

LILLY ELI & CO  
Form 10-K  
February 22, 2010

**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, 2009**

**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:**

| <b>Title of Each Class</b>      | <b>Name of Each Exchange On Which Registered</b> |
|---------------------------------|--|
| 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 ☐ 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 ☐

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 ☐ 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 ☐ 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

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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 ☒

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 ☒

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 \$35,217,500,000

Number of shares of common stock outstanding as of February 12, 2010: 1,153,145,432

Portions of the Registrant's Proxy Statement to be filed on or about March 8, 2010 have been incorporated by reference into Part III of this report.

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## 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 17 other countries. Our products are sold in approximately 128 countries.

### **Products**

Our products include:

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

*Zyprexa*<sup>®</sup>, for the treatment of schizophrenia, acute mixed or manic episodes associated with bipolar I disorder, and bipolar maintenance

*Zyprexa Relprevv*<sup>™</sup> (*Zypadhera*<sup>™</sup> in the European Union), a long-acting intramuscular injection formulation of Zyprexa

*Cymbalta*<sup>®</sup>, for the treatment of major depressive disorder, diabetic peripheral neuropathic pain, generalized anxiety disorder, and in the United States for the management of fibromyalgia

*Strattera*<sup>®</sup>, for the treatment of attention-deficit hyperactivity disorder in children, adolescents, and in the United States in adults

*Prozac*<sup>®</sup>, for the treatment of major depressive disorder, obsessive-compulsive disorder, bulimia nervosa, and panic disorder

*Symbyax*<sup>®</sup>, for the treatment of bipolar depression and treatment-resistant depression

**Endocrinology products**, including:

*Humalog*<sup>®</sup>, *Humalog Mix 75/25*<sup>™</sup>, and *Humalog Mix 50/50*<sup>™</sup>, for the treatment of diabetes

*Humulin*<sup>®</sup>, for the treatment of diabetes

*Byetta*<sup>®</sup>, for the treatment of type 2 diabetes

*Actos*<sup>®</sup>, for the treatment of type 2 diabetes

*Evista*<sup>®</sup>, 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*<sup>®</sup>, for the treatment of osteoporosis in postmenopausal women and men at high risk for fracture and for glucocorticoid-induced osteoporosis in postmenopausal women and men

*Humatrope*<sup>®</sup>, for the treatment of human growth hormone deficiency and certain pediatric growth conditions

**Oncology products, including:**

*Alimta*<sup>®</sup>, for the first-line treatment, in combination with another agent, of non-small cell lung cancer for patients with non-squamous histology; for the second-line treatment of non-small cell lung cancer; and in combination with another agent, for the treatment of malignant pleural mesothelioma

*Gemzar*<sup>®</sup>, 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

*Erbix*<sup>®</sup>, 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*<sup>®</sup>, for the treatment of erectile dysfunction

*Effient*<sup>®</sup>, 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*<sup>®</sup>, for use as an adjunct to PCI

*Xigris*<sup>®</sup>, for the treatment of adults with severe sepsis at high risk of death

**Animal health products, including:**

*Rumensin*<sup>®</sup>, a cattle feed additive that improves feed efficiency and growth and also controls and prevents coccidiosis

*Tylan*<sup>®</sup>, an antibiotic used to control certain diseases in cattle, swine, and poultry

*Micotil*<sup>®</sup>, *Pulmotil*<sup>®</sup>, and *Pulmotil AC*<sup>®</sup>, antibiotics used to treat respiratory disease in cattle, swine, and poultry, respectively

*Paylean*<sup>®</sup> and *Optaflexx*<sup>®</sup>, leanness and performance enhancers for swine and cattle, respectively

*Posilac*<sup>®</sup>, a protein supplement to improve milk productivity in dairy cows. We acquired the worldwide rights to Posilac from Monsanto Company in August 2008.

*Coban*<sup>®</sup>, *Monteban*<sup>®</sup>, and *Maxiban*<sup>®</sup>, anticoccidial agents for use in poultry

*Apralan*<sup>®</sup>, an antibiotic used to control enteric infections in calves and swine

*Surmax*<sup>®</sup> (sold as *Maxus*<sup>®</sup> in some countries), a performance enhancer for swine and poultry

*Elector*<sup>®</sup>, a parasiticide for use on cattle and premises

Two products for dogs: *Comfortis*<sup>®</sup>, the first FDA-approved, chewable tablet that kills fleas and prevents flea infestations on dogs; and *Reconcile*<sup>®</sup>, for treatment of canine separation anxiety in conjunction with behavior modification training

**Other pharmaceuticals, including:**

*Vancocin*<sup>®</sup> HCl, used primarily to treat staphylococcal infections

*Ceclor*<sup>™</sup>, 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. Our marketing policy is designed to assure that products and relevant medical

information are immediately available to physicians, pharmacies, hospitals, public and private payers, and appropriate health care professionals. Three wholesale distributors in the United States—AmerisourceBergen Corporation, McKesson Corporation, and Cardinal Health, Inc.—each accounted for between 12 percent and 17 percent of our worldwide consolidated net sales in 2009. No other distributor accounted for more than 10 percent of consolidated net sales. We also sell pharmaceutical products directly to the United States government and other manufacturers, but those sales are not material.

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 United States and we maintain web sites with information about all our major products. Divisions of our sales force are assigned to therapeutic areas, such as neuroscience, diabetes, osteoporosis, and oncology. 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.

Large purchasers of pharmaceuticals, such as managed-care groups, government agencies, and long-term care institutions, account for a significant portion of total pharmaceutical purchases in the United States. We maintain special business groups to service wholesalers, 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 these organizations which provide for discounts or rebates on one or more 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 sales. 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**

We market certain of our significant products in collaboration with other pharmaceutical companies:

Under an arrangement that ended in 2009, Cymbalta was co-promoted in the United States by Quintiles Transnational Corp. Cymbalta is co-marketed in Japan by Shionogi & Co. Ltd. and is co-promoted or co-marketed in most other major countries outside the U.S. by Boehringer Ingelheim GmbH.

Evista is marketed in major European markets by Daiichi Sankyo Europe GmbH, a subsidiary of Daiichi Sankyo Co., Ltd. of Japan.

We co-promote Byetta with Amylin Pharmaceuticals, Inc. in the United States and Puerto Rico, and we have exclusive marketing rights in other territories.

Erbix is marketed in North America by Bristol-Myers Squibb. We 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 United States, 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.

### **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 United States. 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 on a worldwide basis with products of animal health care companies as well as pharmaceutical, chemical, and other companies that operate animal health divisions or subsidiaries.

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 volume of sales, or both. Manufacturers of generic pharmaceuticals invest far less in research and development than research-based pharmaceutical companies and therefore can price their products much lower than branded products. Accordingly, when a branded pharmaceutical loses its market exclusivity, it normally faces intense price competition from generic forms of the product. In many countries outside the United States, intellectual property protection is weak or nonexistent and we must compete with generic or counterfeit versions of our products. Increasingly, to obtain favorable reimbursement and formulary positioning with government payers, managed care and pharmacy benefits management organizations, we must demonstrate that our products offer not only medical benefits but also cost advantages as compared with other forms of care.

We believe our long-term competitive position depends upon our success in discovering and developing (either alone or in collaboration with others) 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 discovery, development, manufacturing, marketing, and support operations in a highly competitive environment. There can be no assurance that our research and development efforts will result in commercially successful products or that our products or processes will not become uncompetitive from time to time as a result of products or processes 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 United States and many other countries relating to products, product uses, formulations, and manufacturing processes. 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 from marketing alternative products or formulations that might successfully compete with our patented products. In addition, from time to time, competitors or other third parties 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.

Outside the United States, 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 all patent owners. Because of TRIPs transition provisions, dispute resolution mechanisms, and substantive limitations, it is difficult to assess when and how much, if at all, we will benefit commercially from this protection.

When a product patent expires, the patent holder often loses effective market exclusivity for the product. This can result in a severe and rapid decline in sales of the formerly patented product, particularly in the United States. However, in some cases the innovator company may achieve exclusivity beyond the expiry of the product patent through manufacturing trade secrets, later-expiring patents on methods of use or formulations, or data-based exclusivity that may be available under pharmaceutical regulatory laws.

Some of our current products, including Erbitux, Forteo, ReoPro, and Xigris, and many of the potential products in our research pipeline, are biological products ( biologics ). Currently, generic versions of biologics cannot be approved under U.S. law. Competitors seeking approval of biologics must file their own safety and efficacy data, and address the challenges of biologics manufacturing, which typically involves more complex and costly processes than those of traditional pharmaceutical operations. However, certain health care reform bills recently debated in Congress included provisions that would create a regulatory pathway to allow generic biologics. Under these proposals, the innovator would receive data-based exclusivity for a period of years following regulatory approval for marketing. Even in the absence of new legislation, the U.S. Food and Drug Administration (FDA) is taking steps toward allowing generic versions of certain biologics.

### **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, together with expected expiration, for our major marketed products is as follows:

*Alimta* is protected by a compound patent (2016).

*Byetta* is protected by a patent covering its use in treating type 2 diabetes (2017).

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

*Cymbalta* is protected by a compound patent (2013).

*Effient* is protected by a compound patent (2017).

*Evista* is protected by patents on the treatment and prevention of osteoporosis (2012 and 2014), and its dosage form (2017)<sup>1</sup>. *Evista* for use in breast cancer risk reduction is protected by orphan drug exclusivity (2014).

*Gemzar* is protected by a compound patent (November 2010) and a patent covering its antineoplastic use (2013)<sup>1</sup>.

*Humalog* is protected by a compound patent (2013).

*Strattera* is protected by a patent covering its use in treating attention deficit-hyperactivity disorder (2016).

*Zyprexa* is protected by a compound patent (October 2011).

<sup>1</sup> The Evista dosage form patent and Gemzar use patent have been held invalid by federal district courts, and we have appealed those decisions. For more information, see Item 7, Management's Discussion and Analysis Legal and Regulatory Matters.

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 important 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 United States, 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 of a Paragraph IV certification may be entitled to a 180-day period of market exclusivity over all other generic manufacturers.

In recent years, generic manufacturers have used Paragraph IV certifications extensively to challenge patents on a wide array of innovative pharmaceuticals, and we expect this trend to continue. 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, Cymbalta, Evista, Gemzar, and Strattera. 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 United States, and we expect this trend to continue. For more information on significant patent challenges outside the United States, see Item 7, Management's Discussion and Analysis Legal and Regulatory Matters.

## **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 scientific and technical effort, time, and expense and significant 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. In 2007, Congress passed the Food and Drug Administration Amendments Act (FDAAA), which imposes additional requirements for drug development and commercialization and provides the FDA with further authorities and resources, particularly in the area of drug safety.

The FDA extensively regulates all aspects of manufacturing quality under its current Good Manufacturing Practices (cGMP) regulations. In recent years, we have made, and we continue to make, substantial investments of capital and operating expenses to implement comprehensive, company-wide improvements in our manufacturing, product and process development, and quality 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 United States, 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, and Item 7, Management's Discussion and Analysis Legal and Regulatory Matters, for information about currently pending and recently resolved marketing and promotional practices investigations involving Lilly, including 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 payments to 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 have increased their FCPA enforcement activities with respect to pharmaceutical companies. See Item 3, Legal Proceedings, for information about a currently pending investigation involving our operations in several countries.

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 federal health care programs. It is possible that an adverse outcome in pending or future actions could have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

**Regulations Affecting Pharmaceutical Pricing and Reimbursement**

In the United States, we are required to provide rebates to state governments on their purchases of certain of our products under state Medicaid programs. 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.

In the U.S., the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA) provides a prescription drug benefit for seniors under the Medicare program, known as Medicare Part D. Pricing to manufacturers for drugs covered by the program is currently established through competitive negotiations

between the manufacturers and private payers. In addition, comprehensive health care reform was the subject of recent intense debate in Congress, and we expect the health care reform debate to continue. Although it is difficult to predict the direction of the debate, the ultimate outcome could have a material adverse impact on our business. See Item 7,

Management's Discussion and Analysis Executive Overview Legal, Regulatory, and Other Matters, for more discussion of MMA and 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.

We cannot predict the extent to which our business may be affected by these or other potential future legislative or regulatory developments. However, we expect that pressures on pharmaceutical pricing will become more severe.

### **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 2009, we employed approximately 7,600 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 \$3.49 billion in 2007, \$3.84 billion in 2008, and \$4.33 billion in 2009.

Our pharmaceutical research and development focuses on four therapeutic categories: central nervous system and related diseases; endocrine diseases, including diabetes, obesity, and musculoskeletal disorders; cancer; and cardiovascular diseases. However, we remain opportunistic, selectively pursuing promising leads in other therapeutic areas. We are actively engaged in a strong biotechnology research program, including therapeutic proteins, antibodies, and antisense oligonucleotides as well as genomics (the development of therapeutics through identification of disease-causing genes and their cellular function), biomarkers, and targeted therapeutics. In addition to discovering and developing new chemical entities, we seek to expand the value of existing products through new uses, formulations and therapeutic approaches that provide additional value to patients. We also conduct research in animal health, including animal nutrition and physiology, control of parasites, and veterinary medicine (both food and companion animal).

To supplement our internal efforts, we collaborate with others, including educational institutions and research-based pharmaceutical and biotechnology companies, and we contract with others for the performance of research in their facilities. 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 chemical compounds discovered by researchers proves to be both medically effective and safe enough to become 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. Even after approval and launch of a product, we expend considerable resources on post-marketing surveillance and clinical studies. We believe our investments in research, both internally and in

collaboration with others, have been rewarded by the number of new compounds and new indications for existing compounds that we have in all stages of development. At present we have over 60 drug candidates across all stages of human testing. Among our new investigational compounds in the later stages of human testing are potential therapies for diabetes, cancers, and Alzheimer's disease. We are studying many other drug candidates in the earlier stages of development, including compounds targeting cancers, diabetes, schizophrenia, obesity, depression, sleep disorders, pain, alcohol dependence, musculoskeletal disorders, atherosclerosis, and autoimmune disorders including rheumatoid arthritis. We are also developing new uses, formulations, or delivery methods for many of these compounds as well as our currently marketed products, such as Alimta, Byetta, Cialis, Cymbalta, Effient, Erbitux, Forteo, Gemzar, 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 addition, Byetta is manufactured by third-party suppliers to Amylin. 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 five sites in the United States as well as locations in Ireland, Puerto Rico, and the United Kingdom. Finishing operations, including labeling and packaging, take place at a number of sites throughout the world. Effective in January 2010, we sold one of our U.S. sites, Tippecanoe Laboratories 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, and distribution. We have implemented quality-assurance procedures 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 19, 2010, 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. | 56  | Chairman (since January 2009), President (since October 2005), Chief Executive Officer (since April 2008) and a Director (since October 2005) |

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|                       |    |   |
|-----------------------|----|---|
| Robert A. Armitage    | 61 | Senior Vice President and General Counsel (since January 2003)                    |
| Bryce D. Carmine      | 58 | Executive Vice President and President, Lilly Bio-Medicines (since November 2009) |
| Enrique A. Conterno   | 43 | Senior Vice President and President, Lilly Diabetes (since November 2009)         |
| Frank M. Deane, Ph.D. | 60 | President, Manufacturing Operations (since June 2007)                             |

| Name                   | Age | Offices and Business Experience   |
|------------------------|-----|---|
| John H. Johnson        | 52  | Senior Vice President and President, Lilly Oncology (since November 2009). Mr. Johnson was chief executive officer and a director of ImClone Systems Inc. from 2007 until its acquisition by Lilly in November 2008. From 2002 to 2007 he served in various executive positions at Johnson & Johnson, including Group Chairman of that company's worldwide biopharmaceuticals unit from 2005 to 2007. He first joined Johnson & Johnson in 1988. In 2000, Mr. Johnson left J&J to serve as chief executive officer of Parkstone Medical Information Systems, a start-up company that developed a hand-held device for doctors to write prescriptions. That company filed for bankruptcy protection in 2001. |
| Jan M. Lundberg, Ph.D. | 56  | Executive Vice President, Science and Technology and President, Lilly Research Laboratories (since January 2010). From 2002 until he joined Lilly in January 2010, Dr. Lundberg was executive vice president and head of discovery research at AstraZeneca.   |
| Susan Mahony, Ph.D.    | 45  | Senior Vice President, Human Resources (since May 2009)   |
| Anne Nobles            | 53  | Senior Vice President, Enterprise Risk Management (since April 2009) and Chief Ethics and Compliance Officer (since June 2007)  |
| Steven M. Paul, M.D.   | 59  | Executive Vice President, Science and Technology and President, Lilly Research Laboratories (since July 2003; retiring February 28, 2010)   |
| Barton R. Peterson     | 51  | 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         | 45  | Executive Vice President, Global Services (since January 2010) and Chief Financial Officer (since May 2006)   |
| Jeffrey N. Simmons     | 42  | Senior Vice President and President, Elanco Animal Health (since January 2008)  |
| Jacques Tapiero        | 51  | Senior Vice President and President, Emerging Markets (since January 2010)  |

### Employees

At the end of 2009, we employed approximately 40,360 people, including approximately 20,300 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 net sales 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 sales 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 Securities and Exchange Commission (SEC) as soon as reasonably practicable after we electronically file them with, or furnish them to, the SEC. These include our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements, registration statements, and any amendments to those documents. The company 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, and 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, 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 recent years, FDA review times have increased substantially and fewer new drugs are being approved. 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 sales 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.

*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.* Eight significant products, which together comprise 74 percent of our worldwide revenue, will lose their

most significant remaining U.S. patent protection, as well as their intellectual property-based exclusivity in most countries outside the U.S., in the next several years:

| <b>Product</b> | <b>Worldwide Revenues<br/>(2009)</b> | <b>Percent of Total<br/>2009 Revenues</b> | <b>Relevant U.S. Patent Protection</b>      |
|----------------|--------------------------------------|---|---|
| Zyprexa        | \$4.92 billion                       | 23  | 2011  |
| Cymbalta       | \$3.07 billion                       | 14  | 2013  |
| Humalog        | \$1.96 billion                       | 9   | 2013  |
| Alimta         | \$1.71 billion                       | 8   | 2016  |
| Cialis         | \$1.56 billion                       | 7   | 2017  |
| Gemzar         | \$1.36 billion                       | 6   | 2010 (compound); 2013 (use) <sup>1</sup>    |
| Evista         | \$1.03 billion                       | 5   | 2014 (use); 2017 (dosage form) <sup>1</sup> |
| Strattera      | \$609.4 million                      | 3   | 2016  |

<sup>1</sup>The Gemzar use patent and Evista dosage form patent have been held invalid by federal district courts, and we have appealed those decisions. For more information, see Item 7, Management's Discussion and Analysis Legal and Regulatory Matters.

Loss of exclusivity typically results in a rapid and severe decline in sales. See Item 1, Business Patents, Trademarks, and Other Intellectual Property Protection, for more details. Additionally, if these or other significant products were to become subject to a problem such as an early loss of patent protection as a result of litigation, unexpected side effects, regulatory proceedings, material product liability litigation, publicity affecting doctor or patient confidence, or pressure from competitive products, the adverse impact on our revenues, cash flows, and earnings could be significant.

*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 Protection, for more details. We are increasingly facing 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 Protection, 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 sales and profitability. In many countries outside the United States, government agencies strictly control, directly or indirectly, the prices at which our products are sold. In the United States, 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. Many federal and state legislative proposals, including the comprehensive health care reform bills that were the subject of recent debate in Congress, 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 United States to become more severe. See Item I, Business Regulations Affecting Pharmaceutical Pricing and Reimbursement, 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 sales, 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 and private payers and consumers. These claims have resulted in substantial expense and other significant consequences to us. It is possible other products could become subject to investigation and that the outcome of these matters could include criminal charges and fines, penalties, or other monetary or nonmonetary remedies. In particular, See Item 7, Management's Discussion and Analysis Legal and Regulatory Matters, for the discussions of the U.S. sales and marketing practices investigations. 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 Zyprexa, diethylstilbestrol ( DES ), thimerosal, and Byetta, and because of the nature of pharmaceutical products, it is possible that we could become subject to large numbers of product liability claims for 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 sales. See Item 1, Business Raw Materials and Product Supply, for more details.

*A prolonged economic downturn 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. In addition, a prolonged economic downturn could 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 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. In its budget submission to Congress in February 2010, the Obama administration proposed changes to the manner in which the U.S. would tax the international income of U.S.-based

companies. While it is uncertain how the U.S. Congress may address this issue, reform of U.S. taxation, including taxation of international income, continues to be a topic of discussion for the U.S. Congress. 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, 2009, we owned 12 production and distribution sites in the United States and Puerto Rico. Together with the corporate administrative offices, these facilities contain an aggregate of approximately 14.1 million square feet of floor area dedicated to production, distribution, and administration. Major production sites include Indianapolis and Clinton, Indiana; Carolina, Puerto Rico; Branchburg, New Jersey; and Augusta, Georgia.

We own production and distribution sites in 12 countries outside the United States and Puerto Rico, containing an aggregate of approximately 3.6 million square feet of floor area. Major production sites include facilities in France, Ireland, Spain, Brazil, Italy, Mexico, and the United Kingdom.

Our research and development facilities in the United States consist of approximately 3.7 million square feet and are located primarily in Indianapolis, with smaller sites in San Diego and New York City. Our major research and development facilities abroad are located in United Kingdom, Canada, Singapore, and Spain, and contain an aggregate of approximately 350,000 square feet.

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 below or 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, Cymbalta, Evista, Gemzar, Strattera, and Xigris

The patent litigation outside the U.S. involving Zyprexa

The various federal and state investigations relating to our sales, marketing, and promotional practices

The Zyprexa product liability and related litigation, including claims brought on behalf of state Medicaid agencies and private healthcare payers

That information is incorporated into this Item by reference.

**Other Patent Litigation**

*Cialis*: In July 2005, Vanderbilt University filed a lawsuit in the United States District Court in Delaware against ICOS Corporation seeking to add three of its scientists as co-inventors on the *Cialis* compound and method-of-use

patents. In January 2009, the district court judge ruled in our favor, declining to add any of these scientists as an inventor on either patent. The plaintiff appealed this ruling to the Court of Appeals for the Federal Circuit, which heard oral arguments in November 2009. We await the court's decision. We believe these claims are without legal merit and expect to prevail in the appeal; however, it is not possible to determine the outcome. An unfavorable final outcome could have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

In October 2002, Pfizer Inc. was issued a method-of-use patent in the United States and commenced a lawsuit in the United States District Court in Delaware against us, Lilly ICOS LLC, and ICOS Corporation (both later acquired by Lilly) alleging that the marketing of Cialis for erectile dysfunction infringed this patent. This litigation has been stayed pending the outcome of a reexamination of the patent by the U.S. Patent and Trademark Office. The Office has made a final rejection of the relevant patent claims which Pfizer has appealed to the Board of Patent Appeals and Interferences. In February 2010, the Board affirmed the Office's rejection of these claims. Pfizer has the right to appeal this decision. We believe Pfizer's claims are without merit and expect to prevail. However, it is not possible to determine the outcome of this litigation.

### **Other Product Liability Litigation**

We are currently a defendant in a variety of product liability lawsuits in the United States involving primarily Zyprexa, thimerosal, Byetta, and DES.

We have been named as a defendant in approximately 200 actions in the U.S., involving approximately 270 claimants, brought in various state courts and federal district courts on behalf of children with autism or other neurological disorders who received childhood vaccines (manufactured by other companies) that contained thimerosal, a generic preservative used in certain vaccines in the U.S. beginning in the 1930s. We purchased patents and conducted research pertaining to thimerosal in the 1920s. We have been named in the suits even though we discontinued manufacturing the raw material in 1974 and discontinued selling it in the United States to vaccine manufacturers in 1992. The lawsuits typically name the vaccine manufacturers as well as Lilly and other distributors of thimerosal, and allege that the children's exposure to thimerosal-containing vaccines caused their autism or other neurological disorders. We strongly deny any liability in these cases. There is no credible scientific evidence establishing a causal relationship between thimerosal-containing vaccines and autism or other neurological disorders. In addition, we believe the majority of the cases should not be prosecuted in the courts in which they have been brought because the underlying claims are subject to the National Childhood Vaccine Injury Act of 1986. Implemented in 1988, the Act established a mandatory, federally administered no-fault claims process for individuals who allege that they were harmed by the administration of childhood vaccines. Under the Act, claims must first be brought before the U.S. Court of Claims for an award determination under the compensation guidelines established pursuant to the Act. Claimants who are unsatisfied with their awards under the Act may reject the award and seek traditional judicial remedies.

We have been named a defendant in approximately 55 Byetta product liability lawsuits involving approximately 280 plaintiffs, primarily seeking to recover damages for pancreatitis experienced by patients prescribed Byetta. We are aware of approximately 40 additional claimants who have not yet filed suit. The majority of the cases are filed in California and coordinated in a Los Angeles Superior Court. In June 2009, a lawsuit was filed in Louisiana State Court (Ralph Jackson v. Eli Lilly and Company, et al.) seeking to assert similar product liability claims on behalf of Louisiana residents who were prescribed Byetta; however, the plaintiff dropped the class action allegations in a recently-filed amended complaint. We believe these claims are without merit and are prepared to defend against them vigorously.

In approximately 25 U.S. lawsuits against us involving approximately 50 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. 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. We believe these claims are without merit and are prepared to defend against them vigorously.

### **Other Marketing Practices Investigations**

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 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 expanded their investigation and 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 a subpoena related to activities in these countries. We are

cooperating with the SEC and the DOJ in this investigation.

### **Shareholder Derivative Litigation**

In 2007, the company received two demands from shareholders that the board of directors cause the company to take legal action against current and former directors and others for allegedly causing damage to the company through improper marketing of Evista, Prozac, and Zyprexa. In accordance with procedures established under the Indiana Business Corporation Law (Ind. Code § 23-1-32), the board has appointed a committee of independent persons to consider the demands and determine what action, if any, the company should take in response. Since January 2008, we have been served with seven shareholder derivative lawsuits: *Lambrecht, et al. v. Taurel, et al.*, filed January 17, 2008, in the United States District Court for the Southern District of Indiana; *Staehr, et al. v. Eli Lilly and Company, et al.*, filed March 27, 2008, in Marion County Superior Court in Indianapolis, Indiana; *Waldman, et al., v. Eli Lilly and Company, et al.*, filed February 11, 2008, in the United States District Court for the Eastern District of New York; *Solomon v. Eli Lilly and Company, et al.*, filed March 27, 2008, in Marion County Superior Court in

Indianapolis, Indiana; *Robbins v. Taurel, et al.*, filed April 9, 2008, in the United States District Court for the Eastern District of New York; *City of Taylor General Employees Retirement System v. Taurel, et al.*, filed April 15, 2008, in the United States District Court for the Eastern District of New York; and *Zemprelli v. Taurel, et al.*, filed June 24, 2008, in the United States District Court for the Southern District of Indiana. Two of these lawsuits were filed by the shareholders who served the demands described above. All seven lawsuits are nominally filed on behalf of the company, against various current and former directors and officers and allege that the named officers and directors harmed the company through the improper marketing of Zyprexa, and in certain suits, Evista and Prozac. The Zemprelli suit also claims that certain defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934. We believe these lawsuits are without merit and are prepared to defend against them vigorously.

