

LILLY ELI & CO

FORM 10-K (Annual Report)

Filed 3/8/2005 For Period Ending 12/31/2004

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|-------------|---|
| Address | LILLY CORPORATE CTR DROP CODE 1112 INDIANAPOLIS, Indiana 46285 |
| Telephone | 317-276-2000 |
| CIK | 0000059478 |
| Industry | Major Drugs |
| Sector | Healthcare |
| Fiscal Year | 12/31 |

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, 2004

Commission file number 001-6351

Eli Lilly and Company

An Indiana corporation

I.R.S. employer number 35-0470950

Address: Lilly Corporate Center, Indianapolis, Indiana 46285

Telephone number, including area code: (317) 276-2000

Securities registered pursuant to Section 12(b) of the Act:

| <u>Title of Each Class</u> | <u>Name of Each Exchange On Which Registered</u> |
|-----------------------------------|--|
| Common Stock | New York and Pacific Stock Exchanges |
| Preferred Stock Purchase Rights | New York and Pacific Stock Exchanges |
| 8-3/8% Notes Due December 1, 2006 | 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 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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant's knowledge, in the definitive proxy statement incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the Registrant is an accelerated filer as defined in Exchange Act Rule 12b-2. 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 \$68,515,400,000

Number of shares of common stock outstanding as of February 15, 2005: 1,132,720,819

Portions of the following documents have been incorporated by reference into this report:

| <u>Registrant's Document</u> | <u>Parts Into Which Incorporated</u> |
|---|--------------------------------------|
| Annual Report to Shareholders for fiscal year ended December 31, 2004 | Parts I, II, and IV |
| Proxy Statement dated March 8, 2005 | Part III |

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Part I

Item 1. Business

Eli Lilly and Company (the “Company” or “Registrant”, which may be referred to as “we”, “us”, or “our”) 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. We manufacture and distribute our products through owned or leased facilities in the United States, Puerto Rico, and 22 other countries. Our products are sold in approximately 140 countries.

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 and develop innovative new pharmaceutical products. We direct our research efforts primarily toward the search for products to prevent and treat human diseases. We also conduct research to find products to treat diseases in animals and to increase the efficiency of animal food production.

Products

Our principal products are:

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

- *Zyprexa*®, for the treatment of schizophrenia, bipolar mania and bipolar maintenance
- *Strattera*®, for the treatment of attention-deficit hyperactivity disorder in children, adolescents and adults
- *Prozac*®, for the treatment of depression and, in many countries, for bulimia and obsessive-compulsive disorder
- *Cymbalta*®, for the treatment of depression (approved in August 2004 in the U.S. and in December 2004 in the European Union) and diabetic peripheral neuropathic pain (approved in September 2004 in the U.S.)
- *Permax*®, for the treatment of Parkinson’s disease
- *Symbyax*®, for the treatment of bipolar depression
- *Sarafem*®, for the treatment of pre-menstrual dysphoric disorder
- *Yentreve*™, for the treatment of stress urinary incontinence (approved in 2004 in the European Union and several other countries outside the United States).

Endocrine products, including:

- *Humalog*® and *Humalog Mix 75/25*®, injectable human insulin analogs of recombinant DNA origin for the treatment of diabetes
- *Humulin*®, injectable human insulin produced through recombinant DNA technology for the treatment of diabetes
- *Actos*®, an oral agent for the treatment of Type 2 diabetes
- *Evista*®, an oral agent for the prevention and treatment of osteoporosis in post-menopausal women

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- *Humatrope*®, for the treatment of human growth hormone deficiency and idiopathic short stature
- *Forteo*®, an injectable treatment for severe osteoporosis in women and men.

Oncology products , including:

- *Gemzar*®, for the treatment of pancreatic cancer; in combination with other agents, for treatment of metastatic breast cancer and non-small cell lung cancer; and in the European Union for bladder and ovarian cancers
- *Alimta*®, for the treatment of malignant pleural mesothelioma and for second-line treatment of non-small cell lung cancer (approved in 2004 in the U.S. and several other countries).

Animal health products , including:

- *Tylan*®, an antibiotic used to control certain diseases in cattle, swine, and poultry
- *Rumensin*®, a cattle feed additive that improves feed efficiency and growth and also controls and prevents coccidiosis
- *Coban*®, *Monteban*® and *Maxiban*® , anticoccidial agents for use in poultry
- *Apralan*® , an antibiotic used to control enteric infections in calves and swine
- *Micotil*® and *Pulmotil*®, antibiotics used to treat respiratory disease in cattle and swine, respectively
- *Surmax*® (sold as *Maxus*® in some countries), a performance enhancer for swine and poultry
- *Paylean*® and *Optaflexx*®, leanness and performance enhancers for swine and cattle, respectively.

Cardiovascular agents , including:

- *ReoPro*®, a treatment for use as an adjunct to percutaneous coronary intervention (“PCI”), including patients undergoing angioplasty, atherectomy or stent placement
- *Xigris*®, for the treatment of adults with severe sepsis at high risk of death.

Anti-infectives , including:

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

Other pharmaceutical products , including:

- *Cialis*®, for the treatment of erectile dysfunction.

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. Our marketing policy is designed to assure that products and relevant medical information are immediately available to physicians, pharmacies, hospitals, and appropriate health care professionals throughout the country. Three wholesale distributors in the United States – AmerisourceBergen

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Corporation, Cardinal Health, Inc., and McKesson Corporation – each accounted for between 13 and 17 percent of our worldwide consolidated net sales in 2004. 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. Beginning in 2005, we have restructured our arrangements with our U.S. wholesalers. We believe that the new arrangements will provide us with competitive distribution costs as well as more reliable data about wholesaler inventory levels, and will reduce the speculative buying by wholesalers that has sometimes affected U.S. sales growth trends for certain products.

We promote our major pharmaceutical products in the United States through sales representatives who call upon physicians, wholesalers, hospitals, managed-care organizations, retail pharmacists, and other health care professionals. We advertise in medical and drug 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 product lines or practice areas, such as primary care, neuroscience, acute care, endocrinology, and oncology.

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 have created special sales groups to service managed-care organizations, government and long-term care institutions, hospital contract administrators, and certain retail pharmacies. In response to competitive pressures, we have entered into arrangements with a number of these organizations providing for discounts or rebates on one or more Lilly products or other cost-sharing arrangements.

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 and distribution organizations. In some countries, however, we market our products through independent distributors.

Pharmaceutical Marketing Collaborations

Several of our significant products are marketed in collaboration with other pharmaceutical companies:

- We co-promote Actos with a unit of Takeda Chemical Industries Ltd. in the U.S. and certain other countries and we sell it alone in other countries. Our U.S. marketing rights with respect to Actos expire in September 2006.
- We co-promote ReoPro with Centocor, Inc. worldwide except Japan, where we have no rights.
- Cialis is sold in North America and the European Union by a joint venture between Lilly and ICOS Corporation, and is sold by us alone in other territories.
- Cymbalta is co-promoted in the U.S. by Quintiles Transnational Corp. and outside the U.S. (except Japan) by Boehringer Ingelheim GmbH.
- We have entered into an arrangement under which Boehringer Ingelheim will co-market or co-promote Yentreve in all major markets worldwide except Japan.

We have also entered into licensing arrangements under which we have granted exclusive marketing rights to other companies in specified countries for certain older products manufactured by us, such as Permax, Sarafem, Vancocin, the anti-ulcer agent Axid ® , the analgesic Darvon ® , and the anti-infectives Ceclor, Keflex ® , Keftab ® , and Lorabid ® .

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Animal Health Products

Our Elanco Animal Health business unit employs field salespeople throughout the United States to market animal health products. Elanco also has an extensive sales force outside the United States. Elanco sells its products primarily to wholesale distributors.

Raw Materials and Product Supply

Most of the principal materials we use in our manufacturing operations are available from more than one source. We obtain certain raw materials principally from only one source. In addition, three of our significant products are manufactured by others: Actos by Takeda; ReoPro by Centocor; and Xigris by Lonza Biologics (bulk product) and DSM, N.V. (finished product). If we were unable to obtain certain materials from present sources, 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 three sites in Indiana 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.

We seek to design and operate our manufacturing facilities and maintain inventory in a way that will 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. Accordingly, if we were to experience extended plant shutdowns 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.

Patents, Trademarks, and Other Intellectual Property Rights

Overview

Intellectual property protection is, in the aggregate, material to our ability to successfully commercialize our life sciences innovations. We own, have applied for, or are licensed under, a large number of patents, both in the United States and in 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 have been granted 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.

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. However, in many countries, this agreement will not become fully effective for many years. It is still too soon to assess when and how much, if at all, we will benefit commercially from these changes.

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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.

Our Intellectual Property Portfolio

We consider intellectual property protection for certain products, processes, and uses – particularly that relating to Zyprexa, Gemzar, Humalog, Evista, Actos, ReoPro, Xigris, Strattera, Cialis, Alimta, and Cymbalta – 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.

United States compound patent expirations include those claiming the respective active ingredients in Zyprexa, 2011; Humalog, 2013; and ReoPro, 2015. The Gemzar compound patent in the U.S. expires in 2010, but a method-of-use patent covering treatment of neoplasms with Gemzar is in force until 2012. We hold a number of U.S. patents covering Evista and its approved uses in osteoporosis prevention and treatment that we believe should provide us exclusivity in the United States until at least 2012. In the United States, the Actos compound patent extends beyond the duration of our co-promotion agreement, which is in force until 2006. Xigris is a complex glycoprotein biologic product that is produced through recombinant DNA technology. Xigris is not subject to the Abbreviated New Drug Application process under the Hatch-Waxman law as described below. In addition, we hold patents on the DNA materials, certain uses, manufacturing process, and the glycoprotein itself. We believe the intellectual property protection for Xigris should provide us marketing exclusivity in the U.S. until 2015. For Strattera, a method-of-use patent in the U.S. for treating attention deficit-hyperactivity disorder should provide exclusivity until 2016. For Cialis, compound and method-of-use patent protection exists in the U.S. that should provide exclusivity until 2017. The U.S. compound patent for Alimta expires in 2011 but we have applied for a patent term extension that we expect will extend the patent until 2016. For Cymbalta, the U.S. compound patent expires in 2008 but we have applied for a patent term extension that we expect will extend the patent until 2013. We also have a formulation patent for Cymbalta until 2014.

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 Challenges Under the Hatch-Waxman Act

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 in the United States. Before Hatch-Waxman, no drug could be approved without providing the Food and Drug Administration (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 medicines 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 successful 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

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innovator must then file suit against the generic manufacturer to protect its patents. If one or more of the NDA-listed patents are successfully 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. We are currently in litigation with numerous generic manufacturers arising from their Paragraph IV certifications on Zyprexa, Evista, and Sarafem. In the Sarafem litigation, we prevailed at trial and the challenger has appealed to the Court of Appeals for the Federal Circuit. For more information on the Zyprexa and Evista patent litigation, see Part 1, Item 3, Legal Proceedings.

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 product efficacy, safety, and ease of use, price and demonstrated cost-effectiveness, marketing effectiveness, service, and research and development of new products and processes. If competitors introduce new products, delivery systems or processes with therapeutic or cost advantages, our products can be subject to progressive price reductions or decreased volume of sales, or both. Most new products that we introduce must compete with other products already on the market or products that are later developed by competitors. Manufacturers of generic pharmaceuticals typically invest far less in research and development than research-based pharmaceutical companies and therefore can price their products significantly lower than branded products. Accordingly, when a branded product loses its market exclusivity, it normally faces intense price competition from generic forms of the product. In many countries outside the United States, patent protection is weak or nonexistent and we must compete with generic or “knockoff” versions of our products. To successfully compete for business with managed care and pharmacy benefits management organizations, we must often 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 innovative, cost-effective products that serve unmet medical needs, 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.

Government Regulation

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 required governmental approvals is extremely costly and can significantly delay product introductions in a given market. 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 environmental and occupational health and safety laws and regulations. The laws and regulations affecting the manufacture

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and sale of current products and the 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 virtually all of our businesses 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.

New drugs may now be approved across the European Union (EU) using the European Commission's centralized approval process or using the national mutual recognition process. The use of either of these procedures provides a more consistent and, in some cases, a more rapid approval within the EU member states than was the case when each member state operated its own approval process.

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, civil and criminal penalties, and delays in new product approvals.

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 and false claims. 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, both the FDA and many of these other agencies have increased their enforcement activities with respect to pharmaceutical companies. Over this period, several cases brought by these agencies against other companies under these and other laws have resulted in corporate criminal sanctions and very substantial civil settlements. Several pharmaceutical companies, including Lilly, are currently subject to proceedings by one or more of these agencies regarding marketing and promotional practices. See Part I, Item 3, "Legal Proceedings," for information about currently pending marketing and promotional practices investigations in which we are involved. 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 such an action could have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

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. Other 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., we expect branded pharmaceutical products to be subject to increasing pricing pressures. Implementation of the Medicare Prescription Drug, Improvement and Modernization Act of 2003

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(MMA), providing a prescription drug benefit under the Medicare program, will take effect January 1, 2006. While it is difficult to predict the business impact of this legislation prior to 2006, we currently anticipate a relatively neutral short-term impact due to offsets of price and volume in various customer groups. However, in the long term there is additional risk associated with increased pricing pressures. While the MMA prohibits the Secretary of Health and Human Services (HHS) from directly negotiating prescription drug prices with manufacturers, we expect continued challenges to that prohibition over the next several years. Also, the MMA retains the authority of the Secretary of Health and Human Services to prohibit the importation of prescription drugs, but we expect Congress to consider several measures that could remove that authority and allow for the importation of products into the U.S. regardless of their safety or cost. If adopted, such legislation would likely have a negative effect on our U.S. sales. We are encouraged by the release of the HHS Task Force Report on Importation, which concludes that the safety and possible cost savings of an importation scheme are questionable.

As a result of the passage of the MMA, aged and disabled patients jointly eligible for Medicare and Medicaid will receive their prescription drug benefits through Medicare, instead of Medicaid, beginning January 1, 2006. This may relieve some state budget pressures but is unlikely to result in reduced pricing pressures. A majority of states have begun to implement supplemental rebates and restricted formularies in their Medicaid programs, and these programs are expected to continue in the post-MMA environment. Several states are also attempting to extend discounted Medicaid prices to non-Medicaid patients. Additionally, notwithstanding the federal law prohibiting pharmaceutical importation, nine states have implemented importation schemes for their citizens, usually involving a website that links patients to selected Canadian pharmacies. One state has such a program for its state employees. In the absence of federal action to curtail state activities, we expect other states to launch importation efforts. As a result, we expect pressures on pharmaceutical pricing to continue.

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 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 continue in the near term.

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 2004, we employed approximately 8,450 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 \$2.15 billion in 2002, \$2.35 billion in 2003, and \$2.69 billion in 2004.

To improve productivity, in 2004 we terminated our research in the area of inflammation and reallocated resources to other areas of R&D, thus narrowing our pharmaceutical research and development focus from five to four therapeutic categories: central nervous system and related diseases; endocrine diseases, including diabetes and osteoporosis; cancer; and cardiovascular diseases. However, we remain opportunistic, selectively pursuing promising leads in other therapeutic areas. We are actively engaged in biotechnology research programs involving recombinant DNA, therapeutic proteins and antibodies 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 look for ways to expand the value of existing products through new uses and

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formulations that can provide additional benefits to patients. We also conduct research in the animal sciences, including animal nutrition and physiology, control of parasites, and veterinary medicine.

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 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 typically takes 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. 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. Among our new investigational compounds in the later stages of development are potential therapies for diabetes and its complications, osteoporosis, cancer, and acute coronary syndromes. Further, we are studying many other drug candidates in the earlier stages of development, including compounds targeting cancers, thrombotic disorders, atherosclerosis, Alzheimer's disease, diabetes, obesity, and sleep disorders. We are also developing new uses and formulations for many of our important currently marketed products, such as Alimta, Cialis, Cymbalta, Evista, ReoPro, and Symbyax.

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. 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 18, 2005, or on the date his or her successor is chosen and qualified. No director or executive officer of the Company 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.

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There is no understanding between any executive officer and any other person pursuant to which the executive officer was selected.

| <u>Name</u> | <u>Age</u> | <u>Offices</u> |
|---------------------------|------------|---|
| Sidney Taurel | 56 | Chairman of the Board (since January 1999), President and Chief Executive Officer (since June 1998), and a Director |
| Charles E. Golden | 58 | Executive Vice President and Chief Financial Officer (since March 1996) and a Director |
| John C. Lechleiter, Ph.D. | 51 | Executive Vice President, Pharmaceutical Operations (since February 2004) |
| Steven M. Paul, M.D. | 54 | Executive Vice President, Science and Technology (since July 2003) |
| Robert A. Armitage | 56 | Senior Vice President and General Counsel (since January 2003) |
| Scott A. Canute | 44 | President, Manufacturing Operations (since October 2004) |
| Deirdre P. Connelly | 44 | Senior Vice President, Human Resources (since October 2004) |
| Gino Santini | 48 | Senior Vice President, Corporate Strategy and Policy (since July 2004) |
| Lorenzo Tallarigo, M.D. | 54 | President, International Operations (since January 2004) |

Employees

At the end of 2004, we employed approximately 44,500 people, including approximately 20,500 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 our 2004 Annual Report at page 27 under "Segment Information" (page 19 of Exhibit 13 to this Form 10-K). That information is incorporated into this report 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.

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Financial Information Relating to Foreign and Domestic Operations

You can find financial information relating to foreign and domestic operations in our 2004 Annual Report at page 27 under “Segment Information” (page 19 of Exhibit 13). That information is incorporated in this Report 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 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 and results of operations. We actively manage 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. The reports we make available 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/edgar.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/corp-gov.cfm>.

We will provide paper copies of our SEC filings and corporate governance documents free of charge upon request to the company’s secretary at the address listed on the front of this Form 10-K.

Item 2. Properties

Our principal domestic and international executive offices are located in Indianapolis. At December 31, 2004, we owned 13 production and distribution facilities in the United States and Puerto Rico. Together with the corporate administrative offices, these facilities contain an aggregate of approximately 11.7 million square feet of floor area dedicated to production, distribution, and administration. Major production sites include Indianapolis; Clinton and Lafayette, Indiana; and Carolina and Mayaguez, Puerto Rico. We are constructing a new production facility in Prince William County, Virginia.

We own production and distribution facilities in 13 countries outside the United States and Puerto Rico, containing an aggregate of approximately 4.2 million square feet of floor space. Major production sites include facilities in the United Kingdom, France, Ireland, Spain, Italy, Brazil, and Mexico. We lease production and warehouse facilities in Puerto Rico and several countries outside the United States.

Our research and development facilities in the United States consist of approximately 4.4 million square feet and are located primarily in Indianapolis and Greenfield, Indiana. Our major research and development facilities abroad are located in Belgium, United Kingdom, Germany, Canada, and Spain and contain an aggregate of approximately 650,000 square feet.

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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. While it is not possible to predict or determine the outcome of the legal actions, investigations and proceedings described below, we believe that, except as otherwise specifically noted below with respect to the U.S. Zyprexa and Evista patent litigation, the Zyprexa product liability litigation, and the U.S. marketing practices investigation involving Zyprexa, Prozac, and Prozac Weekly, 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.

Zyprexa Patent Litigation

Three generic pharmaceutical manufacturers, Zenith Goldline Pharmaceuticals, Inc. (Zenith), Dr. Reddy's Laboratories, Ltd. (Reddy) and Teva Pharmaceuticals (Teva) have submitted abbreviated new drug applications (ANDAs) seeking permission to market generic versions of Zyprexa in various dosage forms and formulations (including the Zydis® formulation) several years prior to the expiration of our U.S. patents for the product, alleging that our patents are invalid, not infringed, or unenforceable. In April 2001, we filed suit against Zenith in the U.S. District Court for the Southern District of Indiana seeking a ruling that the challenges to our compound patent (expiring in 2011) are without merit. We filed similar suits in the same court against Reddy in June 2001 and Teva in September 2002. The cases have been consolidated. A trial before a district court judge in Indianapolis was held in January and February of 2004 and we are awaiting a ruling from the trial court. Regardless of the trial court's ruling, we anticipate that appeals will follow. If we are unsuccessful at the trial court level, we cannot predict whether any of the generic companies would launch generic versions of Zyprexa prior to a final resolution of any appeals.

In October 2004 we were notified that Barr Laboratories, Inc. (Barr) submitted an ANDA seeking permission to market the Zydis formulation of Zyprexa, asserting that our patents covering Zydis are invalid, not infringed, or unenforceable. In December 2004 we filed suit against Barr in the U.S. District Court for the Southern District of Indiana seeking a ruling that Barr's patent challenges are without merit. That suit has now been stayed pending the decision of the trial court in the Zenith/Reddy/Teva case described above.

