4	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
10.5	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
10.6	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
10.7	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
10.8	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
10.9	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
10.10	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
10.11	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
10.12	Arrangement regarding retirement benefits for Robert A. Armitage	Incorporated by reference from Exhibit 10.15 to the Company s Report on Form 10-K for the year ended December 31, 2004
10.13	Arrangement regarding severance for Dr. Jan Lundberg	Attached
10.14	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
10.15	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
10.16	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
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