### **Employee Litigation**

In April 2006, three former employees and one current employee filed a complaint against the company in the U.S. District Court for the Southern District of Indiana (*Welch, et al. v. Eli Lilly and Company*, filed April 20, 2006) alleging racial discrimination. Plaintiffs have since amended their complaint twice, and the lawsuit currently involves 145 individual plaintiffs as well as the national and local chapters of the National Association for the Advancement of Colored People (NAACP). Although the case was originally filed as a putative class action, in September 2009, plaintiffs withdrew their request for class certification. We believe these claims are without merit and are prepared to defend against them vigorously.

We have also 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 identical lawsuits. The case was transferred to the U.S. District Court for the Southern District of Indiana in August 2007. In February 2008, the Indianapolis court conditionally certified a nationwide opt-in collective action under the Fair Labor Standards Act of all current and former employees who served as a Lilly pharmaceutical sales representative at any time from November 2003 to the present. As of the close of the opt-in period, fewer than 400 of the over 7,500 potential plaintiffs elected to participate in the lawsuit. 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 have filed a motion for reconsideration of the summary judgment decision and have also opposed decertification, and all other matters have been stayed pending a ruling on these issues. If summary judgment is not reconsidered, we expect plaintiffs will appeal the ruling to the 7th Circuit Court of Appeals. We believe this lawsuit is without merit and are prepared to defend against it vigorously.

In September 2009, one of the opt-in plaintiffs in *Schaefer-LaRose, et al. v. Eli Lilly and Company* filed an action in the Superior Court for Alameda County, California, alleging on behalf of a putative class that the company violated California's Business and Professions Code by failing to pay sales representatives overtime and by not providing them with rest and meal breaks under California law. After removing the lawsuit to the federal district court in the Northern District of California, the parties agreed, and the Court ordered, that the lawsuit would be stayed pending a decision from the 9th Circuit in one of the other several lawsuits addressing the exempt status of pharmaceutical sales representatives. We believe the 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 have also been named, along with several other companies, in a lawsuit filed by certain of these individuals in U.S. District Court for the Southern District of Indiana on April 21, 2009, alleging possible harm caused by exposure to pesticides related to our former agricultural chemical manufacturing facility in Cosmopolis,

Brazil. We believe these lawsuits are without merit and are prepared to defend against them vigorously.

**Other Matters**

In October 2005, the U.S. Attorney's office for the Eastern District of Pennsylvania advised that it is conducting an inquiry regarding certain rebate agreements we entered into with a pharmacy benefit manager covering Axid®, Evista, Humalog, Humulin, Prozac, and Zyprexa. The inquiry includes a review of our Medicaid best price reporting related to the product sales covered by the rebate agreements. We are cooperating in this matter.

In October 2005, we received a subpoena from the U.S. Attorney's office for the District of Massachusetts for the production of documents relating to our business relationship with a long-term care pharmacy organization concerning Actos, Evista, Humalog, Humulin, and Zyprexa. We are cooperating in this matter.

Between 2003 and 2005, various municipalities in New York sued us and many other pharmaceutical manufacturers, claiming in general that as a result of alleged improprieties by the manufacturers in the calculation and reporting of average wholesale prices for purposes of Medicaid reimbursement, the municipalities overpaid their portion of the cost of pharmaceuticals. The suits seek monetary and other relief, including civil penalties and treble damages. Similar suits were filed against us and many other manufacturers by the States of Mississippi, Iowa, Utah, and Kansas. These suits are pending either in the U.S. District Court for the District of Massachusetts or in various state courts. All of these suits are in early stages or discovery is ongoing. We believe these lawsuits are without merit and are prepared to defend against them vigorously.

During 2004 we, along with several other pharmaceutical companies, were named in a consolidated lawsuit in California state court brought on behalf of consumers alleging that the conduct of pharmaceutical companies in preventing commercial importation of prescription drugs from outside the United States violated 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. In July 2008, the California Court of Appeals affirmed that decision. The California Supreme Court has accepted plaintiff's appeal, and we expect it to be heard later this year.

In July 2008, we received a request from the Civil Division of the United States Department of Justice requesting the production of documents related to nominal pricing. 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 these matters.

Along with over 100 other pharmaceutical companies operating in Europe, in 2008 we received questionnaires from the European Commission as part of its inquiry into whether pharmaceutical companies improperly blocked or created artificial barriers to pharmaceutical innovation or market entry of medicines through the misuse of patent rights, settlements of claims, litigation, or other means. In July 2009, the Commission released its report in which it concluded that the practices of companies contributed to delays in the entry of medicines onto the market, but that shortcomings in the regulatory framework were also a contributing factor. The Commission has subsequently requested additional information from the companies. We are cooperating with the Commission 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.

During routine inspections in 2006 and 2007, the U.S. Environmental Protection Agency (EPA) identified potential gaps in our leak detection and repair program (LDAR). In addition, in 2006 we voluntarily reported to the state and city environmental agencies that we had exceeded an annual limit for air emissions. In response to these events, we have implemented numerous corrective actions and enhancements to our LDAR program. We are currently working with the EPA towards resolution of this matter, which will likely require the payment of a fine. We do not believe the amount of the fine will be material.

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. Submission of Matters to a Vote of Security Holders***

During the fourth quarter of 2009, no matters were submitted to a vote of security holders.

**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, 2009:

| <b>Period</b> | <b>Total<br/>Number of<br/>Shares<br/>Purchased<br/>(in<br/>thousands)<br/>(a)</b> | <b>Average Price<br/>Paid<br/>per Share<br/>(b)</b> | <b>Total Number of<br/>Shares<br/>Purchased as Part<br/>of<br/>Publicly<br/>Announced<br/>Plans or Programs<br/>(c)</b> | <b>Approximate Dollar<br/>Value<br/>of Shares that May Yet<br/>Be<br/>Purchased Under the<br/>Plans or Programs<br/>(Dollars in millions)<br/>(d)</b> |
|---------------|--|---|---|---|
| October 2009  | 0  | \$  |   | \$ 419.2  |
| November 2009 | 1  | 34.01   |   | 419.2   |
| December 2009 | 0  |   |   | 419.2   |
| <b>Total</b>  | <b>1</b>   |   |   |   |

The amounts presented in columns (a) and (b) above represent purchases of common stock related to employee stock option exercises. 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, 2009, we have purchased \$2.58 billion related to this program.

#### **Item 6. Selected Financial Data**

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

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

### **RESULTS OF OPERATIONS**

#### **EXECUTIVE OVERVIEW**

This section provides an overview of our financial results, recent product and late-stage pipeline developments, significant business development, and legal, regulatory, and other matters affecting our company and the pharmaceutical industry.

#### **Financial Results**

We achieved revenue growth of 7 percent in 2009, which was primarily driven by the collective growth of Alimta, Cymbalta, Humalog, and Zyprexa and the inclusion of Erbitux revenue as a result of the ImClone Systems Inc.

(Imclone) acquisition in November 2008. The impact of changes in foreign currencies compared to the U.S. dollar on international inventories sold during the year decreased our cost of sales in 2009 and increased our cost of sales in 2008, which contributed to an improvement in gross margin. 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 sales. We incurred income tax expense of \$1.03 billion in 2009 resulting in an effective tax rate of 19.2 percent. Earnings increased to \$4.33 billion, and earnings per share increased to \$3.94 per share, in 2009 as compared to a net loss of \$2.07 billion, and a loss per share of \$1.89 in 2008. Net income comparisons between 2009 and 2008 are affected by the impact of the following significant items:

## **2009**

### **Acquisitions (Note 3)**

We incurred acquired in-process research and development (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 14)**

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 to an affiliate of Evonik Industries AG.

We incurred pretax charges of \$230.0 million representing the currently probable and estimable exposures in connection with the claims of several states related to Zyprexa, which decreased earnings per share by \$.13.

## 2008

### Acquisitions (Note 3)

We recognized charges totaling \$4.73 billion (pretax) associated with the acquisition of ImClone, which decreased earnings per share by \$4.46. These amounts include an IPR&D charge of \$4.69 billion (pretax). The remaining net expenses are related to ImClone's operating results subsequent to the acquisition, incremental interest costs, and amortization of the intangible asset associated with Erbitux. We also incurred IPR&D charges of \$28.0 million (pretax) associated with the acquisition of SGX Pharmaceuticals, Inc. (SGX), which decreased earnings per share by \$.03.

We incurred IPR&D charges associated with licensing arrangements with BioMS Medical Corp. (BioMS) and TransPharma Medical Ltd. totaling \$122.0 million (pretax), which decreased earnings per share by \$.07.

### Asset Impairments and Related Restructuring and Other Special Charges (Notes 5 and 14)

We recognized asset impairments, restructuring, and other special charges totaling \$497.0 million (pretax), which decreased earnings per share by \$.30. A similar charge of \$57.1 million (pretax), which decreased earnings per share by \$.04, was included in cost of sales. These charges were primarily associated with the sale of our Greenfield, Indiana site, the termination of the AIR<sup>®</sup> Insulin program; and strategic exit activities related to manufacturing operations.

We recorded charges of \$1.48 billion (pretax) related to the federal and state Zyprexa investigations led by the U.S. Attorney for the Eastern District of Pennsylvania (EDPA), as well as the resolution of a multi-state investigation regarding Zyprexa involving 32 states and the District of Columbia, which decreased earnings per share by \$1.20.

### Other (Note 12)

We recognized a discrete income tax benefit of \$210.3 million as a result of the resolution of a substantial portion of the IRS audit of our federal income tax returns for the years 2001 through 2004, which increased earnings per share by \$.19.

### Late-Stage Pipeline Developments and Business Development Activity

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 over 60 potential new drugs in human testing. A number of late-stage pipeline developments and business development transactions occurred within the past year, including:

#### Pipeline

The United States Food and Drug Administration (FDA) approved an expanded indication for Byetta as a standalone medication (monotherapy) along with diet and exercise to improve glycemic control in adults with type 2 diabetes.

The FDA approved Zyprexa Relprevv for extended release injectable suspension for the treatment of schizophrenia in adults. We also launched this product under the tradename Zypadhera in several countries within the European Union.

We announced initial results from a Phase III clinical trial for arzoxifene. After reviewing the overall clinical profile of arzoxifene in light of currently available treatments, including our own osteoporosis products, we decided not to submit the compound for regulatory review.

The FDA approved a new use for Forteo to treat osteoporosis associated with sustained, systemic glucocorticoid therapy in men and women at high risk of fracture.

We and our partner BioMS discontinued Phase III clinical trials for dirucotide in patients with secondary progressive multiple sclerosis. Data showed that dirucotide did not meet the primary endpoint of delaying disease progression and there were no statistically significant differences between dirucotide and placebo on the secondary endpoints of the study.

The FDA approved Effient tablets for the reduction of thrombotic cardiovascular events (including stent thrombosis) in patients with acute coronary syndromes (ACS) who are managed with an artery-opening procedure known as percutaneous coronary intervention (PCI). We and our partner, Daiichi Sankyo, Inc., launched Effient in the U.S. in August. The European Commission granted marketing authorization for Efient® for the prevention of atherothrombotic events in patients with ACS undergoing PCI.

The FDA approved Alimta as a maintenance therapy for locally advanced or metastatic non-small cell lung cancer (NSCLC), specifically for patients with a nonsquamous histology whose disease has not progressed after four cycles of platinum-based first-line chemotherapy.

The European Commission granted approval for the use of Alimta as monotherapy for maintenance treatment of patients with other than predominantly squamous cell histology in locally-advanced or

metastatic NSCLC, whose disease has not progressed immediately following platinum-based chemotherapy.

Alimta received regulatory approval in Japan as both a first- and second-line treatment of NSCLC.

We and our partners Amylin Pharmaceuticals, Inc. (Amylin) and Alkermes, Inc., submitted a New Drug Application (NDA) to the FDA for exenatide once weekly. Exenatide once weekly is an investigational sustained release medication for type 2 diabetes that is injected subcutaneously and administered only once a week.

We began enrolling patients in two separate but identical Phase III clinical trials of solanezumab, an anti-amyloid beta monoclonal antibody being investigated as a potential treatment to delay the progression of mild to moderate Alzheimer's disease. The trials each include a treatment period that lasts 18 months and are expected to enroll a total of 2,000 patients age 55 and over from 16 countries.

The FDA approved two new combination indications for Zyprexa (olanzapine) and fluoxetine for the acute treatment of bipolar depression and TRD in adults.

We received a complete response letter from the FDA for the first-line squamous cell carcinoma of the head and neck (SCCHN) supplemental Biologics License Application (sBLA) for Erbitux.

## **Business Development**

We entered into an exclusive worldwide license and collaboration agreement with Incyte for the development and commercialization of Incyte's oral JAK1/JAK2 inhibitor, and certain follow-on compounds, for inflammatory and autoimmune diseases. The lead compound is currently being studied in a six-month dose-ranging Phase II trial for rheumatoid arthritis.

We entered into a co-promotion agreement with Kowa Pharmaceutical America to commercialize Livalo<sup>®</sup> (pitavastatin) in the United States. Lilly and Kowa Company, Limited have also entered into a licensing agreement in Latin America. Livalo is a statin approved by the FDA in August 2009 for the treatment of primary hyperlipidemia and mixed dyslipidemia. We plan to launch Livalo in the U.S. in mid-2010.

In January 2010, we restructured the collaboration agreement executed by Bristol-Myers Squibb and ImClone in 2001 to allow for the co-development and co-commercialization of the late-stage oncology molecule necitumumab (IMC-11F8), which is currently in Phase III clinical testing for non-small cell lung cancer. Under the restructured agreement, both companies will share in 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.

## **Legal, Regulatory, and Other Matters**

In September 2009, we set a goal to reduce our expected cost structure by \$1 billion by the end of 2011. We also plan to lower global headcount to 35,000 by the end of 2011, excluding strategic sales force additions in high-growth emerging markets and Japan, which could result in future periodic restructuring charges.

In January 2009, we reached resolution with the Office of the U.S. Attorney for the EDPA, and the State Medicaid Fraud Control Units of 36 states and the District of Columbia, of an investigation related to our U.S. marketing and promotional practices with respect to Zyprexa. We recorded a charge of \$1.42 billion for this matter in the third quarter of 2008. In 2009, we paid substantially all of this amount, as required by the settlement agreements. In addition, in October 2008, we reached a settlement with 32 states and the District of Columbia related to a multistate investigation brought under various state consumer protection laws, under which we paid \$62.0 million. However, we were served with lawsuits brought by attorneys general of a number of states, alleging that Zyprexa caused or

contributed to diabetes or high blood-glucose levels, and that we improperly promoted the drug and seeking to recover the costs paid for Zyprexa through Medicaid and other drug-benefit programs, as well as the costs alleged to have been incurred and that will be incurred to treat Zyprexa-related illnesses. In 2009, we incurred pretax charges of \$230.0 million, reflecting the probable and estimable exposures in connection with these claims. We have reached settlements or are in advanced discussions to settle all of the remaining state claims. The Pennsylvania case is set for trial in April 2010 in state court.

Health care reform is currently the subject of intense debate in the U.S. Congress. The impact of reform on the pharmaceutical industry is uncertain. Most reform proposals intend to provide coverage for the uninsured, include increasing existing price rebates in federally funded health care programs and the expansion of rebates, or other pharmaceutical company discounts, into new programs. There are also proposals that will impose new fees on pharmaceutical industry sales of certain prescription pharmaceutical products. Certain federal and state health care reform proposals that go beyond providing additional health insurance coverage for the uninsured may also place downward pressure on pharmaceutical industry sales or prices. These proposals include reducing incentives for employer-sponsored health care;

the creation of an independent commission to propose changes to Medicare, with a particular focus on the cost of biopharmaceuticals in Medicare Part D, which lowers the projections for future government spending in Medicare; and a government-run public option with biopharmaceutical price-setting capabilities. Additionally, various proposals could legalize the importation of prescription drugs and either allow, or require, the Secretary of Health and Human Services to negotiate drug prices within Medicare Part D directly with pharmaceutical manufacturers. In addition, the federal government is considering creating an expedited regulatory approval pathway for biosimilars (copies of biological compounds) for biologic products in the U.S.; the proposals vary as to which biologic products would be eligible, how quickly a biosimilar might reach the market, and the ability to interchange the biosimilar and the original biologic product at the pharmacy. We expect pricing pressures at the federal and state levels to become more severe, which could have a material adverse effect on our consolidated results of operations.

In its budget submission to Congress in February 2010, the Obama administration proposed changes to the manner in which the U.S. would tax the international income of U.S.-based companies. While it is uncertain how the U.S. Congress may address this issue, reform of U.S. taxation, including taxation of international income, continues to be a topic of discussion for the U.S. Congress. 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.

International operations also are 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. These proposals are expected to increase in both frequency and impact, given the effect of the downturn in the global economy on local governments.

## OPERATING RESULTS 2009

### Revenue

Our worldwide revenue for 2009 increased 7 percent, to \$21.84 billion, driven primarily by growth of Alimta, Cymbalta, Humalog, and Zyprexa, and the inclusion of Erbitux revenue as a result of the ImClone acquisition. Worldwide sales volume increased 7 percent, while selling prices contributed 3 percent of revenue growth, partially offset by the unfavorable impact of foreign exchange rates of 3 percent. Revenue in the U.S. increased 12 percent, to \$12.29 billion, due to higher prices and higher demand. Revenue outside the U.S. increased 1 percent, to \$9.54 billion, due to increased demand, partially offset by the negative impact of foreign exchange rates and lower prices.

The following table summarizes our revenue activity in 2009 compared with 2008:

| Product               | Year Ended<br>December 31, 2009 |                 |                    | Year Ended<br>December 31,<br>2008 | Percent<br>Change<br>from<br>2008 |
|-----------------------|---------------------------------|-----------------|--------------------|------------------------------------|-----------------------------------|
|                       | U.S. <sup>1</sup>               | Outside<br>U.S. | Total <sup>3</sup> | Total                              |                                   |
| (Dollars in millions) |                                 |                 |                    |                                    |                                   |
| Zyprexa               | \$ 2,331.7                      | \$ 2,583.9      | \$ 4,915.7         | \$ 4,696.1                         | 5                                 |
| Cymbalta              | 2,551.8                         | 523.0           | 3,074.7            | 2,697.1                            | 14                                |
| Humalog               | 1,208.4                         | 750.6           | 1,959.0            | 1,735.8                            | 13                                |
| Alimta                | 815.6                           | 890.4           | 1,706.0            | 1,154.7                            | 48                                |
| Cialis                | 623.3                           | 935.8           | 1,559.1            | 1,444.5                            | 8                                 |

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|  |             |            |             |             |      |
|--|-------------|------------|-------------|-------------|------|
| Gemzar                                       | 747.4       | 615.8      | 1,363.2     | 1,719.8     | (21) |
| Animal health products                       | 672.2       | 535.0      | 1,207.2     | 1,093.3     | 10   |
| Evista                                       | 682.2       | 348.1      | 1,030.4     | 1,075.6     | (4)  |
| Humulin                                      | 402.4       | 619.6      | 1,022.0     | 1,063.2     | (4)  |
| Forteo                                       | 518.3       | 298.4      | 816.7       | 778.7       | 5    |
| Strattera                                    | 445.6       | 163.7      | 609.4       | 579.5       | 5    |
| Other pharmaceutical products                | 739.9       | 1,168.4    | 1,908.1     | 1,887.5     | 1    |
|  |             |            |             |             |      |
| Total net product sales                      | 11,738.8    | 9,432.7    | 21,171.5    | 19,925.8    | 6    |
| Collaboration and other revenue <sup>2</sup> | 555.6       | 108.9      | 664.5       | 446.1       | 49   |
|  |             |            |             |             |      |
| Total revenue                                | \$ 12,294.4 | \$ 9,541.6 | \$ 21,836.0 | \$ 20,371.9 | 7    |

<sup>1</sup> U.S. revenue includes revenue in Puerto Rico.

<sup>2</sup> Collaboration and other revenue is primarily composed of Erbitux royalties and 50 percent of Byetta's gross margin in the U.S.

<sup>3</sup> Numbers may not add due to rounding.

Zyprexa, our top-selling product, is a treatment for schizophrenia, acute mixed or manic episodes associated with bipolar I disorder, and bipolar maintenance. Zyprexa sales in the U.S. increased 6 percent in 2009, due to higher prices, partially offset by reduced demand. Sales outside the U.S. increased 4 percent driven by increased demand, partially offset by the unfavorable impact of foreign exchange rates. Demand outside the U.S. was favorably impacted by the withdrawal of generic competition in Germany in early 2009.

Sales of Cymbalta, a product for the treatment of major depressive disorder, diabetic peripheral neuropathic pain, generalized anxiety disorder, and fibromyalgia, increased 13 percent in the U.S., driven by higher prices and increased demand. Sales outside the U.S. increased 18 percent, driven by increased demand, partially offset by the unfavorable impact of foreign exchange rates and lower prices.

Sales of Humalog, our injectable human insulin analog for the treatment of diabetes, increased 20 percent in the U.S., driven by higher prices, increased demand, and wholesaler buying patterns. Sales outside the U.S. increased 3 percent, driven by increased demand, partially offset by the unfavorable impact of foreign exchange rates.

Sales of Alimta, a treatment for various cancers, increased 45 percent in the U.S., primarily driven by increased demand. Sales outside the U.S. increased 50 percent, driven by increased demand, partially offset by the unfavorable impact of foreign exchange rates. Demand outside the U.S. benefited from the addition of the non-small cell lung cancer indication in Japan.

Our sales of Cialis, a treatment for erectile dysfunction, increased 16 percent in the U.S., driven by higher prices, increased demand, and wholesaler buying patterns. Sales outside the U.S. increased 3 percent, driven by increased demand and to a lesser extent, higher prices, partially offset by the unfavorable impact of foreign exchange rates.

Sales of Gemzar, a product approved to treat various cancers, increased 2 percent in the U.S., due primarily to higher prices. Sales outside the U.S. decreased 37 percent, driven by reduced demand and lower prices as a result of the entry of generic competition in most major markets, and to a lesser extent, the unfavorable impact of foreign exchange rates.

Sales of Evista, a product for the prevention and treatment of osteoporosis in postmenopausal women and for reduction of risk of invasive breast cancer in postmenopausal women with osteoporosis and postmenopausal women at high risk for invasive breast cancer, decreased 3 percent in the U.S., driven by reduced demand, partially offset by higher prices. Sales outside the U.S. decreased 7 percent, driven by the outlicensing of Evista in most European markets and, to a lesser extent, lower prices.

Sales of Humulin, an injectable human insulin for the treatment of diabetes, increased 6 percent in the U.S., due primarily to higher prices, partially offset by reduced demand. Sales outside the U.S. decreased 9 percent, driven by the unfavorable impact of foreign exchange rates and, to a lesser extent, lower prices, partially offset by increased demand.

Sales of Forteo, an injectable treatment for osteoporosis in postmenopausal women and men at high risk for fracture, increased 6 percent in the U.S., driven by higher prices, partially offset by reduced demand. Sales outside the U.S. increased 3 percent, driven by increased demand and prices, partially offset by the unfavorable impact of foreign exchange rates.

Sales of Strattera, a treatment for attention-deficit hyperactivity disorder in children, adolescents, and adults, increased 2 percent in the U.S., driven by higher prices, partially offset by reduced demand. Sales outside the U.S. increased 15 percent, driven by increased demand and higher prices, partially offset by the unfavorable impact of foreign exchange rates.

Worldwide sales of Byetta, an injectable product for the treatment of type 2 diabetes, increased 6 percent to \$796.5 million during 2009. We report as revenue our 50 percent share of Byetta's gross margin in the U.S., 100 percent of Byetta sales outside the U.S., and our sales of Byetta pen delivery devices to Amylin. Our revenues increased 13 percent to \$448.5 million in 2009.

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 were \$390.8 million in 2009, compared with \$29.4 million in 2008. We acquired Erbitux as part of our acquisition of ImClone in November 2008.

Animal health product sales in the U.S. increased 25 percent, primarily driven by the inclusion of Posilac sales following the acquisition completed October 2008. Sales outside the U.S. decreased 4 percent, driven primarily by the unfavorable impact of foreign exchange rates.

#### **Gross Margin, Costs, and Expenses**

The 2009 gross margin increased to 80.6 percent of total revenue compared with 78.5 percent for 2008. This increase was due to the impact of changes in foreign currencies compared to the U.S. dollar on

international inventories sold during the year, which decreased cost of sales as in 2009, but increased cost of sales in 2008.

Marketing, selling, and administrative expenses increased 4 percent in 2009 to \$6.89 billion. The increase was driven by the increased marketing and selling expenses outside the U.S., higher incentive compensation, and the impact of the ImClone acquisition, partially offset by the movement of foreign exchange rates. Investment in research and development increased 13 percent, to \$4.33 billion, due primarily to the ImClone acquisition and increased late-stage clinical trial costs.

We incurred an IPR&D charge of \$90.0 million in 2009, associated with the in-licensing agreement with Incyte, compared with \$4.84 billion in 2008. The 2008 IPR&D charge included \$4.69 billion resulting from the acquisition of ImClone. We recognized asset impairments, restructuring, and other special charges of \$692.7 million in 2009, primarily related to asset impairment charges related to the sale of our Tippecanoe Laboratories manufacturing site and special charges related to Zyprexa litigation with multiple state attorneys general, compared with \$1.97 billion in 2008. The 2008 charges were primarily associated with the resolution of Zyprexa investigations with the U.S. Attorney for the EDPA and multiple states. See Notes 3, 5 and 14 to the consolidated financial statements for additional information.

Other net, expense, (income) was a net expense in both years, increasing by \$203.4 million, to \$229.5 million in 2009, primarily due to lower interest income and higher interest expense resulting from the ImClone acquisition.

We incurred income tax expense of \$1.03 billion in 2009 resulting in an effective tax rate of 19.2 percent. The effective tax rate for 2009 was reduced due to the tax benefit of asset impairment and restructuring charges associated with the sale of the Tippecanoe site. 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 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. See Note 12 to the consolidated financial statements for additional information.

## **OPERATING RESULTS 2008**

### **Financial Results**

We achieved worldwide sales growth of 9 percent, which was primarily driven by volume increases in several key products. The favorable impact of foreign exchange rates on cost of sales contributed to an improvement in gross margin. Marketing, selling, and administrative expenses grew at the same rate as sales, driven by pre-launch activities associated with Effient, marketing costs associated with Cymbalta and Evista, the impact of foreign exchange rates, and increased litigation-related expenses, while our investment in research and development grew 10 percent. We completed our acquisition of ImClone, resulting in a significant charge of \$4.69 billion for IPR&D and reached resolution on government investigations related to our past U.S. marketing and promotional practices for Zyprexa, resulting in an additional charge of \$1.48 billion. We incurred tax expense of \$764.3 million, despite a loss before income taxes of \$1.31 billion, primarily caused by the non-deductibility of the ImClone IPR&D charge and the partial deductibility of the Zyprexa investigation settlements. Accordingly, earnings decreased to a net loss of \$2.07 billion, and earnings per share decreased to a loss of \$1.89 per share, in 2008 as compared with net income of \$2.95 billion, and earnings per share of \$2.71, in 2007. Net income comparisons between 2008 and 2007 are affected by the impact of several significant items. The significant items for 2008 are summarized in the Executive Overview. The 2007 items are summarized as follows:

Acquisitions (Note 3)

We incurred IPR&D charges associated with the acquisitions of ICOS Corporation (ICOS), Hypnion, Inc. (Hypnion), and Ivy Animal Health, Inc. (Ivy), totaling \$631.6 million (pretax), which decreased earnings per share by \$.57.