We believe that the generic manufacturers' claims are without merit and we expect to prevail in this litigation. However, it is not possible to predict or determine the outcome of this litigation and, accordingly, we can provide no assurance that we will prevail. An unfavorable outcome would have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

In May 2004, Egis-Gyogyszergyar, a generic pharmaceutical manufacturer, challenged the validity of our Zyprexa compound and method-of-use patents (expiring in 2011) in Germany. We currently anticipate a decision from the German Patent Court in 2006. In addition to our patents, we have data package exclusivity in Germany through September 2006. We are vigorously contesting the legal challenge to this patent. We cannot predict or determine the outcome of this litigation.

Other Patent Litigation

In October 2002, we were notified that Barr had submitted an ANDA with the U.S. FDA seeking permission to market a generic version of Evista several years prior to the expiration of our U.S. patents covering the product, alleging that the patents are invalid or not infringed. In November 2002, we filed suit against Barr in the U.S. District Court for the Southern District of Indiana seeking a ruling that Barr's challenges to our patents claiming the method of use and pharmaceutical form (expiring from 2012 to 2017) are without merit. Recently, Barr has also asserted that the method-of-use patents are unenforceable. On September 28, 2004, the U.S. Patent and Trademark Office issued to us a new patent (expiring in 2017) directed to pharmaceutical compositions containing raloxifene. Barr has challenged this patent, alleging that the patent is invalid, unenforceable, or will not be infringed. This patent has been added to the lawsuit. The suit is in discovery and the trial is now scheduled to begin in February 2006. While we believe that Barr's claims are without merit and expect to prevail, it is not possible to predict or determine the outcome of the litigation. Therefore, we can provide no assurance that we will prevail. An unfavorable outcome could have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

In October 2002, Pfizer Inc. filed a lawsuit in the United States District Court in Delaware against us, Lilly ICOS LLC, and ICOS Corporation alleging that the proposed marketing of Cialis for erectile dysfunction would infringe its newly issued method-of-use patent. In September 2003, the U.S. Patent and Trademark Office, on its own initiative, ordered that Pfizer's patent be reexamined. The Delaware suit has been stayed pending the outcome of the reexamination. Previously, Pfizer's corresponding European method-of-use patent was held invalid in the first stage of an opposition proceeding in the European Patent Office. Pfizer has appealed that decision, and in February 2005, the Technical Board of Appeal of the European Patent Office revoked Pfizer's method-of-use patent in its entirety. The U.K. Court of Appeal has also held the U.K. counterpart to this patent invalid. Litigation relating to the corresponding patent is also pending in Australia, Brazil, Canada, Mexico, New Zealand, and South Africa. We intend to vigorously defend this litigation and expect to prevail. However, it is not possible to predict or determine the outcome of this litigation and therefore we can provide no assurance that we will prevail.

Product Liability Litigation

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

We have been named in approximately 140 product liability cases in the United States involving approximately 360 claimants alleging a variety of injuries from the administration of Zyprexa. Most of the cases allege that the product caused or contributed to diabetes or high blood-glucose levels. The suits seek substantial compensatory and punitive damages and typically accuse us of inadequately testing for and warning about side effects of Zyprexa, and many of the suits also allege that we improperly promoted the drug. We are vigorously defending these suits. All the federal cases, involving approximately 330 claimants, have been or will be transferred to The Honorable Jack Weinstein in the U.S. District Court for the Eastern District of New York for consolidated and coordinated pretrial proceedings. Two cases requesting certification of nationwide class actions on behalf of those who allegedly suffered injuries from the administration of Zyprexa were filed in the U.S. District Court for the Eastern District of New York on April 16, 2004, and May 19, 2004, respectively. The cases seek damages for alleged personal injuries and also seek compensation for medical monitoring of individuals who have taken Zyprexa. A lawsuit was also filed that requests a class action on behalf of Iowa residents who took Zyprexa, and that case has been transferred to the federal court in New York. In addition, we have entered into agreements with various plaintiffs' counsel halting the running of the statutes of limitation (tolling agreements) with respect to more than 3,050 individuals who do not have lawsuits on file and may or may not eventually file suits. This provides counsel additional time to evaluate the potential claims. In exchange, the individuals have agreed not to file suits in state courts and the

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Plaintiffs Steering Committee agreed to dismiss the personal injury claims in the two pending nationwide class actions. The class action claims seeking medical monitoring for Zyprexa patients are not affected by this agreement.

In December 2004, we were served with two lawsuits brought in state court in Louisiana on behalf of the Louisiana Department of Health and Hospitals, alleging that Zyprexa caused or contributed to diabetes or high blood-glucose levels and that we improperly promoted the drug. In these actions, which we have removed to federal court, the Department of Health and Hospitals seeks to recover the costs it paid for Zyprexa through Medicaid and other drug benefit programs and the costs the department alleges it has incurred and will incur to treat Zyprexa-related illnesses.

In early 2005, we were served with four lawsuits seeking class action status in Canada on behalf of patients who took Zyprexa. The allegations in these suits are similar to those in the litigation pending in the United States.

The number of product liability lawsuits and tolled claims relating to Zyprexa continues to increase, and we cannot predict at this time the additional number of lawsuits and claims that may be asserted. As noted, we are vigorously defending this litigation. However, product litigation of this type is inherently unpredictable, with the risk of excessive verdicts not justified by the evidence. Accordingly, it is possible that the ultimate resolution of the Zyprexa product liability litigation could have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

In approximately 125 U.S. actions involving approximately 200 claimants, plaintiffs seek to recover damages on behalf of children or grandchildren of women who were prescribed DES during pregnancy.

We have been named as a defendant in approximately 340 actions in the U.S., involving approximately 1,020 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. from the 1930s until approximately 2000. 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 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 obtained product liability insurance from commercial carriers providing coverage with respect to the claims involving the products noted above, subject to deductibles, self-insurance and coverage limits. However, there can be no assurance that the coverage amounts will be sufficient to cover all exposures or that the carriers will not assert defenses to coverage. In addition, as a result of external events, product liability insurance has become much more difficult to obtain. Consequently, product liability claims could produce exposures that we would manage largely as self-insured risks.

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Marketing Practices Investigations

In July 2002, we received a grand jury subpoena for documents from the Office of Consumer Litigation, Department of Justice, related to our marketing and promotional practices and physician communications with respect to Evista. We received subpoenas seeking additional documents in July 2003, July 2004, and August 2004. We have provided a broad range of information concerning our U.S. marketing and promotional practices, including documents relating to communications with physicians and the remuneration of physician consultants and advisers. We continue to cooperate with the government and are currently in advanced discussions to resolve the matter. In the fourth quarter of 2004 we recorded a provision for \$36.0 million, which we believe will be sufficient to resolve the matter.

In March 2004, the office of the U.S. Attorney for the Eastern District of Pennsylvania advised us that it has commenced a civil investigation relating to our U.S. marketing and promotional practices with respect to Zyprexa, Prozac and Prozac Weekly. We are cooperating with the U.S. Attorney in this investigation and are providing a broad range of documents and information relating to the investigation, including documents relating to communications with physicians and the remuneration of physician consultants and advisers. It is possible that other Lilly products could become subject to this investigation and that the outcome of this matter could include criminal charges and fines and/or civil penalties. We cannot predict or determine the outcome of this matter or reasonably estimate the amount or range of amounts of any fines or penalties that might result from an adverse outcome. It is possible, however, that an adverse outcome could have a material adverse impact on our consolidated results of operations, liquidity, and financial position. We have implemented and continue to review and enhance a broadly based compliance program that includes comprehensive compliance-related activities designed to ensure that our marketing and promotional practices, physician communications, and remuneration of health care professionals comply with promotional laws and regulations.

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. We are cooperating with the SEC in responding to the investigation.

Other Matters

In March 2001, we received a subpoena, issued at the request of the Commonwealth's attorney for the Commonwealth of Massachusetts, for production of documents related to pricing and Medicaid reimbursement of our products in Massachusetts. We are not the only pharmaceutical company to receive such a request. We cooperated with the inquiry and have received no further requests. We believe that all of our practices have been lawful and proper.

In 2003, three counties in New York (Suffolk, Rockland, and Westchester) 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 counties overpaid their portion of the cost of pharmaceuticals. In 2004, Nassau County and New York City filed similar suits. The suits seek monetary and other relief, including civil penalties and treble damages. The five New York suits have been transferred to the U.S. District Court for the District of Massachusetts for pretrial proceedings (along with several other suits to which Lilly is not a party). Litigation activity in the New York cases has been stayed pending a decision on a motion to dismiss. A motion to dismiss that was filed by all of the defendants in the Suffolk County case has been granted in part and denied in part. Our individual motion to dismiss has been granted in part, and we are awaiting a ruling on the remaining issues. Because of the similarities of the New York cases, the court's ruling in the Suffolk County case will likely set a precedent in the other cases. In July 2004, Central Alabama Comprehensive Healthcare, Inc. filed a similar suit in Alabama relating to Public Health

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Service pricing. The suit seeks injunctive and monetary relief. The allegations in the lawsuit are based on a report issued by the Office of the Inspector General for Health and Human Services (OIG) that was subsequently withdrawn by the OIG because it was based on flawed data. We and the other defendants have filed motions to dismiss, which are pending. While we are vigorously defending all these cases, given their early procedural stage, we cannot predict or determine the outcome of this litigation.

During 2004 we, along with several other pharmaceutical companies, were named in one consolidated case in Minnesota federal 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 and one case in California state court brought by several pharmacies in which plaintiffs' claims are less specifically stated, but seem to be substantially similar to the claims asserted in Minnesota. The Minnesota case seeks a class action certification. Both cases seek restitution for alleged overpayments for pharmaceuticals and an injunction against the allegedly violative conduct. We and the other defendants have filed a motion to dismiss in the Minnesota case, which is pending. The magistrate judge has recommended that the motion to dismiss be granted as to the federal claims and denied as to the state law claims. In the California case, the court has granted a motion to dismiss by the defendants but permitted the plaintiffs to re-file their complaint, which plaintiffs have now done. While we intend to vigorously defend these suits, given their early procedural stage, we cannot predict or determine the outcome of this litigation.

Under the Comprehensive Environmental Response, Compensation, and Liability Act, commonly known as Superfund, we have been designated as one of several potentially responsible parties with respect to the cleanup of fewer than 10 sites. Under Superfund, each responsible party may be jointly and severally liable for the entire amount of the cleanup.

We are also a defendant in other litigation and investigations, including product liability and patent suits, 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 2004, 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 in our 2004 Annual Report under "Selected Quarterly Data (unaudited)," at page 28 (page 20 of Exhibit 13), and "Selected Financial Data (unaudited)," at page 29 (page 21 of Exhibit 13). That information is incorporated in this report by reference.

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The following table summarizes the activity related to repurchases of our equity securities during the fourth quarter ended December 31, 2004:

| Period | Total Number of Shares Purchased (a) (in thousands) | Average Price Paid per Share (b) | Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs (c) | Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs (d) (Dollars in millions) |
|---------------|--|--|---|--|
| October 2004 | 47 | \$53.68 | — | \$920.0 |
| November 2004 | 5 | 54.91 | — | 920.0 |
| December 2004 | 7 | 51.00 | — | 920.0 |
| Total | 59 | | — | |

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 \$3.0 billion share repurchase program announced in March 2000. As of December 31, 2004, we have purchased \$2.08 billion related to this program. During 2004, no shares were repurchased pursuant to this program.

Item 6. Selected Financial Data

You can find selected financial data for each of our five most recent fiscal years in our 2004 Annual Report under “Selected Financial Data (unaudited),” at page 29 (page 21 of Exhibit 13). That information is incorporated in this report by reference.

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

You can find management’s discussion and analysis of results of operations and financial condition in the following portions of our 2004 Annual Report (found at pages 1-6, 8, and 10-16 of Exhibit 13):

- “Review of Operations—Executive Overview” (pages 9-11)
- “Review of Operations—Operating Results—2004” (pages 11-13)
- “Review of Operations—Operating Results—2003” (pages 13, 14 and 16)
- “Review of Operations—Financial Condition” (pages 16 and 18-20)
- “Review of Operations—Application of Critical Accounting Policies” (pages 20-22)
- “Review of Operations—Financial Expectations for 2005” (page 22)
- “Review of Operations—Legal and Regulatory Matters” (pages 23-24)
- “Review of Operations—Private Securities Litigation Reform Act of 1995 – A Caution Concerning Forward-Looking Statements” (page 24)

The information referred to above is incorporated in this report by reference.

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Item 7A. Quantitative and Qualitative Disclosures About Market Risk

You can find quantitative and qualitative disclosures about market risk (*e.g.* , interest rate risk) in our 2004 Annual Report at “Review of Operations – Financial Condition” on pages 18-19 (pages 10-11 of Exhibit 13). That information is incorporated in this report by reference.

Item 8. Financial Statements and Supplementary Data

You can find the consolidated financial statements of the Company and its subsidiaries in our 2004 Annual Report at the pages indicated in the parentheses. All of this information is incorporated in this report by reference.

- Consolidated Statements of Income—Years Ended December 31, 2004, 2003, and 2002 (page 15) (page 7 of Exhibit 13)
- Consolidated Balance Sheets—December 31, 2004 and 2003 (page 17) (page 9 of Exhibit 13)
- Consolidated Statements of Cash Flows—Years Ended December 31, 2004, 2003, and 2002 (page 25) (page 17 of Exhibit 13)
- Consolidated Statements of Comprehensive Income—Years Ended December 31, 2004, 2003, and 2002 (page 26) (page 18 of Exhibit 13)
- Segment Information (page 27) (page 19 of Exhibit 13)
- Notes to Consolidated Financial Statements (pages 30-48) (pages 22-40 of Exhibit 13).

Also incorporated by reference are the following portions of the 2004 Annual Report:

- Information on quarterly results of operations, which can be found under “Selected Quarterly Data (unaudited),” at page 28 (page 20 of Exhibit 13)
- The Report of Independent Registered Public Accounting Firm regarding its audit of the financial statements, at page 50 (page 42 of Exhibit 13).

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

None.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

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

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summarized, and reported on a timely basis.

Our management, with the participation of Sidney Taurel, chairman, president, and chief executive officer, and Charles E. Golden, executive vice president and chief financial officer, evaluated our disclosure controls and procedures as of December 31, 2004, and concluded that they are effective.

Internal Control over Financial Reporting

In our 2004 Annual Report, Messrs. Taurel and Golden 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, 2004. In addition, Ernst & Young LLP, the company's independent auditor, provided an attestation report on management's assessment of internal control over financial reporting. You can find the full text of management's report and Ernst & Young's attestation report in our 2004 Annual Report at pages 49 and 51, respectively (pages 41 and 43 of Exhibit 13). Both reports are incorporated in this Form 10-K by reference.

Changes in Internal Controls

During the fourth quarter of 2004, 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

Information relating to the 2005 compensation of our non-employee directors and named executive officers can be found in Exhibits 10.11 and 10.12, respectively.

Part III

Item 10. Directors and Executive Officers of the Registrant

Information relating to our Board of Directors is found in our Proxy Statement dated March 8, 2005, under "Board of Directors" at pages 58-61 (pages 7-10 of Schedule 14A filed with the SEC on the EDGAR database), and is incorporated in this report by reference.

The Board has appointed an audit committee consisting entirely of independent directors in accordance with applicable SEC and New York Stock Exchange rules. The members of the committee are Sir Winfried Bischoff (chairman), Mr. J. Michael Cook, Dr. Martin Feldstein, Dr. Franklyn G. Prendergast, and Ms. Kathi P. Seifert. The Board has determined that Sir Winfried Bischoff and Mr. J. Michael Cook are audit committee financial experts as defined in the SEC rules.

Information relating to our executive officers is found at Part I, Item 1 of this Form 10-K under "Executive Officers of the Company." In addition, information relating to certain filing obligations of directors and executive officers under the federal securities laws is found in the Proxy Statement under "Other Matters – Section 16(a) Beneficial Ownership Reporting Compliance," at page 88 (page 37 of Schedule 14A). That information is incorporated in this report by reference.

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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/code_business_conduct.cfm. 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 five 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.

Item 11. Executive Compensation

You can find information on executive compensation and director compensation in the Proxy Statement under "Directors' Compensation" at page 66 (page 15 of Schedule 14A) and "Executive Compensation" at pages 69-76 (pages 18-25 of Schedule 14A). That information is incorporated in this report by reference, except that the Compensation Committee Report is not incorporated in this report.

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

Security Ownership of Certain Beneficial Owners and Management

You can find 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 in the Proxy Statement under "Ownership of Company Stock," at pages 78-79 (pages 27-28 of Schedule 14A). 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, 2004, regarding our compensation plans under which shares of Lilly common stock have been authorized for issuance.

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| Plan category | (a) Number of securities to be issued upon exercise of outstanding options, warrants, and rights | (b) Weighted-average exercise price of outstanding options, warrants, and rights | (c) Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) |
|---|--|--|---|
| Equity compensation plans approved by security holders | 81,114,816 | \$67.81 | 58,114,082 |
| Equity compensation plan not approved by security holders (1) | <u>12,543,715</u> | \$69.37 | <u>320,555</u> |
| Total | <u>93,658,531</u> | \$68.02 | <u>58,434,637</u> |

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

Item 13. Certain Relationships and Related Transactions

Information related to a time-share arrangement between the company and Mr. Sidney Taurel, chairman and chief executive officer, relating to his board-mandated personal use of the corporate aircraft, can be found in the Proxy Statement under “Related Transaction” at page 76 (page 25 of Schedule 14A). That information is incorporated in this report by reference.

Item 14. Principal Accountant Fees and Services

Information related to the fees and services of our independent auditor, Ernst & Young LLP, can be found in the Proxy Statement under “Services Performed by the Independent Auditor” and “Independent Auditor Fees” at pages 68-69 (pages 17-18 of Schedule 14A). 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, included in our 2004 Annual Report at the pages indicated in parentheses, are incorporated by reference in Item 8:

- Consolidated Statements of Income—Years Ended December 31, 2004, 2003, and 2002 (page 15) (page 7 of Exhibit 13)
- Consolidated Balance Sheets—December 31, 2004 and 2003 (page 17) (page 9 of Exhibit 13)
- Consolidated Statements of Cash Flows—Years Ended December 31, 2004, 2003, and 2002 (page 25) (page 17 of Exhibit 13)

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- Consolidated Statements of Comprehensive Income—Years Ended December 31, 2004, 2003, and 2002 (page 26) (page 18 of Exhibit 13)
- Segment Information (page 27) (page 19 of Exhibit 13)
- Notes to Consolidated Financial Statements (pages 30-48) (pages 22-40 of Exhibit 13)

(a)2. Financial Statement Schedules

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

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

(a)3. Exhibits

- 3.1 Amended Articles of Incorporation
- 3.2 By-laws
- 4.1 Rights Agreement dated as of July 20, 1998, between Eli Lilly and Company and Norwest Bank Minnesota, N.A., as successor Rights Agent
- 4.2 Amendment No. 1 to Rights Agreement dated as of May 27, 2003, between Eli Lilly and Company and Wells Fargo Bank Minnesota, N.A., as successor Rights Agent
- 4.3 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
- 4.4 Form of Standard Multiple-Series Indenture Provisions dated, and filed with the Securities and Exchange Commission on, February 1, 1991
- 4.5 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 ¹
- 4.6 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 May 15, 2037 ¹
- 4.7 Form of Resetable Floating Rate Debt Security due May 15, 2037 ¹
- 10.1 1994 Lilly Stock Plan, as amended ²
- 10.2 1998 Lilly Stock Plan, as amended ²

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

² Indicates management contract or compensatory plan.

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| | |
|-------|---|
| 10.3 | 2002 Lilly Stock Plan, as amended, including forms of nonqualified stock option, incentive stock option, performance award, and restricted stock grant ² |
| 10.4 | Lilly GlobalShares Stock Plan, as amended ² |
| 10.5 | The Lilly Deferred Compensation Plan, as amended ² |
| 10.6 | The Lilly Directors' Deferral Plan, as amended ² |
| 10.7 | The Eli Lilly and Company Bonus Plan ² |
| 10.8 | Eli Lilly and Company Change in Control Severance Pay Plan for Select Employees, as amended ² |
| 10.9 | 2007 Change in Control Severance Pay Plan for Select Employees ² |
| 10.10 | Letter from the Company to Sidney Taurel, Chairman, President, and Chief Executive Officer, concerning Mr. Taurel's request that his base salary for 2002 be reduced to \$1.00 ² |
| 10.11 | Summary of 2005 Compensation for Non-employee Directors ² |
| 10.12 | Summary of 2005 Compensation for Named Executive Officers ² |
| 10.13 | Letter from the Company to Charles E. Golden concerning retirement benefits ² |
| 10.14 | Letter from the Company to Steven M. Paul, M.D. concerning retirement benefits ² |
| 10.15 | Arrangement regarding retirement benefits for Robert A. Armitage ² |
| 10.16 | Time Sharing Agreement between the Company and Sidney Taurel for use of corporate aircraft |
| 12. | Computation of Ratio of Earnings from Continuing Operations to Fixed Charges |
| 13. | Annual Report to Shareholders for the Year Ended December 31, 2004 (portions incorporated by reference in this Form 10-K) |
| 21. | List of Subsidiaries |
| 23. | Consent of Independent Registered Public Accounting Firm |
| 31.1 | Rule 13a-14(a) Certification of Sidney Taurel, Chairman of the Board, President, and Chief Executive Officer |
| 31.2 | Rule 13a-14(a) Certification of Charles E. Golden, Executive Vice President and Chief Financial Officer |
| 32. | Section 1350 Certification |
| 99. | Cautionary Statement under Private Securities Litigation Reform Act of 1995 – "Safe Harbor" for Forward-Looking Disclosures |

² Indicates management contract or compensatory plan.