We incurred IPR&D charges associated with our licensing arrangements with Glenmark Pharmaceuticals Limited India, MacroGenics, Inc., and OSI Pharmaceuticals, totaling \$114.0 million (pretax), which decreased earnings per share by \$.06.

Asset Impairments and Related Restructuring and Other Special Charges (Notes 5 and 14)

We recognized asset impairments, restructuring, and other special charges of \$190.6 million (pretax), which decreased earnings per share by \$.12. These charges were primarily associated with previously announced strategic decisions affecting manufacturing and research facilities.

We incurred a special charge following a settlement with one of our insurance carriers over Zyprexa product liability claims, which led to a reduction of our expected product liability insurance recoveries, and other product liability charges. This resulted in a charge totaling \$111.9 million (pretax), which decreased earnings per share by \$.09.

## Revenue

Our worldwide revenue for 2008 increased 9 percent, to \$20.37 billion, driven primarily by growth of Cymbalta, Cialis, Alimta, Humalog, and Gemzar. Worldwide sales volume increased 5 percent, while foreign exchange rates contributed 3 percent, and selling prices contributed 2 percent. (Numbers do not add due to rounding.) Revenue in the U.S. increased 8 percent, to \$10.93 billion, driven primarily by increased sales of Cymbalta, Humalog, Cialis, and Alimta. Revenue outside the U.S. increased 11 percent, to \$9.44 billion, driven primarily by revenue growth of Alimta, Cialis, Cymbalta, and Humalog.

The following table summarizes our revenue activity in 2008 compared with 2007:

| Product                                      | Year Ended<br>December 31, 2008 |                 |             | Year Ended<br>December 31,<br>2007 | Percent<br>Change<br>from<br>2007 |
|--|---------------------------------|-----------------|-------------|------------------------------------|-----------------------------------|
|  | U.S. <sup>1</sup>               | Outside<br>U.S. | Total       | Total                              |                                   |
| (Dollars in millions)                        |                                 |                 |             |                                    |                                   |
| Zyprexa                                      | \$ 2,202.5                      | \$ 2,493.6      | \$ 4,696.1  | \$ 4,761.0                         | (1)                               |
| Cymbalta                                     | 2,253.8                         | 443.3           | 2,697.1     | 2,102.9                            | 28                                |
| Humalog                                      | 1,008.4                         | 727.4           | 1,735.8     | 1,474.6                            | 18                                |
| Gemzar                                       | 734.8                           | 985.0           | 1,719.8     | 1,592.4                            | 8                                 |
| Cialis <sup>2</sup>                          | 539.0                           | 905.5           | 1,444.5     | 1,143.8                            | 26                                |
| Alimta                                       | 561.9                           | 592.8           | 1,154.7     | 854.0                              | 35                                |
| Animal health products                       | 537.3                           | 556.0           | 1,093.3     | 995.8                              | 10                                |
| Evista                                       | 700.5                           | 375.1           | 1,075.6     | 1,090.7                            | (1)                               |
| Humulin                                      | 380.9                           | 682.3           | 1,063.2     | 985.2                              | 8                                 |
| Forteo                                       | 489.9                           | 288.8           | 778.7       | 709.3                              | 10                                |
| Strattera                                    | 437.8                           | 141.7           | 579.5       | 569.4                              | 2                                 |
| Other pharmaceutical products                | 664.8                           | 1,222.7         | 1,887.5     | 1,895.6                            |                                   |
| Total net product sales                      | 10,511.6                        | 9,414.2         | 19,925.8    | 18,174.7                           | 10                                |
| Collaboration and other revenue <sup>3</sup> | 418.5                           | 27.6            | 446.1       | 458.8                              | (3)                               |
| Total revenue                                | \$ 10,930.1                     | \$ 9,441.8      | \$ 20,371.9 | \$ 18,633.5                        | 9                                 |

<sup>1</sup> U.S. revenue includes revenue in Puerto Rico.

<sup>2</sup> Prior to the acquisition of ICOS in late January 2007, the Cialis revenue shown does not include net product sales in the joint-venture territories of Lilly ICOS LLC (North America, excluding Puerto Rico, and Europe). Our share of the joint-venture territory net product sales for January 2007, net of expenses and income taxes, is reported in other net, expense (income) in our consolidated statements of operations. Subsequent to the acquisition, all Cialis net product sales are reported in our net revenue. Worldwide 2008 revenue for Cialis grew 19 percent from 2007 revenue of \$1.22 billion.

<sup>3</sup> Collaboration and other revenue is primarily composed of 50 percent of Byetta's gross margin in the U.S.

Zyprexa sales in the U.S. decreased 1 percent in 2008, driven by reduced demand, partially offset by higher prices. Sales outside the U.S. decreased 1 percent, driven by decreased demand and, to a lesser extent, lower prices, partially offset by the favorable impact of foreign exchange rates. Demand outside the U.S. was unfavorably impacted by generic competition in Germany and Canada.

Sales of Cymbalta increased 23 percent in the U.S., driven by increased demand and, to a lesser extent, higher prices. Sales outside the U.S. increased 66 percent, driven by increased demand and, to a lesser extent, the favorable impact of foreign exchange rates and higher prices. Higher demand outside the U.S. reflects increased demand in established markets as well as recent launches in new markets.

Sales of Humalog increased 14 percent in the U.S., driven by increased demand and higher prices. Sales outside the U.S. increased 24 percent, driven by increased demand and, to a lesser extent, the favorable impact of foreign exchange rates.

Sales of Gemzar increased 10 percent in the U.S., driven by increased demand and higher prices. Sales outside the U.S. increased 7 percent, driven primarily by the favorable impact of foreign exchange rates and, to a lesser extent, increased demand, partially offset by lower prices.

Sales of Cialis increased 27 percent in the U.S., driven by increased demand and higher prices. Sales outside the U.S. increased 26 percent, driven by increased demand and, to a lesser extent, the favorable impact of foreign exchange rates and higher prices. Total worldwide sales of Cialis increased 19 percent

to \$1.44 billion in 2008 as compared to \$1.22 billion in 2007. This includes \$72.7 million of sales in the Lilly ICOS joint-venture territories for the 2007 period prior to the acquisition of ICOS.

Sales of Alimta increased 25 percent in the U.S., driven by increased demand and, to a lesser extent, higher prices. Sales outside the U.S. increased 46 percent, driven by increased demand and, to a lesser extent, the favorable impact of foreign exchange rates.

Sales of Evista decreased 1 percent in the U.S., driven by decreased demand, partially offset by higher prices. Sales outside the U.S. decreased 2 percent, driven by reduced demand and lower prices, partially offset by the favorable impact of foreign exchange rates.

Sales of Humulin increased 4 percent in the U.S., driven by higher prices. Sales outside the U.S. increased 10 percent, driven by the favorable impact of foreign exchange rates and increased demand.

Sales of Forteo decreased 1 percent in the U.S., driven by decreased demand, partially offset by higher prices. Sales outside the U.S. increased 34 percent, driven by increased demand and, to a lesser extent, the favorable impact of foreign exchange rates.

Sales of Strattera decreased 6 percent in the U.S., driven by decreased demand, partially offset by higher prices. Sales outside the U.S. increased 35 percent, driven primarily by increased demand.

Worldwide sales of Byetta increased 16 percent to \$751.4 million during 2008. Our revenues increased 20 percent to \$396.1 million in 2008.

Animal health product sales in the U.S. increased 12 percent, driven by the inclusion of U.S. Posilac sales since the date of acquisition. Sales outside the U.S. increased 8 percent, driven by increased demand and, to a lesser extent, the favorable impact of foreign exchange rates.

### **Gross Margin, Costs, and Expenses**

The 2008 gross margin increased to 78.5 percent of total revenue compared with 77.2 percent for 2007. This increase was primarily due to the favorable impact of foreign exchange rates.

Marketing, selling, and administrative expenses increased 9 percent in 2008, to \$6.63 billion. This increase was due to increased marketing and selling expenses, including prelaunch expenses for Effient and marketing costs associated with Cymbalta and Evista; the impact of foreign exchange rates; and increased litigation-related expenses. Investment in research and development increased 10 percent, to \$3.84 billion, due to increased late-stage clinical trial and discovery research costs.

Acquired IPR&D charges related to the acquisitions of ImClone and SGX, as well as our in-licensing arrangements with BioMS and TransPharma, were \$4.84 billion in 2008 as compared to \$745.6 million in 2007. We recognized asset impairments, restructuring, and other special charges of \$1.97 billion in 2008, as compared to \$302.5 million in 2007. The 2008 charges were primarily associated with the resolution of Zyprexa investigations with the U.S. Attorney for the EDPA and multiple states. See Notes 3, 5 and 14 to the consolidated financial statements for additional information.

Other net, expense (income) changed from net income of \$122.0 million in 2007 to net expense of \$26.1 million in 2008, primarily as a result of lower outlicensing income and increased net losses on investment securities in 2008 (the majority of which consisted of unrealized losses).

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. The effective tax rate was 23.8 percent in 2007. See Note 12 to the consolidated financial statements for additional information.

## FINANCIAL CONDITION

As of December 31, 2009, cash, cash equivalents, and short-term investments totaled \$4.50 billion compared with \$5.93 billion at December 31, 2008. The decrease in cash was driven by a reduction in short-term borrowings of \$5.82 billion and dividends paid of \$2.15 billion, partially offset by cash from operations of \$4.34 billion (which included payments related to the Zyprexa EDPA settlement of \$1.39 billion) and proceeds of long-term debt issuances of \$2.40 billion.

Capital expenditures of \$765.0 million during 2009 were \$182.2 million less than in 2008. We expect 2010 capital expenditures to be approximately \$1.0 billion as we invest in our biotechnology capabilities, continue to upgrade our manufacturing and research facilities to enhance productivity and quality systems, and invest in the long-term growth of our diabetes care products.

Total debt at December 31, 2009, was \$6.66 billion, a decrease of \$3.80 billion from December 31, 2008 reflecting the pay-down of our commercial paper that was issued to finance our acquisition of ImClone, partially offset by \$2.40 billion of long-term debt we issued in March 2009. Our current debt ratings from Standard & Poor's and Moody's remain at AA and A1, respectively.

Dividends of \$1.96 per share were paid in 2009, an increase of 4 percent from 2008. In the fourth quarter of 2009, effective for the first-quarter dividend in 2010, the quarterly dividend was maintained at \$.49 per share, resulting in an indicated annual rate for 2010 of \$1.96 per share. The year 2009 was the 125th consecutive year in which we made dividend payments.

Despite increasing unemployment and declines in real consumer spending, consumer confidence has grown and job losses have slowed during the second half of 2009. Many financial institutions continue to have tightened lines of credit, thus reducing funding available to stimulate near-term economic growth. While there are some positive signs, the prospects for recovery are uncertain. Pharmaceutical consumption has traditionally been relatively unaffected by economic downturns; however, an extended downturn could lead to a decline in overall prescriptions corresponding to the growth of the uninsured and underinsured population in the U.S. In addition, both private and public health care payers are facing heightened fiscal challenges due to the economic slowdown and are taking aggressive steps to reduce the costs of care, including pressures for increased pharmaceutical discounts and rebates and efforts to drive greater use of generic drugs. We continue to monitor the potential near-term impact of prescription trends, the creditworthiness of our wholesalers and other customers and suppliers, the evolving health care debate, the federal government's involvement in the economic crisis, and various international government funding levels.

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, costs associated with litigation and government investigations, and dividends in 2010. We believe that amounts accessible through existing commercial paper markets should be adequate to fund short-term borrowings. Our access to credit markets has not been adversely affected by the illiquidity in the markets because of the high credit quality of our short- and long-term debt. We currently have \$1.24 billion of unused committed bank credit facilities, \$1.20 billion of which backs our commercial paper program and matures in May 2011. Various risks and uncertainties, including those discussed in Item 1A, Risk Factors, may affect our operating results and cash generated from operations.

We depend on patents or other forms of intellectual property protection for most of our revenues, cash flows, and earnings. In the next three years we will lose effective exclusivity for Zyprexa in major European countries (September 2011) and the U.S. (October 2011); and for Humalog in major European countries (November 2010). Gemzar has already lost effective exclusivity in major European countries. In addition, we face U.S. patent litigation over several key patent-protected products whose exclusivity extends beyond 2012, including Alimta, Cymbalta, Evista, Gemzar, and Strattera and it is possible we could face an unexpected loss of our effective exclusivity for one or more of these products prior to the end of 2012. Revenue from each of these products contributes materially to our results of operations, liquidity, and financial position, and the loss of exclusivity could result in a rapid and severe decline in revenue from the affected product. However, we plan to mitigate the effect on our operations, liquidity and financial position through growth in our remaining business and the previously announced plan to reduce our expected cost structure by \$1 billion by the end of 2011.

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, 2009 and 2008, 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, 2009

and 2008, 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 use forward contracts and purchased options to manage our foreign currency exposures. 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, 2009 and 2008, a hypothetical 10 percent change in exchange rates (primarily against the U.S. dollar) as of December 31, 2009 and 2008,

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 have to 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 any one 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 clinical testing 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<br>1 Year | 1-3<br>Years | 3-5<br>Years | More<br>Than<br>5 Years |
| Long-term debt, including interest payments <sup>1</sup>                | \$ 10,519.8            | \$ 243.4            | \$ 2,093.4   | \$ 1,563.7   | \$ 6,619.3              |
| Capital lease obligations   | 39.2                   | 13.5                | 13.3         | 9.0          | 3.4                     |
| Operating leases  | 403.4                  | 109.1               | 156.1        | 78.3         | 59.9                    |
| Purchase obligations <sup>2</sup>                                       | 11,367.1               | 7,259.9             | 1,599.6      | 1,471.5      | 1,036.1                 |
| Other long-term liabilities reflected on our balance sheet <sup>3</sup> | 1,136.9                |                     | 298.6        | 195.0        | 643.3                   |
| Other <sup>4</sup>  | 198.8                  | 198.8               |              |              |                         |
| Total   | \$ 23,665.2            | \$ 7,824.7          | \$ 4,161.0   | \$ 3,317.5   | \$ 8,362.0              |

- <sup>1</sup> 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, 2009 to compute the amount of the contractual obligation for interest on the variable rate debt instruments and swaps.
- <sup>2</sup> We have included the following:
- Purchase obligations, consisting primarily of all open purchase orders at our significant operating locations as of December 31, 2009. 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.
- <sup>3</sup> We have included long-term liabilities consisting primarily of our nonqualified supplemental pension funding requirements and deferred compensation liabilities. We excluded liabilities for unrecognized tax benefits of \$1,088.4 million, as we cannot reasonably estimate the timing of future cash outflows associated with those liabilities.
- <sup>4</sup> This category comprises primarily minimum pension funding requirements.

The contractual obligations table is current as of December 31, 2009. 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. For more than 85 percent of our sales, this is at the time products are shipped to the customer, typically a wholesale distributor or a major retail chain. The remaining sales, which are outside the U.S., are recorded at the point of delivery. 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 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.

We establish sales return accruals for anticipated product returns. We record the return amounts as a deduction to arrive at our net product sales. Once the product is returned, it is destroyed. Consistent with Revenue Recognition accounting guidance, we estimate a reserve when the sales occur 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. 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, 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 pharmaceutical budget deficit 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 budget deficit, 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 \$1.20 billion, \$1.03 billion, and \$738.8 million in 2009, 2008, and 2007, respectively. A 5 percent change in the sales return, Medicaid, and Medicare rebate amounts we recognized in 2009 would lead to an approximate \$60 million effect on our income before income taxes. As of December 31, 2009, our sales returns, Medicaid, and Medicare rebate liability was \$692.3 million.

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 84 percent and 80 percent of our global sales return, rebate, and discount liability resulted from sales of our products in the U.S. as of December 31, 2009 and 2008, respectively. The following represents a roll-forward of our most significant U.S. returns, rebate, and discount liability balances, including Medicaid (in millions):

|  | 2009      | 2008      |
|--|-----------|-----------|
| Sales return, rebate, and discount liabilities, beginning of year                | \$ 806.5  | \$ 693.5  |
| Reduction of net sales due to sales returns, discounts, and rebates <sup>1</sup> | 2,233.8   | 1,864.9   |
| Cash payments of discounts and rebates   | (2,076.7) | (1,751.9) |
| Sales return, rebate, and discount liabilities, end of year                      | \$ 963.6  | \$ 806.5  |

<sup>1</sup> Adjustments of the estimates for these returns, rebates, and discounts to actual results were less than 0.1 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. In the past few 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 can be no assurance that we will be able to fully collect from our insurance carriers in the future.

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.

We believe that the accruals and related insurance recoveries we have established for product litigation liabilities and other contingencies are appropriate based on current facts and circumstances.

#### **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 13 to the consolidated financial statements for additional information regarding our retirement benefits.

Periodically, 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 88 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.

We believe our pension and retiree medical plan assumptions are appropriate based upon the above factors. 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 2009 annual expense would increase by \$18.9 million. A one-percentage-point decrease would lower the aggregate of the 2009 service cost and interest cost by \$15.8 million. If the 2009 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 \$23.6 million. If the 2009 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 \$16.8 million. If our assumption regarding the 2009 expected age of future retirees for U.S. plans were adjusted by one year, our income before income taxes would be affected by \$27.7 million. The U.S. plans represent approximately 82 percent of the total accumulated postretirement benefit obligation and approximately 83 percent of total plan assets at December 31, 2009.

### **Impairment of 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. The estimated future cash flows, based on 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.

We believe that our estimates for the uncertain tax positions and valuation allowances against the deferred tax assets are appropriate based on current facts and circumstances. 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 \$41.8 million and \$41.8 million, respectively.

#### **FINANCIAL EXPECTATIONS FOR 2010**

For the full year of 2010, we expect earnings per share to be in the range of \$4.65 to \$4.85, excluding the potential impact of health care reform in the U.S. and restructuring charges resulting from previously announced strategic headcount reductions. We expect volume-driven revenue growth in the high-single digits, driven primarily by Alimta, Cymbalta, Humalog, Cialis, Effient and the exenatide franchise. We anticipate that gross margin as a percent of revenue will be flat to declining. Marketing, selling, and

administrative expenses are projected to grow in the low- to mid-single digits while research and development expenses are projected to grow in the low-double digits. Other net, expense (income) is expected to be a net expense of between \$150.0 million and \$200.0 million. Cash flows are expected to be sufficient to fund capital expenditures of approximately \$1.0 billion, anticipated business development activity, and our dividend.

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 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 in-process research and development 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; and the impact of governmental actions regarding pricing, importation, and reimbursement for pharmaceuticals, as well as proposed health care reform currently being discussed by the U.S. Congress. 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. While it is not possible to determine the outcome of these matters, we believe that, except as specifically noted below, 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 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):

*Cymbalta:* Sixteen generic drug manufacturers have submitted Abbreviated New Drug Applications (ANDAs) seeking permission to market generic versions of Cymbalta prior to the expiration of our relevant U.S. patents (the earliest of which expires in 2013). Of these challengers, all allege non-infringement of the patent claims directed to the commercial formulation, and nine allege invalidity of the patent claims directed to the active ingredient duloxetine. Of the nine challengers to the compound patent claims, one further alleges invalidity of the claims directed to the use of Cymbalta for treating fibromyalgia, and one alleges the patent having claims directed to the active ingredient is unenforceable. In November 2008 we filed lawsuits in U.S. District Court for the Southern District of Indiana against Actavis Elizabeth LLC; Aurobindo Pharma Ltd.; Cobalt Laboratories, Inc.; Impax Laboratories, Inc.; Lupin Limited; Sandoz Inc.; and Wockhardt Limited, seeking rulings that the patents are valid, infringed, and enforceable. We filed similar lawsuits in the same court against Sun Pharma Global, Inc. in December 2008 and against Anchen Pharmaceuticals, Inc. in August 2009. The cases have been consolidated and actions against all but Wockhardt Limited have been stayed pursuant to stipulations by the defendants to be bound by the outcome of the litigation through appeal.

*Gemzar:* Mayne Pharma (USA) Inc., now Hospira, Inc. (Hospira); Fresenius Kabi Oncology Plc (Fresenius); Sicor Pharmaceuticals, Inc., now Teva Parenteral Medicines, Inc. (Teva); and Sun Pharmaceutical Industries Inc. (Sun) each submitted an ANDA seeking permission to market generic versions of Gemzar prior to the expiration of our relevant U.S. patents (compound patent expiring in 2010 and method-of-use patent expiring in 2013), and alleging that these patents are invalid. Sandoz Inc. (Sandoz) and APP Pharmaceuticals, LLC (APP) have similarly challenged our method-of-use patent. We filed lawsuits in the U.S. District Court for the Southern District of Indiana against Teva (February 2006), Hospira (October 2006 and January 2008), Sandoz (October 2009), APP (December 2009), and Fresenius (February 2010), seeking rulings that our patents are valid and are being

infringed. Sandoz withdrew its ANDA and the suit against it was dismissed in February 2010. The trial against Teva was held in September 2009 and we are waiting for a ruling. Teva's ANDAs have been approved by the FDA; however, Teva must provide 90 days notice prior to marketing generic Gemzar to allow time for us to seek a preliminary injunction. Both suits against Hospira have been administratively closed, and the parties have agreed to be bound by the results of the Teva suit. In November 2007, Sun filed a declaratory judgment action in the United States District Court for the Eastern District of Michigan, seeking rulings that our method-of-use and compound patents are invalid or unenforceable, or would not be infringed by the sale of Sun's generic product. In August 2009, the District Court granted a motion by Sun for partial summary judgment, invalidating our method-of-use patent. We have appealed this decision. This ruling has no bearing on the compound patent. The trial originally scheduled for December 2009 has been postponed while the court considers Sun's second summary judgment motion, related to the validity of our compound patent.

Sun and APP have received tentative approval for their products from the FDA, but are prohibited from entering the market by 30-month stays, which expire in June 2010 for Sun and May 2012 for APP.

*Alimta:* Teva Parenteral Medicines, Inc. (Teva), 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. patent (licensed from the Trustees of Princeton University and expiring in 2016), and alleging the patent is 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. Trial is scheduled for November 2010 against Teva and APP.

*Evista:* In 2006, Teva Pharmaceuticals USA, Inc. (Teva) submitted an ANDA seeking permission to market a generic version of Evista prior to the expiration of our relevant U.S. patents (expiring in 2012-2017) and alleging that these patents are invalid, not enforceable, or not infringed. In June 2006, we filed a lawsuit against Teva in the U.S. District Court for the Southern District of Indiana, seeking a ruling that these patents are valid, enforceable, and being infringed by Teva. The trial against Teva was completed in March 2009. In September 2009, the court upheld our method-of-use patents (the last expires in 2014). Teva has appealed that ruling. In addition, the court held that our particle-size patent (expiring 2017) is invalid. We have appealed that ruling.

*Strattera:* Actavis Elizabeth LLC (Actavis), Apotex Inc. (Apotex), Aurobindo Pharma Ltd. (Aurobindo), Mylan Pharmaceuticals Inc. (Mylan), Sandoz Inc. (Sandoz), Sun Pharmaceutical Industries Limited (Sun), and Teva Pharmaceuticals USA, Inc. (Teva) each submitted an ANDA seeking permission to market generic versions of Strattera prior to the expiration of our relevant U.S. patent (expiring in 2017), and alleging that this patent is invalid. In 2007, we brought a lawsuit against Actavis, Apotex, Aurobindo, Mylan, Sandoz, Sun, and Teva in the United States District Court for the District of New Jersey. The court has ruled on all pending summary judgment motions, and granted our infringement motion. The remaining invalidity defenses will be decided at trial, which could take place as early as the third quarter of 2010. Several companies have received tentative approval to market generic atomoxetine, but are prohibited from entering the market by a 30-month stay which expires in November 2010.

We believe each of these Hatch-Waxman challenges is 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 in any of these cases could have a material adverse impact on our future consolidated results of operations, liquidity, and financial position.

We have received challenges to Zyprexa patents in a number of countries outside the U.S.:

In Canada, several generic pharmaceutical manufacturers have challenged the validity of our Zyprexa patent (expiring in 2011). In April 2007, the Canadian Federal Court ruled against the first challenger, Apotex Inc. (Apotex), and that ruling was affirmed on appeal in February 2008. In June 2007, the Canadian Federal Court held that an invalidity allegation of a second challenger, Novopharm Ltd. (Novopharm), was justified and denied our request that Novopharm be prohibited from receiving marketing approval for generic olanzapine in Canada. Novopharm began selling generic olanzapine in Canada in the third quarter of 2007. In September 2009, the Canadian Federal Court ruled against us in the Novopharm suit, finding our patent invalid. We have appealed this decision. If the decision is upheld, we could face liability for damages related to delays in the launch of generic olanzapine products; however, we have concluded at this time that the damages are not probable or estimable.

In Germany, the German Federal Supreme Court upheld the validity of our Zyprexa patent (expiring in 2011) in December 2008, reversing an earlier decision of the Federal Patent Court. Following the decision of the Supreme Court, the generic companies who launched generic olanzapine based on the earlier decision either agreed to

withdraw from the market or were subject to injunction. We are pursuing these companies for damages arising from infringement.

We have received challenges in a number of other countries, including Spain, the United Kingdom (U.K.), and several smaller European countries. In Spain, we have been successful at both the trial and appellate court levels in defeating the generic manufacturers' challenges, but additional actions are now pending. In the U.K., the generic pharmaceutical manufacturer Dr. Reddy's Laboratories (UK) Limited (Dr. Reddy's) has challenged the validity of our Zyprexa patent (expiring in 2011). In October 2008, the Patents Court in the High Court, London ruled that our patent was valid. Dr. Reddy's appealed this decision. The U.K. Court of Appeal affirmed the validity of the patent in December 2009. Dr. Reddy's did not seek further appeal to the U.K. Supreme Court, therefore the U.K. proceedings are concluded.

We are vigorously contesting the various legal challenges to our Zyprexa patents on a country-by-country basis. We cannot determine the outcome of this litigation. The availability of generic olanzapine in additional markets could have a material adverse impact on our consolidated results of operations.

*Xigris and Evista:* In June 2002, Ariad Pharmaceuticals, Inc. (Ariad), the Massachusetts Institute of Technology, the Whitehead Institute for Biomedical Research, and the President and Fellows of Harvard

College in the U.S. District Court for the District of Massachusetts sued us, alleging that sales of two of our products, Xigris and Evista, were inducing the infringement of a patent related to the discovery of a natural cell signaling phenomenon in the human body, and seeking royalties on past and future sales of these products. Following jury and bench trials on separate issues, the U.S. District Court of Massachusetts entered final judgment in September 2007 that Ariad's claims were valid, infringed, and enforceable, and finding damages in the amount of \$65 million plus a 2.3 percent royalty on net U.S. sales of Xigris and Evista since the time of the jury decision. However, the Court deferred the requirement to pay any damages until after all rights to appeal are exhausted. In April 2009, the Court of Appeals for the Federal Circuit overturned the District Court judgment, concluding that Ariad's asserted patent claims are invalid. In August 2009, the Court of Appeals agreed to review this decision en banc, thereby vacating the Court of Appeals decision. The en banc hearing occurred in December 2009 and we are awaiting a decision. Nevertheless, we believe that these allegations are without legal merit, that we will ultimately prevail on these issues, and therefore that the likelihood of any monetary damages is remote.

### **Zyprexa Litigation**

We have been named as a defendant in a large number of Zyprexa product liability lawsuits in the U.S. and have been notified of many other claims of individuals who have not filed suit. The lawsuits and unfiled claims (together the claims) 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. Almost all of the federal lawsuits 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 (MDL No. 1596).

Since June 2005, we have entered into agreements with various claimants' attorneys involved in U.S. Zyprexa product liability litigation to settle a substantial majority of the claims. The agreements cover a total of approximately 32,670 claimants, including a large number of previously filed lawsuits and other asserted claims. The two primary settlements were as follows:

In 2005, we settled and paid more than 8,000 claims for \$690.0 million, plus \$10.0 million to cover administration of the settlement.

In 2007, we settled and paid more than 18,000 claims for approximately \$500 million.

We are prepared to continue our vigorous defense of Zyprexa in all remaining claims. The U.S. Zyprexa product liability claims not subject to these agreements include approximately 170 lawsuits in the U.S. covering approximately 260 plaintiffs, of which about 140 cases covering about 150 plaintiffs are part of the MDL. The MDL cases have been scheduled for trial in groups, and no specific trial dates for trial groups have been assigned. We also have trials scheduled in Texas state court in May and August 2010 and in Ohio in August 2010.

In January 2009, we reached resolution with the Office of the U.S. Attorney for the Eastern District of Pennsylvania (EDPA), and the State Medicaid Fraud Control Units of 36 states and the District of Columbia, of an investigation related to our U.S. marketing and promotional practices with respect to Zyprexa. As part of the resolution, we pled guilty to one misdemeanor violation of the Food, Drug, and Cosmetic Act for the off-label promotion of Zyprexa in elderly populations as treatment for dementia, including Alzheimer's dementia, between September 1999 and March 2001. We recorded a charge of \$1.42 billion for this matter in the third quarter of 2008. In 2009, we paid substantially all of this amount, as required by the settlement agreements. As part of the settlement, we have entered into a corporate integrity agreement with the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS), 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, policies, procedures, and practices.

In October 2008, we reached a settlement with 32 states and the District of Columbia related to a multistate investigation brought under various state consumer protection laws. While there is no finding that we have violated any provision of the state laws under which the investigations were conducted, we accrued and paid \$62.0 million and agreed to undertake certain commitments regarding Zyprexa for a period of six years, through consent decrees filed with the settling states.

We have been served with lawsuits filed by the states of Alaska, Arkansas, Connecticut, Idaho, Louisiana, Minnesota, Mississippi, Montana, New Mexico, Pennsylvania, South Carolina, Utah, and West Virginia alleging that Zyprexa caused or contributed to diabetes or high blood-glucose levels, and that we improperly promoted the drug. These suits seek to recover the costs paid for Zyprexa through Medicaid and other drug-benefit programs, as well as the costs alleged to have been incurred and that will be incurred by the states to treat Zyprexa-related illnesses. The Connecticut, Idaho, Louisiana, Minnesota, Mississippi, Montana, New Mexico, and West Virginia cases are part of the MDL proceedings in the EDNY.

The Alaska case was settled in March 2008 for a payment of \$15.0 million, plus terms designed to ensure, subject to certain limitations and conditions, that Alaska is treated as favorably as certain other states that may settle with us in the future over similar claims. We are in advanced discussions with the attorneys general for several of these states, seeking to resolve their Zyprexa-related claims, and we have agreed to settlements with the states of Arkansas, Connecticut, Idaho, Mississippi, New Mexico, South Carolina, Utah, and West Virginia. In the second and third quarters of 2009, we incurred pretax charges of \$105.0 million and \$125.0 million, respectively, reflecting the currently probable and estimable exposures in connection with these claims. The Pennsylvania case is set for trial in April 2010 in state court.

In 2005, two 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 have made or will make payments for their members or insured patients being prescribed Zyprexa. These actions have now been consolidated into a single lawsuit, which is brought under certain state consumer protection statutes, the federal civil RICO statute, and common law theories, seeking a refund of the cost of Zyprexa, treble damages, punitive damages, and attorneys' fees. Two additional lawsuits were filed in the EDNY in 2006 on similar grounds. In September 2008, Judge Weinstein certified a class consisting of third-party payors, excluding governmental entities and individual consumers. We appealed the certification order, and Judge Weinstein's order denying our motion for summary judgment, in September 2008. While the Second Circuit Court of Appeals heard oral arguments on the appeal in December 2009, no opinions have been rendered. In 2007, The Pennsylvania Employees Trust Fund brought claims in state court in Pennsylvania as insurer of Pennsylvania state employees, who were prescribed Zyprexa on similar grounds as described in the New York cases. 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 December 2009, the court granted our summary judgment motion, dismissing the case. Plaintiffs have appealed this decision.

In early 2005, we were served with four lawsuits seeking class action status in Canada on behalf of patients who took Zyprexa. One of these four lawsuits has been certified for residents of Quebec, and a second has been certified in Ontario and includes all Canadian residents except for residents of Quebec and British Columbia. The allegations in the Canadian actions are similar to those in the product liability litigation pending in the U.S. We are in advanced discussions to resolve all Zyprexa class-action litigation in Canada.

We cannot determine with certainty the additional number of lawsuits and claims that may be asserted. The ultimate resolution of Zyprexa product liability and related litigation could have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

#### **Other Product Liability Litigation**

We have been named as a defendant in numerous other product liability lawsuits involving primarily diethylstilbestrol (DES), thimerosal, and Byetta. The majority of 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 attain 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.

#### **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 made in this document, are based on management's expectations at the time they are made, but they are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Economic, competitive, governmental, technological, legal, and other factors that may affect our operations and prospects are discussed earlier in this section and in Item 1A, Risk Factors. We undertake no duty to update forward-looking statements.

***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**

| <b>(Dollars in millions, except per-share data) Year Ended December 31</b> | <b>2009</b>       | <b>2008</b>     | <b>2007</b>     |
|--|-------------------|-----------------|-----------------|
| Revenue  | \$ 21,836.0       | \$ 20,371.9     | \$ 18,633.5     |
| Cost of sales  | 4,247.0           | 4,376.7         | 4,248.8         |
| Research and development   | 4,326.5           | 3,840.9         | 3,486.7         |
| Marketing, selling, and administrative                                     | 6,892.5           | 6,626.4         | 6,095.1         |
| Acquired in-process research and development (Note 3)                      | 90.0              | 4,835.4         | 745.6           |
| Asset impairments, restructuring, and other special charges (Note 5)       | 692.7             | 1,974.0         | 302.5           |
| Other net, expense (income)  | 229.5             | 26.1            | (122.0)         |
|  | <b>16,478.2</b>   | <b>21,679.5</b> | <b>14,756.7</b> |
| Income (loss) before income taxes  | <b>5,357.8</b>    | (1,307.6)       | 3,876.8         |
| Income taxes (Note 12)   | <b>1,029.0</b>    | 764.3           | 923.8           |
| Net income (loss)  | \$ <b>4,328.8</b> | \$ (2,071.9)    | \$ 2,953.0      |
| Earnings (loss) per share basic and diluted (Note 11)                      | \$ <b>3.94</b>    | \$ (1.89)       | \$ 2.71         |

See notes to consolidated financial statements.

*Consolidated Balance Sheets***ELI LILLY AND COMPANY AND SUBSIDIARIES****(Dollars in millions) December 31**

|  | <b>2009</b>  | <b>2008</b>  |
|--|--------------|--------------|
| <b>Assets</b>  |              |              |
| <i>Current Assets</i>  |              |              |
| Cash and cash equivalents  | \$ 4,462.9   | \$ 5,496.7   |
| Short-term investments   | 34.7         | 429.4        |
| Accounts receivable, net of allowances of \$109.9 (2009) and \$97.4 (2008) | 3,343.3      | 2,778.8      |
| Other receivables (Note 9)   | 488.5        | 498.5        |
| Inventories  | 2,849.9      | 2,493.2      |
| Deferred income taxes (Note 12)  | 271.0        | 382.1        |
| Prepaid expenses (Note 9)  | 1,036.2      | 374.6        |
| <br>Total current assets   | <br>12,486.5 | <br>12,453.3 |
| <i>Other Assets</i>  |              |              |
| Investments (Note 6)   | 1,155.8      | 1,544.6      |
| Goodwill and other intangibles net (Note 3)                                | 3,699.8      | 3,929.1      |
| Sundry (Note 9)  | 1,921.4      | 2,659.3      |
|  | 6,777.0      | 8,133.0      |
| <br><i>Property and Equipment, net</i>                                     | <br>8,197.4  | <br>8,626.3  |
|  | \$ 27,460.9  | \$ 29,212.6  |
| <br><b>Liabilities and Shareholders' Equity</b>                            |              |              |
| <i>Current Liabilities</i>   |              |              |
| Short-term borrowings and current maturities of long-term debt (Note 7)    | \$ 27.4      | \$ 5,846.3   |
| Accounts payable   | 968.1        | 885.8        |
| Employee compensation  | 894.2        | 771.0        |
| Sales rebates and discounts  | 1,109.8      | 873.4        |
| Dividends payable  | 538.0        | 536.8        |
| Income taxes payable (Note 12)   | 346.7        | 229.2        |
| Other current liabilities (Note 9)   | 2,683.9      | 3,967.2      |
| <br>Total current liabilities  | <br>6,568.1  | <br>13,109.7 |
| <br><i>Other Liabilities</i>   |              |              |

|  |                    |             |
|--|--------------------|-------------|
| Long-term debt (Note 7)                                      | <b>6,634.7</b>     | 4,615.7     |
| Accrued retirement benefits (Note 13)                        | <b>2,334.7</b>     | 2,387.6     |
| Long-term income taxes payable (Note 12)                     | <b>1,088.4</b>     | 906.2       |
| Deferred income taxes (Note 12)                              | <b>84.8</b>        | 74.7        |
| Other noncurrent liabilities (Note 9)                        | <b>1,224.9</b>     | 1,381.0     |
|  | <b>11,367.5</b>    | 9,365.2     |
| Commitments and contingencies (Note 14)                      |                    |             |
| <i>Shareholders' Equity</i> (Notes 8 and 10)                 |                    |             |
| Common stock - no par value                                  |                    |             |
| Authorized shares: 3,200,000,000                             |                    |             |
| Issued shares: 1,149,916,107 (2009) and 1,137,837,608 (2008) | <b>718.7</b>       | 711.1       |
| Additional paid-in capital                                   | <b>4,635.6</b>     | 3,976.6     |
| Retained earnings  | <b>9,830.4</b>     | 7,654.9     |
| Employee benefit trust                                       | <b>(3,013.2)</b>   | (2,635.0)   |
| Deferred costs - ESOP  | <b>(77.4)</b>      | (86.3)      |
| Accumulated other comprehensive loss (Note 15)               | <b>(2,471.9)</b>   | (2,786.8)   |
| Noncontrolling interests                                     | <b>1.6</b>         | 2.4         |
|  | <b>9,623.8</b>     | 6,836.9     |
| Less cost of common stock in treasury                        |                    |             |
| 2009 - 882,340 shares  |                    |             |
| 2008 - 888,998 shares  | <b>98.5</b>        | 99.2        |
|  | <b>9,525.3</b>     | 6,737.7     |
|  | <b>\$ 27,460.9</b> | \$ 29,212.6 |

See notes to consolidated financial statements.

*Consolidated Statements of Cash Flows***ELI LILLY AND COMPANY AND SUBSIDIARIES****(Dollars in millions) Year Ended December 31**

|  | <b>2009</b>       | <b>2008</b>  | <b>2007</b> |
|--|-------------------|--------------|-------------|
| <b>Cash Flows From Operating Activities</b>                      |                   |              |             |
| Net income (loss)  | \$ <b>4,328.8</b> | \$ (2,071.9) | \$ 2,953.0  |
| <b>Adjustments To Reconcile Net Income To</b>                    |                   |              |             |
| <b>Cash Flows From Operating Activities</b>                      |                   |              |             |
| Net marketing investigation charges accrued (paid) (Note 14)     | <b>(1,313.6)</b>  | 1,423.6      |             |
| Depreciation and amortization                                    | <b>1,297.8</b>    | 1,122.6      | 1,047.9     |
| Change in deferred taxes   | <b>189.9</b>      | 442.6        | 60.7        |
| Stock-based compensation expense                                 | <b>368.5</b>      | 255.3        | 282.0       |
| Acquired in-process research and development, net of tax         | <b>58.5</b>       | 4,792.7      | 692.6       |
| Other, net   | <b>362.5</b>      | 406.5        | 172.1       |
|  | <b>5,292.4</b>    | 6,371.4      | 5,208.3     |
| Changes in operating assets and liabilities, net of acquisitions |                   |              |             |
| Receivables (increase) decrease                                  | <b>(492.9)</b>    | 799.1        | (842.7)     |
| Inventories (increase) decrease                                  | <b>(179.0)</b>    | 84.8         | 154.3       |
| Other assets (increase) decrease                                 | <b>(84.9)</b>     | 1,648.6      | (355.8)     |
| Accounts payable and other liabilities increase (decrease)       | <b>(200.1)</b>    | (1,608.3)    | 990.4       |
|  | <b>(956.9)</b>    | 924.2        | (53.8)      |
| <b>Net Cash Provided by Operating Activities</b>                 | <b>4,335.5</b>    | 7,295.6      | 5,154.5     |
| <b>Cash Flows From Investing Activities</b>                      |                   |              |             |
| Purchases of property and equipment                              | <b>(765.0)</b>    | (947.2)      | (1,082.4)   |
| Disposals of property and equipment                              | <b>17.7</b>       | 25.7         | 32.3        |
| Net change in short-term investments                             | <b>399.1</b>      | 957.6        | (376.9)     |
| Proceeds from sales and maturities of noncurrent investments     | <b>1,107.8</b>    | 1,597.3      | 800.1       |
| Purchases of noncurrent investments                              | <b>(432.3)</b>    | (2,412.4)    | (750.7)     |
| Purchases of in-process research and development                 | <b>(90.0)</b>     | (122.0)      | (111.0)     |
| Cash paid for acquisitions, net of cash acquired                 |                   | (6,083.0)    | (2,673.2)   |
| Other, net   | <b>(94.5)</b>     | (284.8)      | (166.3)     |
| <b>Net Cash Provided by (Used for) Investing Activities</b>      | <b>142.8</b>      | (7,268.8)    | (4,328.1)   |
| <b>Cash Flows From Financing Activities</b>                      |                   |              |             |
| Dividends paid   | <b>(2,152.1)</b>  | (2,056.7)    | (1,853.6)   |

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|  |                   |                   |                   |
|--|-------------------|-------------------|-------------------|
| Net change in short-term borrowings                          | (5,824.2)         | 5,060.5           | (468.5)           |
| Proceeds from issuance of long-term debt                     | 2,400.0           | 0.1               | 2,512.6           |
| Repayments of long-term debt                                 |                   | (649.8)           | (1,059.5)         |
| Other, net   | 42.6              | (8.1)             | 24.1              |
| <b>Net Cash Provided by (Used for) Financing Activities</b>  | <b>(5,533.7)</b>  | 2,346.0           | (844.9)           |
| Effect of exchange rate changes on cash and cash equivalents | 21.6              | (96.6)            | 129.7             |
| Net (decrease) increase in cash and cash equivalents         | (1,033.8)         | 2,276.2           | 111.2             |
| Cash and cash equivalents at beginning of year               | 5,496.7           | 3,220.5           | 3,109.3           |
| <b>Cash and Cash Equivalents at End of Year</b>              | <b>\$ 4,462.9</b> | <b>\$ 5,496.7</b> | <b>\$ 3,220.5</b> |

See notes to consolidated financial statements.

*Consolidated Statements of Comprehensive Income (Loss)***ELI LILLY AND COMPANY AND SUBSIDIARIES****(Dollars in millions) Year Ended December 31**

|  | <b>2009</b>       | <b>2008</b>  | <b>2007</b> |
|--|-------------------|--------------|-------------|
| Net income (loss)  | \$ <b>4,328.8</b> | \$ (2,071.9) | \$ 2,953.0  |
| Other comprehensive income (loss)  |                   |              |             |
| Foreign currency translation gains (losses)                                      | <b>284.9</b>      | (766.1)      | 756.6       |
| Net unrealized gains (losses) on securities                                      | <b>289.8</b>      | (190.6)      | (11.4)      |
| Defined benefit pension and retiree health benefit plans<br>(Note 13)            | <b>(280.3)</b>    | (2,941.2)    | 943.8       |
| Effective portion of cash flow hedges  | <b>48.2</b>       | 23.2         | (0.1)       |
| Other comprehensive income (loss) before income taxes                            | <b>342.6</b>      | (3,874.7)    | 1,688.9     |
| Provision for income taxes related to other comprehensive<br>income (loss) items | <b>(27.7)</b>     | 1,074.7      | (287.0)     |
| Other comprehensive income (loss) (Note 15)                                      | <b>314.9</b>      | (2,800.0)    | 1,401.9     |
| Comprehensive income (loss)  | \$ <b>4,643.7</b> | \$ (4,871.9) | \$ 4,354.9  |

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**

|                                     | <b>2009</b>        | <b>2008</b> | <b>2007</b> |
|-------------------------------------|--------------------|-------------|-------------|
| Net sales to unaffiliated customers |                    |             |             |
| Neuroscience                        | \$ <b>8,976.4</b>  | \$ 8,371.5  | \$ 7,851.0  |
| Endocrinology                       | <b>5,677.4</b>     | 5,493.5     | 5,037.7     |
| Oncology                            | <b>3,161.7</b>     | 2,877.1     | 2,446.4     |
| Cardiovascular                      | <b>1,971.1</b>     | 1,882.7     | 1,624.1     |
| Animal health                       | <b>1,207.2</b>     | 1,093.3     | 995.8       |
| Other pharmaceuticals               | <b>177.7</b>       | 207.7       | 219.7       |
| Net product sales                   | <b>21,171.5</b>    | 19,925.8    | 18,174.7    |
| Collaboration and other revenue     | <b>664.5</b>       | 446.1       | 458.8       |
| Total revenue                       | <b>\$ 21,836.0</b> | \$ 20,371.9 | \$ 18,633.5 |

**Geographic Information**

|   |                    |             |             |
|---|--------------------|-------------|-------------|
| Total revenue to unaffiliated customers |                    |             |             |
| United States                           | \$ <b>12,294.4</b> | \$ 10,930.1 | \$ 10,145.5 |
| Europe                                  | <b>5,227.2</b>     | 5,333.5     | 4,731.8     |
| Other foreign countries                 | <b>4,314.4</b>     | 4,108.3     | 3,756.2     |
|   | <b>\$ 21,836.0</b> | \$ 20,371.9 | \$ 18,633.5 |
| Long-lived assets                       |                    |             |             |
| United States                           | \$ <b>5,310.0</b>  | \$ 5,750.0  | \$ 5,905.4  |
| Europe                                  | <b>2,313.3</b>     | 2,119.0     | 2,057.7     |
| Other foreign countries                 | <b>1,723.3</b>     | 1,753.0     | 1,768.6     |
|   | <b>\$ 9,346.6</b>  | \$ 9,622.0  | \$ 9,731.7  |

<sup>1</sup> Net sales are 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, Byetta, Actos, Evista, Forteo, and Humatrope. Oncology products consist primarily of Alimta and Gemzar. Cardiovascular products consist primarily of Cialis, ReoPro, Xigris, and Effient. Animal health products include Posilac, Tylan, Rumensin, Coban, and other products for livestock and poultry, and 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. Collaboration and other revenue includes our share of the U.S. gross margin on Byetta and the global Erbitux royalty. See Note 4 for additional information.

Most of our pharmaceutical products are distributed through wholesalers that serve pharmacies, physicians and other health care professionals, and hospitals. In 2009, our three largest wholesalers each accounted for between 12 percent and 17 percent of consolidated total revenue. Further, they each accounted for between 9 percent and 16 percent of accounts receivable as of December 31, 2009. 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 \$217 million, \$192 million, and \$173 million in 2009, 2008, and 2007, 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) 2009**

|   | <b>Fourth</b>     | <b>Third</b> | <b>Second</b> | <b>First</b> |
|---|-------------------|--------------|---------------|--------------|
| Revenue   | \$ <b>5,934.2</b> | \$ 5,562.0   | \$ 5,292.8    | \$ 5,047.0   |
| Cost of sales   | <b>1,431.3</b>    | 1,051.9      | 947.4         | 816.4        |
| Operating expenses  | <b>3,170.0</b>    | 2,823.9      | 2,748.6       | 2,476.5      |
| Acquired in-process research and development                | <b>90.0</b>       |              |               |              |
| Asset impairments, restructuring, and other special charges | <b>37.9</b>       | 549.8        | 105.0         |              |
| Other net, expense  | <b>67.8</b>       | 66.9         | 24.1          | 70.7         |
| Income before income taxes                                  | <b>1,137.2</b>    | 1,069.5      | 1,467.7       | 1,683.4      |
| Net income  | <b>915.4</b>      | 941.8        | 1,158.5       | 1,313.1      |
| Earnings per share basic and diluted                        | <b>.83</b>        | .86          | 1.06          | 1.20         |
| Dividends paid per share                                    | <b>.49</b>        | .49          | .49           | .49          |
| Common stock closing prices                                 |                   |              |               |              |
| High  | <b>37.51</b>      | 35.15        | 35.95         | 40.57        |
| Low   | <b>32.47</b>      | 32.40        | 31.88         | 27.47        |

| <b>2008</b>   | <b>Fourth</b>     | <b>Third</b> | <b>Second</b> | <b>First</b> |
|---|-------------------|--------------|---------------|--------------|
| Revenue   | \$ <b>5,204.4</b> | \$ 5,209.5   | \$ 5,150.4    | \$ 4,807.6   |
| Cost of sales   | <b>909.3</b>      | 1,155.2      | 1,200.9       | 1,111.3      |
| Operating expenses  | <b>2,785.9</b>    | 2,602.2      | 2,651.6       | 2,427.6      |
| Acquired in-process research and development                | <b>4,685.4</b>    | 28.0         | 35.0          | 87.0         |
| Asset impairments, restructuring, and other special charges | <b>80.0</b>       | 1,659.4      | 88.9          | 145.7        |
| Other net, expense (income)                                 | <b>81.2</b>       | (2.5)        | (32.3)        | (20.3)       |
| Income (loss) before income taxes                           | <b>(3,337.4)</b>  | (232.8)      | 1,206.3       | 1,056.3      |
| Net income (loss) <sup>1</sup>                              | <b>(3,629.4)</b>  | (465.6)      | 958.8         | 1,064.3      |
| Earnings (loss) per share basic and diluted                 | <b>(3.31)</b>     | (.43)        | .88           | .97          |
| Dividends paid per share                                    | <b>.47</b>        | .47          | .47           | .47          |
| Common stock closing prices                                 |                   |              |               |              |
| High  | <b>43.69</b>      | 49.25        | 53.06         | 57.18        |
| Low   | <b>29.91</b>      | 43.92        | 45.61         | 47.81        |

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

<sup>1</sup> 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 in-process research and development (IPR&D) charge for ImClone in the fourth quarter and the \$1.48 billion Zyprexa investigation settlements recorded in the third quarter. 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 in the fourth quarter in 2008, as well as a discrete income tax benefit of \$210.3 million in the first quarter of 2008 for the resolution of a substantial

portion of the 2001-2004 Internal Revenue Service (IRS) audit.

*Selected Financial Data (unaudited)***AND COMPANY AND SUBSIDIARIES**

(millions, except total revenue per employee and per-share data)

|  | 2009        | 2008                 | 2007        | 2006        |
|--|-------------|----------------------|-------------|-------------|
|  | \$ 21,836.0 | \$ 20,371.9          | \$ 18,633.5 | \$ 15,691.0 |
|  | 4,247.0     | 4,376.7              | 4,248.8     | 3,546.5     |
| development  | 4,326.5     | 3,840.9              | 3,486.7     | 3,129.3     |
| elling, and administrative   | 6,892.5     | 6,626.4              | 6,095.1     | 4,889.8     |
|  | 1,012.2     | 6,835.5 <sup>1</sup> | 926.1       | 707.4       |
| before income taxes and cumulative effect of a change in principle | 5,357.8     | (1,307.6)            | 3,876.8     | 3,418.0     |
|  | 1,029.0     | 764.3                | 923.8       | 755.3       |
| loss)  | 4,328.8     | (2,071.9)            | 2,953.0     | 2,662.7     |
| s a percent of revenue   | 19.8%       | NM                   | 15.8%       | 17.0%       |
| loss) per share diluted  | 3.94        | (1.89)               | 2.71        | 2.45        |
| clared per share   | 1.96        | 1.90                 | 1.75        | 1.63        |
| verage number of shares outstanding diluted (thousands)            | 1,098,367   | 1,094,499            | 1,090,750   | 1,087,490   |
| position   |             |                      |             |             |
| s  | \$ 12,486.5 | \$ 12,453.3          | \$ 12,316.1 | \$ 9,753.6  |
| ities  | 6,568.1     | 13,109.7             | 5,436.8     | 5,254.0     |
| equipment net  | 8,197.4     | 8,626.3              | 8,575.1     | 8,152.3     |
|  | 27,460.9    | 29,212.6             | 26,874.8    | 22,042.4    |
| bt   | 6,634.7     | 4,615.7              | 4,593.5     | 3,494.4     |
| equity   | 9,525.3     | 6,737.7              | 13,510.3    | 10,825.3    |
| ary Data   |             |                      |             |             |
| areholders equity  | 51.0%       | (16.3)%              | 24.3%       | 24.8%       |
| ets  | 15.8%       | (7.5)%               | 12.1%       | 11.1%       |
| ditures  | \$ 765.0    | \$ 947.2             | \$ 1,082.4  | \$ 1,077.8  |
| and amortization   | 1,297.8     | 1,122.6              | 1,047.9     | 801.8       |
| rate   | 19.2%       | NM <sup>2</sup>      | 23.8%       | 22.1%       |
| employee   | \$ 540,000  | \$ 504,000           | \$ 459,000  | \$ 378,000  |
| mployees   | 40,360      | 40,450               | 40,600      | 41,500      |
| areholders of record   | 38,400      | 39,800               | 41,700      | 44,800      |

NM Not Meaningful

<sup>1</sup> The increase reflects the in-process research and development expense of \$4.69 billion associated with the ImClone acquisition and \$1.48 billion associated with the Zyprexa investigation settlements.

<sup>2</sup> 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 2005 through 2009. The graph assumes that, on December 31, 2004, 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 2004****Comparison of Five-Year Cumulative Total Return Among Lilly, S&P 500 Stock Index, Peer Group<sup>1</sup>, and Peer Group (Previous)<sup>2</sup>**

|        |    | <b>Lilly</b> | <b>Peer<br/>Group</b> | <b>Peer<br/>Group<br/>(Previous)</b> | <b>S&amp;P 500</b> |
|--------|----|--------------|-----------------------|--------------------------------------|--------------------|
| Dec-04 | \$ | 100.00       | \$ 100.00             | \$ 100.00                            | \$ 100.00          |
| Dec-05 | \$ | 102.53       | \$ 103.28             | \$ 99.29                             | \$ 104.90          |
| Dec-06 | \$ | 97.18        | \$ 116.07             | \$ 112.42                            | \$ 121.43          |
| Dec-07 | \$ | 102.70       | \$ 116.21             | \$ 114.87                            | \$ 128.09          |
| Dec-08 | \$ | 80.74        | \$ 99.55              | \$ 97.59                             | \$ 80.77           |
| Dec-09 | \$ | 75.80        | \$ 113.46             | \$ 108.78                            | \$ 102.08          |

<sup>1</sup> We constructed the peer group as the industry index for this graph. It comprises the ten companies in the pharmaceutical industry that we used to benchmark 2009 compensation of executive officers: Abbott Laboratories; Amgen Inc.; AstraZeneca PLC; Bristol-Myers Squibb Company; GlaxoSmithKline plc; Johnson & Johnson; Merck & Co., Inc.; Novartis AG.; Pfizer Inc.; and Sanofi-Aventis.