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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/Sidney Taurel
Sidney Taurel, Chairman of the Board,
President and Chief Executive Officer

March 8, 2005

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below on March 8, 2005 by the following persons on behalf of the Registrant and in the capacities indicated.

| Signature | Title |
|---|---|
| <u>/s/ Sidney Taurel</u> SIDNEY TAUREL | Chairman of the Board, President, Chief Executive Officer, and a Director (principal executive officer) |
| <u>/s/Charles E. Golden</u> CHARLES E. GOLDEN | Executive Vice President, Chief Financial Officer, and a Director (principal financial officer) |
| <u>/s/Arnold C. Hanish</u> ARNOLD C. HANISH | Chief Accounting Officer (principal accounting officer) |
| <u>/s/Steven C. Beering</u> STEVEN C. BEERING, M.D. | Director |
| <u>/s/ Sir Winfried Bischoff</u> SIR WINFRIED BISCHOFF | Director |
| <u>/s/ J. Michael Cook</u> J. MICHAEL COOK | Director |
| <u>/s/Martin S. Feldstein</u> MARTIN S. FELDSTEIN, Ph.D. | Director |

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| Signature | Title |
|---|----------|
| <hr/> <u>/s/George M. C. Fisher</u> GEORGE M. C. FISHER | Director |
| <hr/> <u>/s/Karen N. Horn</u> KAREN N. HORN, Ph.D. | Director |
| <hr/> <u>/s/Alfred G. Gilman</u> ALFRED G. GILMAN, M.D., Ph.D. | Director |
| <hr/> <u>/s/Ellen R. Marram</u> ELLEN R. MARRAM | Director |
| <hr/> <u>/s/Franklyn G. Prendergast</u> FRANKLYN G. PRENDERGAST, M.D., Ph.D. | Director |
| <hr/> <u>/s/Sir John Rose</u> SIR JOHN ROSE | Director |
| <hr/> <u>/s/Kathi P. Seifert</u> KATHI P. SEIFERT | Director |

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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.

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Index to Exhibits

The following documents are filed as part of this report:

| Exhibit | | Location |
|---------|---|--|
| 3.1 | Amended Articles of Incorporation | Incorporated by reference from Exhibit 3.1 to the Company's Report on Form 10-K for the year ended December 31, 2003 |
| 3.2 | By-laws, as amended | Incorporated by reference from Exhibit 3 to the Company's Report on Form 10-Q for the quarter ended June 30, 2001 |
| 4.1 | Rights Agreement dated as of July 20, 1998, between Eli Lilly and Company and Wells Fargo Bank Minnesota, N.A., as successor Rights Agent | Incorporated by reference from Exhibit 4.1 to the Company's Report on Form 10-K for the year ended December 31, 2003 |
| 4.2 | Amendment No. 1 to Rights Agreement dated as of May 27, 2003, between Eli Lilly and Company and Wells Fargo Bank Minnesota, N.A., as successor Rights Agent | Incorporated by reference from Exhibit 4.2 to the Company's Form 8-A/A, Amendment No. 1, dated May 29, 2003 |
| 4.3 | 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 |
| 4.4 | 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 |
| 4.5 | 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 | * |
| 4.6 | 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 May 15, 2037 | * |

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

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| Exhibit | | Location |
|---------|--|---|
| 4.7 | Form of Resettable Floating Rate Debt Security due May 15, 2037 | * |
| 10.1 | 1994 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, 2001 |
| 10.2 | 1998 Lilly Stock 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, 2001 |
| 10.3 | 2002 Lilly Stock Plan, as amended, including forms of nonqualified stock option, incentive stock option, performance award, and restricted stock grant | Incorporated by reference from Exhibit 10 to the Company's Report on Form 10-Q for the quarter ended September 30, 2004 |
| 10.4 | The Lilly GlobalShares Stock Plan, as amended | Incorporated by reference from Exhibit 10.5 to the Company's Report of Form 10-K for the year ended December 31, 2003 |
| 10.5 | The Lilly Deferred Compensation Plan, as amended | Incorporated by reference from Exhibit 10.1 to the Company's Report on Form 10-Q for the quarter ended June 30, 2004 |
| 10.6 | The Lilly Directors' Deferral Plan, as amended | Incorporated by reference from Exhibit 10.7 to the Company's Report on Form 10-K for the year ended December 31, 2003 |
| 10.7 | The Eli Lilly and Company Bonus Plan | Incorporated by reference from Appendix B to the Company's Proxy Statement dated March 12, 2004 |
| 10.8 | Eli Lilly and Company Change in Control Severance Pay Plan for Select Employees, as amended | Incorporated by reference from Exhibit 10.2 to the Company's Report on Form 10-Q for the quarter ended June 30, 2004 |
| 10.9 | 2007 Change in Control Severance Pay Plan for Select Employees | Incorporated by reference from Exhibit 10.3 to the Company's Report on Form 10-Q for the quarter ended June 30, 2004 |

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

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| Exhibit | | Location |
|----------------|---|---|
| 10.10 | Letter dated September 17, 2001 from the Company to Sidney Taurel, Chairman, President, and Chief Executive Officer, concerning Mr. Taurel's request that his base salary for 2002 be reduced to \$1.00 | Incorporated by reference from Exhibit 10.4 to the Company's Report on Form 10-Q for the quarter ended September 30, 2001 |
| 10.11 | Summary of 2005 Compensation for Non-employee Directors | Attached |
| 10.12 | Summary of 2005 Compensation for Named Executive Officers | Attached |
| 10.13 | Letter from the Company to Charles E. Golden concerning retirement benefits | Attached |
| 10.14 | Letter from the Company to Steven M. Paul, M.D. concerning retirement benefits | Attached |
| 10.15 | Arrangement regarding retirement benefits for Robert A. Armitage | Attached |
| 10.16 | Time Sharing Agreement between the Company and Sidney Taurel for use of corporate aircraft | Attached |
| 12. | Statement regarding Computation of Ratio of Earnings from Continuing Operations to Fixed Charges | Attached |
| 13. | Annual Report to Shareholders for the Year Ended December 31, 2004 (portions incorporated by reference in this Form 10-K) | Attached |
| 21. | List of Subsidiaries | Attached |
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| 31.1 | Rule 13a-14(a) Certification of Sidney Taurel, Chairman of the Board, President, and Chief Executive Officer | Attached |
| 31.2 | Rule 13a-14(a) Certification of Charles E. Golden, Executive Vice President and Chief Financial Officer | Attached |
| 32 | Section 1350 Certification | Attached |
| 99 | Cautionary Statement Under Private Securities Litigation Reform Act of 1995—"Safe Harbor" for Forward-Looking Disclosures | Attached |

Exhibit 10.11 Summary of 2005 Compensation for Non-employee Directors

For 2005, the board of directors has approved the following annual compensation to directors who are not employees:

Cash compensation

- Retainer of \$3,750 per month
- \$1,600 for each board meeting attended (or \$1,600 per day for multi-day meetings)
- \$1,600 for each committee or other meeting attended if not held on the same day as a board meeting
- \$2,000 to the committee chairpersons for each committee meeting attended as compensation for the chairperson's preparation time
- Reimbursement for customary and usual travel expenses

Stock compensation

- 1,500 shares of Lilly stock in a deferred stock account in the Lilly Directors' Deferral Plan, payable after service on the board has ended.

Lilly Directors' Deferral Plan

This plan allows directors to defer receipt of all or part of their retainer and meeting fees until after their service on the board has ended. Each director can choose to invest the funds in either of two accounts:

- Deferred Compensation Account. Funds in this account earn interest each year at an annual rate of 120 percent of the applicable federal long-term rate as established for the preceding December by the U.S. Treasury Department under Section 1274(d) of the Internal Revenue Code with monthly compounding.
- Deferred Share Account. This account allows the director, in effect, to invest his or her deferred cash compensation in Lilly stock. In addition, the annual award of shares to each director noted above is credited to this account. Funds in this account are credited as hypothetical shares of Lilly stock based on the market price of the stock at the time the compensation would otherwise have been earned. Hypothetical dividends are "reinvested" in additional shares based on the market price of the stock on the date dividends are paid. All shares in the deferred share accounts are hypothetical and are not issued or transferred until the director ends his or her service on the board or dies.

Both accounts may be paid in a lump sum or in annual installments for up to 10 years. The deferred compensation account may also be paid in monthly installments for up to 10 years. Amounts in the deferred share account are paid in the form of shares of Lilly stock.

Insurance

The company provides \$250,000 of accidental death and dismemberment insurance to each non-employee director.

Exhibit 10.12 Summary of 2005 Compensation for Named Executive Officers

At its meeting on December 20, 2004, the Compensation Committee of the Board of Directors of Eli Lilly and Company approved the 2005 compensation of the company's named executive officers (as defined in Regulation S-K Item 402(a)(3)) as described below:

| Executive Officer | Salary (1) | Bonus (2) | Option Grant (3) | | Performance | Award (4) |
|---|-------------|-------------|------------------|---------------|---------------|---------------|
| | | | No. of shares | Present value | No. of shares | Present value |
| Sidney Taurel Chairman, President, and Chief Executive Officer | \$1,580,000 | \$1,726,800 | 255,621 | \$4,320,000 | 51,752 | \$2,880,000 |
| John C. Lechleiter, Ph.D. Executive Vice President, Pharmaceutical Operations | \$ 929,800 | \$ 692,875 | 127,811 | \$2,160,000 | 25,876 | \$1,440,000 |
| Charles E. Golden Executive Vice President and Chief Financial Officer | \$ 845,700 | \$ 631,200 | 78,107 | \$1,320,000 | 15,813 | \$ 880,000 |
| Steven M. Paul, M.D. Executive Vice President, Science and Technology | \$ 831,060 | \$ 617,415 | 85,207 | \$1,440,000 | 17,251 | \$ 960,000 |
| Robert A. Armitage Senior Vice President and General Counsel | \$ 637,940 | \$ 411,370 | 53,254 | \$ 900,000 | 10,782 | \$ 600,000 |

- (1) Annualized base salaries effective as of March 1, 2005, the merit increase date for U.S. employees.
- (2) Target bonus under the Eli Lilly and Company Bonus Plan. Actual bonuses earned for 2005 may vary from zero to 200 percent of the target amount, depending on the company's 2005 results relative to predetermined corporate performance measures that are based 25 percent on sales growth and 75 percent on earnings-per-share growth (adjusted for unusual items in accordance with predetermined criteria).
- (3) Granted February 11, 2005. The options vest February 11, 2008 and expire February 10, 2015. The exercise price is \$55.65, the market value of Lilly stock on the date of grant. Present values are as of the grant date and are based on the company's trinomial lattice valuation method of 30.37 percent of the exercise price of \$55.65.
- (4) Target payout under the performance award program for 2005. Actual payouts earned for 2005 may vary from zero to 200 percent of the target amount, depending on the growth in the company's 2005 earnings per share (adjusted for unusual items in accordance with predetermined criteria). Present values are as of February 11, 2005, and are based on 100 percent of the market value of Lilly stock on that date (\$55.65 per share).

The named executive officers will continue to participate in other employee benefits as described in the company's proxy statements, including a defined benefit retirement plan, a 401(k) plan, the Lilly Deferred Compensation Plan, and the company's change in control severance pay program.

Exhibit 10.13

September 4, 2002

Charles E. Golden
Executive Vice President and
Chief Financial Officer
Eli Lilly and Company
Lilly Corporate Center
Indianapolis, IN 46285

Re: Offer Letter Clarification

Dear Charlie:

You have requested clarification regarding the terms of your original offer of employment with Eli Lilly and Company, dated February 20, 1996, as clarified and supplemented by letters dated December 20, 1996 and November 30, 2000. Specifically, you have asked that Lilly clarify your eligibility for retiree medical benefits. This letter will restate our understanding relating to your eligibility for retirement benefits and confirm our understanding regarding related benefits.

As described in your Offer Letter, you will be entitled to a retirement benefit (provided through The Lilly Retirement Plan and The Lilly Excess Benefit Plan [Retirement]) using 26 years 1 month of service in addition to your actual service with Lilly. All of the provisions of the various formulae provided under the Retirement Plan will apply. However, after determining the benefit in this manner, the deferred vested retirement benefit you will be eligible to receive from General Motors Corporation at the date of your retirement from Lilly will be subtracted from the Lilly benefit calculation to provide the actual benefit. If your benefit under the General Motors plan is not payable at the time of your retirement from the Company, the unreduced Lilly benefit will be paid until such time as the General Motors benefit becomes payable. At that time, your Lilly benefit will be reduced by the amount payable from General Motors.

To receive this retirement benefit, you will be required to work a minimum of 10 years from the date of your initial employment with Lilly, or until March 1, 2006, except that the 10-year minimum work requirement will be waived if any of the following circumstances occur prior to March 1, 2006:

1. Lilly requests your retirement, or your employment is terminated, for any reason other than Disciplinary Termination as defined in Section 4.03 of The Lilly Severance Pay Plan;
 2. You become disabled under the terms of The Eli Lilly and Company Extended Disability Plan; or
-

EXHIBIT 10.14

September 15, 2004

Steven M. Paul, M.D.
Executive Vice President,
Science and Technology
Eli Lilly and Company
Lilly Corporate Center
Indianapolis, IN 46285

Re: Eligibility for Retirement Benefits

Dear Steve:

I wanted to confirm the details of your recent conversation with Sidney regarding your eligibility for future retirement benefits. This letter replaces your prior letter dated July 17, 1997, on the same subject.

On July 19, 2004, the Compensation Committee of the Board of Directors approved your eligibility for an enhanced retirement benefit. Under this enhanced benefit, you will be entitled to 10 years of benefit service credit in addition to your actual service with Lilly if you remain employed with Lilly at least until November 30, 2010. Such service would be used to calculate your retirement benefit only (provided through the Lilly Retirement Plan and the Lilly Excess Benefit Plan (Retirement)). All of the terms of the Lilly Retirement Plan would apply, except that your benefit will not be reduced for early retirement. Your additional service credit does not apply to other benefits.

As described above, you will be required to work at least until November 30, 2010 to be eligible for this enhanced retirement benefit. However, this minimum work requirement will be waived if any of the following occur prior to November 30, 2010:

- Your employment is terminated by Lilly, for any reason other than a disciplinary termination (e.g., insubordination, misconduct) as defined in the Lilly Severance Pay Plan;
 - You become disabled under the terms of The Eli Lilly and Company Extended Disability Plan; or
 - a Change in Control occurs and you suffer a Covered Termination, as both terms are defined under the Eli Lilly and Company Change in Control Severance Pay Plan for Select Employees ("CIC Plan"). It is understood that in the event of such Covered Termination, you would receive, in addition to the retirement benefit described above, the Pension Supplement as set forth in Section 8.C. of the CIC Plan.
-

Steven M. Paul, M.D.
September 15, 2004
Page 2

If you do not satisfy this minimum work requirement or any of the conditions above for waiver of the requirement, you will not be eligible for an enhanced retirement benefit, but would remain eligible for any vested benefit under the Lilly Retirement Plan.

Steve, please let Sharon or me know if you have any questions. I look forward to your continued work with Eli Lilly and Company.

ELI LILLY AND COMPANY

By: /s/ Pedro P. Granadillo
Pedro P. Granadillo
Senior Vice President

cc: Sharon L. Sullivan

Exhibit 10.15 Arrangement Regarding Retirement Benefits for Robert A. Armitage

Since Mr. Armitage will not be eligible to receive a retirement benefit from The Lilly Retirement Plan at age 60, Lilly has agreed to offer him a special retirement benefit, provided that he works at Lilly until age 60. The benefit will be calculated using the Retirement Plan benefit formula that yields the highest payment based on his actual years of service and age at the time he leaves Lilly, but at a minimum will provide an annual benefit of \$75,000. Should he continue to work at Lilly until he is eligible to receive a retirement benefit under the Retirement Plan, he will receive a benefit from such plan in lieu of the benefit described above at the time of his retirement.

TIME SHARING AGREEMENT

This Time Sharing Agreement (this "Agreement") is made effective as of March 4, 2005 by and between Eli Lilly and Company, an Indiana corporation ("Company"), and Sidney Taurel ("Executive").

RECITALS

WHEREAS, Company owns or rightfully possesses and operates three (3) Gulfstream Aerospace model G-IV civil aircraft bearing United States Registration Numbers N310EL (S/N 1021), N311EL (S/N 1095) and N312EL (S/N 1105) (individually and collectively, as the context requires, "the Aircraft" or "Aircraft"); and

WHEREAS, Company employs a fully qualified flight crew to operate the Aircraft; and

WHEREAS, Executive is Chairman of the Board and Chief Executive Officer of Company; and

WHEREAS, in order to protect the safety and security of Executive and maximize his availability to carry out his responsibilities, Company's Board of Directors has adopted a policy that generally requires Executive to travel on the Aircraft for all his air travel, whether on Company business or personal travel; and

WHEREAS, Executive desires to lease the Aircraft from time to time on a time-sharing basis as defined in Section 91.501(c) (1) of the Federal Aviation Regulations ("FARs") when he is required under the Board's policy to fly on the Aircraft for personal travel.

NOW, THEREFORE, in consideration of the foregoing, and the other promises contained herein, the parties, intending to be legally bound hereby, agree as follows:

1. Company agrees to lease the Aircraft to Executive on a non-exclusive basis from time to time as mutually agreed between the parties pursuant to the provisions of FAR 91.501(c)(1) and to provide a fully qualified flight crew for all operations conducted under this Agreement. This Agreement shall be effective on the date set forth above and shall remain in effect until terminated by either party upon ten (10) days prior written notice to the other.

2. (a) Executive shall pay to Company for each flight conducted under this Agreement a lease fee (“Lease Fee”) equal to the actual expenses of each specific flight as authorized by FAR Part 91.501(d) subject to the limitations set forth in subparagraph 2(b) below. Such actual expenses shall include:

- Fuel, oil, lubricants, and other additives;
- Travel expenses of the crew, including food, lodging and ground transportation;
- Hangar and tie-down costs away from the Aircraft’s base of operation;
- Insurance obtained for the specific flight;
- Landing fees, airport taxes and similar assessments;
- Customs, foreign permits, and similar fees directly related to the flight;
- In-flight food and beverages;
- Passenger ground transportation; and
- Flight planning and weather contract services.

(b) Notwithstanding the foregoing, in no event shall Executive be obligated to pay Company a Lease Fee in excess of the greater of (x) or (y) below, where:

(x) equals the applicable subsection (i) or (ii) below:

- (i) For travel between cities served by regularly scheduled first class commercial airline service, an amount equal to the published cost of the lowest first class airfare available to the general public, which will be solicited within one business day of the date the Executive requests the specific flight, for the dates traveled multiplied by the number of persons in Executive’s party for the flight; or
- (ii) For travel between cities served by regularly scheduled coach or business class, but not first class commercial airline service, an amount equal to the published cost of the lowest unrestricted coach (or, if available, business class) airfare available to the general public, which will be solicited within one business day of the date the Executive requests the specific flight, for

the dates traveled multiplied by the number of persons in Executive's party for the flight; and

- (y) equals the amount of income that would be imputed to Executive for the flight under the applicable Standard Industry Fare Levels as set forth in 26 C.F.R. §1.61-21(g) assuming that Executive did not pay the Lease Fee.

For purposes of the foregoing computation, if a city is not served by regularly scheduled commercial airline service, the foregoing provisions shall be applied utilizing a city selected by Company as close as reasonably practicable to the city without such service. Company's determination of the Lease Fee shall be conclusive. Prior to any proposed flight, Company shall provide Executive with an estimate of the Lease Fee for the particular flight. If Executive proceeds with the proposed flight, he shall be obligated to pay the Lease Fee. Executive shall also be responsible to pay, together with any Lease Fee, applicable state and federal taxes (including, without limitation, federal excise taxes). If Executive declines the proposed flight, neither Executive nor Company shall have any further obligation with respect to the proposed flight.

3. Company will pay all expenses related to the operation of the Aircraft when incurred, and will provide an invoice to Executive for the Lease Fee determined in accordance with paragraph 2 above within fifteen (15) days after any flight or flights for the account of Executive. Executive shall pay Company the Lease Fee, together with applicable taxes, within ten (10) days of receipt of the invoice.

4. Executive will provide Company with requests for flight time and proposed flight schedules as far in advance of any given flight as possible, and in any case, at least two (2) business days in advance of Executive's planned departure (unless Company agrees to a shorter notice in a particular case in its discretion). Requests for flight time shall be in a form, whether written or oral, mutually convenient to, and agreed upon by the parties. In addition to the proposed schedules and flight times, Executive shall provide at least the following information

for each proposed flight prior to scheduled departure as required by the Company or Company's flight crew:

- (a) proposed departure point;
- (b) destination;
- (c) date and time of flight;
- (d) the number, name, and relationship to the Executive of anticipated passengers;
- (e) the nature and extent of luggage and/or cargo to be carried;
- (f) the date and time of return flight, if any; and
- (g) any other information concerning the proposed flight that may be pertinent or required by Company or Company's flight crew.

5. Company shall have final authority over the scheduling of the Aircraft, provided, however, that Company will use reasonable efforts to accommodate Executive's requests and to avoid conflicts in scheduling. It is understood that Company shall not be obligated to retain or contract for additional flight crew or maintenance personnel or equipment in order to accommodate Executive's schedule requests.

6. Company shall be solely responsible for securing maintenance, preventive maintenance and required or otherwise necessary inspections on the Aircraft, and shall take such requirements into account in scheduling the Aircraft. No period of maintenance, preventative maintenance or inspection shall be delayed or postponed for the purpose of scheduling the Aircraft, unless said maintenance or inspection can be safely conducted at a later time in compliance with all applicable laws and regulations, and within the sound discretion of the pilot in command. The pilot in command shall have final and complete authority to cancel any flight for any reason or condition that in his or her judgment would compromise the safety of the flight.

7. Company shall ensure that for each flight conducted under this Agreement, the Aircraft will be under the command of a qualified flight crew. All flight operations by or on behalf of Executive under this Agreement shall be conducted under Part 91 of the FAR. The Company

shall have and exercise exclusive operational control of the Aircraft during all phases of all flights under this Agreement, including, without limitation, all flights during which Executive, and/or his guests, designees, or property are on-board the Aircraft.

8. In accordance with applicable FARs, the qualified flight crew provided by Company will exercise all of its duties and responsibilities in regard to the safety of each flight conducted hereunder. Executive specifically agrees that the flight crew, in its sole discretion, may terminate any flight, refuse to commence any flight, or take other action that in the considered judgment of the pilot in command is necessitated by considerations of safety. No such action of the pilot in command shall create or support any liability for loss, injury, damage or delay to Executive or any other person. The parties further agree that Company shall not be liable for delay or failure to furnish the Aircraft and crew pursuant to this Agreement for any reason whatsoever.

9. Company will provide such additional insurance coverage as Executive shall request or require, provided, however, that the cost of such additional insurance shall be borne by Executive as set forth in paragraph 2.

10. Executive warrants that:

- (a) He will use the Aircraft for and on account of his own business or personal use only, and will not use the Aircraft for the purpose of providing transportation of passengers or cargo in air commerce for compensation or hire;
- (b) He will refrain from incurring any mechanics or other lien in connection with inspection, preventative maintenance, maintenance or storage of the Aircraft, whether permissible or impermissible under this Agreement, nor shall there be any attempt by Executive to convey, mortgage, assign, lease or any way alienate the Aircraft or create any kind of lien or security interest involving the Aircraft or do anything or take any action that might mature into such a lien; and
- (c) During the term of this Agreement, he will, and will cause any passengers in his party to, abide by and conform to all such laws, governmental and airport orders,

rules and regulations, as shall from time to time be in effect relating in any way to the operation and use of the Aircraft by a timesharing lessee.

11. The Company assumes and shall bear the entire risk of loss, theft, confiscation, damage to, or destruction of the Aircraft. The Company shall release, indemnify, defend and hold harmless the Executive and his heirs, executors and personal representatives from and against any and all losses, liabilities, claims, judgments, damages, fines, penalties, deficiencies and expenses (including, without limitation, reasonable attorneys fees and expenses) incurred or suffered by Executive on account of a claim or action made or instituted by a third person arising out of or resulting from operations of the Aircraft hereunder and/or any services provided by the Company to Executive hereunder, except to the extent attributable to the gross negligence or willful misconduct of Executive or his guests on the Aircraft.

12. For purposes of this Agreement, the permanent base of operation of the Aircraft shall be Indianapolis International Airport.

13. Executive hereby acknowledges and agrees that all rights of Executive under this Agreement with respect to the Gulfstream Aerospace model G-IV aircraft bearing FAA registration number N310EL and manufacturer's serial number 1021, are and will be subject and expressly subordinate to the terms and conditions contained in that certain Aircraft Lease Agreement (S/N 02) (the "Main Lease") dated June 3, 2004, between Company and SunTrust Leasing Corporation (the "Lender") and the rights of the Lender contained therein. Notwithstanding anything to the contrary contained herein, this Agreement shall terminate, or be canceled, at the option of the Lender, upon written notice to Executive upon the occurrence of an Event of Default (as such term is defined in the Main Lease).

14. Neither this Agreement nor any party's interest herein shall be assignable to any other party whatsoever. This Agreement shall inure to the benefit of and be binding upon the parties hereto, and their respective heirs, representatives and successors.

15. This Agreement constitutes the entire agreement of the parties with respect to the time-share of the Aircraft as set forth herein. This Agreement shall be governed by, and construed in accordance with, the laws of the State of Indiana.

[REMAINDER OF PAGE INTENTIONALLY BLANK]

16. TRUTH IN LEASING STATEMENT

THE AIRCRAFT, GULFSTREAM AEROSPACE MODEL G-IV AIRCRAFT, BEARING MANUFACTURER'S SERIAL NUMBERS 1021, 1095 AND 1105, CURRENTLY REGISTERED WITH THE FEDERAL AVIATION ADMINISTRATION AS N310EL, N311EL AND N312EL, RESPECTIVELY, HAVE BEEN MAINTAINED AND INSPECTED UNDER FAR PART 91.409(f)(3) DURING THE 12 MONTH PERIOD PRECEDING THE DATE OF THIS LEASE.

THE AIRCRAFT WILL BE MAINTAINED AND INSPECTED UNDER FAR PART 91.409(f)(3) FOR OPERATIONS TO BE CONDUCTED UNDER THIS LEASE.

ELI LILLY AND COMPANY, AN INDIANA CORPORATION, IS CONSIDERED RESPONSIBLE FOR OPERATIONAL CONTROL OF ALL AIRCRAFT IDENTIFIED AND TO BE OPERATED UNDER THIS LEASE. I, THE UNDERSIGNED, DEIRDRE P. CONNELLY, AS SENIOR VICE PRESIDENT OF ELI LILLY AND COMPANY, CERTIFY THAT IT IS RESPONSIBLE FOR OPERATIONAL CONTROL OF THE AIRCRAFT FOR OPERATIONS TO BE CONDUCTED UNDER THIS LEASE AND THAT IT UNDERSTANDS ITS RESPONSIBILITIES FOR COMPLIANCE WITH APPLICABLE FEDERAL AVIATION REGULATIONS.

AN EXPLANATION OF FACTORS BEARING ON OPERATIONAL CONTROL AND PERTINENT FEDERAL AVIATION REGULATIONS CAN BE OBTAINED FROM THE NEAREST FAA FLIGHT STANDARDS DISTRICT OFFICE.

THE ADDRESS OF ELI LILLY AND COMPANY IS LILLY CORPORATE CENTER, INDIANAPOLIS, INDIANA 46285.

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first above written.

ELI LILLY AND COMPANY

By: /s/ Deirdre P. Connelly

Name: Deirdre P. Connelly

Title: Senior Vice President

/s/ Sidney Taurel

SIDNEY TAUREL

EXHIBIT 12. STATEMENT RE: COMPUTATION OF RATIO OF EARNINGS FROM CONTINUING OPERATIONS TO FIXED CHARGES

ELI LILLY AND COMPANY AND SUBSIDIARIES
(Dollars in millions)

| | Years Ended December 31, | | | | |
|--|--------------------------|------------------|------------------|------------------|------------------|
| | 2004 | 2003 | 2002 | 2001 | 2000 |
| Consolidated pretax income from continuing operations | \$2,941.9 | \$3,261.7 | \$3,457.7 | \$3,506.9 | \$3,858.7 |
| Interest from continuing operations and other fixed charges | 162.9 | 121.9 | 140.0 | 253.3 | 225.4 |
| Less interest capitalized during the period from continuing operations | (111.3) | (60.9) | (60.3) | (61.5) | (43.1) |
| Earnings | <u>\$2,993.5</u> | <u>\$3,322.7</u> | <u>\$3,537.4</u> | <u>\$3,698.7</u> | <u>\$4,041.0</u> |
| Fixed charges | <u>\$ 162.9</u> | <u>\$ 121.9</u> | <u>\$ 140.0</u> | <u>\$ 253.3</u> | <u>\$ 225.4</u> |
| Ratio of earnings to fixed charges | <u>18.4</u> | <u>27.3</u> | <u>25.3</u> | <u>14.6</u> | <u>17.9</u> |

EXHIBIT 13. ANNUAL REPORT TO SHAREHOLDERS FOR THE YEAR ENDED DECEMBER 31, 2004

Review of Operations

EXECUTIVE OVERVIEW

This section provides an overview of our financial results, product launches and late-stage product pipeline developments, and legal and governmental matters affecting our company and the pharmaceutical industry.

Graph 2: Revenues (see data table on page 44).

Financial Results

We achieved worldwide sales growth of 10 percent, due in part to the launch during the year of five new products as well as six new indications or formulations for expanded use of new and existing products in key markets. We continued our substantial investments in our manufacturing operations and research and development activities, resulting in cost of products sold and research and development costs increasing at rates greater than sales. Despite significant product launch expenditures, our cost-containment and productivity measures resulted in marketing and administrative expenses increasing at a rate significantly less than sales. We also benefited from an increase in net other income in 2004. Net income was \$1.81 billion, or \$1.66 per share, in 2004 as compared with \$2.56 billion, or \$2.37 per share, in 2003, decreases of 29 and 30 percent, respectively. Net income comparisons between 2004 and 2003 are negatively affected in the aggregate by the impact of the following significant items that are reflected in our financial results (see Notes 3, 4, and 11 to the consolidated financial statements for additional information):

2004

- We recognized asset impairment charges, streamlined our infrastructure, and provided for the anticipated resolution of the government investigation of Evista[®] marketing and promotional practices, resulting in charges of \$108.9 million (pretax) in the second quarter and \$494.1 million (pretax) in the fourth

quarter, which decreased earnings per share by \$.08 and \$.30, respectively.

- We incurred charges for acquired in-process research and development (IPR&D) of \$362.3 million (no tax benefit) in the first quarter related to the acquisition of Applied Molecular Evolution, Inc. (AME), and \$29.9 million (pretax) in the fourth quarter related to our acquisition of a Phase I compound currently under development as a potential treatment for insomnia, which decreased earnings per share by \$.33 in the first quarter and \$.02 in the fourth quarter.
- As discussed further in Financial Condition, we recognized tax expenses of \$465.0 million in the fourth quarter associated with the anticipated repatriation in 2005 of \$8.00 billion of our earnings reinvested outside the U.S., as a result of the passage of the American Jobs Creation Act of 2004 (AJCA). This tax expense decreased earnings per share by \$.43 in that quarter.

2003

- We recognized asset impairments, primarily relating to manufacturing assets in the U.S., and streamlined our infrastructure, resulting in severance-related and other charges totaling \$167.1 million (pretax) in the first quarter and \$28.3 million (pretax) in the fourth quarter, which decreased earnings per share by approximately \$.10 and \$.02 in the first and fourth quarters of 2003, respectively.
- Separately, we recognized asset impairments and other charges of \$186.8 million (pretax) in the first quarter of 2003 related primarily to our common stock ownership and loan agreements with Isis Pharmaceuticals, Inc. (Isis), which decreased earnings per share by \$.13 in that quarter.
- In the fourth quarter of 2003, we recorded a gain of \$65.0 million (pretax) related to the sale of patent rights to dapoxetine for development in the field of genitourinary disorders to PPD, Inc., which increased earnings per share by \$.04 in that quarter.

Recent Product Launches and Late-Stage Product Pipeline Developments

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 have achieved a number of successes with recent product launches and late-stage pipeline developments, including:

- We are in the process of rolling out the global launches of a number of new products, which include Alimta[®], Cialis[®], Cymbalta[®], Forteo[®], Strattera[®], Symbyax[™], and Yentreve[™]. In addition, we have launched new indications or formulations of Alimta, Cymbalta, Gemzar[®], Humatrope[®], and Zyprexa[®].



- The U.S. Food and Drug Administration (FDA) approved Cymbalta, a balanced and potent selective serotonin and norepinephrine reuptake inhibitor, for the treatment of major depressive disorder in August 2004. This breakthrough antidepressant, which addresses both the emotional and painful physical symptoms of depression, was launched in the U.S. later that month. In September, following an accelerated review by the FDA, Cymbalta received its second U.S. approval and became the first FDA-approved treatment for pain caused by diabetic peripheral neuropathy. In addition, Cymbalta was approved in the European Union in late December 2004 for the treatment of major depressive episodes, and we expect to launch the product in a number of European markets during 2005.
- In August, the FDA granted accelerated approval for Alimta for the treatment of locally advanced or metastatic non-small-cell lung cancer. This represents the second approval for Alimta in 2004; the product was approved and launched for malignant pleural mesothelioma in the first quarter. In September, Alimta was granted marketing authorization by the European Commission for the treatment of malignant pleural mesothelioma and as a second-line treatment for non-small-cell lung cancer. Alimta will continue to be launched in a number of European countries in 2005.
- The European Commission granted marketing authorization throughout the European Union for Yentreve, duloxetine for the treatment of moderate-to-severe stress urinary incontinence (SUI) in women. Yentreve has been launched in nine European countries and will be available in many additional countries in the coming months. To date, we have received marketing authorization for the product in 27 countries worldwide. In late January 2005, we withdrew the New Drug Application from the FDA for duloxetine for the treatment of SUI. This decision was based on discussions with the FDA suggesting the agency is not prepared at this time to grant approval for the product for the treatment of the SUI patient population based on the data package submitted. With our marketing partner Boehringer Ingelheim, we will evaluate our options for next steps for the SUI indication in consultation with the FDA. Ongoing clinical trials for the product's treatment of SUI will continue.
- The FDA granted approval in May for Gemzar, in combination with paclitaxel, for the first-line treatment of patients with metastatic breast cancer.
- In late June, Lilly and Amylin Pharmaceuticals, Inc., submitted a New Drug Application to the FDA for regulatory approval of exenatide, the first in a new class of medicines known as incretin mimetics, for the treatment of type 2 diabetes. We expect regulatory action by the FDA during the first half of 2005.

Legal and Governmental Matters

Certain generic manufacturers have challenged our U.S. compound patent for Zyprexa and are seeking permission to market generic versions of Zyprexa prior to its patent expiration in 2011. The trial regarding the defense of these patents concluded in February 2004. We are awaiting the court's decision, and appeals are expected to follow.

In March 2004, we were notified by the U.S. Attorney's office for the Eastern District of Pennsylvania that it has commenced a civil investigation relating to our U.S. marketing and promotional practices. The products involved include Zyprexa, Prozac[®], and Prozac Weekly[™].

In July 2002, we received the first of several grand jury subpoenas for documents from the Office of Consumer Litigation, U.S. Department of Justice, related to our marketing and promotional practices and physician communications with respect to Evista. We continue to cooperate in this matter and are in discussions with the government to resolve it. In the fourth quarter of 2004, we expensed \$36.0 million, which we believe will be sufficient to resolve the matter.

We have been named in a number of product liability cases in the United States alleging a variety of injuries from the administration of Zyprexa. Most of the cases allege that the product caused or contributed to diabetes or high blood-glucose levels. The suits seek substantial compensatory and punitive damages and typically accuse the company of inadequately testing for and warning about side effects of Zyprexa. Many of the suits also allege that we improperly promoted the drug. We are vigorously defending these suits.

In the United States, we expect branded pharmaceutical products to be subject to increasing pricing pressures. Implementation of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), which provides a prescription drug benefit under the Medicare program, will take effect January 1, 2006. While it is difficult to predict the business impact of this legislation prior to 2006, we currently anticipate a relatively neutral short-term impact due to offsets of price and volume in various customer groups. However, in the long term there is additional risk associated with increased pricing pressures. While the MMA prohibits the Secretary of Health and Human Services (HHS) from directly negotiating prescription drug prices with manufacturers, we expect continued challenges to that prohibition over the next several years. Also, the MMA retains the authority of the Secretary of HHS to prohibit the importation of prescription drugs, but we expect Congress to consider several measures that could remove that authority and allow for the importation of products into the U.S. regardless of their safety or cost. If adopted, such legislation would likely have a negative effect on our U.S. sales. We were encouraged by the

release of the HHS Task Force Report on Importation, which concludes that the safety and possible savings of an importation scheme are questionable.

As a result of the passage of the MMA, aged and disabled patients jointly eligible for Medicare and Medicaid will receive their prescription drug benefits through the Medicare program, instead of Medicaid, on January 1, 2006. This may relieve some state budget pressures but is unlikely to result in reduced pricing pressures at the state level. A majority of states have begun to implement supplemental rebates and restricted formularies in their Medicaid programs, and these programs are expected to continue in the post-MMA environment. Several states are also attempting to extend discounted Medicaid prices to non-Medicaid patients. Additionally, notwithstanding the federal law prohibiting drug importation, nine states have implemented importation schemes for their citizens, usually involving a website that links patients to selected Canadian pharmacies. One state has such a program for its state employees. In the absence of federal action to curtail state activities, more states are expected to launch importation efforts. As a result, we expect pressures on pharmaceutical pricing to continue.

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 or reduce the value of our intellectual property protection.

OPERATING RESULTS—2004

Sales

Our worldwide sales for 2004 increased 10 percent, to \$13.86 billion, due primarily to the increased global sales of Strattera, Gemzar, Forteo, Zyprexa, Evista, Humatrope, and Cialis, and sales related to the launches of Alimta and Cymbalta. Sales in the U.S. increased 6 percent, to \$7.67 billion. Sales outside the U.S. increased 15 percent, to \$6.19 billion. Worldwide sales reflected a volume increase of 5 percent, with global selling prices contributing 2 percent and an increase due to favorable changes in exchange rates contributing 3 percent.

Zyprexa, our top-selling product, is a treatment for schizophrenia, bipolar mania, and bipolar maintenance. Zyprexa sales in the U.S. decreased 8 percent in 2004 due to a decline in underlying demand from continued competitive pressures. Zyprexa sales outside the U.S. increased 22 percent, driven by volume growth in a number of major markets outside the U.S. International Zyprexa sales growth also benefited from the impact of foreign exchange rates. Excluding the impact of exchange rates, sales of Zyprexa outside the U.S. increased by 13 percent in 2004. While we expect Zyprexa sales in the U.S. to decline in 2005, we believe the erosion will start to slow sometime in 2005. In addition, we continue to expect double-digit growth of Zyprexa sales outside the U.S. As a result, we expect a slight decline in our 2005 worldwide Zyprexa sales.

The following table summarizes our net sales activity in 2004:

| Product | Year Ended December 31, 2004 | | | Year Ended December 31, 2003 | Percent Change from 2003 |
|-------------------------------|---------------------------------|--------------|------------|---------------------------------|--------------------------------|
| | U.S. ¹ | Outside U.S. | Total | Total | |
| (Dollars in millions) | | | | | |
| Zyprexa | \$2,422.2 | \$ 1,997.6 | \$ 4,419.8 | \$ 4,276.9 | 3 |
| Gemzar | 565.1 | 649.3 | 1,214.4 | 1,021.7 | 19 |
| Humalog [®] | 685.4 | 416.2 | 1,101.6 | 1,021.3 | 8 |
| Evista | 667.9 | 344.8 | 1,012.7 | 922.1 | 10 |
| Humulin [®] | 422.7 | 575.0 | 997.7 | 1,060.4 | (6) |
| Animal health products | 338.9 | 459.8 | 798.7 | 726.6 | 10 |
| Strattera | 656.4 | 10.3 | 666.7 | 370.3 | 80 |
| Fluoxetine products | 327.3 | 231.7 | 559.0 | 645.1 | (13) |
| Anti-infectives | 110.2 | 367.8 | 478.0 | 489.9 | (2) |
| Actos [®] | 340.4 | 112.5 | 452.9 | 431.2 | 5 |
| Humatrope | 204.8 | 225.5 | 430.3 | 370.9 | 16 |
| ReoPro [®] | 175.4 | 187.4 | 362.8 | 364.4 | 0 |
| Forteo | 198.0 | 40.6 | 238.6 | 65.3 | NM |
| Xigris [®] | 123.3 | 78.5 | 201.8 | 160.4 | 26 |
| Alimta | 121.8 | 20.8 | 142.6 | — | NM |
| Cialis ² | 1.4 | 129.2 | 130.6 | 73.5 | 78 |
| Cymbalta | 92.7 | 1.2 | 93.9 | — | NM |
| Symbyax | 70.1 | 0.1 | 70.2 | — | NM |
| Other pharmaceutical products | 144.5 | 341.1 | 485.6 | 582.5 | (17) |
| Total net sales | \$7,668.5 | \$ 6,189.4 | \$13,857.9 | \$ 12,582.5 | 10 |

NM—Not meaningful

¹ U.S. sales include sales in Puerto Rico.