<sup>2</sup> Due to changes in the pharmaceutical industry, the peer group used to benchmark 2008 compensation of executive officers was revised, with the previous peer group consisting of the following companies: Abbott Laboratories; Amgen Inc.; Bristol-Myers Squibb Company; GlaxoSmithKline plc; Johnson & Johnson; Merck & Co., Inc.; Pfizer Inc.; Schering-Plough Corporation; and Wyeth. The Peer Group (Previous) excludes Schering-Plough Corporation and Wyeth as both companies were acquired during 2009.

*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 non-controlling 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 on February 22, 2010. We have evaluated subsequent events up to the time of the filing.

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

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

**Inventories:** We state all inventories at the lower of cost or market. We use the last-in, first-out (LIFO) method for the majority of our inventories located in the continental United States, or approximately 40 percent of our total inventories. Other inventories are valued by the first-in, first-out (FIFO) method. FIFO cost approximates current replacement cost. Inventories at December 31 consisted of the following:

|                            | 2009       | 2008       |
|----------------------------|------------|------------|
| Finished products          | \$ 938.3   | \$ 771.0   |
| Work in process            | 1,830.1    | 1,657.1    |
| Raw materials and supplies | 227.8      | 236.3      |
|                            | 2,996.2    | 2,664.4    |
| Reduction to LIFO cost     | (146.3)    | (171.2)    |
|                            | \$ 2,849.9 | \$ 2,493.2 |

**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 are 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 (income). 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 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 and option 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 (income). The purchased option contracts are used to hedge anticipated foreign currency transactions, primarily intercompany inventory activities expected to occur within the next year. These contracts are designated as cash flow hedges of those future transactions and the impact on earnings is included in cost of sales. We may enter into foreign currency forward contracts and currency swaps as fair value hedges of firm commitments. Forward and option 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.

**Goodwill and other intangibles:** Goodwill is not amortized. All other intangibles arising from acquisitions and research alliances have finite lives and are amortized over their estimated useful lives, ranging from 5 to 20 years, using the straight-line method. The remaining weighted-average amortization period for developed product technology is approximately 11 years. Amortization expense for 2009, 2008, and 2007 was \$277.0 million, \$193.4 million, and \$172.8 million before tax, respectively. The estimated amortization expense for each of the five succeeding years approximates \$280.0 million before tax, per year. Substantially all of the amortization expense is included in cost of sales. See Note 3 for further discussion of goodwill and other intangibles acquired in 2009, 2008, and 2007.

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

|                                    | 2009       | 2008       |
|------------------------------------|------------|------------|
| Goodwill                           | \$ 1,175.0 | \$ 1,167.5 |
| Developed product technology gross | 3,035.4    | 3,035.4    |
| Less accumulated amortization      | (612.8)    | (346.6)    |
| Developed product technology net   | 2,422.6    | 2,688.8    |

|                               |            |            |
|-------------------------------|------------|------------|
| Other intangibles gross       | 158.4      | 118.2      |
| Less accumulated amortization | (56.2)     | (45.4)     |
| Other intangibles net         | 102.2      | 72.8       |
| Total intangibles net         | \$ 3,699.8 | \$ 3,929.1 |

Goodwill and net other intangibles are reviewed to assess recoverability at least annually and when certain impairment indicators are present. No significant impairments occurred with respect to the carrying value of our goodwill or other intangible assets in 2009, 2008, or 2007.

**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:

|                               | 2009       | 2008       |
|-------------------------------|------------|------------|
| Land                          | \$ 216.8   | \$ 219.0   |
| Buildings                     | 6,121.9    | 5,953.4    |
| Equipment                     | 7,813.0    | 8,045.2    |
| Construction in progress      | 948.3      | 1,098.3    |
|                               | 15,100.0   | 15,315.9   |
| Less accumulated depreciation | (6,902.6)  | (6,689.6)  |
|                               | \$ 8,197.4 | \$ 8,626.3 |

Depreciation expense for 2009, 2008, and 2007 was \$813.5 million, \$731.7 million, and \$682.3 million, respectively. Interest costs of \$30.2 million, \$48.2 million, and \$95.3 million were capitalized as part of property and equipment in 2009, 2008, and 2007, respectively. Total rental expense for all leases, including contingent rentals (not material), amounted to \$337.8 million, \$327.4 million, and \$294.2 million for 2009, 2008, and 2007, 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 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. For more than 85 percent of our sales, this is at the time products are shipped to the customer, typically a wholesale distributor or a major retail chain. The remaining sales are recorded at the point of delivery. 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 are 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, 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 (income). 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.

Royalty revenue from licensees, which are based on third-party sales of licensed products and technology, are 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:

|  | 2009        | 2008        | 2007        |
|--|-------------|-------------|-------------|
| Net product sales                        | \$ 21,171.5 | \$ 19,925.8 | \$ 18,174.7 |
| Collaboration and other revenue (Note 4) | 664.5       | 446.1       | 458.8       |
| Total revenue                            | \$ 21,836.0 | \$ 20,371.9 | \$ 18,633.5 |

**Acquired research and development:** We recognize as incurred the cost of directly acquiring assets to be used in the research and development process that have not yet received regulatory approval for marketing and for which no alternative future use has been identified. Beginning in 2009, in process research and development acquired in a business combination is capitalized at the fair value as of the time of the acquisition. For in-process research and development assets acquired in both direct acquisitions and business combinations, once the product has obtained regulatory approval, we capitalize any milestones paid and amortize them over the period benefited. Milestones paid prior to regulatory approval of the product are generally expensed when the event requiring payment of the milestone occurs.

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

|                  | 2009     | 2008     | 2007       |
|------------------|----------|----------|------------|
| Interest expense | \$ 261.3 | \$ 228.3 | \$ 228.3   |
| Interest income  | (75.2)   | (210.7)  | (215.3)    |
| Other            | 43.4     | 8.5      | (135.0)    |
|                  | \$ 229.5 | \$ 26.1  | \$ (122.0) |

**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 11 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, 2008 and 2007 consolidated financial statements and accompanying notes to conform with the December 31, 2009 presentation.

## **Note 2: Implementation of New Financial Accounting Pronouncements**

The Financial Accounting Standards Board (FASB) Statement on Business Combinations was effective for us for business combinations with the acquisition date on or after January 1, 2009. This Statement, with its amendment, changes the way in which the acquisition method is to be applied in a business combination. The primary revisions require an acquirer in a business combination to measure assets acquired, liabilities assumed, and any noncontrolling interest in the acquiree at the acquisition date, at their fair values as of that date, with limited exceptions specified in the Statement. This Statement also requires the acquirer in a business combination achieved in stages to recognize the identifiable assets and liabilities, as well as the noncontrolling interest in the acquiree, at the full amounts of their fair values (or other amounts determined in accordance with the Statement). Assets acquired and liabilities assumed arising from contingencies are to be measured at fair value if it can be determined during the measurement period. If fair value cannot be determined, the asset or liability should be recognized at the acquisition date if it is probable that an asset existed or a liability had been incurred and the amount can be reasonably estimated. This Statement significantly amends other authoritative guidance on Business

Combinations as well, and now requires the capitalization of research and development assets acquired in a business combination at their acquisition-date fair values, separately from goodwill. The accounting for income taxes was also amended by this Statement to require the acquirer to recognize changes in the amount of its deferred tax benefits that are recognizable because of a business combination either in income from continuing operations in the period of the combination or directly in contributed capital, depending on the circumstances.

We adopted the provisions of the FASB Statement on Consolidations relating to the accounting for noncontrolling interests on January 1, 2009. This Statement amends previous authoritative guidance, by requiring companies to report a noncontrolling interest in a subsidiary as equity in its consolidated financial statements. Disclosure of the amounts of consolidated net income attributable to the parent and the noncontrolling interest will be required. This Statement also clarifies that transactions that result in a change in a parent's ownership interest in a subsidiary that do not result in deconsolidation will be treated as equity transactions, while a gain or loss will be recognized by the parent when a subsidiary is deconsolidated. We now classify our noncontrolling interest in a subsidiary as part of shareholders' equity in our consolidated statements of financial position at December 31, 2009 and reclassified the December 31, 2008 balances accordingly. The net income attributed to the noncontrolling interest in a subsidiary for 2009 and 2008 is not material and is included in other-net, expense (income).

We adopted the provisions of the FASB Statement on disclosures relating to Derivatives and Hedging on January 1, 2009. This Statement requires entities to provide enhanced disclosures about how and why an entity uses derivative instruments, how derivative instruments and related hedged items are accounted for, and how derivative instruments and related hedged items affect an entity's financial position, results of operations, and cash flows. These disclosures are included in Note 6.

We adopted the provisions of the Emerging Issues Task Force (EITF) guidance related to Collaborative Arrangements on January 1, 2009. This guidance defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. This guidance has been applied retrospectively to all prior periods presented for significant collaborative arrangements existing as of the effective date by classifying revenues into two separate components: net product sales and collaboration and other revenue. See Note 4 for additional information.

We adopted the provisions of the FASB Staff Position (FSP) relating to Investments on January 1, 2009. This FSP amends the other-than-temporary recognition guidance for debt securities and requires additional interim and annual disclosures of other-than-temporary impairments on debt and equity securities. Pursuant to the new guidance, an other-than-temporary impairment has occurred if a company does not expect to recover the entire amortized cost basis of the security. In this situation, if the company does not intend to sell the impaired security, and it is not more likely than not it will be required to sell the security before the recovery of its amortized cost basis, the amount of the other-than-temporary impairment recognized in earnings is limited to the portion attributed to the credit loss. The remaining portion of the other-than-temporary impairment is then recorded in other comprehensive income (loss). This FSP has been applied to existing and new securities as of January 1, 2009. The applicable disclosures are included in Note 6. The implementation of this FSP was not material to our consolidated financial position or results of operations and there was no cumulative effect adjustment.

We adopted the provisions of a FSP relating to Fair Value Measurements and Disclosures, as of March 31, 2009. This FSP provides additional guidance on estimating fair value when the volume and level of activity for an asset or liability have significantly decreased in relation to normal market activity. The FSP also provides additional guidance on circumstances that may indicate that a transaction is not orderly and requires additional disclosures. The implementation of this FSP had no effect on our consolidated financial position or results of operations.

We adopted the provisions of a FSP on Financial Instruments, as of March 31, 2009. This FSP required disclosures about fair value of all financial instruments for interim reporting periods. The implementation of this FSP had no effect on our consolidated financial position or results of operations.

We adopted the provisions of a FSP on Compensation Retirement Benefits, as of December 31, 2009. This FSP required disclosures about plan assets of a defined benefit pension or other postretirement plan. The applicable disclosures are included in Note 13. The implementation of this FSP had no effect on our consolidated financial position or results of operations.

During 2009, we adopted the provisions of the FASB Statement on Subsequent Events. This Statement provides authoritative accounting literature and disclosure requirements for material events occurring subsequent to the balance sheet date and prior to the issuance of the financial statements. The implementation of this Statement had no effect on our consolidated financial position or results of operations.

In 2009, the FASB issued a Statement on Transfers and Servicing, an amendment of previous authoritative guidance. The most significant amendments resulting from this Statement consist of the removal of the concept of a qualifying special-purpose entity (SPE) from previous authoritative guidance, and the elimination of the exception for qualifying SPEs from the Consolidation guidance regarding variable interest entities. This Statement is effective for us January 1, 2010 and is not expected to be material to our consolidated financial position or results of operations.

In 2009, the FASB issued a Statement which amends the previous Consolidations guidance regarding variable interest entities and addresses the effects of eliminating the qualifying SPE concept from the guidance on Transfers and Servicing. This Statement responds to concerns about the application of certain key provisions of the previous guidance on Consolidations regarding variable interest entities, including concerns over the transparency of enterprises' involvement with variable interest entities. This Statement is effective for us January 1, 2010 and is not expected to be material to our consolidated financial position or results of operations.

In 2009, the FASB ratified EITF guidance 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 is effective for us January 1, 2011 and is not expected to be material to our consolidated financial position or results of operations.

### **Note 3: Acquisitions**

During 2008 and 2007 we acquired several businesses. These acquisitions were accounted for as business combinations under the purchase method of accounting. Under the purchase 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.

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. 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 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. Pursuant to the existing rules, these acquired IPR&D intangible assets totaling \$4.71 billion and \$340.5 million in 2008 and 2007, respectively, were expensed immediately subsequent to the acquisition because the products had no alternative future use. The ongoing expenses with respect to each of these products 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.

In addition to the acquisitions of businesses, we also acquired several products in development. The acquired IPR&D related to these products of \$90.0 million, \$122.0 million, and \$405.1 million in 2009, 2008, and 2007, respectively, was also written off by a charge to income immediately upon acquisition because the products had no alternative future use.

**ImClone Acquisition**

On November 24, 2008, we acquired all of the outstanding shares of ImClone Systems Inc. (ImClone), a biopharmaceutical company focused on advancing oncology care, for a total purchase price of approximately \$6.5 billion, which was financed through borrowings. This strategic combination offered both targeted therapies and oncolytic agents along with a pipeline spanning all phases of clinical development. The combination also expanded our biotechnology capabilities.

The acquisition was accounted for as a business combination under the purchase method of accounting, resulting in goodwill of \$425.9 million. No portion of this goodwill was or is expected to be deductible for tax purposes.

**Allocation of Purchase Price**

The purchase price was allocated based on the fair value of assets acquired and liabilities assumed as of the date of acquisition.

|   | <b>Fair Value<br/>at November 24,<br/>2008</b> |
|---|--|
| Cash and short-term investments                   | \$ 982.9                                       |
| Inventories                                       | 136.2  |
| Developed product technology (Erbix) <sup>1</sup> | 1,057.9  |
| Goodwill  | 425.9  |
| Property and equipment                            | 338.9  |
| Debt assumed                                      | (600.0)  |
| Deferred taxes                                    | (311.5)  |
| Deferred income                                   | (127.7)  |
| Other assets and liabilities net                  | (81.1)   |
| Acquired in-process research and development      | 4,685.4  |
| Total purchase price                              | \$ 6,506.9                                     |

<sup>1</sup> This intangible asset is being amortized on a straight-line basis through 2023 in the U.S. and 2018 in the rest of the world.

All of the estimated fair value of the acquired IPR&D was attributable to oncology-related products in development, including \$1.33 billion to line extensions for Erbitux. A significant portion (81 percent) of the remaining value of acquired IPR&D was attributable to ramucirumab, necitumumab, and cixutumumab. At the time of the acquisition, ramucirumab was in Phase III clinical testing, while necitumumab and cixutumumab were in Phase II clinical testing. The discount rate we used in valuing the acquired IPR&D projects was 13.5 percent, and the charge for acquired IPR&D of \$4.69 billion recorded in the fourth quarter of 2008 was not deductible for tax purposes.

**Pro Forma Financial Information (unaudited)**

The following pro forma financial information presents the combined results of our operations with ImClone as if the acquisition and the financing for the acquisition had occurred as of the beginning of each of the years presented. We have adjusted the historical consolidated financial information to give effect to pro forma events that are directly attributable to the acquisition. The pro forma financial information is not necessarily indicative of what our consolidated results of operations actually would have been had we completed the acquisition at the beginning of each year. In addition, the pro forma financial information does not attempt to project the future results of operations of our combined company.

|         | <b>2008</b> | <b>2007</b> |
|---------|-------------|-------------|
| Revenue | \$ 20,732.2 | \$ 19,051.4 |

|                         |         |         |
|-------------------------|---------|---------|
| Net income <sup>1</sup> | 2,356.2 | 2,704.1 |
| Earnings per share:     |         |         |
| Basic and diluted       | 2.15    | 2.48    |

<sup>1</sup> The pro forma financial information above excludes the non-recurring charge incurred for acquired IPR&D of \$4.69 billion and other merger-related costs.

The pro forma financial information above reflects the following:

a reduction of the amortization of ImClone's deferred income of \$86.2 million (2008) and \$98.4 million (2007);

the increase of amortization expense of \$78.8 million in 2008 and 2007 related to the estimated fair value of identifiable intangible assets from the purchase price allocation which are being amortized over their estimated useful lives through 2023 in the U.S. and through 2018 in the rest of the world. The change in depreciation expense related to the change in the estimated fair value of property and equipment from the book value at the time of the acquisition was not material;

the adjustment to increase interest expense related to the debt incurred to finance the acquisition and the adjustment to decrease interest income related to the lost interest income on the cash used to purchase ImClone by a total of \$301.0 million in 2008 and 2007;

the reduction of ImClone's income tax expense to provide for income taxes at the statutory tax rate and the adjustment to income taxes for pro forma adjustments at the statutory tax rate, totaling \$139.3 million (2008) and \$189.5 million (2007). This excludes the acquired IPR&D charge of \$4.69 billion, which was not tax deductible;

certain reclassifications to conform to accounting policies and classifications that are consistent with our practices (e.g., ImClone's license fees and milestones were classified as other net, expense (income), rather than net sales).

### **Posilac**

On October 1, 2008, we acquired the worldwide rights to the dairy cow supplement Posilac, as well as the product's supporting operations, from Monsanto Company (Monsanto). The acquisition of Posilac provides us with a product that complements those of our animal health business. Under the terms of the agreement, we acquired the rights to the Posilac brand, as well as the product's U.S. sales force and manufacturing facility, for an aggregate purchase price of \$403.9 million, which included a \$300.0 million upfront payment, transaction costs, and an accrual for contingent consideration to Monsanto based on estimated future Posilac sales for which payment is considered likely beyond a reasonable doubt.

This acquisition has been accounted for as a business combination under the purchase method of accounting. We allocated \$204.3 million to identifiable intangible assets related to Posilac, \$167.6 million to inventories, and \$99.5 million of the purchase price to property and equipment. We also assumed \$67.5 million of liabilities. Substantially all of the identifiable intangible assets are being amortized over their estimated remaining useful lives of 20 years. The amount allocated to each of the intangible assets acquired is deductible for tax purposes.

### **SGX Pharmaceuticals, Inc.**

On August 20, 2008, we acquired all of the outstanding common stock of SGX Pharmaceuticals, Inc. (SGX), a collaboration partner since 2003. The acquisition allows us to integrate SGX's structure-guided drug discovery platform into our drug discovery efforts. It also gives us access to FAST™, SGX's fragment-based, protein structure guided drug discovery technology, and to a portfolio of preclinical oncology compounds focused on a number of kinase targets. Under the terms of the agreement, the outstanding shares of SGX common stock were redeemed for an aggregate purchase price of \$66.8 million.

The acquisition has been accounted for as a business combination under the purchase method of accounting. We allocated \$29.6 million of the purchase price to deferred tax assets and \$28.0 million to acquired IPR&D. The acquired IPR&D charge of \$28.0 million was recorded in the third quarter of 2008 and was not deductible for tax purposes.

### **ICOS Corporation**

On January 29, 2007, we acquired all of the outstanding common stock of ICOS Corporation (ICOS), our partner in the Lilly ICOS LLC joint venture for the manufacture and sale of Cialis for the treatment of erectile dysfunction. The acquisition brought the full value of Cialis to us and enabled us to realize operational efficiencies in the further development, marketing, and selling of this product. The aggregate cash purchase price of approximately \$2.3 billion was financed through borrowings.

The acquisition has been accounted for as a business combination under the purchase method of accounting, resulting in goodwill of \$646.7 million. No portion of this goodwill is expected to be deductible for tax purposes.

The other significant components of the purchase price allocation were developed product technology (Cialis) of \$1,659.9 million, the tax benefit of net operating losses of \$404.1 million, acquired IPR&D of \$303.5 million, cash

and short-term investments of \$197.7 million, deferred tax liability of \$583.5 million and long-term debt assumed of \$275.6 million. The developed product technology is being amortized over the remaining expected patent lives of Cialis in each country; patent expiration dates range from 2015 to 2017.

#### **Other Acquisitions**

During the second quarter of 2007, we acquired all of the outstanding stock of both Hypnion, Inc. (Hypnion), a privately held neuroscience drug discovery company focused on sleep disorders, and Ivy Animal Health, Inc. (Ivy), a privately held applied research and pharmaceutical product development company focused on the animal health industry, for \$445.0 million in cash.

The acquisition of Hypnion provided us with a broader and more substantive presence in the area of sleep disorder research and ownership of LY2624803, a novel Phase II compound with a dual mechanism of action aimed at promoting better sleep onset and sleep maintenance. This was Hypnion's only significant asset. For this acquisition, we recorded an acquired IPR&D charge of \$291.1 million, which was not deductible for tax purposes. Because Hypnion was a development-stage company, the transaction was

accounted for as an acquisition of assets rather than as a business combination and, therefore, goodwill was not recorded.

The acquisition of Ivy provided us with products that complement those of our animal health business. This acquisition has been accounted for as a business combination under the purchase method of accounting. We allocated \$88.7 million of the purchase price to other identifiable intangible assets, primarily related to marketed products, \$37.0 million to acquired IPR&D, and \$25.0 million to goodwill. The other identifiable intangible assets are being amortized over their estimated remaining useful lives of 10 to 20 years. The \$37.0 million allocated to acquired IPR&D was charged to expense in the second quarter of 2007. Goodwill resulting from this acquisition was fully allocated to the animal health business segment. The amount allocated to each of the intangible assets acquired, including goodwill of \$25.0 million and the acquired IPR&D of \$37.0 million, was deductible for tax purposes.

### **Product Acquisitions**

In December 2009, we entered into a licensing and collaboration agreement with Incyte Corporation 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. As with many development-phase compounds, launch of the product, if approved, was not expected in the near term. 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 United States.

In June 2008, we entered into a licensing and development agreement with TransPharma Medical Ltd. (TransPharma) to acquire rights to its product and related drug delivery system for the treatment of osteoporosis. The product, which is administered transdermally using TransPharma's proprietary technology, was in Phase II clinical testing, and had no alternative future use. Under the arrangement, we also gained non-exclusive access to TransPharma's ViaDerm drug delivery system for the product. As with many development-phase products, launch of the product, if approved, was not expected in the near term. The charge of \$35.0 million for acquired IPR&D related to this arrangement was included as expense in the second quarter of 2008 and is deductible for tax purposes.

In January 2008, our agreement with BioMS Medical Corp. to acquire the rights to its compound for the treatment of multiple sclerosis became effective. At the inception of this agreement, this compound was in the development stage (Phase III clinical trials) and had no alternative future use. As with many development-phase compounds, launch of the product, if approved, was not expected in the near term. In the third quarter of 2009, data from the Phase III clinical trials showed there were no statistically significant differences between dirucotide and placebo on the primary or secondary endpoints of the study, and ongoing clinical trials and the arrangement were discontinued. The charge of \$87.0 million for acquired IPR&D related to this arrangement was included as expense in the first quarter of 2008 and is deductible for tax purposes.

In October 2007, we entered into an agreement with Glenmark Pharmaceuticals Limited India to acquire the rights to a portfolio of transient receptor potential vanilloid sub-family 1 (TRPV1) antagonist molecules, including a clinical-phase compound. The compound was in early clinical phase development as a potential next-generation treatment for various pain conditions, including osteoarthritic pain, and had no alternative future use. As with many development-phase compounds, launch of the product, if approved, was not expected in the near term. The charge of \$45.0 million for acquired IPR&D was deductible for tax purposes and was included as expense in the fourth quarter of 2007. Development of this compound has been suspended.

In October 2007, we entered into a global strategic alliance with MacroGenics, Inc. (MacroGenics) to develop and commercialize teplizumab, a humanized anti-CD3 monoclonal antibody, as well as other potential next-generation

anti-CD3 molecules for use in the treatment of autoimmune diseases. As part of the arrangement, we acquired the exclusive rights to the molecule, which was in the development stage (Phase II/III clinical trial for individuals with recent-onset type 1 diabetes) and had no alternative future use. As with many development-phase compounds, launch of the product, if approved, was not expected in the near term. The charge of \$44.0 million for acquired IPR&D was deductible for tax purposes and was included as expense in the fourth quarter of 2007.

In January 2007, we entered into an agreement with OSI Pharmaceuticals, Inc. to acquire the rights to its compound for the treatment of type 2 diabetes. At the inception of this agreement, this compound was in the development stage (Phase I clinical trials) and had no alternative future use. As with many development-phase compounds, launch of the product, if approved, was not expected in the near term. The charge of \$25.0 million for acquired IPR&D related to this arrangement was included as expense in the first quarter of 2007 and was deductible for tax purposes.

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 might 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.

#### **Erbix**

Prior to our acquisition in November 2008, ImClone entered into several collaborations with respect to Erbitux, a product approved to fight cancer, while still in its development phase. The most significant collaborations operate in these geographic territories: 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. The following table summarizes the revenue recognized with respect to Erbitux:

|                                 | 2009     | 2008    |
|---------------------------------|----------|---------|
| Net product sales               | \$ 92.5  | \$ 2.7  |
| Collaboration and other revenue | 298.3    | 26.7    |
| Total revenue                   | \$ 390.8 | \$ 29.4 |

#### ***Bristol-Myers Squibb Company***

Pursuant to a commercial agreement with Bristol-Myers Squibb Company and E.R. Squibb (collectively, BMS), relating to Erbitux, ImClone is co-developing and co-promoting Erbitux in the U.S. and Canada with BMS, exclusively, and in Japan with BMS and Merck KGaA. 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, up to threshold amounts, are the sole responsibility of BMS, with costs in excess of the thresholds shared by both companies according to a predetermined ratio.

Responsibilities associated with clinical and other ongoing studies are apportioned between the parties as determined pursuant to the agreement. Collaborative reimbursements received by ImClone 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 between ImClone and Merck KGaA (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 ImClone in Japan. Merck also has rights to manufacture Erbitux for supply in its territory. We manufacture and provide a portion of Merck's requirements for API, which is included in net product sales. 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 supply of product; for research and 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**

In January 2010, we restructured the collaboration agreement executed by ImClone and BMS in 2001 to allow for the co-development and co-commercialization of necitumumab, which is currently in Phase III clinical testing for non-small cell lung cancer. Within this restructured arrangement, we and BMS have agreed to share in 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**

We are in a collaborative arrangement with Amylin Pharmaceuticals (Amylin) for the joint development, marketing, and selling of Byetta (exenatide injection) and other forms of exenatide such as exenatide once weekly. Byetta is presently approved as an adjunctive therapy to improve glycemic control in patients with type 2 diabetes who have not achieved adequate glycemic control using metformin, a sulfonylurea or a combination of metformin and sulfonylurea; and in the U.S. only, using a thiazolidinedione (with or without metformin) and as a monotherapy. Lilly and Amylin are co-promoting exenatide in the U.S. Amylin is responsible for manufacturing and primarily utilizes third-party contract manufacturers to supply Byetta. However, we are manufacturing Byetta pen delivery devices for Amylin. We are responsible for development and commercialization costs outside the U.S.