² Cialis sales shown in the table above represent results in the territories in which we market Cialis exclusively. The remaining sales relate to the joint-venture territories of Lilly ICOS LLC (North America, excluding Puerto Rico, and Europe). Our share of the joint-venture-territory sales, net of expenses, is reported in net

other income in our consolidated income statement.

Graph 3: Thirteen Key Products Collectively Delivered 17 Percent Increase in Net Sales (see data table on page 45).

Diabetes care products, composed primarily of Humulin, biosynthetic human insulin; Humalog, our insulin analog; and Actos, an oral agent for the treatment of type 2 diabetes, had aggregate worldwide revenues of \$2.61 billion in 2004, an increase of 2 percent. Diabetes care revenues in the U.S. decreased 6 percent, to \$1.49 billion. Diabetes care revenues outside the U.S. increased 14 percent, to \$1.12 billion. Humulin sales in the U.S. decreased 19 percent, driven primarily by volume declines due to competitive pressures. Humulin sales outside the U.S. increased 7 percent. Humalog sales in the U.S. increased 3 percent as increased prices offset slight volume declines. Humalog sales outside the U.S. increased 16 percent, to \$416.2 million. Actos revenues, the majority of which represent service revenues from a copromotion agreement in the U.S. with Takeda Pharmaceuticals North America (Takeda), increased 5 percent in 2004. Actos is manufactured by Takeda Chemical Industries, Ltd., and sold in the U.S. by Takeda.

Sales of Gemzar, a product approved to fight various cancers, increased 8 percent in the U.S. largely due to the May 2004 approval for the treatment of late-stage metastatic breast cancer. Gemzar sales increased 31 percent outside the U.S., driven by strong volume growth in a number of cancer indications as well as favorable foreign exchange rates.

Sales of Evista, a product for the prevention and treatment of osteoporosis, increased 1 percent in the U.S. due to continued competitive pressures. Outside the U.S., Evista maintained a strong growth rate of 32 percent, driven by volume growth in several markets and the early 2004 launch of the product in Japan.

Strattera, the only nonstimulant medicine approved for the treatment of attention-deficit hyperactivity disorder in children, adolescents, and adults, was launched in the U.S. in January 2003 and in the United Kingdom in July 2004. In 2004, Strattera generated an 80 percent increase over 2003 sales despite a very competitive landscape. In December 2004, we added a bolded warning to the product label, which indicates that the medication

should be discontinued in patients with jaundice (yellowing of the skin or whites of the eyes) or in the event of laboratory evidence of liver injury. We expect the 2005 growth rate to moderate significantly as a result of the substantial increase in the sales base and anticipated wholesaler destocking due to our restructured arrangements with our U.S. wholesalers, which is discussed further in Financial Expectations for 2005.

Forteo, an osteoporosis treatment for patients at high risk for a fracture, generated \$238.6 million in sales in 2004, which continues its strong growth trajectory following its U.S. launch in December 2002 and European launches in late 2003 and during 2004.

Xigris, a treatment for severe sepsis, had 2004 sales growth of 12 percent in the U.S. compared with 2003, while sales outside the U.S. increased 56 percent during the same period.

The erectile dysfunction treatment Cialis was launched in the U.S. in December 2003 by Lilly and ICOS Corporation. The \$552.3 million of worldwide Cialis sales in 2004, an increase of 172 percent compared to 2003, comprises \$130.6 million of sales in our territories, which are reported in our net sales, and \$421.7 million of sales in the joint-venture territories. Within the joint-venture territories, U.S. sales of Cialis were \$206.6 million for 2004. In early 2004, Lilly ICOS began a direct-to-consumer advertising campaign in the U.S. Cialis continues to increase its market share in most major markets in this extremely competitive category.

Alimta was launched in the U.S. in February 2004 for the treatment of malignant pleural mesothelioma and in August for second-line treatment of non-small-cell lung cancer (NSCLC). In addition, in September 2004, Alimta was granted marketing authorization by the European Commission for both the treatment of malignant pleural mesothelioma and as a second-line treatment of non-small-cell lung cancer. Alimta was launched in several European countries in the second half of 2004, with additional European market launches scheduled in 2005. We are encouraged by early sales results for Alimta, which exceeded our expectations by generating \$142.6 million in 2004.

Cymbalta was launched in the U.S. in late August 2004 for the treatment of major depressive disorder and in September 2004 for the treatment of diabetic peripheral neuropathic pain. Cymbalta has been well accepted, generating \$93.9 million in sales in 2004.

Symbyax, launched in the U.S. in January 2004, combines olanzapine (the active ingredient in Zyprexa) and fluoxetine (the active ingredient in Prozac) to treat bipolar depression. Symbyax is the first FDA-approved medication for this difficult-to-treat condition. Symbyax sales in 2004 did not meet our expectations. Several initiatives are underway to reposition the product in the marketplace.

Animal health product sales in the U.S. increased 9 percent, while sales outside the U.S. increased 10 percent, led by Tylan[®], Rumensin[®], and Paylean[®].



Gross Margin, Costs, and Expenses

The 2004 gross margin decreased to 76.7 percent of sales compared with 78.7 percent for 2003. The decrease was due primarily to continued investment in our manufacturing technical capabilities and capacity and the impact of foreign exchange rates, offset partially by favorable changes in product mix due to growth in sales of higher margin products.

Graph 4: Gross Margin (see data table on page 45).

Operating expenses (the aggregate of research and development and marketing and administrative expenses) increased 9 percent in 2004. Investment in research and development increased 15 percent, to \$2.69 billion, due to increased clinical trial and development expenses and increased incentive compensation and benefits expenses, partially offset by reimbursements for research activities from our collaboration partners. We continue to be a leader in our industry peer group by reinvesting more than 19 percent of our sales into research and development. Marketing and administrative expenses increased 6 percent in 2004, to \$4.28 billion, attributable primarily to increased selling expenses in support of the new and anticipated product launches, the impact of foreign exchange rates, increased incentive compensation and benefits expenses, increased charitable contributions to the Lilly Foundation, and increased product liability expenses, offset partially by ongoing marketing cost-containment measures and marketing expense reimbursement from collaboration partners. A majority of the reimbursements are ongoing.

Net other income for 2004 increased \$126.9 million to \$330.0 million. The increase for 2004 was primarily due to income related to the outlicensing of legacy products outside the United States, milestone payments from collaborations on the duloxetine molecule, income related to a previously assigned patent arrangement of \$30.0 million that was recognized in the first quarter of 2004, and other miscellaneous income. This was offset partially by an increase in the net loss of the Lilly ICOS LLC joint venture, due primarily to increased market-

Graph 5: Research and Development (see data table on page 45).

ing costs of Cialis in joint-venture territories, and the 2003 sale of dapoxetine patent rights. We report our 50 percent share of the operating results of the Lilly ICOS joint venture in our net other income. For 2004, our net loss from the joint venture was \$79.0 million, compared with \$52.4 million in 2003.

The effective tax rate for 2004 was 38.5 percent, compared with 21.5 percent for 2003. The increase in the effective tax rate was caused by the tax provision related to the expected repatriation of \$8.00 billion of earnings reinvested outside the U.S. pursuant to the AJCA and the charge for acquired IPR&D related to the AME acquisition, which is not deductible for tax purposes. See Note 11 to the consolidated financial statements for additional information.

OPERATING RESULTS—2003

Financial Results

Net income was \$2.56 billion, or \$2.37 per share, in 2003 and \$2.71 billion, or \$2.50 per share, in 2002, a decline of 5 percent. We achieved strong worldwide sales growth of 14 percent, to \$12.58 billion; however, in order to position ourselves for sustained growth in an increasingly competitive environment, we chose to significantly increase our investments in a number of areas. To ensure the successful launches of our new products, we substantially increased our sales and marketing efforts. In addition, we made substantial investments in our manufacturing operations and research and development activities. These investments into the business, together with lower net other income, negatively affected earnings in 2003.

Certain items, reflected in our operating results for 2003 and 2002, should be considered in comparing the two years. The significant items for 2003 are summarized in the Executive Overview. The 2002 charge is summarized as follows (see Note 3 to the consolidated financial statements for additional information).

2002

- In the third quarter of 2002, we recognized a charge of \$84.0 million (pretax) for acquired in-process research and development related to a collaboration arrangement with Amylin Pharmaceuticals, Inc. (Amylin), to jointly develop and commercialize exenatide, a potential new treatment for type 2 diabetes, which decreased earnings per share by approximately \$.05 in that quarter.

Sales

Our worldwide sales for 2003 increased 14 percent, to \$12.58 billion, due primarily to the strong performance of Zyprexa, diabetes care products, Gemzar, and Evista, and sales related to the launches of Strattera, Cialis, and Forteo. Sales in the U.S. increased 10 percent, to \$7.22 billion. Sales outside the U.S. increased 19 percent, to \$5.36 billion. Worldwide sales reflected a volume increase of 7 percent, with global selling prices contributing 2 percent and an increase due to favorable changes in exchange rates contributing 5 percent.

Zyprexa sales increased 4 percent in the U.S., where continuing competitive pressures contributed to the slower growth. Sales outside the U.S. increased 42 percent. Excluding the impact of exchange rates, our sales outside the U.S. grew 26 percent. The strong international sales growth of Zyprexa was primarily driven by increased unit volume attributable to the bipolar mania indication and the ongoing conversion from

typical to atypical antipsychotics and, to a lesser extent, the impact of exchange rates. Zyprexa recorded strong growth in several key markets, including several major European Union countries and in Japan.

Diabetes care products had aggregate worldwide revenues of \$2.57 billion in 2003, an increase of 12 percent. Diabetes care revenues in the U.S. increased 10 percent, to \$1.59 billion. Diabetes care revenues outside the U.S. increased 17 percent, to \$981.5 million. Humulin sales in the U.S. decreased 2 percent, while sales of the product outside the U.S. increased 13 percent. Humalog sales in the U.S. increased 25 percent, and sales outside the U.S. increased 19 percent.

Gemzar became a billion-dollar product in 2003, with sales increases in the U.S. of 8 percent and outside the U.S. of 27 percent.

Evista sales in the U.S. increased 5 percent. The U.S. growth was negatively affected by the exit of patients from the osteoporosis prevention market. Sales outside the U.S. increased 36 percent.

In November 2002, the FDA approved Strattera for the treatment of attention-deficit hyperactivity disorder in children, adolescents, and adults. Strattera sales were \$370.3 million in 2003.

Cialis was launched in 2003 in several markets outside the U.S. by Lilly and ICOS, and the product was launched in the U.S. in early December 2003. Cialis had total sales of \$203.3 million in 2003. Of this total, \$73.5 million represent sales in our exclusive territories

The following table summarizes our net sales activity in 2003 compared with 2002:

| Product | Year Ended December 31, 2003 | | | Year Ended December 31, 2002 | Percent Change from 2002 |
|-------------------------------|---------------------------------|------------------|--------------------|---------------------------------|--------------------------------|
| | U.S. ¹ | Outside U.S. | Total | Total | |
| (Dollars in millions) | | | | | |
| Zyprexa | \$2,645.5 | \$1,631.4 | \$ 4,276.9 | \$ 3,688.9 | 16 |
| Humulin | 521.9 | 538.5 | 1,060.4 | 1,004.1 | 6 |
| Gemzar | 524.2 | 497.5 | 1,021.7 | 874.6 | 17 |
| Humalog | 662.7 | 358.6 | 1,021.3 | 834.2 | 22 |
| Evista | 660.6 | 261.5 | 922.1 | 821.9 | 12 |
| Animal health products | 310.2 | 416.4 | 726.6 | 693.1 | 5 |
| Fluoxetine products | 399.4 | 245.7 | 645.1 | 733.7 | (12) |
| Anti-infectives | 69.9 | 420.0 | 489.9 | 577.4 | (15) |
| Actos | 362.4 | 68.8 | 431.2 | 391.7 | 10 |
| Humatrope | 167.0 | 203.9 | 370.9 | 329.3 | 13 |
| Strattera | 369.9 | 0.4 | 370.3 | 2.6 | NM |
| ReoPro | 201.4 | 163.0 | 364.4 | 384.0 | (5) |
| Xigris | 110.0 | 50.4 | 160.4 | 100.2 | 60 |
| Cialis ² | 0.3 | 73.2 | 73.5 | — | NM |
| Forteo | 63.2 | 2.1 | 65.3 | 5.6 | NM |
| Other pharmaceutical products | 153.0 | 429.5 | 582.5 | 636.2 | (8) |
| Total net sales | \$7,221.6 | \$5,360.9 | \$ 12,582.5 | \$11,077.5 | 14 |

NM—Not meaningful

¹ U.S. sales include sales in Puerto Rico.

² Cialis sales shown in the table above represent results in the territories in which we market Cialis exclusively. The remaining sales relate to the joint-venture territories of Lilly ICOS LLC (North America, excluding Puerto Rico, and Europe). Our share of the joint-venture-territory sales, net of expenses, is reported in net other income in our consolidated income statement.

Consolidated Statements of Income

ELI LILLY AND COMPANY AND SUBSIDIARIES
(Dollars in millions, except per-share data)

| Year Ended December 31 | 2004 | 2003 | 2002 |
|--|-------------------|------------|------------|
| Net sales | \$13,857.9 | \$12,582.5 | \$11,077.5 |
| Cost of sales | 3,223.9 | 2,675.1 | 2,176.5 |
| Research and development | 2,691.1 | 2,350.2 | 2,149.3 |
| Marketing and administrative | 4,284.2 | 4,055.4 | 3,424.0 |
| Acquired in-process research and development (Note 3) | 392.2 | — | 84.0 |
| Asset impairments, restructuring, and other special charges (Note 4) | 603.0 | 382.2 | — |
| Interest expense | 51.6 | 61.0 | 79.7 |
| Other income—net | (330.0) | (203.1) | (293.7) |
| | 10,916.0 | 9,320.8 | 7,619.8 |
| Income before income taxes | 2,941.9 | 3,261.7 | 3,457.7 |
| Income taxes (Note 11) | 1,131.8 | 700.9 | 749.8 |
| Net income | \$ 1,810.1 | \$ 2,560.8 | \$ 2,707.9 |
| Earnings per share—basic (Note 10) | \$ 1.67 | \$ 2.38 | \$ 2.51 |
| Earnings per share—diluted (Note 10) | \$ 1.66 | \$ 2.37 | \$ 2.50 |

See notes to consolidated financial statements.

and are reported in our net sales. The remaining Cialis sales relate to the joint-venture territories of Lilly ICOS LLC (North America and Europe) and are reported in the Lilly ICOS joint-venture income statement along with related expenses. We report our 50 percent share of the operating results of the joint venture in our net other income.

Forteo was officially launched in the U.S. in December 2002, and we received an approval in Europe in June 2003. Forteo sales were \$65.3 million in 2003.

Animal health product sales in the U.S. increased 2 percent, while sales outside the U.S. increased 7 percent.

Gross Margin, Costs, and Expenses

The 2003 gross margin decreased to 78.7 percent of sales compared with 80.4 percent for 2002. This decrease was attributed primarily to increased costs associated with quality improvements and growth in capacity of our manufacturing operations and the impact of foreign exchange rates, offset partially by favorable changes in product mix due to growth in sales of higher margin products.

Operating expenses (the aggregate of research and development and marketing and administrative expenses) increased 15 percent in 2003. Investment in research and development increased 9 percent, to \$2.35 billion, due to increased clinical-trial expenses, the impact of foreign exchange rates, and milestone payments to Amylin for successful Phase III studies of exenatide. Maintaining our strong commitment to innovation, we invested approximately 19 percent of our sales in research and development efforts in 2003. Marketing and administrative expenses increased 18 percent compared with 2002, attributable primarily to increased marketing expenses in support of new product launches, preparation for anticipated launches, and the impact of foreign exchange rates.

Net other income for 2003 was \$203.1 million, a decrease of \$90.6 million. The decrease was primarily due to lower interest and miscellaneous income. For 2003, our net loss from the Lilly ICOS LLC joint venture was \$52.4 million, compared with \$37.8 million in 2002.

The effective tax rate for 2003 was 21.5 percent compared with 21.7 percent for 2002. See Note 11 to the consolidated financial statements for additional information.

FINANCIAL CONDITION

Cash flow from operations of \$2.87 billion, net proceeds from the sales of long-term investments of \$2.88 billion in preparation of implementation of the AJCA repatriation (as discussed later in this section), and an increase in short-term borrowings of \$1.48 billion were partially offset by dividends paid of \$1.54 billion and net capital expenditures of \$1.88 billion. As a consequence, cash,

cash equivalents, and short-term investments increased \$3.75 billion to \$7.46 billion at December 31, 2004.

Our inventories increased by \$328.6 million during 2004, to \$2.29 billion, due primarily to exchange rate translation of overseas inventories to adjust for U.S. dollar weakness and to the buildup of inventory for new product launches and our growth products.

Graph 6: Capital Expenditures (see data table on page 46).

Capital expenditures of \$1.90 billion during 2004 were \$191.5 million more than in 2003 as we continued to invest in manufacturing and research and development initiatives and related infrastructure. We expect near-term capital expenditures to remain approximately the same as 2004 levels while we continue to prepare for the long-term growth of our diabetes care and other products, as well as increased research and development activities.

Total debt at December 31, 2004, was \$6.51 billion, an increase of \$1.63 billion from December 31, 2003, primarily due to the issuance of commercial paper to fund U.S. operating activities. In addition, in August 2004, we issued \$1.00 billion of floating rate notes. The majority of the proceeds of this debt offering were used to redeem other outstanding debt. Our current debt ratings from Standard & Poor's and Moody's remain at AA and Aa3, respectively.

Dividends of \$1.42 per share were paid in 2004, an increase of 6 percent from 2003. In the fourth quarter of 2004, effective for the first-quarter dividend in 2005, the quarterly dividend was increased to \$.38 per share (a 7 percent increase), resulting in an indicated annual rate for 2005 of \$1.52 per share. The year 2004 was the 120th consecutive year in which we made dividend payments and the 37th consecutive year in which dividends have been increased.

On October 22, 2004, President Bush signed into law the American Jobs Creation Act of 2004 (AJCA), which creates a temporary incentive for U.S. corporations to repatriate undistributed income earned abroad by providing an 85 percent dividends received deduction for certain dividends from controlled foreign corpora-



Consolidated Balance Sheets

ELI LILLY AND COMPANY AND SUBSIDIARIES
(Dollars in millions)

December 31

2004

2003

| | December 31 | 2004 | 2003 |
|---|-------------|--------------------|--------------------|
| Assets | | | |
| <i>Current Assets</i> | | | |
| Cash and cash equivalents | | \$ 5,365.3 | \$ 2,756.3 |
| Short-term investments | | 2,099.1 | 957.0 |
| Accounts receivable, net of allowances of \$66.1 (2004) and \$69.3 (2003) | | 2,058.7 | 1,864.9 |
| Other receivables | | 494.3 | 477.6 |
| Inventories | | 2,291.6 | 1,963.0 |
| Deferred income taxes (Note 11) | | 255.3 | 500.6 |
| Prepaid expenses | | 271.5 | 249.5 |
| Total current assets | | <u>12,835.8</u> | <u>8,768.9</u> |
| <i>Other Assets</i> | | | |
| Prepaid pension (Note 12) | | 2,253.8 | 1,613.3 |
| Investments (Note 5) | | 561.4 | 3,374.6 |
| Sundry (Note 8) | | 1,665.1 | 1,392.5 |
| | | <u>4,480.3</u> | <u>6,380.4</u> |
| <i>Property and Equipment, net</i> | | 7,550.9 | 6,539.0 |
| | | <u>\$ 24,867.0</u> | <u>\$ 21,688.3</u> |
| Liabilities and Shareholders' Equity | | | |
| <i>Current Liabilities</i> | | | |
| Short-term borrowings (Note 6) | | \$ 2,020.6 | \$ 196.5 |
| Accounts payable | | 648.6 | 875.9 |
| Employee compensation | | 471.6 | 387.4 |
| Sales rebates and discounts | | 475.3 | 488.9 |
| Dividends payable | | 414.4 | 398.3 |
| Income taxes payable (Note 11) | | 1,703.9 | 1,749.8 |
| Other current liabilities (Note 8) | | 1,859.3 | 1,464.0 |
| Total current liabilities | | <u>7,593.7</u> | <u>5,560.8</u> |
| <i>Other Liabilities</i> | | | |
| Long-term debt (Note 6) | | 4,491.9 | 4,687.8 |
| Deferred income taxes (Note 11) | | 620.4 | 386.1 |
| Other noncurrent liabilities (Note 8) | | 1,241.1 | 1,288.8 |
| | | <u>6,353.4</u> | <u>6,362.7</u> |
| Commitments and contingencies (Note 13) | | — | — |
| <i>Shareholders' Equity (Notes 7 and 9)</i> | | | |
| Common stock—no par value | | | |
| Authorized shares: 3,200,000,000 | | | |
| Issued shares: 1,132,884,801 (2004) and 1,124,677,097 (2003) | | 708.0 | 702.3 |
| Additional paid-in capital | | 3,119.4 | 2,610.0 |
| Retained earnings | | 9,724.6 | 9,470.4 |
| Employee benefit trust | | (2,635.0) | (2,635.0) |
| Deferred costs—ESOP | | (111.9) | (118.6) |
| Accumulated other comprehensive income (loss) (Note 14) | | 218.6 | (160.1) |
| | | <u>11,023.7</u> | <u>9,869.0</u> |
| Less cost of common stock in treasury | | | |
| 2004—942,677 shares | | | |
| 2003—951,578 shares | | 103.8 | 104.2 |
| | | <u>103.8</u> | <u>104.2</u> |
| | | <u>\$ 24,867.0</u> | <u>\$ 21,688.3</u> |

See notes to consolidated financial statements.



Graph 7: Return on Shareholders' Equity (see data table on page 46).

tions. Although the deduction is subject to a number of limitations and uncertainty remains as to how to interpret certain provisions of the AJCA, we believe we have the information necessary to make an informed decision on the impact of the AJCA on our repatriation plans. Based on that decision, we plan to repatriate \$8.00 billion in incentive dividends, as defined in the AJCA, during 2005 and accordingly have recorded a related tax liability of \$465.0 million as of December 31, 2004. Potential uses of proceeds from the incentive dividends include research and development activities, capital asset expenditures, and other permitted activities. As noted above, in anticipation of the repatriation of overseas earnings into the U.S. in 2005, we began to liquidate our long-term investments held internationally during the latter part of 2004 into cash, cash equivalents and short-term investments.

We believe that cash generated from operations, along with available cash and cash equivalents, will be sufficient to fund our operating needs, including debt service, capital expenditures, dividends, and taxes in 2005. We believe that amounts available through our existing commercial paper program should be adequate to fund maturities of short-term borrowings, if necessary. Our commercial paper program is also currently

Graph 8: Dividends Paid Per Share (see data table on page 46).

backed by \$1.25 billion of unused committed bank credit facilities. We will likely repay our outstanding commercial paper and a portion of our other debt during 2005 using available cash. Various risks and uncertainties, including those discussed in the Financial Expectations for 2005 section, may affect our operating results and cash generated from operations.

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, 2004 and 2003, 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, 2004 and 2003, 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. 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 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, 2004 and 2003, a hypothetical 10 percent change in exchange rates (primarily against the U.S. dollar) as of December 31, 2004 and 2003, 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 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). 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.

These arrangements are not material individually. However, if milestones for multiple products covered by these arrangements would happen to be reached in the same year, the aggregate charge to expense could be material to the results of operations in any one period. The inherent risk in pharmaceutical development makes it unlikely that this will occur, as the failure rate for products in development is very high. In addition, 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 1 Year | 1-3 Years | 3-5 Years | More Than 5 Years |
| Long-term debt, including interest payments ¹ | \$ 10,170.6 | \$ 473.4 | \$ 2,172.0 | \$557.6 | \$ 6,967.6 |
| Capital lease obligations | 165.9 | 28.9 | 34.6 | 27.0 | 75.4 |
| Operating leases | 354.4 | 89.3 | 139.0 | 78.2 | 47.9 |
| Purchase obligations ² | 2,927.3 | 2,596.0 | 191.1 | 88.9 | 51.3 |
| Other long-term liabilities reflected on our balance sheet under GAAP ³ | 589.2 | — | 90.6 | 90.6 | 408.0 |
| Other ⁴ | 70.6 | 63.1 | 7.5 | — | — |
| Total | \$ 14,278.0 | \$ 3,250.7 | \$ 2,634.8 | \$842.3 | \$ 7,550.2 |

¹ Our long-term debt obligations include both our expected principal and interest obligations, including our interest rate swaps. The interest rate forward curve at December 31, 2004, was used to compute the amount of the contractual obligation for the variable rate debt instruments and swaps.

² We have included the following:

- Purchase obligations, consisting primarily of all open purchase orders at our significant operating locations as of December 31, 2004. Some of these purchase orders may be cancelable; however, for purposes of this disclosure, we have not distinguished between cancelable and noncancelable purchase obligations.
- Contractual payment obligations with each of our significant vendors, which are noncancelable and are not contingent.

³ We have included our long-term liabilities consisting primarily of our nonqualified supplemental pension funding requirements and deferred compensation liabilities.

⁴ This category comprises primarily cash to be used in loan funding requirements to our collaboration partners, and our minimum pension funding requirements.

The contractual obligations table is current as of December 31, 2004. The amount of these obligations can be expected to change materially over time as new contracts are initiated and existing contracts are 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, there may also be other estimates or assumptions that are reasonable; however, 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 are described below. We have discussed the nature and the inherent judgment used in the application of our critical accounting policies with our audit committee.

Revenue Recognition and Sales 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. This is generally at the time products are shipped to the customer, typically a wholesale distributor. Provisions for discounts and rebates to customers 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. We are generally able to determine when significant wholesaler stocking or destocking has occurred during a particular period, but we cannot accurately quantify the amount of stocking or destocking. An unusual buying pattern compared with underlying demand of our products is often the result of speculative buying by wholesalers in anticipation of price increases. Other causes include product supply issues and changes in wholesaler business operations. 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 the amount is believed to be material to the product sales trend.

As a result of recently restructuring our arrangements with our U.S. wholesalers, we anticipate reductions in wholesaler inventory levels for certain products (primarily Strattera, Prozac, and Gemzar) in the first part of 2005. While this could affect the sales growth rates for certain individual products in the near term, it is unlikely to have a material impact on our consolidated sales or results of operations for 2005. We expect that the new structure will reduce the speculative wholesaler buying we have seen in the past and provide us improved data on inventory levels at our U.S. wholesalers. Wholesaler stocking and destocking activity historically has not caused any material changes in the rate of actual product returns, which have been approximately 1 percent or less 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/discount amounts are recorded as a deduction to arrive at our net sales. Sales rebates/discounts that require the use of judgment in the establishment of the accrual include Medicaid, managed care, long-term-care, hospital, discount card programs, and various other government programs. We base these accruals primarily upon our historical rebate/discount payments made to our customer segment groups and the provisions of current rebate/discount contracts. We calculate these rebates/discounts based upon a percentage of our sales for each of our products as defined by the statutory rates and the contracts with our various customer groups.

The largest of our sales rebate/discount amounts are rebates associated with sales covered by Medicaid. Although we generally 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 billed up to six months later. Due to the time lag, in any particular period our rebate adjustments may incorporate revisions of accruals for several periods. 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/discount contracts.

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, the 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, our rebate reserves are adjusted.

We believe that our accruals for sales rebates and discounts are reasonable and appropriate based on current facts and circumstances. However, it is possible that other people applying reasonable judgment to the same facts and circumstances could develop a different accrual amount for sales rebates and discounts. Federally mandated Medicaid rebate and state pharmaceutical assistance programs reduced sales by \$641.0 million, \$567.6 million, and \$438.2 million in 2004, 2003, and 2002, respectively. A 5 percent change in the Medicaid rebate expense we recognized in 2004 would lead to an approximate \$32 million effect on our income before income taxes. As of December 31, 2004, our Medicaid rebate liability was \$279.6 million.

Approximately 86 percent and 92 percent of our global rebate and discount liability results from sales of our products in the United States as of December 31, 2004 and 2003, respectively. The following represents a roll-forward of our most significant U.S. rebate and discount liability balances, including Medicaid (in millions):

| | 2004 | 2003 |
|--|------------------|------------------|
| Rebate and discount liability, beginning of year | \$ 398.0 | \$ 328.1 |
| Reduction of net sales due to discounts and rebates ¹ | 1,157.0 | 1,225.2 |
| Cash payments of discounts and rebates | <u>(1,187.1)</u> | <u>(1,155.3)</u> |
| Rebate and discount liability, end of year | <u>\$ 367.9</u> | <u>\$ 398.0</u> |

¹ Adjustments of the estimates for these rebates and discounts to actual results were less than 0.3 percent of net sales for each of the years presented.

Product Litigation Liabilities and Other Contingencies

Product litigation liabilities and other contingencies are, by their nature, uncertain and are based upon complex judgments and probabilities. The factors we consider in developing our product litigation liability reserves and other contingent liability amounts include the merits and jurisdiction of the litigation, the nature and the number of other similar current and past litigation cases, the nature of the product and the current assessment of the science subject to the litigation, and the likelihood of settlement and current state of settlement discussions, if any. In addition, we have accrued 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 also consider the insurance coverage we have to diminish the exposure. 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 position of the insurers, and the possibility of and the length of time for collection.

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. However, it is possible that other people applying reasonable judgment to the same facts and circumstances could develop a different liability amount for product litigation liabilities and other contingencies or a different recovery amount from the insurance companies. A 5 percent change in the product litigation liabilities and other contingencies accrual would lead to an approximate \$13 million effect on our income before income taxes; however, we would expect much of this effect to be offset by recoveries from our insurance coverages. A 5 percent change in the insurance recoveries estimate would lead to an approximate \$4 million effect on our income before income taxes.

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 12 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 the 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 85 percent to 95 percent of which are growth investments); and the views of leading financial advisers and economists. 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. However, other people applying reasonable judgment to the same facts and circumstances could develop a different estimate of these 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 2004 annual expense would increase by approximately \$16 million. A one-percentage-point decrease would decrease the aggregate of the 2004 service cost and interest cost by approximately \$14 million. If the discount rate for 2004 were to be changed by a quarter percentage point, income before income taxes would change by approximately \$21 million. If the expected return on plan assets for 2004 were to be changed by a quarter percentage point, income before income taxes would change by approximately \$11 million. If our assumption regarding the expected age of future retirees for 2004 were adjusted by one year, that would affect our income before income taxes by approximately \$26 million.

Income Taxes

We have recorded valuation allowances against certain of our deferred tax assets, primarily those that have been generated from net operating losses 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. 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 valuation allowances reserved against the deferred tax assets are appropriate based on current facts and circumstances. However, other people applying reasonable judgment to the same facts and circumstances could develop a different estimate of these factors.

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. Such examinations may result in future tax and interest assessments by these taxing authorities. Inherent uncertainties exist in estimates of tax contingencies due to changes in tax law resulting from legislation, regulation and/or as concluded through the various jurisdictions' tax court systems. We record a liability for tax contingencies when we believe it is probable that we will be assessed and the amount of the contingency can be reasonably estimated. The tax contingency reserve is adjusted for changes in facts and circumstances, and additional uncertainties. 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 tax contingency reserves are appropriate and sufficient to pay assessments that may result from examinations of our tax returns; however, other people applying reasonable judgment to the same facts and circumstances could develop a different estimate and the amount ultimately paid upon resolution of issues raised may differ from the amounts accrued.

FINANCIAL EXPECTATIONS FOR 2005

For the full year 2005, we currently expect earnings per share to be in the range of \$2.80 to \$2.90, including the incremental equity compensation expense estimated at \$.25 per share as a result of expensing stock options (see Note 2 to the consolidated financial statements for additional information) and compensation structural changes. For the full year 2005, we expect sales to grow 8 percent to 10 percent (with acceleration in the second half of the year), gross margins as a percentage of sales to decline by roughly 50 basis points to 75 basis points, marketing and administrative expenses to grow in the low single digits, and research and development expenses to grow in the mid-single digits. Further, we expect other income to contribute approximately \$175 million to \$225 million, and the effective tax rate to be about 22 percent. As a result of recently restructuring our arrangements with our U.S. wholesalers, we anticipate reductions in wholesaler inventory levels for certain products (primarily Strattera, Prozac, and Gemzar) in the first part of 2005. While this could affect the sales growth rates for certain individual products in the near term, it is unlikely to have a material impact on our consolidated sales or results of operations for 2005.

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; foreign exchange rates; wholesaler inventory changes; other regulatory developments, litigation, and government investigations; and the impact of governmental actions regarding pricing, importation, and reimbursement for pharmaceuticals. In particular, as described later in Legal and Regulatory Matters, certain generic pharmaceutical manufacturers have challenged our U.S. compound patent for Zyprexa. We are awaiting the trial court decision on the challenge. If the decision is unfavorable and the generic companies launch generic olanzapine prior to resolution of appeals, our financial results would be very negatively affected. We undertake no duty to update these forward-looking statements.

LEGAL AND REGULATORY MATTERS

Three generic pharmaceutical manufacturers, Zenith Goldline Pharmaceuticals, Inc. (Zenith), Dr. Reddy's Laboratories, Ltd. (Reddy), and Teva Pharmaceuticals (Teva), have submitted abbreviated new drug applications (ANDAs) seeking permission to market generic versions of Zyprexa in various dosage forms several years prior to the expiration of our U.S. patents for the product, alleging that our patents are invalid, unenforceable, or not infringed. We filed suit against the three companies in the U.S. District Court for the Southern District of Indiana seeking a ruling that the challenges to our compound patent (expiring in 2011) are without merit. The cases have been consolidated. A trial before a district court judge in Indianapolis was held in January and February of 2004, and we are awaiting the court's decision. Regardless of the trial court ruling, we anticipate that appeals will follow. If we are unsuccessful at the trial court level, we cannot predict whether any of the generic companies would launch generic versions of Zyprexa prior to a final resolution of any appeals. We believe that the generic manufacturers' claims are without merit and we expect to prevail in this litigation. However, it is not possible to predict or determine the outcome of this litigation and, accordingly, we can provide no assurance that we will prevail. An unfavorable outcome would have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

In October 2002, we were notified that Barr Laboratories, Inc. (Barr), had submitted an ANDA with the FDA seeking permission to market a generic version of Evista several years prior to the expiration of our U.S. patents covering the product, alleging that the patents are invalid or not infringed. In November 2002, we filed suit against Barr in the U.S. District Court for the Southern District of Indiana seeking a ruling that Barr's challenges to our patents claiming the methods of use and pharmaceutical form (expiring from 2012 to 2017) are without merit. Recently, Barr has also asserted that the method of use patents are unenforceable. On September 28, 2004, the U.S. Patent and Trademark Office issued to us a new patent (expiring in 2017) directed to pharmaceutical compositions containing raloxifene. Barr has challenged this patent, alleging that the patent is invalid, unenforceable, or will not be infringed. This patent has been added to the lawsuit. The suit is in discovery and the trial is now scheduled to begin in February 2006. While we believe that Barr's claims are without merit and we expect to prevail, it is not possible to predict or determine the outcome of the litigation. Therefore, we can provide no assurance that we will prevail. An unfavorable outcome could have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

In July 2002, we received a grand jury subpoena for documents from the Office of Consumer Litigation, U.S. Department of Justice, related to our marketing and promotional practices and physician communications with respect to Evista. We received subpoenas seeking additional documents in July 2003, July 2004, and August 2004. We continue to cooperate with the government and have provided a broad range of information concerning our U.S. marketing and promotional practices, including documents relating to communications with physicians and the remuneration of physician consultants and advisers. Based upon advanced discussions with the government to resolve this matter, which commenced in the fourth quarter of 2004, we have expensed \$36.0 million, which we believe will be sufficient to resolve the matter.

In March 2004, the office of the U.S. Attorney for the Eastern District of Pennsylvania advised us that it has commenced a civil investigation related to our U.S. marketing and promotional practices with respect to Zyprexa, Prozac, and Prozac Weekly. We are cooperating with the U.S. Attorney in this investigation and are providing a broad range of documents and information related to the investigation, including documents relating to communications with physicians and the remuneration of physician consultants and advisers. It is possible that other Lilly products could become subject to this investigation and that the outcome of this matter could include criminal charges and fines and/or civil penalties. We cannot predict or determine the outcome of this matter or reasonably estimate the amount or range of amounts of any fines or penalties that might result from an adverse outcome. It is possible, however, that an adverse outcome could have a material adverse impact on our consolidated results of operations, liquidity, and financial position. We have implemented and continue to review and enhance a broadly based compliance program that includes comprehensive compliance-related activities designed to ensure that our marketing and promotional practices, physician communications, and remuneration of health care professionals comply with promotional laws and regulations.

We have been named in approximately 140 product liability cases in the United States involving approximately 360 claimants alleging a variety of injuries from the use of Zyprexa. Most of the cases allege that the product caused or contributed to diabetes or high blood-glucose levels. The lawsuits seek substantial compensatory and punitive damages and typically accuse us of inadequately testing for and warning about side effects of Zyprexa. Many of the lawsuits also allege that we improperly promoted the drug. We are vigorously defending these suits. All the federal cases, involving approximately 330 claimants, have been or will be transferred to The Honorable Jack Weinstein in the Federal District Court for the Eastern District of New

York for consolidated and coordinated pretrial proceedings. Two cases requesting certification of nationwide class actions on behalf of those who allegedly suffered injuries from the administration of Zyprexa were filed in the Federal District Court for the Eastern District of New York on April 16, 2004, and May 19, 2004, respectively. The cases seek damages for alleged personal injuries and also seek compensation for medical monitoring of individuals who have taken Zyprexa. A lawsuit was also filed that requests a class action on behalf of Iowa residents who took Zyprexa, and that case has been transferred to the federal court in New York. In addition, we have entered into agreements with various plaintiffs' counsel halting the running of the statutes of limitation (tolling agreements) with respect to more than 3,050 individuals who do not have lawsuits on file and may or may not eventually file suits. This provides counsel additional time to evaluate the potential claims. In exchange, the individuals have agreed not to file suits in state courts, and the Plaintiffs Steering Committee agreed to dismiss the personal injury claims in the two pending nationwide class actions. The class action claims seeking medical monitoring for Zyprexa patients are not affected by this agreement.

In December 2004, we were served with two lawsuits brought in state court in Louisiana on behalf of the Louisiana Department of Health and Hospitals, alleging that Zyprexa caused or contributed to diabetes or high blood-glucose levels and that we improperly promoted the drug. In these actions, which we have removed to federal court, the Department of Health and Hospitals seeks to recover the costs it paid for Zyprexa through Medicaid and other drug benefit programs and the costs the department alleges it has incurred and will incur to treat Zyprexa-related illnesses.

In early 2005, we were served with four lawsuits seeking class action status in Canada on behalf of patients who took Zyprexa. The allegations in these suits are similar to those in the litigation pending in the United States.

The number of product liability lawsuits and tolled claims relating to Zyprexa continues to increase, and we cannot predict at this time the additional number of lawsuits and claims that may be asserted. As noted, we are vigorously defending this litigation. However, product litigation of this type is inherently unpredictable, with the risk of excessive verdicts not justified by the evidence. Accordingly, it is possible that the ultimate resolution of the Zyprexa product liability litigation could have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

In Germany, Egis-Gyogyszergyar, a generic pharmaceutical manufacturer, has challenged the validity of our Zyprexa compound and method of use patents (expiring in 2011) in that country. We currently anticipate a decision from the German Patent Court in 2006. In

addition to our patents, we have data package exclusivity in Germany through September 2006. We are vigorously contesting the legal challenge to this patent. We cannot predict or determine the outcome of this litigation.

We have been named as a defendant in numerous other product liability lawsuits, involving primarily diethylstilbestrol (DES) and thimerosal. See Note 13 to the consolidated financial statements for further information on those matters.

While it is not possible to predict or determine the outcome of the patent, product liability, or other legal actions brought against us, we believe that, except as noted previously with respect to the U.S. Zyprexa and Evista patent litigation, the Zyprexa, Prozac, and Prozac Weekly marketing and promotional practices investigation, and the Zyprexa product liability litigation, 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 the consolidated results of operations in any one accounting period.

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 Exhibit 99 to our most recent report on Forms 10-Q and 10-K filed with the Securities and Exchange Commission. We undertake no duty to update forward-looking statements.