Under the terms of our arrangement, we report as collaboration and other revenue our 50 percent share of gross margin on Amylin's net product sales in the U.S. We report as net product sales 100 percent of sales outside the U.S. and our sales of Byetta pen delivery devices to Amylin. The following table summarizes the revenue recognized with respect to Byetta:

|                                 | <b>2009</b>         | <b>2008</b>  | <b>2007</b>  |
|---------------------------------|---------------------|--------------|--------------|
| Net product sales               | \$ <b>147.7</b>     | \$ 96.7      | \$ 39.6      |
| Collaboration and other revenue | <b>300.8</b>        | 299.4        | 291.1        |
| <br>Total revenue               | <br>\$ <b>448.5</b> | <br>\$ 396.1 | <br>\$ 330.7 |

We pay Amylin a percentage of the gross margin of exenatide sales outside of the U.S., and these costs are recorded in cost of sales. 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 report 50 percent of U.S. research and development costs and marketing and selling costs in the respective line items on the consolidated statements of operations.

A New Drug Application has been submitted to the U.S. Food and Drug Administration (FDA) for exenatide once weekly. Amylin is constructing and will operate a manufacturing facility for exenatide once weekly, and we have entered into a supply agreement in which Amylin will supply exenatide once weekly product to us for sales outside the U.S. The estimated total cost of the facility is approximately \$550 million. In 2008, we paid \$125.0 million to Amylin, which we will amortize to cost of sales over the estimated life of the supply agreement beginning with product launch. We would be required to reimburse Amylin for a portion of any future impairment of this facility, recognized in accordance with GAAP. A portion of the \$125.0 million payment we made to Amylin would be creditable against any amount we would owe as a result of impairment. We have also agreed to loan up to \$165.0 million to Amylin at an indexed rate beginning December 1, 2009; no amounts were loaned in 2009 and any borrowings have to be repaid by June 30, 2014. We have also agreed to cooperate with Amylin in the development, manufacturing, and marketing of exenatide once weekly in a dual-chamber cartridge pen configuration. We will contribute 60 percent of the total initial capital costs of the project, our portion of which will be approximately \$130 million, of which we have contributed approximately \$50 million as of December 31, 2009.

### **Cymbalta**

#### ***Boehringer Ingelheim***

We are in a collaborative arrangement with Boehringer Ingelheim (BI) to jointly market and promote Cymbalta, a product for the treatment of major depressive disorder, diabetic peripheral neuropathic pain, generalized anxiety disorder, and fibromyalgia, outside the U.S. Pursuant to the terms of the agreement, we generally share equally in development, marketing, and selling expenses, and pay BI a commission on

sales in the co-promotion territories. We manufacture the product for all territories. Reimbursements or payments for the cost sharing of marketing, selling, and administrative expenses are recorded in the respective expense line items in the consolidated statements of operations. The commission paid to BI is recognized in marketing, selling, and administrative expenses.

### ***Quintiles***

We were in a collaborative arrangement with Quintiles Transnational Corp. (Quintiles) to jointly market and promote Cymbalta in the U.S. since Cymbalta's launch in 2004. Pursuant to the terms of the agreement, Quintiles shared in the costs to co-promote Cymbalta with us and receives a commission based upon net product sales. According to that agreement, Quintiles' obligation to promote Cymbalta expired during 2009, and we will pay a lower rate on net product sales for three years after completion of the promotion efforts specified in that agreement. The commissions paid to Quintiles are recorded in marketing, selling, and administrative expenses.

### **Effient**

We are in a collaborative arrangement with Daiichi Sankyo Company, Limited (D-S) to develop, market, and promote Effient, an antiplatelet agent for the treatment of patients with acute coronary syndromes (ACS) who are being managed with an artery-opening procedure known as percutaneous coronary intervention (PCI). The product was approved for marketing by the European Commission under the tradename Efient in February 2009, and the initial sales were recorded in the first quarter of 2009. The product was also approved for marketing by the FDA under the tradename Effient in July 2009, and the initial sales in the U.S. were recorded in the third quarter. Within this arrangement, we and D-S have agreed to co-promote under the same trademark 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. Under the agreement, we paid D-S an upfront license fee and agreed to pay future success milestones. 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 will 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 \$27.0 million in 2009. The product is in the early phases of launch in both the U.S. and Europe.

### **TPG-Axon Capital**

In 2008, we entered into an agreement with an affiliate of TPG-Axon Capital (TPG) for the Phase III development of a gamma-secretase inhibitor and an A-beta antibody, our two lead molecules for the treatment of mild to moderate Alzheimer's disease. Under the agreement, both we and TPG will provide funding for the Alzheimer's clinical trials. Funding from TPG will not exceed \$325 million and could extend into 2014. In exchange for their funding, TPG may receive success-based milestones totaling \$330 million and mid- to high-single digit royalties that are contingent upon the successful development of the Alzheimer's treatments. The royalties will be paid for approximately eight years after launch of a product. Reimbursements received from TPG for its portion of research and development costs incurred related to the Alzheimer's treatments are recorded as a reduction to the research and development expense line item on the consolidated statements of operations. The reimbursement from TPG is not expected to be material in any period.

### **Summary of Collaboration Related Commission and Profit Share Payments**

The aggregate amount of commission and profit share payments included in marketing, selling, and administrative expense pursuant to the collaborations described above was \$319.2 million, \$307.6 million, and \$217.5 million in 2009, 2008, and 2007, 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.

**Asset Impairments and Related Restructuring and Other Charges**

Asset impairments, restructuring, and other special charges of \$37.9 million were recognized in the fourth quarter of 2009 as a result of our announced initiatives to reduce our cost structure and global workforce. These charges relate to severance costs which are expected to be paid in the first half of 2010.

We recognized asset impairments, restructuring, and other special charges of \$424.8 million in the third quarter of 2009 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 active pharmaceutical ingredient (API) for certain of our human and animal health products. The decision to sell the site was based upon a projected decline in utilization of the site due to several factors, including upcoming patent expirations on certain medicines made at the site; our strategic decision to purchase, rather than manufacture, many late-stage chemical intermediates; and the evolution of our pipeline toward more biotechnology medicines. In addition to the sale of the Tippecanoe site, in the third quarter of 2009 we announced a voluntary exit program for certain U.S. sales employees. Components of the third-quarter restructuring charge include non-cash asset impairment charges and other charges of \$363.7 million, and \$61.1 million in severance related charges, substantially all of which is expected to be paid in cash by early 2010. The fair value of assets used in determining impairment charges was based on contracted sales prices.

We incurred asset impairments, restructuring, and other special charges of \$80.0 million in the fourth quarter of 2008. These charges were the result of decisions approved by management in the fourth quarter as well as previously announced strategic decisions. The primary components of this charge include non-cash asset impairments of \$35.1 million for the write down of impaired assets, all of which have no future use, and other charges of \$44.9 million, primarily related to severance and environmental cleanup charges in connection with previously announced strategic decisions made in prior periods. Substantially all of these costs were paid during 2009.

Further, in the third quarter of 2008, as a result of our previously announced agreements with Covance Inc. (Covance), Quintiles Transnational Corp. (Quintiles), and Ingenix Pharmaceutical Services, Inc., doing business as i3 Statprobe (i3), and as part of our efforts to transform into a more flexible organization, we recognized asset impairments, restructuring, and other special charges of \$182.4 million. We sold our Greenfield, Indiana site to Covance, a global drug development services firm, and entered into a 10-year service agreement under which Covance will provide preclinical toxicology work and perform additional clinical trials for us as well as operate the site to meet our needs and those of other pharmaceutical industry clients. In addition, we signed agreements with Quintiles for clinical trial monitoring services and with i3 for clinical data management services. Components of the third-quarter restructuring charge include non-cash charges of \$148.3 million primarily related to the loss on sale of assets sold to Covance, severance costs of \$27.8 million, and exit costs of \$6.3 million. Substantially all of these costs were paid in 2008.

In the second quarter of 2008, we recognized restructuring and other special charges of \$88.9 million. In addition, we recognized non-cash charges of \$57.1 million for the write down of impaired manufacturing assets that had no future use, which were included in cost of sales. In April 2008, we announced a voluntary exit program that was offered to employees primarily in manufacturing. Components of the second-quarter restructuring charge include total severance costs of \$53.5 million related to these programs and \$35.4 million related to exit costs incurred during the second quarter in connection with previously announced strategic decisions made in prior periods. Substantially all of these costs were paid by the end of July 2008.

In March 2008, we terminated development of our AIR Insulin program, which was being conducted in collaboration with Alkermes, Inc. The program had been in Phase III clinical development as a potential treatment for type 1 and type 2 diabetes. This decision was not a result of any observations during AIR Insulin trials relating to the safety of the product, but rather was a result of increasing uncertainties in the regulatory environment, and a thorough evaluation of the evolving commercial and clinical potential of the product compared to existing medical therapies. As a result of this decision, we halted our ongoing clinical studies and transitioned the AIR Insulin patients in these studies to other appropriate therapies. We implemented a patient program in the U.S., and other regions of the world where allowed, to provide clinical trial participants with appropriate financial support to fund their medications and diagnostic supplies through the end of 2008.

We recognized asset impairments, restructuring, and other special charges of \$145.7 million in the first quarter of 2008. These charges were primarily related to the decision to terminate development of AIR Insulin. Components of these charges included non-cash charges of \$40.9 million for the write down of impaired manufacturing assets that had no use beyond the AIR Insulin program, as well as charges of \$91.7 million for estimated contractual obligations and wind-down costs associated with the termination of clinical trials and certain development activities, and costs associated with the patient program to transition participants from AIR Insulin. This amount includes an estimate of Alkermes' wind-down costs for which we were contractually obligated. The wind-down activities and patient programs were substantially complete by the end of 2008. The remaining component of these charges, \$13.1 million, is related to exit costs incurred in the first quarter of 2008 in connection with previously announced strategic decisions made in prior periods.

We incurred asset impairments, restructuring, and other special charges of \$67.6 million in the fourth quarter of 2007. These charges were a result of decisions approved by management in the fourth quarter as well as previously announced strategic decisions. Components of this charge include non-cash charges of \$42.5 million for the write down of impaired assets, all of which have no future use, and other charges of \$25.1 million, primarily related to additional severance and environmental cleanup charges related to previously announced strategic decisions. The impairment charges were necessary to adjust the carrying value of the assets to fair value. These restructuring activities were substantially complete at December 31, 2007.

In connection with previously announced strategic decisions, we recorded asset impairments, restructuring, and other special charges of \$123.0 million in the first quarter of 2007. These charges primarily related to a voluntary severance program at one of our U.S. plants and other costs related to this action as well as management actions taken in the fourth quarter of 2006 to close two research and development facilities and one production facility outside the U.S. The component of these charges related to the non-cash asset impairment was \$67.6 million, and were necessary to adjust the carrying value of the assets to fair value. These restructuring activities were substantially complete at December 31, 2007.

#### **Product Liability and Other Special Charges**

In the second and the third quarters of 2009, we incurred other special charges of \$105.0 million and \$125.0 million, respectively, related to advanced discussions with the attorneys general for several states that were not part of the Eastern District of Pennsylvania settlement, seeking to resolve their Zyprexa-related claims. The charge represents the currently probable and estimable exposures in connection with the states' claims. Refer to Note 14 for additional information.

As discussed further in Note 14, in the third quarter of 2008, we recorded a charge of \$1.48 billion related to the Zyprexa investigations led by the U.S. Attorney for the Eastern District of Pennsylvania, as well as the resolution of a multi-state investigation regarding Zyprexa involving 32 states and the District of Columbia.

As a result of our product liability exposures, the substantial majority of which were related to Zyprexa, we recorded net pretax charges of \$111.9 million in 2007. These charges, which are net of anticipated insurance recoveries, include the costs of product liability settlements and related defense costs, reserves for product liability exposures and defense costs regarding known product liability claims, and expected future claims to the extent we could formulate a reasonable estimate of the probable number and cost of the claims. See Note 14 for further discussion.

#### **Note 6: Financial Instruments and Investments**

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, 2009, we had outstanding foreign currency forward commitments to purchase 518 million British pounds and sell 578 million euro, commitments to purchase 194 million U.S. dollars and sell 131 million euro, and commitments to buy 151 million euro and sell 218 million U.S. dollars, which will settle within 35 days.

At December 31, 2009, approximately 97 percent of our total debt is at a fixed rate. We have converted approximately 65 percent of our fixed-rate debt to floating rates through the use of interest rate swaps.

**The Effect of Risk-Management Instruments on the Statement of Operations**

Both the gains on the hedged fixed-rate debt and the offsetting losses on the related interest rate swaps for 2009 were \$369.5 million. All of these amounts net to zero and are included in other-net, expense (income).

We expect to reclassify \$12.0 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.

Other-net, expense (income) for 2009 includes the effective portion of losses on interest rate contracts in designated cash flow hedging relationships reclassified from accumulated other comprehensive loss into income of \$10.2 million, and the net gains on foreign exchange contracts not designated as hedging instruments recognized in income of \$43.4 million. The effective portions of net gains on interest rate contracts in designated cash flow hedging relationships recorded in other comprehensive income (loss) for 2009 was \$38.0 million.

During the years ended December 31, 2009, 2008, and 2007, net losses related to ineffectiveness and net losses related to the portion of our risk-management hedging instruments, fair value and cash flow hedges excluded from the assessment of effectiveness were not material.

**Fair Value of Financial Instruments**

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

| Description   | Carrying<br>Amount | Amortized<br>Cost | Fair Value Measurements Using   |   |  | Fair<br>Value |
|---|--------------------|-------------------|---|---|--|---------------|
|   |                    |                   | Quoted<br>Prices<br>in<br>Active<br>Markets<br>for<br>Identical<br>Assets<br>(Level<br>1) | Significant<br>Other<br>Observable<br>Inputs<br>(Level 2) | Significant<br>Unobservable<br>Inputs<br>(Level 3) |               |
| <b>December 31, 2009</b>                                  |                    |                   |   |   |  |               |
| Short-term investments                                    |                    |                   |   |   |  |               |
| Corporate debt securities                                 | \$ 15.8            | \$ 16.1           | \$  | \$ 15.8   | \$   | \$ 15.8       |
| U.S. government and agencies                              | 18.5               | 18.8              | 18.5  |   |  | 18.5          |
| Other securities  | 0.4                | 0.4               |   | 0.4   |  | 0.4           |
|   | \$ 34.7            | \$ 35.3           |   |   |  |               |
| Noncurrent investments                                    |                    |                   |   |   |  |               |
| Corporate debt securities                                 | \$ 185.9           | \$ 195.4          | \$  | \$ 185.9  | \$   | \$ 185.9      |
| Mortgage-backed   | 240.3              | 310.0             |   | 240.3   |  | 240.3         |
| Asset-backed  | 78.7               | 94.1              |   | 78.7  |  | 78.7          |
| U.S. government and agencies                              | 81.3               | 81.7              | 81.3  |   |  | 81.3          |
| Other debt securities                                     | 34.4               | 12.8              |   | 3.6   | 30.8   | 34.4          |
| Marketable equity   | 378.7              | 184.0             | 378.7   |   |  | 378.7         |
| Equity method and other investments                       | 156.5              | 156.5             |   |   |  | NA            |
|   | \$ 1,155.8         | \$ 1,034.5        |   |   |  |               |
| Long-term debt, including current portion                 | \$ (6,655.0)       | NA                | \$  | \$ (6,827.8)  | \$   | \$ (6,827.8)  |
| Risk-management instruments                               |                    |                   |   |   |  |               |
| Interest rate contracts designated as hedging instruments |                    |                   |   |   |  |               |
| Sundry  | \$ 134.9           | NA                | \$  | \$ 134.9  | \$   | \$ 134.9      |

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|  |          |          |          |          |
|--|----------|----------|----------|----------|
| Other noncurrent liabilities                                     | (6.2)    | NA       | (6.2)    | (6.2)    |
| Foreign exchange contracts not designated as hedging instruments |          |          |          |          |
| Prepaid expenses   | 8.8      | NA       | 8.8      | 8.8      |
| Other current liabilities  | (10.7)   | NA       | (10.7)   | (10.7)   |
| <b>December 31, 2008</b>   |          |          |          |          |
| Short-term investments   |          |          |          |          |
| Corporate debt securities  | \$ 172.4 | \$ 180.1 | \$ 172.4 | \$ 172.4 |
| U.S. government and agencies                                     | 212.3    | 212.0    | 212.3    | 212.3    |
| Other securities   | 44.7     | 41.8     | 44.7     | 44.7     |
|  | \$ 429.4 | \$ 433.9 |          |          |

| Description   | Carrying<br>Amount | Amortized<br>Cost | Fair Value Measurements Using   |   |  | Fair<br>Value |
|---|--------------------|-------------------|---|---|--|---------------|
|   |                    |                   | Quoted<br>Prices<br>in<br>Active<br>Markets<br>for<br>Identical<br>Assets<br>(Level<br>1) | Significant<br>Other<br>Observable<br>Inputs<br>(Level 2) | Significant<br>Unobservable<br>Inputs<br>(Level 3) |               |
| Noncurrent investments  |                    |                   |   |   |  |               |
| Corporate debt securities   | \$ 466.4           | \$ 542.2          | \$  | \$ 466.4  | \$   | \$ 466.4      |
| Mortgage-backed   | 330.6              | 436.6             |   | 330.6   |  | 330.6         |
| Asset-backed  | 204.0              | 240.1             |   | 204.0   |  | 204.0         |
| U.S. government and agencies  | 179.2              | 176.8             | 179.2   |   |  | 179.2         |
| Other debt securities   | 14.7               | 10.6              |   | 3.6   | 11.1   | 14.7          |
| Marketable equity   | 221.9              | 175.1             | 221.9   |   |  | 221.9         |
| Equity methods and other<br>investments                             | 127.8              | 127.8             |   |   |  | NA            |
|   | \$ 1,544.6         | \$ 1,709.2        |   |   |  |               |
| Long-term debt, including current<br>portion                        | \$ (5,036.1)       | NA                | \$  | \$ (5,180.1)  | \$   | \$ (5,180.1)  |
| Risk-management instruments   |                    |                   |   |   |  |               |
| Interest rate contracts designated<br>as hedging instruments        |                    |                   |   |   |  |               |
| Sundry  | \$ 500.3           | NA                | \$  | \$ 500.3  | \$   | \$ 500.3      |
| Foreign exchange contracts not<br>designated as hedging instruments |                    |                   |   |   |  |               |
| Prepaid expenses  | 12.0               | NA                |   | 12.0  |  | 12.0          |
| Other current liabilities   | (57.3)             | NA                |   | (57.3)  |  | (57.3)        |

NA Not applicable

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 and other investments is not readily available. Approximately \$235 million of our investments in debt securities, measured at fair value, 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 at December 31 follows:

|   | <b>2009</b>     | <b>2008</b> |
|---|-----------------|-------------|
| Unrealized gross gains                                  | \$ <b>222.4</b> | \$ 69.9     |
| Unrealized gross losses                                 | <b>101.7</b>    | 239.0       |
| Fair value of securities in an unrealized gain position | <b>579.8</b>    | 767.5       |
| Fair value of securities in an unrealized loss position | <b>449.4</b>    | 1,046.1     |

As discussed further in Note 2, a new accounting pronouncement effective in 2009 changed the accounting for other-than-temporary impairment losses for debt securities, providing that the amount of the other-than-temporary losses recorded in earnings is limited to the portion attributed to credit losses, with the remaining portion recorded in other comprehensive income (loss). A summary of other-than-temporary losses on our investments in debt securities follows:

|  | <b>2009</b>    |
|--|----------------|
| Losses recognized in the statement of operations       | \$ <b>22.4</b> |
| Losses recognized in other comprehensive income (loss) | <b>9.6</b>     |
| Total other-than-temporary impairment losses           | \$ <b>32.0</b> |

The other-than-temporary losses recognized in the statement of operations primarily relate to credit losses on certain mortgage-backed securities. The amount of credit losses represents the difference between the present value of cash flows expected to be collected on these securities and the amortized cost. Factors considered in assessing the credit loss were the position in the capital structure, vintage and amount of collateral, delinquency rates, current credit support, and geographic concentration.

The securities in an unrealized loss position are comprised of fixed-rate debt securities of varying maturities. The value of fixed income securities is sensitive to changes to the yield curve and other market conditions which led to the decline in value during 2008. Approximately 50 percent of the securities in a loss position are investment-grade debt securities. The majority of these securities first moved into an unrealized loss position during 2008. 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, 2009. The fair values of our auction rate securities and collateralized debt obligations held at December 31, 2009 were determined using Level 3 inputs. We do not hold securities issued by structured investment vehicles at December 31, 2009.

The net adjustment to unrealized gains and losses (net of tax) on available-for-sale securities increased (decreased) other comprehensive income (loss) by \$186.6 million, \$(125.8) million, and \$(5.4) million in 2009, 2008, and 2007, respectively. Activity related to our available-for-sale investment portfolio was as follows:

|                                | 2009       | 2008       | 2007       |
|--------------------------------|------------|------------|------------|
| Proceeds from sales            | \$ 1,227.4 | \$ 1,876.4 | \$ 1,212.1 |
| Realized gross gains on sales  | 68.9       | 45.7       | 21.4       |
| Realized gross losses on sales | 6.8        | 8.7        | 6.1        |

#### Note 7: Borrowings

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

|  | 2009       | 2008       |
|--|------------|------------|
| 3.55 to 7.13 percent notes (due 2012-2037) | \$ 6,387.4 | \$ 3,987.4 |
| Floating rate bonds (due 2037)             |            | 400.0      |
| Other, including capitalized leases        | 105.3      | 116.8      |
| Fair value adjustment                      | 162.3      | 531.9      |
|  | 6,655.0    | 5,036.1    |
| Less current portion                       | (20.3)     | (420.4)    |

\$ 6,634.7 \$ 4,615.7

In March 2009, we issued \$2.40 billion of fixed-rate notes with interest to be paid semi-annually. The \$400.0 million of floating rate bonds outstanding at December 31, 2008 were repaid with proceeds from this issuance.

The 6.55 percent Employee Stock Ownership Plan (ESOP) debentures are obligations of the ESOP but are shown on the consolidated balance sheet because we guarantee them. The principal and interest on the debt are funded by contributions from us and by dividends received on certain shares held by the ESOP. Because of the amortizing feature of the ESOP debt, bondholders will receive both interest and principal payments each quarter. The balance was \$72.8 million and \$81.9 million at December 31, 2009 and 2008, respectively, 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: 2010, \$20.3 million; 2011, \$15.8 million; 2012, \$1.51 billion; 2013, \$13.9 million; and 2014, \$1.01 billion.

At December 31, 2009 and 2008, short-term borrowings included \$7.1 million and \$5.43 billion, respectively, of notes payable to banks and commercial paper. Commercial paper was issued in late 2008 for the acquisition of ImClone. At December 31, 2009, we have \$1.24 billion of unused committed bank credit facilities, \$1.20 billion of which backs our commercial paper program and matures in May, 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.

We have converted approximately 65 percent of all fixed-rate debt to floating rates through the use of interest rate swaps. The weighted-average effective borrowing rates based on debt obligations and interest rates at December 31, 2009 and 2008, including the effects of interest rate swaps for hedged debt obligations, were 3.07 percent and 4.77 percent, respectively.

In 2009, 2008, and 2007, cash payments of interest on borrowings totaled \$205.9 million, \$203.1 million, and \$159.2 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 8: Stock-Based Compensation**

Stock-based compensation expense in the amount of \$368.5 million, \$255.3 million, and \$282.0 million was recognized in 2009, 2008, and 2007, respectively, as well as related tax benefits of \$128.9 million, \$88.6 million, and \$96.4 million, respectively. Our stock-based compensation expense consists primarily of performance awards (PAs), and shareholder value awards (SVAs). 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 and SVA 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, 2009, additional stock-based compensation awards may be granted under the 2002 Lilly Stock Plan for not more than 84.6 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. 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 fiscal year of the grant. The fair values of performance awards granted in 2009 were \$36.17 for the one-year award and \$34.12 for the two-year award. The fair values of PAs granted in 2008 and 2007 were \$51.22 and \$54.23, respectively. The number of shares ultimately issued for the performance award program is dependent upon the earnings achieved during the vesting period. Pursuant to this plan, approximately 2.8 million shares, 2.5 million shares, and 2.3 million shares were issued in 2009, 2008, and 2007, respectively. Approximately 4.4 million shares are expected to be issued in 2010. As of December 31, 2009, the total remaining unrecognized compensation cost related to nonvested PAs amounted to \$88.8 million, which will be amortized over the weighted-average remaining requisite service period of 12.0 months.

#### **Shareholder Value Award Program**

In 2007, we implemented a SVA program, which replaced our stock option 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

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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 2009, 2008, and 2007 were \$33.97, \$43.46, and \$49.85, respectively, determined using the following assumptions:

|                         | 2009            | 2008            | 2007            |
|-------------------------|-----------------|-----------------|-----------------|
| Expected dividend yield | 4.00%           | 3.00%           | 2.75%           |
| Risk-free interest rate | .44% - 1.48%    | 2.05% - 2.29%   | 4.81% - 5.16%   |
| Range of volatilities   | 24.34% - 24.92% | 20.48% - 21.48% | 22.54% - 23.90% |

A summary of the SVA activity is presented below:

|                                  | <b>Units<br/>Attributable to SVAs<br/>(in thousands)</b> |
|----------------------------------|--|
| Outstanding at January 1, 2007   |  |
| Granted                          | 969  |
| Forfeited or expired             | (47)   |
| Outstanding at December 31, 2007 | 922  |
| Granted                          | 1,282  |
| Forfeited or expired             | (301)  |
| Outstanding at December 31, 2008 | 1,903  |
| Granted                          | 1,416  |
| Forfeited or expired             | (559)  |
| Outstanding at December 31, 2009 | 2,760  |

The maximum number of shares that could ultimately be issued upon vesting of the SVA units outstanding at December 31, 2009, is 3.7 million. Approximately 0.4 million shares are expected to be issued in 2010. As of December 31, 2009, the total remaining unrecognized compensation cost related to nonvested SVAs amounted to \$48.1 million, which will be amortized over the weighted-average remaining requisite service period of 20.7 months.

### Stock Option Program

Stock options were granted prior to 2007 to officers and management at exercise prices equal to the fair market value of our stock price at the date of grant. No stock options were granted subsequent to 2007. Options fully vest three years from the grant date and have a term of 10 years.