Consolidated Statements of Cash Flows

ELI LILLY AND COMPANY AND SUBSIDIARIES
(Dollars in millions)

| | Year Ended December 31 | 2004 | 2003 | 2002 |
|--|------------------------|-------------------|-------------------|-------------------|
| Cash Flows From Operating Activities | | | | |
| Net income | | \$ 1,810.1 | \$ 2,560.8 | \$ 2,707.9 |
| Adjustments To Reconcile Net Income to Cash Flows From Operating Activities | | | | |
| Depreciation and amortization | | 597.5 | 548.5 | 493.0 |
| Change in deferred taxes | | 772.4 | 130.9 | 346.5 |
| Acquired in-process research and development, net of tax | | 381.7 | — | 54.6 |
| Asset impairments, restructuring, and other special charges, net of tax | | 374.3 | 261.7 | — |
| Other, net | | 171.5 | 61.0 | 10.8 |
| | | 4,107.5 | 3,562.9 | 3,612.8 |
| Changes in operating assets and liabilities: | | | | |
| Receivables—increase | | (240.8) | (195.1) | (321.1) |
| Inventories—increase | | (111.6) | (170.8) | (285.1) |
| Other assets—increase | | (765.2) | (211.9) | (667.4) |
| Accounts payable and other liabilities—increase (decrease) | | (120.4) | 661.6 | (268.5) |
| | | (1,238.0) | 83.8 | (1,542.1) |
| Net Cash Provided by Operating Activities | | 2,869.5 | 3,646.7 | 2,070.7 |
| Cash Flows From Investing Activities | | | | |
| Purchase of property and equipment | | (1,898.1) | (1,706.6) | (1,130.9) |
| Disposals of property and equipment | | 20.5 | 61.2 | 36.8 |
| Net change in short-term investments | | (1,119.0) | 774.0 | (651.8) |
| Proceeds from sales and maturities of noncurrent investments | | 14,849.3 | 6,762.4 | 4,777.9 |
| Purchase of noncurrent investments | | (11,967.7) | (7,005.3) | (5,190.3) |
| Purchase of in-process research and development | | (29.9) | — | (84.0) |
| Cash paid for acquisition of Applied Molecular Evolution, net of cash acquired | | (71.7) | — | — |
| Other, net | | (468.2) | (217.2) | (232.1) |
| Net Cash Used in Investing Activities | | (684.8) | (1,331.5) | (2,474.4) |
| Cash Flows From Financing Activities | | | | |
| Dividends paid | | (1,539.8) | (1,443.0) | (1,335.8) |
| Purchase of common stock and other capital transactions | | — | (281.1) | (385.2) |
| Issuances of common stock under stock plans | | 104.5 | 103.1 | 64.6 |
| Net change in short-term borrowings | | 1,478.2 | (247.3) | (18.0) |
| Proceeds from issuance of long-term debt | | 1,000.0 | 830.0 | 1,259.6 |
| Repayments of long-term debt | | (839.2) | (540.0) | (7.2) |
| Net Cash Provided by (Used for) Financing Activities | | 203.7 | (1,578.3) | (422.0) |
| Effect of exchange rate changes on cash | | 220.6 | 73.5 | 69.3 |
| Net increase (decrease) in cash and cash equivalents | | 2,609.0 | 810.4 | (756.4) |
| Cash and cash equivalents at beginning of year | | 2,756.3 | 1,945.9 | 2,702.3 |
| Cash and cash equivalents at end of year | | \$ 5,365.3 | \$ 2,756.3 | \$ 1,945.9 |

See notes to consolidated financial statements.

Consolidated Statements of Comprehensive Income

ELI LILLY AND COMPANY AND SUBSIDIARIES
(Dollars in millions)

| | Year Ended December 31 | 2004 | 2003 | 2002 |
|---|------------------------|-------------------|------------|------------|
| Net income | | \$ 1,810.1 | \$ 2,560.8 | \$ 2,707.9 |
| Other comprehensive income (loss) | | | | |
| Foreign currency translation gains | | 441.7 | 473.0 | 273.6 |
| Net unrealized gains (losses) on securities | | (25.9) | 72.0 | (67.4) |
| Minimum pension liability adjustment | | (4.4) | (9.8) | (4.6) |
| Effective portion of cash flow hedges | | (53.7) | (2.1) | (217.9) |
| Other comprehensive income (loss) before income taxes | | 357.7 | 533.1 | (16.3) |
| Provision for income taxes related to other comprehensive income (loss) items | | 21.0 | (22.4) | 93.9 |
| Other comprehensive income (Note 14) | | 378.7 | 510.7 | 77.6 |
| Comprehensive income | | \$ 2,188.8 | \$ 3,071.5 | \$ 2,785.5 |

See notes to consolidated financial statements.

Segment Information

ELI LILLY AND COMPANY AND SUBSIDIARIES
(Dollars in millions)

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

| | Year Ended December 31 | 2004 | 2003 | 2002 |
|-------------------------------------|------------------------|--------------------|--------------------|--------------------|
| Net sales—to unaffiliated customers | | | | |
| Neurosciences | | \$ 6,052.5 | \$ 5,554.8 | \$ 4,668.3 |
| Endocrinology | | 4,290.9 | 3,926.7 | 3,444.6 |
| Oncology | | 1,366.2 | 1,039.8 | 893.1 |
| Animal health | | 798.7 | 726.6 | 693.1 |
| Cardiovascular | | 658.7 | 669.3 | 624.9 |
| Anti-infectives | | 478.0 | 489.9 | 577.4 |
| Other pharmaceutical | | 212.9 | 175.4 | 176.1 |
| Net sales | | <u>\$ 13,857.9</u> | <u>\$ 12,582.5</u> | <u>\$ 11,077.5</u> |

Geographic Information

| | | | | |
|--|--|--------------------|--------------------|--------------------|
| Net sales—to unaffiliated customers ¹ | | | | |
| United States | | \$ 7,668.5 | \$ 7,221.6 | \$ 6,582.3 |
| Europe | | 3,534.7 | 3,102.9 | 2,471.9 |
| Other foreign countries | | 2,654.7 | 2,258.0 | 2,023.3 |
| | | <u>\$ 13,857.9</u> | <u>\$ 12,582.5</u> | <u>\$ 11,077.5</u> |

Long-lived assets

| | | | | |
|-------------------------|--|-------------------|-------------------|-------------------|
| United States | | \$ 5,874.1 | \$ 5,296.0 | \$ 4,725.1 |
| Europe | | 1,606.7 | 1,279.1 | 997.1 |
| Other foreign countries | | 1,577.3 | 1,209.2 | 673.3 |
| | | <u>\$ 9,058.1</u> | <u>\$ 7,784.3</u> | <u>\$ 6,395.5</u> |

¹ Net sales are attributed to the countries based on the location of the customer.

The largest category of products is the neurosciences group, which includes Zyprexa, Prozac, Strattera, Cymbalta, Permax[®], Symbyax, and Yentreve. Endocrinology products consist primarily of Humalog, Humulin, Actos, Evista, Forteo, and Humatrope. Oncology products consist primarily of Gemzar and Alimta. Animal health products include Tylan[®], Rumensin[®], Coban[®], and other products for livestock and poultry. Cardiovascular products consist primarily of ReoPro and Xigris. Anti-infectives include primarily Ceclor[®] and Vancocin[®]. The other pharmaceutical product group includes Cialis, Axid[®], and other miscellaneous pharmaceutical products and services.

Most of the pharmaceutical products are distributed through wholesalers that serve pharmacies, physicians and other health care professionals, and hospitals. In 2004, our three largest wholesalers each accounted for between 13 percent and 17 percent of consolidated net sales. Further, they each accounted for between 1 percent and 13 percent of accounts receivable as of December 31, 2004. 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 \$223 million, \$204 million, and \$221 million in 2004, 2003, and 2002, 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)

| 2004 | Fourth | Third | Second | First |
|---|--------------------|------------|------------|------------|
| Net sales | \$ 3,644.3 | \$ 3,280.4 | \$ 3,556.3 | \$ 3,376.9 |
| Cost of sales | 865.7 | 810.1 | 796.4 | 751.7 |
| Operating expenses | 1,803.7 | 1,606.7 | 1,854.4 | 1,710.5 |
| Acquired in-process research and development | 29.9 | — | — | 362.3 |
| Asset impairments, restructuring, and other special charges | 494.1 | — | 108.9 | — |
| Other—net | (69.1) | (104.6) | (41.6) | (63.1) |
| Income before income taxes | 520.0 | 968.2 | 838.2 | 615.5 |
| Net income (loss) | (2.4) ¹ | 755.2 | 656.9 | 400.4 |
| Earnings per share—basic | .00 | .70 | .61 | .37 |
| Earnings per share—diluted | .00 | .69 | .60 | .37 |
| Dividends paid per share | .355 | .355 | .355 | .355 |
| Common stock closing prices | | | | |
| High | 62.01 | 69.37 | 76.26 | 74.70 |
| Low | 50.44 | 60.05 | 67.60 | 65.00 |
| 2003 | Fourth | Third | Second | First |
| Net sales | \$ 3,465.5 | \$ 3,139.4 | \$ 3,088.2 | \$ 2,889.4 |
| Cost of sales | 731.5 | 679.3 | 643.0 | 621.3 |
| Operating expenses | 1,844.2 | 1,531.5 | 1,585.8 | 1,444.1 |
| Asset impairments, restructuring, and other special charges | 28.3 | — | — | 353.9 |
| Other—net | (102.5) | 12.7 | (28.5) | (23.8) |
| Income before income taxes | 964.0 | 915.9 | 887.9 | 493.9 |
| Net income | 747.2 | 714.4 | 692.2 | 407.0 |
| Earnings per share—basic | .69 | .66 | .64 | .38 |
| Earnings per share—diluted | .69 | .66 | .64 | .38 |
| Dividends paid per share | .335 | .335 | .335 | .335 |
| Common stock closing prices | | | | |
| High | 73.89 | 70.33 | 69.83 | 67.98 |
| Low | 60.78 | 57.99 | 57.73 | 53.70 |

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

¹ The net loss in the fourth quarter of 2004 included tax expenses of \$465.0 million associated with the anticipated repatriation of \$8.00 billion of our earnings reinvested outside the U.S. as a result of the American Jobs Creation Act (see Note 11).

Selected Financial Data (unaudited)

ELI LILLY AND COMPANY AND SUBSIDIARIES
(Dollars in millions, except per-share data)

| | 2004 | 2003 | 2002 | 2001 | 2000 |
|--|-------------|-------------|-------------|-------------|-------------|
| Operations | | | | | |
| Net sales | \$ 13,857.9 | \$ 12,582.5 | \$ 11,077.5 | \$ 11,542.5 | \$ 10,862.2 |
| Cost of sales | 3,223.9 | 2,675.1 | 2,176.5 | 2,160.2 | 2,055.7 |
| Research and development | 2,691.1 | 2,350.2 | 2,149.3 | 2,235.1 | 2,018.5 |
| Marketing and administration | 4,284.2 | 4,055.4 | 3,424.0 | 3,417.4 | 3,228.3 |
| Other | 716.8 | 240.1 | (130.0) | 222.9 | (299.0) |
| Income before income taxes | 2,941.9 | 3,261.7 | 3,457.7 | 3,506.9 | 3,858.7 |
| Income taxes | 1,131.8 | 700.9 | 749.8 | 726.9 | 800.9 |
| Net income | 1,810.1 | 2,560.8 | 2,707.9 | 2,780.0 | 3,057.8 |
| Net income as a percent of sales | 13.1% | 20.4% | 24.4% | 24.1% | 28.2% |
| Net income per share—diluted | 1.66 | 2.37 | 2.50 | 2.55 | 2.79 |
| Dividends declared per share | 1.45 | 1.36 | 1.27 | 1.15 | 1.06 |
| Weighted-average number of shares outstanding—diluted (thousands) | 1,088,936 | 1,082,230 | 1,085,088 | 1,090,793 | 1,097,725 |
| Financial Position | | | | | |
| Current assets | \$ 12,835.8 | \$ 8,768.9 | \$ 7,804.1 | \$ 6,938.9 | \$ 7,943.0 |
| Current liabilities | 7,593.7 | 5,560.8 | 5,063.5 | 5,203.0 | 4,960.7 |
| Property and equipment—net | 7,550.9 | 6,539.0 | 5,293.0 | 4,532.4 | 4,176.6 |
| Total assets | 24,867.0 | 21,688.3 | 19,042.0 | 16,434.1 | 14,690.8 |
| Long-term debt | 4,491.9 | 4,687.8 | 4,358.2 | 3,132.1 | 2,633.7 |
| Shareholders' equity | 10,919.9 | 9,764.8 | 8,273.6 | 7,104.0 | 6,046.9 |
| Supplementary Data | | | | | |
| Return on shareholders' equity | 17.5% | 28.4% | 35.2% | 42.3% | 55.3% |
| Return on assets | 7.8% | 12.6% | 15.2% | 17.8% | 22.9% |
| Capital expenditures | \$ 1,898.1 | \$ 1,706.6 | \$ 1,130.9 | \$ 884.0 | \$ 677.9 |
| Depreciation and amortization | 597.5 | 548.5 | 493.0 | 454.9 | 435.8 |
| Effective tax rate | 38.5% | 21.5% | 21.7% | 20.7% | 20.8% |
| Number of employees | 44,500 | 45,000 | 42,900 | 40,500 | 35,200 |
| Number of shareholders of record | 52,400 | 54,600 | 56,200 | 57,700 | 59,200 |

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 practices 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 outside shareholders' interests are reflected in other noncurrent liabilities. 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.

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 and the effect of all potentially dilutive common shares (primarily unexercised stock options).

Cash equivalents: We consider all highly liquid investments, generally with a maturity of three months or less, to be cash equivalents. The cost of these investments approximates fair value. If items meeting this definition are part of a larger investment pool, they are classified consistent with the classification of the pool.

Inventories: We state all inventories at the lower of cost or market. We use the last-in, first-out (LIFO) method for substantially all our inventories located in the continental United States, or approximately 39 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:

| | 2004 | 2003 |
|----------------------------|------------|------------|
| Finished products | \$ 717.5 | \$ 542.1 |
| Work in process | 1,356.3 | 1,169.0 |
| Raw materials and supplies | 305.7 | 315.9 |
| | 2,379.5 | 2,027.0 |
| Reduction to LIFO cost | (87.9) | (64.0) |
| | \$ 2,291.6 | \$ 1,963.0 |

Investments: Substantially all debt and marketable equity securities are classified as available-for-sale. Available-for-sale securities are carried at fair value with the unrealized gains and losses, net of tax, reported in other comprehensive income. Unrealized losses considered to be other-than-temporary are recognized in earnings. Factors we consider in making this evaluation include company-specific drivers of the decrease in stock price, status of projects in development, near-term prospects of the issuer, the length of time the value has been depressed, and the financial condition of the industry. 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. 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 income. We own no investments that are considered to be trading securities.

Derivative financial 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 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 enter into foreign currency forward and option contracts to reduce the effect of fluctuating currency exchange rates (principally the euro and the Japanese yen). Generally, 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 currency. These contracts are recorded at fair value with the gain or loss recognized in current earnings. 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: Other intangibles with finite lives arising from acquisitions and research alliances are amortized over their estimated useful lives, ranging from 5-10 years, using the straight-line method. Goodwill is not amortized. Goodwill and other intangibles are reviewed to assess recoverability at least annually and when certain impairment indicators are present. Unamortized goodwill and other intangibles with finite lives were \$110.3 million and \$92.2 million, respectively, at December 31, 2004 and 2003, and were included in sundry assets in the consolidated balance sheets. We currently have no other intangible assets with indefinite lives. No material impairments occurred with respect to the carrying value of our goodwill or other intangible assets in 2004, 2003, or 2002.

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 (generally 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 the asset's fair value, and the cost basis is adjusted.

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

| | 2004 | 2003 |
|----------------------------------|-------------------|-------------------|
| Land | \$ 147.0 | \$ 124.8 |
| Buildings | 3,569.5 | 3,134.7 |
| Equipment | 5,627.2 | 5,305.8 |
| Construction in progress | 2,995.2 | 2,502.7 |
| | <u>12,338.9</u> | <u>11,068.0</u> |
| Less allowances for depreciation | 4,788.0 | 4,529.0 |
| | <u>\$ 7,550.9</u> | <u>\$ 6,539.0</u> |

Depreciation expense for 2004, 2003, and 2002 was \$495.9 million, \$469.3 million, and \$437.8 million, respectively. Approximately \$111.3 million, \$61.0 million, and \$60.3 million of interest costs were capitalized as part of property and equipment in 2004, 2003, and 2002, respectively. Total rental expense for all leases, including contingent rentals (not material), amounted to approximately \$286.8 million, \$268.5 million, and \$240.8 million for 2004, 2003, and 2002, respectively. 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.

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. This is generally at the time products are shipped to the customer. Provisions for discounts and rebates to customers are established in the same period the related sales are recorded. Revenue from copromotion services (primarily Actos) is based upon net sales reported by our copromotion partner and, if applicable, the number of sales calls we perform. We immediately recognize the full amount of milestone payments due 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 income-net. 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 as net sales over the term of the supply agreement.

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. If the product has obtained regulatory approval, we generally capitalize the 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.

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. See Note 11 regarding the 2004 tax expense associated with the expected repatriation of earnings reinvested outside the U.S. pursuant to the American Job Creations Act.

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.

Stock-based compensation: As discussed further in Note 7, we elected to follow Accounting Principles Board (APB) Opinion 25, Accounting for Stock Issued to Employees, and related interpretations in accounting for our stock options and performance awards. Under APB 25, because the exercise price of our employee stock options equals the market price of the underlying stock on the date of grant, no compensation expense is recognized. However, SFAS 123, Accounting for Stock-Based Compensation, as amended by SFAS 148, Accounting for Stock-Based Compensation-Transition and Disclosure, requires us to present pro forma information as if we had accounted for our employee stock options and performance awards under the fair value method of that statement. For purposes of pro forma disclosure, the estimated fair value of the options and performance awards at the date of the grant is amortized to expense over the vesting period. The following table illustrates the effect on net income and earnings per share if we had applied the fair value recognition provisions of SFAS 123 to stock-based employee compensation.

| | 2004 | 2003 | 2002 |
|---|-------------------|-------------------|-------------------|
| Net income, as reported | \$ 1,810.1 | \$ 2,560.8 | \$ 2,707.9 |
| Add: Compensation expense for stock-based performance awards included in reported net income, net of related tax effects | 34.5 | — | — |
| Deduct: Total stock-based employee compensation expense determined under fair-value-based method for all awards, net of related tax effects | (294.2) | (210.8) | (307.2) |
| Pro forma net income | <u>\$ 1,550.4</u> | <u>\$ 2,350.0</u> | <u>\$ 2,400.7</u> |
| Earnings per share: | | | |
| Basic, as reported | <u>\$ 1.67</u> | <u>\$ 2.38</u> | <u>\$ 2.51</u> |
| Basic, pro forma | <u>\$ 1.43</u> | <u>\$ 2.18</u> | <u>\$ 2.23</u> |
| Diluted, as reported | <u>\$ 1.66</u> | <u>\$ 2.37</u> | <u>\$ 2.50</u> |
| Diluted, pro forma | <u>\$ 1.42</u> | <u>\$ 2.17</u> | <u>\$ 2.21</u> |

As discussed more fully in Note 2, we plan to adopt SFAS 123(R) effective January 1, 2005.

Note 2: Implementation of New Financial Accounting Pronouncements

In 2001, the Financial Accounting Standards Board (FASB) issued SFAS 143, Accounting for Asset Retirement Obligations. SFAS 143 requires companies to record the fair value of a liability for an asset retirement obligation in the period in which it is incurred, which is adjusted to its present value each subsequent period. In addition, companies must capitalize a corresponding amount by increasing the carrying amount of the related long-lived asset, which is depreciated over the useful life of the related long-lived asset. The adoption of SFAS 143 on January 1, 2003, had no impact on our consolidated financial position or results of operations.

In 2002, the FASB issued SFAS 146, Accounting for Costs Associated with Exit or Disposal Activities. SFAS 146 requires that a liability for a cost associated with an exit or disposal activity be recognized when the liability is incurred. Severance pay under SFAS 146, in many cases, would be recognized over the remaining service period rather than at the time the plan is communicated. The provisions of SFAS 146 are effective for exit or disposal activities that are initiated after December 31, 2002. We adopted SFAS 146 for any actions initiated after January 1, 2003, and any future exit costs or disposal activities will be subject to this statement.

In 2002, the FASB issued FASB Interpretation (FIN) 45, Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others. FIN 45 requires an issuer of a guarantee to recognize an initial liability for the fair value of the obligations covered by the guarantee. FIN 45 also addresses the disclosures required by a guarantor in interim and annual financial statements regarding obligations under guarantees. We have adopted the requirement for recognition of liabilities for the fair value of guaranteed obligations prospectively for guarantees entered into after January 1, 2003.

In 2003, the FASB issued FASB Interpretation (FIN) 46, Consolidation of Variable Interest Entities. FIN 46 defines a variable interest entity (VIE) as a corporation, partnership, trust, or any other legal structure that does not have equity investors with a controlling financial interest or has equity investors that do not provide sufficient financial resources for the entity to support its activities. FIN 46 requires consolidation of a VIE by the primary beneficiary of the assets, liabilities, and results of activities. FIN 46 also requires certain disclosures by all holders of a significant variable interest in a VIE that are not the primary beneficiary. We do not have any material investments in variable interest entities; therefore, the adoption of this interpretation in the first quarter of 2004 had no material impact on our consolidated financial position or results of operations.

In 2003, the FASB issued SFAS 150, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity. SFAS 150 establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. Financial instruments within the scope of SFAS 150 will now be required to be classified as a liability. This statement also requires enhanced disclosures regarding alternative methods of settling the instruments and the capital structure of entities. SFAS 150 is effective for all financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. The adoption of this statement had no impact on our consolidated financial position or results of operations.