Stock option activity during 2009 is summarized below:

|                                | <b>Shares of<br/>Common<br/>Stock<br/>Attributable<br/>to</b> | <b>Weighted-Average</b>              | <b>Weighted-Average</b>                                  | <b>Aggregate</b>           |
|--------------------------------|---|--------------------------------------|--|----------------------------|
|                                | <b>Options<br/>(in thousands)</b>                             | <b>Exercise<br/>Price of Options</b> | <b>Remaining<br/>Contractual<br/>Term<br/>(in years)</b> | <b>Intrinsic<br/>Value</b> |
| Outstanding at January 1, 2009 | 72,025  | \$ 69.35                             |  |                            |
| Exercised                      | (14)  | 15.08                                |  |                            |

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|                                  |          |       |     |    |     |
|----------------------------------|----------|-------|-----|----|-----|
| Forfeited or expired             | (12,562) | 69.51 |     |    |     |
| Outstanding at December 31, 2009 | 59,449   | 69.36 | 3.0 | \$ | 1.2 |
| Exercisable at December 31, 2009 | 59,449   | 69.36 | 3.0 |    | 1.2 |

A summary of the status of nonvested options as of December 31, 2009, and changes during the year then ended, is presented below:

|                              | Shares<br>(in thousands) | Weighted-Average<br>Grant Date<br>Fair Value |
|------------------------------|--------------------------|--|
| Nonvested at January 1, 2009 | 3,992                    | \$ 15.26                                     |
| Vested                       | (3,918)                  | 17.49  |
| Forfeited                    | (74)                     | 16.06  |

Nonvested at December 31, 2009

The intrinsic value of options exercised during 2009, 2008, and 2007 amounted to \$0.3 million, \$4.8 million, and \$1.5 million, respectively. The total grant date fair value of options vested during 2009, 2008, and 2007 amounted to \$68.5 million, \$84.1 million, and \$381.8 million, respectively. We received cash of \$0.2 million, \$2.9 million, and \$15.2 million from exercises of stock options during 2009, 2008, and 2007, respectively. The recognized related tax benefits for all three years were not material.

#### Note 9: Other Assets and Other Liabilities

Our other receivables include receivables from our collaboration partners, tax receivables, interest receivable for our interest rate swaps, and a variety of other items. The decrease in other receivables is

primarily attributable to a decrease in receivables from our collaboration partners and a decrease in tax receivables, offset by an increase in interest rate swap receivables.

Our prepaid expenses include prepaid income taxes and other global prepaid expenses. The increase in prepaid expenses is primarily attributable to income taxes paid on prepaid intercompany royalties.

Our sundry assets primarily include our capitalized computer software, deferred tax assets (Note 12), receivables from our collaboration partners, and the fair value of our interest rate swaps. The decrease in sundry assets is primarily attributable to a decrease in deferred tax assets and a decrease in the fair value of our interest rate swaps.

Our other current liabilities include product litigation, tax liabilities, deferred income from our collaboration arrangements, and a variety of other items. The decrease in other current liabilities is caused primarily by a decrease in product litigation liabilities, specifically, the \$1.42 billion related to the EDPA settlements which was paid in 2009 as discussed in Note 14, and a decrease in current deferred taxes.

Our other noncurrent liabilities include deferred income from our collaboration and out-licensing arrangements, the long-term portion of our estimated product return liabilities, product litigation, and a variety of other items. The decrease in other noncurrent liabilities is primarily due to a decrease in deferred income and a decrease in product litigation reserves.

#### **Note 10: Shareholders' Equity**

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

|  | <b>Additional<br/>Paid-in<br/>Capital</b> | <b>Retained<br/>Earnings</b> | <b>Deferred<br/>Costs -<br/>ESOP</b> | <b>Common Stock in<br/>Treasury<br/>Shares<br/>(in<br/>thousands)</b> | <b>Amount</b> |
|--|---|------------------------------|--------------------------------------|---|---------------|
| Balance at January 1, 2007                       | \$ 3,571.9                                | \$ 10,766.2                  | \$ (100.7)                           | 910   | \$ 101.4      |
| Net income                                       |   | 2,953.0                      |                                      |   |               |
| Cash dividends declared per share: \$1.75        |   | (1,903.9)                    |                                      |   |               |
| Retirement of treasury shares                    | (3.9)                                     |                              |                                      | (76)  | (3.9)         |
| Issuance of stock under employee stock plans-net | (55.2)                                    |                              |                                      | 65  | 3.0           |
| Stock-based compensation                         | 282.0                                     |                              |                                      |   |               |
| ESOP transactions                                | 10.4                                      |                              | 5.5                                  |   |               |
| FIN 48 implementation (Note 12)                  |   | (8.6)                        |                                      |   |               |
| Balance at December 31, 2007                     | 3,805.2                                   | 11,806.7                     | (95.2)                               | 899   | 100.5         |
| Net loss   |   | (2,071.9)                    |                                      |   |               |
| Cash dividends declared per share: \$1.90        |   | (2,079.9)                    |                                      |   |               |
| Retirement of treasury shares                    | (10.9)                                    |                              |                                      | (170)   | (11.1)        |
|  | (84.9)                                    |                              |                                      | 160   | 9.8           |

|  |            |            |           |       |         |
|--|------------|------------|-----------|-------|---------|
| Issuance of stock under employee stock plans-net |            |            |           |       |         |
| Stock-based compensation                         | 255.3      |            |           |       |         |
| ESOP transactions                                | 11.9       |            | 8.9       |       |         |
| Balance at December 31, 2008                     | 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 |

As of December 31, 2009, we have purchased \$2.58 billion of our announced \$3.0 billion share repurchase program. No shares were repurchased in 2009, 2008, or 2007.

We have 5 million authorized shares of preferred stock. As of December 31, 2009 and 2008, no preferred stock has been issued.

We have funded an employee benefit trust with 50 million and 40 million shares of our common stock at December 31, 2009 and 2008, respectively, to provide a source of funds to assist us in meeting our obligations under various employee benefit plans. In February 2009, we contributed an additional 10 million shares to the employee benefit trust, which resulted in a reclassification within equity from additional paid-in capital of \$371.9 million and common stock of \$6.3 million to the employee benefit trust of \$378.2 million. The funding had no net impact on shareholders' equity as we consolidate the employee benefit trust. The cost basis of the shares held in the trust was \$3.01 billion and \$2.64 billion at December 31, 2009 and 2008, respectively, and is shown as a reduction in shareholders' equity, which offsets the resulting increases of \$2.98 billion and \$2.61 billion in additional paid-in capital and \$31.3 million and \$25.0 million in common stock at December 31, 2009 and 2008, respectively. 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 in 2009, 2008, or 2007.

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 \$200.0 million of third-party debt, repayment of which was guaranteed by us (see Note 7). The proceeds were used to purchase shares of our common stock on the open market. Shares of common stock held by the ESOP will be allocated to participating employees annually through 2017 as part of our savings plan contribution. The fair value of shares allocated each period is recognized as compensation expense.

#### **Note 11: Earnings (Loss) Per Share**

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

|  | <b>2009</b>                  | <b>2008</b>  | <b>2007</b> |
|--|------------------------------|--------------|-------------|
|  | <b>(Shares in thousands)</b> |              |             |
| Income (loss) available to common shareholders                                     | \$ <b>4,328.8</b>            | \$ (2,071.9) | \$ 2,953.0  |
| Basic earnings (loss) per share  |                              |              |             |
| Weighted-average number of common shares outstanding, including incremental shares | <b>1,098,338</b>             | 1,094,499    | 1,090,430   |
| Basic earnings (loss) per share  | \$ <b>3.94</b>               | \$ (1.89)    | \$ 2.71     |
| Diluted earnings (loss) per share  |                              |              |             |
| Weighted-average number of common shares outstanding                               | <b>1,094,623</b>             | 1,092,041    | 1,088,929   |

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|  |                  |           |           |
|--|------------------|-----------|-----------|
| Stock options and other incremental shares                   | <b>3,744</b>     | 2,458     | 1,821     |
| Weighted-average number of common shares outstanding diluted | <b>1,098,367</b> | 1,094,499 | 1,090,750 |
| Diluted earnings (loss) per share                            | \$ <b>3.94</b>   | \$ (1.89) | \$ 2.71   |

**Note 12: Income Taxes**

Following is the composition of income tax expense:

|              | <b>2009</b>       | <b>2008</b> | <b>2007</b> |
|--------------|-------------------|-------------|-------------|
| Current      |                   |             |             |
| Federal      | \$ <b>45.7</b>    | \$ (207.6)  | \$ 489.5    |
| Foreign      | <b>772.2</b>      | 623.6       | 412.1       |
| State        | <b>49.2</b>       | (44.6)      | 27.7        |
|              | <b>867.1</b>      | 371.4       | 929.3       |
| Deferred     |                   |             |             |
| Federal      | <b>82.5</b>       | 363.0       | 53.0        |
| Foreign      | <b>79.8</b>       | 23.7        | (27.9)      |
| State        | <b>(0.4)</b>      | 6.2         | (30.6)      |
|              | <b>161.9</b>      | 392.9       | (5.5)       |
| Income taxes | \$ <b>1,029.0</b> | \$ 764.3    | \$ 923.8    |

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

|   | <b>2009</b>       | <b>2008</b> |
|---|-------------------|-------------|
| Deferred tax assets                     |                   |             |
| Compensation and benefits               | \$ <b>1,153.2</b> | \$ 1,154.6  |
| Tax credit carryforwards and carrybacks | <b>738.2</b>      | 755.0       |
| Tax loss carryforwards and carrybacks   | <b>458.2</b>      | 562.3       |
| Intercompany profit in inventories      | <b>270.6</b>      | 473.9       |
| Asset purchases                         | <b>253.4</b>      | 251.5       |
| Asset disposals                         | <b>173.6</b>      | 3.2         |
| Contingencies                           | <b>162.0</b>      | 345.2       |
| Sale of intangibles                     | <b>122.6</b>      | 117.9       |
| Product return reserves                 | <b>85.0</b>       | 100.8       |
| Debt                                    | <b>45.9</b>       | 211.6       |
| Other                                   | <b>510.2</b>      | 310.4       |

|                                |                                  |                    |
|--------------------------------|----------------------------------|--------------------|
| Valuation allowances           | <b>3,972.9</b><br><b>(836.8)</b> | 4,286.4<br>(845.4) |
| Total deferred tax assets      | <b>3,136.1</b>                   | 3,441.0            |
| Deferred tax liabilities       |                                  |                    |
| Intangibles                    | <b>(818.4)</b>                   | (860.2)            |
| Property and equipment         | <b>(623.8)</b>                   | (620.7)            |
| Inventories                    | <b>(544.4)</b>                   | (431.6)            |
| Unremitted earnings            | <b>(442.9)</b>                   | (467.3)            |
| Other                          | <b>(195.4)</b>                   | (287.8)            |
| Total deferred tax liabilities | <b>(2,624.9)</b>                 | (2,667.6)          |
| Deferred tax assets net        | <b>\$ 511.2</b>                  | <b>\$ 773.4</b>    |

At December 31, 2009, we had net operating losses and other carryforwards for international and U.S. income tax purposes of \$942.8 million: \$126.3 million will expire within 5 years; \$804.0 million will expire between 5 and 20 years; and \$12.5 million of the carryforwards will never expire. The primary component of the remaining portion of the deferred tax asset for tax loss carryforwards and carrybacks is related to net operating losses for state income tax purposes that are fully reserved. We also have tax credit carryforwards and carrybacks of \$738.2 million available to reduce future income taxes; \$268.7 million will be carried back; \$37.6 million of the tax credit carryforwards will expire between 10 and 20 years; and \$12.9 million of the tax credit carryforwards will never expire. The remaining portion of the tax credit carryforwards is related to federal tax credits of \$94.6 million and state tax credits of \$324.4 million, both of which are fully reserved.

Domestic and Puerto Rican companies contributed approximately 39 percent and 7 percent in 2009 and 2007, respectively, to consolidated income before income taxes and generated the entire consolidated loss before income taxes in 2008. 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, 2009, we had an aggregate of \$15.46 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 (refunds) of income taxes totaled \$1.14 billion, \$(52.0) million, and \$1.01 billion in 2009, 2008, and 2007, respectively.

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

|  | 2009       | 2008       | 2007       |
|--|------------|------------|------------|
| Income tax (benefit) at the U.S. federal statutory tax rate                  | \$ 1,875.2 | \$ (457.7) | \$ 1,356.9 |
| Add (deduct)   |            |            |            |
| International operations, including Puerto Rico                              | (741.1)    | (641.3)    | (450.7)    |
| General business credits   | (79.4)     | (58.0)     | (60.3)     |
| Government investigation charges   | 0.6        | 359.3      |            |
| Acquisitions and non-deductible acquired in-process research and development |            | 1,819.4    | 208.1      |
| IRS audit conclusion   | (54.4)     | (210.3)    |            |
| Sundry   | 28.1       | (47.1)     | (130.2)    |
| Income tax expense   | \$ 1,029.0 | \$ 764.3   | \$ 923.8   |

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

|  | 2009       | 2008       |
|--|------------|------------|
| Beginning balance at January 1                               | \$ 1,012.3 | \$ 1,657.4 |
| Additions based on tax positions related to the current year | 179.1      | 115.6      |
| Additions for tax positions of prior years                   | 133.2      | 288.8      |
| Reductions for tax positions of prior years                  | (104.2)    | (234.9)    |
| Lapses of statutes of limitation                             | (3.3)      | (216.2)    |
| Settlements  | (178.8)    | (598.4)    |

|                        |                   |            |
|------------------------|-------------------|------------|
| Balance at December 31 | <b>\$ 1,038.3</b> | \$ 1,012.3 |
|------------------------|-------------------|------------|

The total amount of unrecognized tax benefits that, if recognized, would affect our effective tax rate was \$836.8 million and \$863.8 million at December 31, 2009 and 2008, 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 2002. During the first quarter of 2008, we completed and effectively settled our IRS audit of tax years 2001-2004 except for one matter for which we were seeking resolution through the IRS administrative appeals process. As a result of the IRS audit conclusion, gross unrecognized tax benefits were reduced by approximately \$618 million, and the consolidated results of operations were benefited by \$210.3 million through a reduction in income tax expense. The majority of the reduction in gross unrecognized tax benefits related to intercompany pricing positions that were agreed with the IRS in a prior audit cycle for which a prepayment of tax was made in 2005. Application of the prepayment and utilization of tax carryovers resulted in a refund of approximately \$50 million.

The IRS began its examination of tax years 2005-2007 during the third quarter of 2008. In addition, the IRS administrative appeals matter from the 2001-2004 IRS audit was settled in the third quarter of 2009. Considering the current status of the 2005-2007 IRS examination and the settlement of the IRS administrative appeals matter from the 2001-2004 audit, gross unrecognized tax benefits were reduced approximately \$190 million in the third quarter of 2009. As a result, our income tax expense was reduced by \$54.4 million. After utilization of all tax credit carryovers, a cash payment of \$52.8 million was paid in the third quarter of 2009 upon settlement of the IRS appeals matter. While the IRS is currently examining tax years 2005-2007, the resolution of all issues in this audit period will likely extend beyond the next 12 months.

We recognize both accrued interest and penalties related to unrecognized tax benefits in income tax expense. During the years ended December 31, 2009, 2008, and 2007, we recognized income tax expense (benefits) of \$(1.9) million, \$(118.0) million, and \$66.6 million, respectively, related to interest and penalties. At December 31, 2009 and 2008, our accruals for the payment of interest and penalties totaled \$166.7 million and \$177.6 million, respectively. Substantially all of the expense (benefit) and accruals relate to interest.

### Note 13: 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<br>Pension Plans |            | Retiree Health<br>Benefit Plans |            |
|--|----------------------------------|------------|---------------------------------|------------|
|  | 2009                             | 2008       | 2009                            | 2008       |
| Change in benefit obligation                                 |                                  |            |                                 |            |
| Benefit obligation at beginning of year                      | \$ 6,353.7                       | \$ 6,561.0 | \$ 1,796.3                      | \$ 1,622.8 |
| Service cost   | 242.1                            | 260.1      | 53.7                            | 62.1       |
| Interest cost  | 417.5                            | 409.8      | 119.6                           | 105.7      |
| Actuarial (gain) loss  | 819.9                            | (257.4)    | 162.0                           | 101.6      |
| Benefits paid  | (351.7)                          | (338.4)    | (94.5)                          | (92.2)     |
| Plan amendments  |                                  | (2.4)      | (8.4)                           |            |
| Foreign currency exchange rate changes and other adjustments | 72.4                             | (279.0)    | 4.1                             | (3.7)      |
| Benefit obligation at end of year                            | 7,553.9                          | 6,353.7    | 2,032.8                         | 1,796.3    |
| Change in plan assets  |                                  |            |                                 |            |
| Fair value of plan assets at beginning of year               | 4,796.1                          | 7,304.2    | 905.6                           | 1,348.5    |
| Actual return on plan assets                                 | 1,033.8                          | (2,187.8)  | 278.9                           | (438.6)    |
| Employer contribution  | 447.6                            | 236.0      | 90.7                            | 87.9       |
| Benefits paid  | (351.7)                          | (338.4)    | (94.5)                          | (92.2)     |
| Foreign currency exchange rate changes and other adjustments | 82.7                             | (217.9)    |                                 |            |
| Fair value of plan assets at end of year                     | 6,008.5                          | 4,796.1    | 1,180.7                         | 905.6      |
| Funded status  | (1,545.4)                        | (1,557.6)  | (852.1)                         | (890.7)    |
| Unrecognized net actuarial loss                              | 3,804.3                          | 3,474.8    | 1,340.5                         | 1,409.6    |
| Unrecognized prior service cost (benefit)                    | 65.1                             | 72.7       | (234.1)                         | (261.6)    |

|   |            |            |          |          |
|---|------------|------------|----------|----------|
| Net amount recognized   | \$ 2,324.0 | \$ 1,989.9 | \$ 254.3 | \$ 257.3 |
| Amounts recognized in the consolidated balance sheet consisted of |            |            |          |          |
| Other current liabilities   | \$ (56.8)  | \$ (52.9)  | \$ (6.0) | \$ (7.8) |
| Accrued retirement benefit  | (1,488.6)  | (1,504.7)  | (846.1)  | (882.9)  |
| Accumulated other comprehensive loss before income taxes          | 3,869.4    | 3,547.5    | 1,106.4  | 1,148.0  |
| Net amount recognized   | \$ 2,324.0 | \$ 1,989.9 | \$ 254.3 | \$ 257.3 |

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, 2009.

In 2010, we expect to recognize from accumulated other comprehensive loss as components of net periodic benefit cost, \$176.4 million of unrecognized net actuarial loss and \$6.4 million of unrecognized prior service cost related to our defined benefit pension plans, and \$86.5 million of unrecognized net actuarial loss and \$37.2 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 2010.

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

|  | <b>Defined<br/>Benefit<br/>Pension<br/>Plans</b> |             | <b>Retiree<br/>Health<br/>Benefit Plans</b> |             |
|--|--|-------------|---|-------------|
| <b>(Percents)</b>                                    | <b>2009</b>                                      | <b>2008</b> | <b>2009</b>                                 | <b>2008</b> |
| Weighted-average assumptions as of December 31       |  |             |   |             |
| Discount rate for benefit obligation                 | <b>5.9</b>                                       | 6.7         | 6.0   | 6.9         |
| Discount rate for net benefit costs                  | <b>6.7</b>                                       | 6.4         | 6.9   | 6.7         |
| Rate of compensation increase for benefit obligation | <b>3.7</b>                                       | 4.1         |   |             |
| Rate of compensation increase for net benefit costs  | <b>4.1</b>                                       | 4.6         |   |             |
| Expected return on plan assets for net benefit costs | <b>8.8</b>                                       | 9.0         | 9.0   | 9.0         |

In evaluating the expected return on plan assets, we have considered our historical assumptions compared with actual results, an analysis of current market conditions, our current and expected asset allocations, and the views of leading financial advisers and economists for future asset class returns. Our plan assets in our U.S. defined benefit pension and retiree health plans comprise approximately 83 percent of our worldwide benefit plan assets. Including the investment losses due to overall market conditions in 2001, 2002, and 2008, our 20-year annualized rate of return on our U.S. defined benefit pension plans and retiree health benefit plan was approximately 8.3 percent as of December 31, 2009. Health-care-cost trend rates are assumed to increase at an annual rate of 8.0 percent in 2010, decreasing by approximately 0.3 percent per year to an ultimate rate of 5.3 percent by 2018.

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

|                                    | <b>2010</b> | <b>2011</b> | <b>2012</b> | <b>2013</b> | <b>2014</b> | <b>2015-2019</b> |
|------------------------------------|-------------|-------------|-------------|-------------|-------------|------------------|
| Defined benefit pension plans      | \$ 385.0    | \$ 391.3    | \$ 400.6    | \$ 411.6    | \$ 427.9    | \$ 2,385.2       |
| Retiree health benefit plans-gross | \$ 104.3    | \$ 109.6    | \$ 110.1    | \$ 115.7    | \$ 116.3    | \$ 656.0         |
| Medicare rebates                   | (19.8)      | (8.6)       | (10.1)      | (11.0)      | (12.6)      | (81.1)           |
| Retiree health benefit plans-net   | \$ 84.5     | \$ 101.0    | \$ 100.0    | \$ 104.7    | \$ 103.7    | \$ 574.9         |

The total accumulated benefit obligation for our defined benefit pension plans was \$6.67 billion and \$5.64 billion at December 31, 2009 and 2008, 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 \$7.55 billion and \$6.01 billion, respectively, as of December 31, 2009, and \$6.35 billion and \$4.80 billion, respectively, as of December 31, 2008. 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 \$1.01 billion and \$107.4 million, respectively, as of December 31, 2009, and \$4.98 billion and \$4.06 billion, respectively, as of December 31, 2008.

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

|  | Defined Benefit<br>Pension Plans |          |          | Retiree Health<br>Benefit Plans |         |          |
|--|----------------------------------|----------|----------|---------------------------------|---------|----------|
|  | 2009                             | 2008     | 2007     | 2009                            | 2008    | 2007     |
| Components of net periodic benefit cost      |                                  |          |          |                                 |         |          |
| Service cost                                 | \$ 242.1                         | \$ 260.1 | \$ 287.1 | \$ 53.7                         | \$ 62.1 | \$ 70.4  |
| Interest cost                                | 417.5                            | 409.8    | 362.4    | 119.6                           | 105.7   | 101.4    |
| Expected return on plan assets               | (584.9)                          | (603.0)  | (548.2)  | (117.9)                         | (118.4) | (102.1)  |
| Amortization of prior service cost (benefit) | 8.0                              | 8.2      | 7.7      | (36.0)                          | (36.0)  | (15.7)   |
| Recognized actuarial loss                    | 84.5                             | 76.6     | 130.0    | 71.8                            | 62.7    | 95.0     |
| Net periodic benefit cost                    | \$ 167.2                         | \$ 151.7 | \$ 239.0 | \$ 91.2                         | \$ 76.1 | \$ 149.0 |

If the health-care-cost trend rates were to be increased by one percentage point each future year, the December 31, 2009, accumulated postretirement benefit obligation would increase by \$167.5 million (8.3 percent) and the aggregate of the service cost and interest cost components of the 2009 annual expense would increase by \$18.9 million (10.9 percent). A one percentage point decrease in these rates

would decrease the December 31, 2009, accumulated postretirement benefit obligation by \$153.0 million (7.6 percent) and the aggregate of the 2009 service cost and interest cost by \$15.8 million (9.1 percent).

The following represents the amounts recognized in other comprehensive income (loss) in 2009:

|   | <b>Defined Benefit<br/>Pension Plans</b> | <b>Retiree Health<br/>Benefit Plans</b> |
|---|--|---|
| Actuarial loss arising during period                                | \$ 371.0                                 | \$ 1.0                                  |
| Plan amendments during period                                       |  | (8.4)                                   |
| Amortization of prior service cost (benefit) included in net income | (8.0)                                    | 36.0                                    |
| Amortization of net actuarial loss included in net income           | (84.5)                                   | (71.8)                                  |
| Foreign currency exchange rate changes                              | 43.4                                     | 1.6                                     |
| <br>Total other comprehensive loss (gain) during period             | <br>\$ 321.9                             | <br>\$ (41.6)                           |

We have defined contribution savings plans that cover our eligible employees worldwide. The purpose of these defined contribution plans is generally to provide additional financial security during retirement by providing employees with an incentive to save. Our contributions to the plan are based on employee contributions and the level of our match. Expenses under the plans totaled \$127.6 million, \$114.1 million, and \$112.3 million for the years 2009, 2008, and 2007, 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 in 2009, 2008, and 2007 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. plans represent 83 percent of our global investments. Given the long term nature of our U.S. liabilities, the U.S. 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 U.S. defined benefit pension and retiree health benefit plan allocation strategy is currently comprised of approximately 88 percent growth investments and 12 percent fixed income investments. The growth investment allocation encompasses U.S. and international public equity securities, hedge funds, and private equity-like investments. 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.

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.

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.

Fixed income investments are primarily made in investment grade fixed income securities in U.S. Treasuries and Agencies, investment grade corporates, mortgage-backed securities and commercial mortgage-backed obligations.

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.

The fair values of our defined benefit pension plan and retiree health plan assets as of December 31, 2009 by asset category are as follows:

| Asset Category                       | Fair Value Measurements Using |                   |  |  |  |
|--------------------------------------|-------------------------------|-------------------|--|--|--|
|                                      | 2008<br>Total                 | 2009 Total        | Quoted<br>Prices in<br>Active<br>Markets for<br>Identical<br>Assets<br>(Level 1) | Significant<br>Observable<br>Inputs<br>(Level 2) | Significant<br>Unobservable<br>Inputs<br>(Level 3) |
| <b>Defined Benefit Pension Plans</b> |                               |                   |  |  |  |
| Public equity securities             |                               |                   |  |  |  |
| U.S.                                 | \$ 437.7                      | \$ 864.7          | \$ 354.4   | \$ 510.3   | \$   |
| International                        | 1,532.6                       | 2,160.2           | 1,105.9  | 1,050.4  | 3.9  |
| Fixed income                         | 493.0                         | 600.5             | 76.0   | 521.0  | 3.5  |
| Private alternative investments      |                               |                   |  |  |  |
| Hedge funds                          | 1,387.1                       | 1,381.5           |  |  | 1,381.5  |
| Equity-like funds                    | 699.7                         | 743.6             |  |  | 743.6  |
| Other                                | 246.0                         | 258.0             | 241.8  | 16.2   |  |
| <b>Total</b>                         | <b>\$ 4,796.1</b>             | <b>\$ 6,008.5</b> | <b>\$ 1,778.1</b>  | <b>\$ 2,097.9</b>                                | <b>\$ 2,132.5</b>                                  |

**Retiree Health Benefit Plans**

## Public equity securities

|  |    |       |    |         |    |       |    |       |    |       |
|--|----|-------|----|---------|----|-------|----|-------|----|-------|
| U.S.   | \$ | 43.6  | \$ | 87.0    | \$ | 34.8  | \$ | 52.2  | \$ |       |
| International                                |    | 98.6  |    | 154.0   |    | 85.8  |    | 67.8  |    | 0.4   |
| Fixed income                                 |    | 43.4  |    | 46.9    |    |       |    | 46.5  |    | 0.4   |
| Private alternative investments              |    |       |    |         |    |       |    |       |    |       |
| Hedge funds                                  |    | 137.1 |    | 140.9   |    |       |    |       |    | 140.9 |
| Equity-like funds                            |    | 64.9  |    | 63.6    |    |       |    |       |    | 63.6  |
| Cash value of trust owned insurance contract |    | 490.9 |    | 675.7   |    |       |    | 675.7 |    |       |
| Other  |    | 27.1  |    | 12.6    |    | 12.0  |    | 0.6   |    |       |
| Total  | \$ | 905.6 | \$ | 1,180.7 | \$ | 132.6 | \$ | 842.8 | \$ | 205.3 |

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 activity in the Level 3 investments during 2009 was as follows:

|  | <b>Hedge<br/>Funds</b> | <b>Equity-like<br/>Funds</b> | <b>International<br/>Equity</b> | <b>Fixed<br/>Income</b> | <b>Total</b> |
|--|------------------------|------------------------------|---------------------------------|-------------------------|--------------|
| <b>Defined Benefit Pension Plans</b>                                       |                        |                              |                                 |                         |              |
| Beginning balance at January 1, 2009                                       | \$ 1,387.1             | \$ 699.6                     | \$ 3.6                          | \$ 6.5                  | \$ 2,096.8   |
| Actual return on plan assets, including changes in foreign exchange rates: |                        |                              |                                 |                         |              |
| Relating to assets still held at the reporting date                        | 158.0                  | (41.6)                       | 0.7                             | 1.1                     | 118.2        |
| Relating to assets sold during the period                                  |                        | (22.9)                       |                                 |                         | (22.9)       |
| Purchases, sales and settlements   | (163.6)                | 108.5                        | (0.4)                           | 1.5                     | (54.0)       |
| Transfers in and/or out of Level 3   |                        |                              |                                 | (5.6)                   | (5.6)        |
| Ending balance at December 31, 2009  | \$ 1,381.5             | \$ 743.6                     | \$ 3.9                          | \$ 3.5                  | \$ 2,132.5   |
| <b>Retiree Health Benefit Plans</b>  |                        |                              |                                 |                         |              |
| Beginning balance at January 1, 2009                                       | \$ 137.1               | \$ 64.8                      | \$ 0.4                          | \$ 0.7                  | \$ 203.0     |
| Actual return on plan assets, including changes in foreign exchange rates: |                        |                              |                                 |                         |              |
| Relating to assets still held at the reporting date                        | 15.2                   | (4.4)                        | 0.1                             | 0.1                     | 11.0         |
| Relating to assets sold during the period                                  |                        |                              |                                 |                         |              |
| Purchases, sales and settlements   | (11.4)                 | 3.2                          | (0.1)                           | 0.2                     | (8.1)        |
| Transfers in and/or out of Level 3   |                        |                              |                                 | (0.6)                   | (0.6)        |
| Ending balance at December 31, 2009  | \$ 140.9               | \$ 63.6                      | \$ 0.4                          | \$ 0.4                  | \$ 205.3     |

In 2010, we expect to contribute approximately \$100 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 2010 to our global defined benefit pension and post retirement health benefit plans.

#### **Note 14: Contingencies**

We are a party to various legal actions, government investigations, and environmental proceedings. The most significant of these are described below. While it is not possible to determine the outcome of these matters, we believe that, except as specifically noted below, 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 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):

**Cymbalta:** Sixteen generic drug manufacturers have submitted Abbreviated New Drug Applications (ANDAs) seeking permission to market generic versions of Cymbalta prior to the expiration of our relevant U.S. patents (the earliest of which expires in 2013). Of these challengers, all allege non-infringement of the patent claims directed to the commercial formulation, and nine allege invalidity of the patent claims directed to the active ingredient duloxetine. Of the nine challengers to the compound patent claims, one further alleges invalidity of the claims directed to the use of Cymbalta for treating fibromyalgia, and one alleges the patent having claims directed to the active ingredient is unenforceable. In November 2008 we filed lawsuits in U.S. District Court for the Southern District of Indiana against Actavis Elizabeth LLC; Aurobindo Pharma Ltd.; Cobalt Laboratories, Inc.; Impax Laboratories, Inc.; Lupin Limited; Sandoz Inc.; and Wockhardt Limited, seeking rulings that the patents are valid, infringed, and enforceable. We filed similar lawsuits in the same court against Sun Pharma Global, Inc. in December 2008 and against Anchen Pharmaceuticals, Inc. in August 2009. The cases have been consolidated and actions against all but Wockhardt Limited have been stayed pursuant to stipulations by the defendants to be bound by the outcome of the litigation through appeal.

**Gemzar:** Mayne Pharma (USA) Inc., now Hospira, Inc. (Hospira); Fresenius Kabi Oncology Plc (Fresenius); Sicor Pharmaceuticals, Inc., now Teva Parenteral Medicines, Inc. (Teva); and Sun Pharmaceutical Industries Inc. (Sun) each submitted an ANDA seeking permission to market generic versions of Gemzar prior to the expiration of our relevant U.S. patents (compound patent expiring in

2010 and method-of-use patent expiring in 2013), and alleging that these patents are invalid. Sandoz Inc. (Sandoz) and APP Pharmaceuticals, LLC (APP) have similarly challenged our method-of-use patent. We filed lawsuits in the U.S. District Court for the Southern District of Indiana against Teva (February 2006), Hospira (October 2006 and January 2008), Sandoz (October 2009), APP (December 2009), and Fresenius (February 2010), seeking rulings that our patents are valid and are being infringed. Sandoz withdrew its ANDA and the suit against it was dismissed in February 2010. The trial against Teva was held in September 2009 and we are waiting for a ruling. Teva's ANDAs have been approved by the FDA; however, Teva must provide 90 days notice prior to marketing generic Gemzar to allow time for us to seek a preliminary injunction. Both suits against Hospira have been administratively closed, and the parties have agreed to be bound by the results of the Teva suit. In November 2007, Sun filed a declaratory judgment action in the United States District Court for the Eastern District of Michigan, seeking rulings that our method-of-use and compound patents are invalid or unenforceable, or would not be infringed by the sale of Sun's generic product. In August 2009, the District Court granted a motion by Sun for partial summary judgment, invalidating our method-of-use patent. We have appealed this decision. This ruling has no bearing on the compound patent. The trial originally scheduled for December 2009 has been postponed while the court considers Sun's second summary judgment motion, related to the validity of our compound patent. Sun and APP have received tentative approval for their products from the FDA, but are prohibited from entering the market by 30-month stays, which expire in June 2010 for Sun and May 2012 for APP.

Alimta: Teva Parenteral Medicines, Inc. (Teva), 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. patent (licensed from the Trustees of Princeton University and expiring in 2016), and alleging the patent is 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. Trial is scheduled for November 2010 against Teva and APP.

Evista: In 2006, Teva Pharmaceuticals USA, Inc. (Teva) submitted an ANDA seeking permission to market a generic version of Evista prior to the expiration of our relevant U.S. patents (expiring in 2012-2017) and alleging that these patents are invalid, not enforceable, or not infringed. In June 2006, we filed a lawsuit against Teva in the U.S. District Court for the Southern District of Indiana, seeking a ruling that these patents are valid, enforceable, and being infringed by Teva. The trial against Teva was completed in March 2009. In September 2009, the court upheld our method-of-use patents (the last expires in 2014). Teva has appealed that ruling. In addition, the court held that our particle-size patent (expiring 2017) is invalid. We have appealed that ruling.

Strattera: Actavis Elizabeth LLC (Actavis), Apotex Inc. (Apotex), Aurobindo Pharma Ltd. (Aurobindo), Mylan Pharmaceuticals Inc. (Mylan), Sandoz Inc. (Sandoz), Sun Pharmaceutical Industries Limited (Sun), and Teva Pharmaceuticals USA, Inc. (Teva) each submitted an ANDA seeking permission to market generic versions of Strattera prior to the expiration of our relevant U.S. patent (expiring in 2017), and alleging that this patent is invalid. In 2007, we brought a lawsuit against Actavis, Apotex, Aurobindo, Mylan, Sandoz, Sun, and Teva in the United States District Court for the District of New Jersey. The court has ruled on all pending summary judgment motions, and granted our infringement motion. The remaining invalidity defenses will be decided at trial, which could take place as early as the third quarter of 2010. Several companies have received tentative approval to market generic atomoxetine, but are prohibited from entering the market by a 30-month stay which expires in November 2010.

We believe each of these Hatch-Waxman challenges is 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 in any of these cases could have a material adverse impact on our future

consolidated results of operations, liquidity, and financial position.

We have received challenges to Zyprexa patents in a number of countries outside the U.S.:

In Canada, several generic pharmaceutical manufacturers have challenged the validity of our Zyprexa patent (expiring in 2011). In April 2007, the Canadian Federal Court ruled against the first challenger, Apotex Inc. (Apotex), and that ruling was affirmed on appeal in February 2008. In June 2007, the Canadian Federal Court held that an invalidity allegation of a second challenger, Novopharm Ltd. (Novopharm), was justified and denied our request that Novopharm be prohibited from receiving marketing approval for generic olanzapine in Canada. Novopharm began selling generic olanzapine in Canada in the third quarter of 2007. In September 2009, the Canadian Federal Court ruled against us in the Novopharm suit, finding our patent invalid. We have appealed this decision. If the decision is upheld, we could face liability for damages related to delays in the launch of generic olanzapine products; however, we have concluded at this time that the damages are not probable or estimable.

In Germany, the German Federal Supreme Court upheld the validity of our Zyprexa patent (expiring in 2011) in December 2008, reversing an earlier decision of the Federal Patent Court. Following the

decision of the Supreme Court, the generic companies who launched generic olanzapine based on the earlier decision either agreed to withdraw from the market or were subject to injunction. We are pursuing these companies for damages arising from infringement.

We have received challenges in a number of other countries, including Spain, the United Kingdom (U.K.), and several smaller European countries. In Spain, we have been successful at both the trial and appellate court levels in defeating the generic manufacturers' challenges, but additional actions are now pending. In the U.K., the generic pharmaceutical manufacturer Dr. Reddy's Laboratories (UK) Limited (Dr. Reddy's) has challenged the validity of our Zyprexa patent (expiring in 2011). In October 2008, the Patents Court in the High Court, London ruled that our patent was valid. Dr. Reddy's appealed this decision. The U.K. Court of Appeal affirmed the validity of the patent in December 2009. Dr. Reddy's did not seek further appeal to the U.K. Supreme Court, therefore the U.K. proceedings are concluded.

We are vigorously contesting the various legal challenges to our Zyprexa patents on a country-by-country basis. We cannot determine the outcome of this litigation. The availability of generic olanzapine in additional markets could have a material adverse impact on our consolidated results of operations.

**Xigris and Evista:** In June 2002, Ariad Pharmaceuticals, Inc. (Ariad), the Massachusetts Institute of Technology, the Whitehead Institute for Biomedical Research, and the President and Fellows of Harvard College in the U.S. District Court for the District of Massachusetts sued us, alleging that sales of two of our products, Xigris and Evista, were inducing the infringement of a patent related to the discovery of a natural cell signaling phenomenon in the human body, and seeking royalties on past and future sales of these products. Following jury and bench trials on separate issues, the U.S. District Court of Massachusetts entered final judgment in September 2007 that Ariad's claims were valid, infringed, and enforceable, and finding damages in the amount of \$65 million plus a 2.3 percent royalty on net U.S. sales of Xigris and Evista since the time of the jury decision. However, the Court deferred the requirement to pay any damages until after all rights to appeal are exhausted. In April 2009, the Court of Appeals for the Federal Circuit overturned the District Court judgment, concluding that Ariad's asserted patent claims are invalid. In August 2009, the Court of Appeals agreed to review this decision en banc, thereby vacating the Court of Appeals decision. The en banc hearing occurred in December 2009 and we are awaiting a decision. Nevertheless, we believe that these allegations are without legal merit, that we will ultimately prevail on these issues, and therefore that the likelihood of any monetary damages is remote.

### **Zyprexa Litigation**

We have been named as a defendant in a large number of Zyprexa product liability lawsuits in the U.S. and have been notified of many other claims of individuals who have not filed suit. The lawsuits and unfiled claims (together the claims) 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. Almost all of the federal lawsuits 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 (MDL No. 1596).

Since June 2005, we have entered into agreements with various claimants' attorneys involved in U.S. Zyprexa product liability litigation to settle a substantial majority of the claims. The agreements cover a total of approximately 32,670 claimants, including a large number of previously filed lawsuits and other asserted claims. The two primary settlements were as follows:

In 2005, we settled and paid more than 8,000 claims for \$690.0 million, plus \$10.0 million to cover administration of the settlement.

In 2007, we settled and paid more than 18,000 claims for approximately \$500 million.

We are prepared to continue our vigorous defense of Zyprexa in all remaining claims. The U.S. Zyprexa product liability claims not subject to these agreements include approximately 170 lawsuits in the U.S. covering approximately 260 plaintiffs, of which about 140 cases covering about 150 plaintiffs are part of the MDL. The MDL cases have been scheduled for trial in groups, and no specific trial dates for trial groups have been assigned. We also have trials scheduled in Texas state court in May and August 2010 and in Ohio in August 2010.

In January 2009, we reached resolution with the Office of the U.S. Attorney for the Eastern District of Pennsylvania (EDPA), and the State Medicaid Fraud Control Units of 36 states and the District of Columbia, of an investigation related to our U.S. marketing and promotional practices with respect to Zyprexa. As part of the resolution, we pled guilty to one misdemeanor violation of the Food, Drug, and Cosmetic Act for the off-label promotion of Zyprexa in elderly populations as treatment for dementia, including Alzheimer's dementia, between September 1999 and March 2001. We recorded a charge of \$1.42 billion for this matter in the third quarter of 2008. In 2009, we paid substantially all of this amount, as required

by the settlement agreements. As part of the settlement, we have entered into a corporate integrity agreement with the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS), 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, policies, procedures, and practices.

In October 2008, we reached a settlement with 32 states and the District of Columbia related to a multistate investigation brought under various state consumer protection laws. While there is no finding that we have violated any provision of the state laws under which the investigations were conducted, we accrued and paid \$62.0 million and agreed to undertake certain commitments regarding Zyprexa for a period of six years, through consent decrees filed with the settling states.

We have been served with lawsuits filed by the states of Alaska, Arkansas, Connecticut, Idaho, Louisiana, Minnesota, Mississippi, Montana, New Mexico, Pennsylvania, South Carolina, Utah, and West Virginia alleging that Zyprexa caused or contributed to diabetes or high blood-glucose levels, and that we improperly promoted the drug. These suits seek to recover the costs paid for Zyprexa through Medicaid and other drug-benefit programs, as well as the costs alleged to have been incurred and that will be incurred by the states to treat Zyprexa-related illnesses. The Connecticut, Idaho, Louisiana, Minnesota, Mississippi, Montana, New Mexico, and West Virginia cases are part of the MDL proceedings in the EDNY. The Alaska case was settled in March 2008 for a payment of \$15.0 million, plus terms designed to ensure, subject to certain limitations and conditions, that Alaska is treated as favorably as certain other states that may settle with us in the future over similar claims. We are in advanced discussions with the attorneys general for several of these states, seeking to resolve their Zyprexa-related claims, and we have agreed to settlements with the states of Arkansas, Connecticut, Idaho, Mississippi, New Mexico, South Carolina, Utah, and West Virginia. In the second and third quarters of 2009, we incurred pretax charges of \$105.0 million and \$125.0 million, respectively, reflecting the currently probable and estimable exposures in connection with these claims. The Pennsylvania case is set for trial in April 2010 in state court.

In 2005, two 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 have made or will make payments for their members or insured patients being prescribed Zyprexa. These actions have now been consolidated into a single lawsuit, which is brought under certain state consumer protection statutes, the federal civil RICO statute, and common law theories, seeking a refund of the cost of Zyprexa, treble damages, punitive damages, and attorneys' fees. Two additional lawsuits were filed in the EDNY in 2006 on similar grounds. In September 2008, Judge Weinstein certified a class consisting of third-party payors, excluding governmental entities and individual consumers. We appealed the certification order, and Judge Weinstein's order denying our motion for summary judgment, in September 2008. While the Second Circuit Court of Appeals heard oral arguments on the appeal in December 2009, no opinions have been rendered. In 2007, The Pennsylvania Employees Trust Fund brought claims in state court in Pennsylvania as insurer of Pennsylvania state employees, who were prescribed Zyprexa on similar grounds as described in the New York cases. 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 December 2009, the court granted our summary judgment motion dismissing the case. Plaintiffs have appealed this decision.

In early 2005, we were served with four lawsuits seeking class action status in Canada on behalf of patients who took Zyprexa. One of these four lawsuits has been certified for residents of Quebec, and a second has been certified in Ontario and includes all Canadian residents except for residents of Quebec and British Columbia. The allegations in the Canadian actions are similar to those in the product liability litigation pending in the U.S. We are in advanced discussions to resolve all Zyprexa class-action litigation in Canada.

We cannot determine with certainty the additional number of lawsuits and claims that may be asserted. The ultimate resolution of Zyprexa product liability and related litigation could have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

**Other Product Liability Litigation**

We have been named as a defendant in numerous other product liability lawsuits involving primarily diethylstilbestrol (DES), thimerosal, and Byetta. The majority of 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 attain 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.

### Environmental Matters

Under the Comprehensive Environmental Response, Compensation, and Liability Act, commonly known as Superfund, we have been designated as one of several potentially responsible parties with respect to fewer than 10 sites. Under Superfund, each responsible party may be jointly and severally liable for the entire amount of the cleanup. We also continue remediation of certain of our own sites. We have accrued for estimated Superfund cleanup costs, remediation, and certain other environmental matters. This takes into account, as applicable, available information regarding site conditions, potential cleanup methods, estimated costs, and the extent to which other parties can be expected to contribute to payment of those costs. We have limited liability insurance coverage for certain environmental liabilities.

### Note 15: Other Comprehensive Income (Loss)

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

|   | Foreign<br>Currency<br>Translation<br>Gains | Unrealized<br>Gains<br>(Losses)<br>on<br>Securities | Defined<br>Benefit<br>Pension and<br>Retiree<br>Health<br>Benefit Plans | Effective<br>Portion of<br>Cash Flow<br>Hedges | Accumulated<br>Other<br>Comprehensive<br>Loss |
|---|---|---|---|--|---|
| Beginning balance at<br>January 1, 2009 | \$ 550.9                                    | \$ (111.2)  | \$ (3,076.4)  | \$ (150.1)                                     | \$ (2,786.8)                                  |
| Other comprehensive income<br>(loss)    | 284.9                                       | 186.6   | (187.9)   | 31.3   | 314.9   |
| Balance at December 31, 2009            | \$ 835.8                                    | \$ 75.4   | \$ (3,264.3)  | \$ (118.8)                                     | \$ (2,471.9)                                  |

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 13) were a benefit of \$92.4 million for 2009. The income taxes associated with the unrealized gains (losses) on securities was an expense of \$103.2 million for 2009. 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 \$19.0 million, \$(1.7) million, and \$5.8 million, net of tax, in 2009, 2008, and 2007, 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 zero, \$9.6 million, and \$8.8 million, net of tax, in 2009, 2008, and 2007, respectively, for realized losses on foreign currency options and \$6.7 million, \$7.9 million, and \$11.6 million, net of tax, in 2009, 2008, and 2007, 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.

## *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. *The Red Book* is reviewed on a periodic basis with employees worldwide, and all employees 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 nonaudit 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, 2009. 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. Their responsibility is to evaluate whether internal control over financial reporting was designed and operating effectively.

John C. Lechleiter, Ph.D.

*Chairman, President, and Chief Executive Officer*

Derica W. Rice

*Executive Vice President, Global Services and Chief Financial Officer*

February 22, 2010

*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, 2009 and 2008, and the related consolidated statements of operations, cash flows, and comprehensive income (loss) for each of the three years in the period ended December 31, 2009. 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, 2009 and 2008, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2009, 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, 2009, 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 22, 2010 expressed an unqualified opinion thereon.

Indianapolis, Indiana  
February 22, 2010

*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, 2009, 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, 2009, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the 2009 consolidated financial statements of Eli Lilly and Company and subsidiaries and our report dated February 22, 2010 expressed an unqualified opinion thereon.

Indianapolis, Indiana  
February 22, 2010



**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, 2009, 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, 2009. In addition, Ernst & Young LLP, 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 2009, there were no changes in our internal control over financial reporting that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B.        *Other Information***

Not applicable.

**Part III**

**Item 10.        *Directors, Executive Officers, and Corporate Governance***

**Directors and Executive Officers**

Information relating to our Board of Directors is found in our Proxy Statement to be dated on or about March 8, 2010 (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://investor.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 9, 2009.

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, 2009, about our compensation plans under which shares of Lilly stock have been authorized for issuance.

| Plan Category  | (a) Number of securities to be                                    | (b)  |  | (c) Number of securities remaining available for future issuance        |
|--|---|--|--|---|
|  | issued upon exercise of outstanding options, warrants, and rights | Weighted-average exercise price of outstanding options, warrants, and rights |  | under equity compensation plans (excluding securities reflected in (a)) |
| Equity compensation plans approved by security holders | 52,854,572  | \$ 68.52   |  | 84,578,959  |

|   |            |          |                |
|---|------------|----------|----------------|
| Equity compensation plans not approved by security holders <sup>1</sup> | 6,594,445  | 76.11    | 0 <sup>2</sup> |
| Total   | 59,449,017 | \$ 69.36 | 84,578,959     |

<sup>1</sup> 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.

<sup>2</sup> The Lilly GlobalShares Stock Plan was terminated in February 2009. No more grants can be made under this plan.

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

**Related Person Transactions**

Information relating to 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, 2009, 2008, and 2007

Consolidated Balance Sheets   December 31, 2009 and 2008

Consolidated Statements of Cash Flows   Years Ended December 31, 2009, 2008, and 2007

Consolidated Statements of Comprehensive Income (Loss)   Years Ended December 31, 2009, 2008, and 2007

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 Indenture dated March 10, 1998, among The Lilly Savings Plan Master Trust Fund C, as issuer; Eli Lilly and Company, as guarantor; and The Chase Manhattan Bank, as Trustee, relating to ESOP Amortizing Debentures due 2017<sup>1</sup>
- 4.5 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<sup>1</sup>

**(a)3. Exhibits**

- 4.6 Form of Resetable Floating Rate Debt Security due 2037<sup>1</sup>
- 10.1 1998 Lilly Stock Plan, as amended<sup>2</sup>
- 10.2 2002 Lilly Stock Plan, as amended<sup>2</sup>
- 10.3 Form of two-year Performance Award under the 2002 Lilly Stock Plan<sup>2</sup>
- 10.4 Form of Shareholder Value Award under the 2002 Lilly Stock Plan<sup>2</sup>
- 10.5 Form of Restricted Stock Unit under the 2002 Lilly Stock Plan<sup>2</sup>
- 10.6 The Lilly Deferred Compensation Plan, as amended<sup>2</sup>
- 10.7 The Lilly Directors' Deferral Plan, as amended<sup>2</sup>
- 10.8 The Eli Lilly and Company Bonus Plan, as amended<sup>2</sup>
- 10.9 2007 Change in Control Severance Pay Plan for Select Employees, as amended effective January 1, 2009<sup>2</sup>
- 10.10 2007 Change in Control Severance Pay Plan for Select Employees, as amended effective October 20, 2010<sup>2</sup>
- 10.11 Letter agreement dated September 15, 2004 between the company and Steven M. Paul, M.D. concerning retirement benefits<sup>2</sup>
- 10.12 Letter agreement dated November 11, 2009 between the company and Steven M. Paul, M.D. concerning retirement benefits<sup>2</sup>
- 10.13 Arrangement regarding retirement benefits for Robert A. Armitage<sup>2</sup>
- 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

<sup>1</sup> This exhibit is not filed with this report. Copies will be furnished to the Securities and Exchange Commission upon request.

<sup>2</sup> 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 22, 2010

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below on February 22, 2010 by the following persons on behalf of the Registrant and in the capacities indicated.

| <b>Signature</b>  | <b>Title</b>   |
|---|--|
| <p>/s/ John C. Lechleiter, Ph.D.</p> <p>JOHN C. LECHLEITER, Ph.D.</p>         | <p>Chairman of the Board, President, and Chief Executive Officer, and a Director (principal executive officer)</p> |
| <p>/s/ Derica W. Rice</p> <p>DERICA W. RICE</p>                               | <p>Executive Vice President, Global Services and Chief Financial Officer (principal financial officer)</p>         |
| <p>/s/ Arnold C. Hanish</p> <p>ARNOLD C. HANISH</p>                           | <p>Vice President, Finance and Chief Accounting Officer (principal accounting officer)</p>                         |
| <p>/s/ Ralph Alvarez</p> <p>RALPH ALVAREZ</p>                                 | <p>Director</p>  |
| <p>/s/ Sir Winfried Bischoff</p> <p>SIR WINFRIED BISCHOFF</p>                 | <p>Director</p>  |
| <p>/s/ Michael L. Eskew</p> <p>MICHAEL L. ESKEW</p>                           | <p>Director</p>  |
| <p>/s/ Martin S. Feldstein, Ph.D.</p> <p>MARTIN S. FELDSTEIN, Ph.D.</p>       | <p>Director</p>  |
| <p>/s/ J. Erik Fyrwald</p> <p>J. ERIK FYRWALD</p>                             | <p>Director</p>  |
| <p>/s/ Alfred G. Gilman, M.D., Ph.D.</p> <p>ALFRED G. GILMAN, M.D., Ph.D.</p> | <p>Director</p>  |
| <p>/s/ R. David Hoover</p> <p>R. DAVID HOOVER</p>                             | <p>Director</p>  |
| <p>/s/ Karen N. Horn, Ph.D.</p>   | <p>Director</p>  |

KAREN N. HORN, Ph.D.

/s/ Ellen R. Marram Director

ELLEN R. MARRAM

/s/ Douglas R. Oberhelman Director

DOUGLAS R. OBERHELMAN

/s/ Franklyn G. Prendergast, M.D., Ph.D. Director

FRANKLYN G. PRENDERGAST, M.D., Ph.D.

/s/ Kathi P. Seifert Director

KATHI P. SEIFERT

### **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

Byetta® is a trademark of Amylin Pharmaceuticals, Inc.

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 Indenture dated March 10, 1998, among The Lilly Savings Plan Master Trust Fund C, as issuer; Eli Lilly and Company, as guarantor; and The Chase Manhattan Bank, as Trustee, relating to ESOP Amortizing Debentures due 2017 | *  |
| 4.5     | 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   | *  |
| 4.6     | Form of Resettable Floating Rate Debt Security due 2037   | *  |

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|      |  |   |
|------|--|---|
| 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 | Attached  |
| 10.4 | Form of Shareholder Value Award under 2002 Lilly Stock Plan    | Attached  |
| 10.5 | Form of Restricted Stock Unit under 2002 Lilly Stock Plan      | Attached  |

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

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| Exhibit |  | Location  |
|---------|--|---|
| 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, 2008 |
| 10.8    | The Eli Lilly and Company Bonus Plan, as amended   | Attached  |
| 10.9    | 2007 Change in Control Severance Pay Plan for Select Employees, as amended effective January 1, 2009   | Incorporated by reference from Exhibit 10.4 to the Company's Report on Form 10-Q for the quarter ended September 30, 2008 |
| 10.10   | 2007 Change in Control Severance Pay Plan for Select Employees, as amended effective October 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   | Letter agreement dated September 15, 2004 between the Company and Steven M. Paul, M.D. concerning retirement benefits  | Incorporated by reference from Exhibit 10.14 to the Company's Report on Form 10-K for the year ended December 31, 2004    |
| 10.12   | Letter agreement dated November 11, 2009 between the Company and Steven M. Paul, M.D. concerning retirement benefits   | Attached  |
| 10.13   | 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    |
| 10.14   | Guilty Plea Agreement in <i>The United States District Court for the Eastern District of Pennsylvania, United States of America v. Eli Lilly and Company</i>   | 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 | Incorporated by reference from Exhibit 10.16 to the Company's Report on Form 10-K for the year ended December 31, 2008    |

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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 | 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   |