In 2004, the FASB issued FASB Staff Position (FSP) 106-2, which provides guidance regarding accounting for the effects of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). The FSP specifies that, for plans with benefits that are determined to be actuarially equivalent to the Medicare Part D benefits, the plan sponsor will be entitled to a tax-free subsidy under the MMA. We have determined that our plan is actuarially equivalent and, therefore, we are entitled to the subsidy. Following our adoption of the provisions of FSP 106-2 in the second quarter of 2004, we remeasured the accumulated postretirement benefit obligation (APBO) to reflect the effects of the MMA as of the effective date of the MMA (December 8, 2003), and recognized the financial statement effect retroactively. This had no material impact on the APBO, our consolidated financial position, or results of operations.

In December 2004, the FASB revised and issued SFAS 123, Share-Based Payment (SFAS 123(R)). SFAS 123(R) eliminates the alternative of using the APB 25 intrinsic value method of accounting for stock options. This revised statement will require recognition of the cost of employee services received in exchange for awards of equity instruments based on the fair value of the award at the grant date. This cost is required to be recognized over the vesting period of the award. The stock-based compensation table in Note 1 illustrates the effect on net income and earnings per share if we had applied the fair value recognition provisions of SFAS 123 to stock-based employee compensation. SFAS 123(R) applies to all awards granted, modified, repurchased, or cancelled after June 30, 2005. We will early-adopt SFAS 123(R) effective January 1, 2005, using the modified prospective method. As a result of the adoption of this statement, our compensation expense for share-based payments is expected to be approximately \$450 million in 2005 (\$300 million net of related tax effects), assuming target levels are achieved for incentive-based equity awards.

Note 3: Acquisitions and Collaboration

Applied Molecular Evolution, Inc. Acquisition

On February 12, 2004, we acquired all the outstanding common stock of Applied Molecular Evolution, Inc. (AME) in a tax-free merger. Under the terms of the merger agreement, each outstanding share of AME common stock was exchanged for our common stock or a combination of cash and our stock valued at \$18. The aggregate purchase price of approximately \$442.8 million consisted of issuance of 4.2 million shares of our common stock valued at \$314.8 million, issuance of 0.7 million replacement options to purchase shares of our common stock in exchange for the remaining outstanding AME options valued at \$37.6 million, cash of \$85.4 million for AME common stock and options for certain AME employees, and transaction costs of \$5.0 million. The fair value of our common stock was derived using a per-share value of \$74.14, which was our average closing stock price for February 11 and 12, 2004. The fair value for the options granted was derived using a Black-Scholes valuation method using assumptions consistent with those we used in valuing employee options. Replacement options to purchase our common stock granted as part of this acquisition have terms equivalent to the AME options being replaced.

In addition to acquiring the rights to two compounds currently under development, we expect the acquisition of AME's protein optimization technology to create synergies that will accelerate our ability to discover and optimize biotherapeutic drugs for cancer, critical care, diabetes, and obesity, areas in which proteins are of great therapeutic benefit.

In accordance with SFAS 141, Business Combinations, the acquisition has been accounted for as a purchase business combination. Under the purchase method of accounting, the assets acquired and liabilities assumed from AME at the date of acquisition are recorded at their respective fair values as of the acquisition date in our consolidated financial statements. The excess of the purchase price over the fair value of the acquired net assets has been recorded as goodwill in the amount of \$9.6 million. Goodwill resulting from this acquisition has been fully allocated to the pharmaceutical products segment. No portion of this goodwill is expected to be deductible for tax purposes. AME's results of operations are included in our consolidated financial statements from the date of acquisition.

As of the date of acquisition, we determined the following estimated fair values for the assets purchased and liabilities assumed. The determination of estimated fair value requires management to make significant estimates and assumptions. We hired independent third parties to assist in the valuation of assets that were difficult to value.

Estimated Fair Value at February 12, 2004

| | | |
|--|----|--------------|
| Cash and short-term investments | \$ | 38.7 |
| Acquired in-process research and development | | 362.3 |
| Platform technology | | 17.9 |
| Goodwill | | 9.6 |
| Other assets and liabilities—net | | 14.3 |
| Total estimated purchase price | \$ | <u>442.8</u> |

The acquired in-process research and development (IPR&D) represents compounds currently under development that have not yet achieved regulatory approval for marketing. The estimated fair value of these intangible assets was derived using a valuation from an independent third party. AME's two lead compounds for the treatment of non-Hodgkin's lymphoma and rheumatoid arthritis represent approximately 80 percent of the estimated fair value of the IPR&D. In accordance with FIN 4, Applicability of FASB Statement No. 2 to Business Combinations Accounted for by the Purchase Method, these IPR&D intangible assets have been written off by a charge to income immediately subsequent to the acquisition because the compounds do not have any alternative future use. This charge is not deductible for tax purposes. The ongoing activity with respect to each of these compounds under development is not material to our research and development expenses.

There are several methods that can be used to determine the estimated fair value of the acquired IPR&D. 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. The discount rate we used in valuing the acquired IPR&D projects was 18.75 percent.

Product Acquisition

In October 2004, we entered into an agreement with Merck KGaA (Merck) to acquire Merck's compound for a



potential treatment for insomnia. At the inception of this agreement, this compound was in the development stage (Phase I clinical trials) and no alternative future uses were identified. As with many development phase compounds, launch of the product, if approved, is not expected in the near term. Our charge for acquired in-process research and development expense related to this arrangement was \$29.9 million in the fourth quarter of 2004.

Amylin Collaboration

In September 2002, we entered into a collaboration arrangement with Amylin Pharmaceuticals, Inc. (Amylin), to jointly develop and commercialize Amylin's synthetic exendin-4 compound, a potential new treatment for type 2 diabetes. The ongoing activity with respect to this agreement is not material to our research and development expenses.

At the inception of this collaboration, this compound was in the development phase and no alternative future uses were identified. As with many development phase compounds, launch of the product, if approved, was not expected in the near term. Our charge for acquired in-process research and development expense related to this arrangement totaled \$84.0 million in 2002.

In conjunction with this collaboration arrangement, we also entered into a loan agreement. Following the successful completion of the ongoing clinical trials and contingent upon certain other events, we have agreed to loan Amylin up to \$110 million during the development period of the product, repayable in cash or Amylin stock at our option. As of December 31, 2004, no loans to Amylin were outstanding.

Note 4: 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 income are described below.

In the fourth quarter of 2004, management approved actions designed to increase productivity, to address current challenges in the marketplace, and to leverage prior investments in our product portfolio. These actions, which are described further below, affect primarily operations in the manufacturing, research and development, and sales and marketing components and resulted in asset impairments, severance and other related charges. We expect to substantially complete the restructuring activities by March 31, 2005, although certain activities may require additional time for completion throughout 2005.

We discontinued our plans to produce the bulk active ingredient for Xigris at our Indianapolis operations. Although we remain committed to this important lifesaving product, we have determined that our manufacturing partner, Lonza Biologics plc, has enough capacity to supply anticipated Xigris demand for the foreseeable future. In addition, we determined that a redesign of our Prince William County, Virginia, facility that is currently under construction was warranted. This decision rendered obsolete certain engineering and construction costs that have already been incurred. Also, the mission of our Clinton, Indiana, manufacturing site will be narrowed to make products solely for the Elanco Animal Health business. The portion of that site that currently produces human pharmaceutical products has ceased operation.

We will focus our research efforts on the therapeutic areas of neuroscience, endocrine, oncology, and cardiovascular and will discontinue our efforts in inflammation. In addition to this narrowing of therapeutic focus, we have closed our RTP Laboratory site in Research Triangle Park, North Carolina. This site has historically been our center for high-throughput screening and combinatorial chemistry, but much of that technology has evolved such that these operations can be more efficiently performed in existing facilities in Indianapolis. The site has been written down to fair value less cost to sell and is currently held for sale.

We closed all district and regional sales offices throughout the United States, and these operations are now managed from home-based offices. In addition, we have reorganized our U.S. sales force to create an organization that better meets customer needs and maximizes sales potential. We are also streamlining some sales and marketing support activities as well as our field-based operations that support our medical function.

As a result of the above actions, we recognized asset impairment charges of \$377.4 million in the fourth quarter of 2004. The charges principally relate to Xigris manufacturing equipment in Indianapolis, the Prince William County assets, human pharmaceutical manufacturing buildings and equipment in Clinton, Indiana, and the RTP Laboratory building and equipment, which are described above. We have ceased using these assets, and they will be disposed of or destroyed. The impairment charges are necessary to adjust the carrying value of the assets to fair value. Other site charges, including lease termination payments, were \$12.2 million.

In addition, nearly 1,400 positions globally were eliminated as a result of these actions. While a substantial number of the affected employees were successfully placed in other positions in the company, severance expenses were incurred in the fourth quarter of 2004 for those employees who elected a severance package. The restructuring and other special charges incurred in the fourth quarter of 2004 related to the elimination of positions totaled

\$68.5 million, including \$35.1 million of severance charges related to restructuring activities in our overseas affiliates. The severance charges consisted primarily of voluntary severance expenses. Substantially all of this charge has been expended.

The other significant component of our fourth-quarter 2004 special charges was a provision for \$36.0 million for the anticipated resolution of the previously reported Evista marketing and promotional practices investigation. See Note 13 for additional discussion.

In addition, in the second quarter of 2004, as part of our ongoing review of our manufacturing and research and development strategies to maximize performance and efficiencies, including the streamlining of manufacturing operations and research and development activities, we also made decisions that resulted in the impairment of certain assets. This review did not result in any closure of facilities or layoffs, but certain assets located at various sites were affected. We have ceased using these assets, written down their carrying value to zero, and are in the process of disposing of or destroying all of the assets. The asset impairment charges incurred in the second quarter of 2004 aggregated \$108.9 million.

Similar to 2004, during 2003, management approved global manufacturing strategies across our product portfolio to improve plant performance and efficiency, including the outsourcing of production of certain anti-infective products. These decisions resulted in the impairment of certain assets, primarily manufacturing assets in the U.S. This review did not result in any closure of facilities, but certain assets located at various manufacturing sites were affected. We have ceased using these assets, and all these assets have been disposed of or their destruction commenced. The impairment charges were necessary to adjust the carrying value of these assets to zero. These asset impairment charges incurred totaled \$142.9 million, of which \$114.6 million was incurred in the first quarter of 2003 with the remaining \$28.3 million incurred in the fourth quarter of 2003.

In December 2002, we initiated a plan of eliminating approximately 700 positions worldwide in order to streamline our infrastructure. While a substantial majority of affected employees were successfully placed in other positions in the company, severance expenses were incurred in the first quarter of 2003 for those employees who elected a severance package. The restructuring and other special charges incurred in the first quarter of 2003 were \$52.5 million, consisting primarily of voluntary severance expenses. All of this charge has been expended.

In August 2001, we licensed from Isis Pharmaceuticals, Inc. (Isis), Affinitak, a non-small-cell lung cancer drug candidate, and entered into an agreement regarding an ongoing research collaboration. In conjunction with this agreement, we purchased approximately 4.2 million shares of Isis common stock with a cost basis of approximately \$68.0 million, and we committed to loan Isis \$100 million over the four-year term of the research agreement. The Isis loan is repayable at the end of the research agreement term in cash or Isis stock, at Isis's option, using a conversion price of \$40 per share. In addition, we committed to loan Isis \$21.2 million for the building of a manufacturing suite for Affinitak. On March 17, 2003, we announced, along with Isis, the results of the Phase III trial that evaluated Affinitak when combined with chemotherapy in patients with advanced non-small-cell lung cancer. No difference was observed in the overall survival of the two groups. Due to this announcement and the decline in Isis's stock price that occurred in the previous 12 months, we concluded in the first quarter of 2003 that our investment in Isis common stock was other-than-temporarily impaired as defined by generally accepted accounting principles. For the same reasons, it was probable that the value of the consideration that we will be eligible to receive from Isis pursuant to the terms of the loan agreements will be less than the carrying amount of the loans. Therefore, in the first quarter of 2003, we recognized an impairment in our investment in Isis common stock of \$55.0 million and a reserve related to the loans of \$92.9 million. In addition, we recognized a charge of \$38.9 million for contractual obligations related to Affinitak. The primary portion of this charge resulted from our supply agreement with Isis. The supply agreement obligated us to pay certain costs associated with work-in-process and raw materials and other costs that were triggered when we canceled our order of Affinitak. The remaining portion of the charge resulted from our contractual obligations related to the conduct of Affinitak clinical trials. Substantially all our contractual obligations have been fulfilled. The stock and loan impairments and other special charges incurred in the first quarter of 2003 related to this relationship totaled \$186.8 million.

Note 5: 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 and managed care organizations 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. We place substantially all our interest-bearing investments with major financial institutions, in U.S. government securities, or with top-rated corporate issuers.

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 financial instruments but do not expect any counterparties to fail to meet their obligations given their high credit ratings.

Fair Value of Financial Instruments

A summary of our outstanding financial instruments and other investments at December 31 follows:

| | 2004 | | 2003 | |
|---|-----------------|------------|-------------------|------------|
| | Carrying Amount | Fair Value | Carrying Amount | Fair Value |
| Short-term investments | | | | |
| Debt securities | \$ 2,099.1 | \$ 2,099.1 | \$ 957.0 | \$ 957.0 |
| Noncurrent investments | | | | |
| Marketable equity | \$ 80.4 | \$ 80.4 | \$ 105.5 | \$ 105.5 |
| Debt securities | 366.1 | 366.1 | 3,173.1 | 3,173.1 |
| Equity method and other investments | 114.9 | N/A | 96.0 | N/A |
| | <u>\$ 561.4</u> | | <u>\$ 3,374.6</u> | |
| Long-term debt, including current portion | \$ 4,858.5 | \$ 4,868.6 | \$ 4,867.5 | \$ 4,874.4 |

We determine fair values based on quoted market values where available or discounted cash flow analyses (principally long-term debt). The fair value of equity method investments is not readily available and disclosure is not required. The fair value and carrying amount of risk-management instruments in the aggregate were not material at December 31, 2004 and 2003. Approximately \$2.1 billion of our investments in debt securities mature within five years.

A summary of the unrealized gains and losses (pretax) of our available-for-sale securities in other comprehensive income at December 31 follows:

| | 2004 | 2003 |
|-------------------------|---------|---------|
| Unrealized gross gains | \$ 43.7 | \$ 72.3 |
| Unrealized gross losses | 7.9 | 10.6 |

The net adjustment to unrealized gains and losses (net of tax) on available-for-sale securities increased (decreased) other comprehensive income by (\$18.2) million, \$45.4 million, and (\$45.0) million in 2004, 2003, and 2002, respectively. Activity related to our available-for-sale investment portfolio was as follows:

| | 2004 | 2003 | 2002 |
|--------------------------------|------------|------------|------------|
| Proceeds from sales | \$ 7,774.7 | \$ 5,303.7 | \$ 3,724.2 |
| Realized gross gains on sales | 37.3 | 72.1 | 57.0 |
| Realized gross losses on sales | 17.6 | 26.4 | 35.2 |

During the years ended December 31, 2004, 2003, and 2002, net losses related to ineffectiveness and net losses related to the portion of fair value and cash flow hedging instruments excluded from the assessment of effectiveness were not material.

We expect to reclassify an estimated \$47.0 million of pretax net losses on cash flow hedges of anticipated foreign currency transactions and the variability in expected future interest payments on floating rate debt from accumulated other comprehensive loss to earnings during 2005. This assumes that short-term interest rates remain unchanged from the prevailing rates at December 31, 2004.

Note 6: Borrowings

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

| | 2004 | 2003 |
|--|-------------------|-------------------|
| 4.50 to 7.13 percent notes (due 2012-2036) | \$ 1,487.4 | \$ 1,487.4 |
| 2.90 to 8.38 percent notes (due 2006-2008) | 811.4 | 811.4 |
| Floating rate bonds (due 2007-2037) | 1,424.7 | 417.8 |
| Private placement bonds (due 2007-2008) | 652.6 | 810.5 |
| Floating rate capital securities (due 2029) | — | 525.0 |
| 8.38 percent eurodollar bonds (due 2005) | 150.0 | 150.0 |
| Resetable coupon capital securities (due 2029) | — | 300.0 |
| 6.55 percent ESOP debentures (due 2017) | 93.6 | 94.6 |
| Other, including capitalized leases | 122.8 | 130.3 |
| SFAS 133 fair value adjustment | 116.0 | 140.5 |
| | 4,858.5 | 4,867.5 |
| Less current portion | 366.6 | 179.7 |
| | \$ 4,491.9 | \$ 4,687.8 |

In August 2004, we issued \$1.00 billion of floating rate notes due in 2007. The floating rate notes pay interest at the three-month LIBOR rate plus 0.05 percent (2.41 percent at December 31, 2004). We may redeem these notes in August 2005 for a defined redemption price. In March 2003, we issued \$300.0 million of 2.9 percent 5-year notes and \$200.0 million of 4.5 percent 15-year notes. In July 2002 and May 2001, we issued \$150.0 million and \$250.0 million, respectively, of floating rate bonds that mature in 2037. The variable interest rate on these bonds is at LIBOR (2.58 percent at December 31, 2004) and beginning May 15, 2004, adjusts every six months to reflect our six-month credit spread. The interest accumulates over the life of the bonds and is payable upon maturity. We have an option to begin periodic interest payments at any time. At the time of option exercise, we would owe all previously accrued interest on the bonds. Additionally, in July 2003 and July 2002, respectively, we executed a \$330.0 million and \$542.8 million private placement note with a financial institution. Principal and interest are due semiannually over the five-year terms of each of these notes. In conjunction with these notes, we entered into interest rate swap agreements with the same financial institution, which converts the fixed rate into a variable rate of interest at essentially LIBOR over the term of the notes. In March 2002, we issued \$500.0 million of 10-year 6.0 percent notes.

The floating rate capital securities paid cumulative interest at an annual rate equal to LIBOR plus a predetermined spread, reset quarterly. The rate at December 31, 2003, was 2.37 percent. The resettable coupon capital securities paid cumulative interest at an annual rate of 7.72 percent. Both the floating rate capital securities and the resettable coupon capital securities were redeemed in 2004. In 2003, we repurchased \$257.1 million of floating rate debt securities due in 2008.

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 aggregate amounts of maturities on long-term debt for the next five years are as follows: 2005, \$366.6 million; 2006, \$720.2 million; 2007, \$1.21 billion; 2008, \$392.5 million; and 2009, \$15.5 million.

At December 31, 2004 and 2003, short-term borrowings included \$1.65 billion and \$16.8 million, respectively, of notes payable to banks and commercial paper. At December 31, 2004, unused committed lines of credit totaled approximately \$1.25 billion. 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 substantially all fixed rate debt to floating rates through the use of interest rate swaps. The weighted-average effective borrowing rate based on debt obligations and interest rates at December 31, 2004 and 2003, including the effects of interest rate swaps for hedged debt obligations, was 2.7 percent.

In 2004, capitalized interest exceeded cash payments of interest on borrowings, due in large part to certain debt instruments requiring interest payments only at maturity, as previously noted. In 2003 and 2002, cash payments of interest on borrowings totaled \$44.7 million and \$54.6 million, respectively, net of capitalized interest.

In accordance with the requirements of SFAS 133, the portion of our fixed-rate debt obligations that is hedged is reflected in the consolidated balance sheet 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 7: Stock Plans

Stock options are granted to employees at exercise prices equal to the fair market value of the company's stock at the dates of grant. Generally, options vest 100 percent three years from the grant date and have a term of 10 years. Performance awards are granted to officers and key employees and are payable in shares of our common stock. The number of performance award shares actually issued, if any, varies depending upon the achievement of certain earnings-per-share targets. In general, performance awards vest 100 percent at the end of the fiscal year following the grant date. No performance awards were granted in 2002.

We have elected to follow APB Opinion 25 and related interpretations in accounting for our stock options and performance awards. See Note 1 for a calculation of our net income and earnings per share under the fair value method pursuant to SFAS 123. As discussed more fully in Note 2, we plan to adopt SFAS 123(R) effective January 1, 2005.

The weighted-average per-share fair values of the individual options and performance awards granted during 2004, 2003, and 2002 were as follows on the date of grant:

| | 2004 | 2003 | 2002 |
|------------------------|----------|----------|----------|
| Employee stock options | \$ 26.19 | \$ 20.59 | \$ 25.98 |
| Performance awards | 70.33 | 63.51 | N/A |

The fair values of the options calculated in accordance with SFAS 123 were determined using a Black-Scholes option-pricing model with the following assumptions:

| | 2004 | 2003 | 2002 |
|-------------------------|---------|---------|---------|
| Dividend yield | 1.57% | 1.50% | 1.54% |
| Volatility | 35.20% | 35.10% | 35.00% |
| Risk-free interest rate | 3.43% | 3.32% | 3.14% |
| Forfeiture rate | 0 | 0 | 0 |
| Expected life | 7 years | 7 years | 7 years |

Stock option activity during 2002-2004 is summarized below:

| | Shares of Common Stock Attributable to Options (in thousands) | Weighted-Average Exercise Price of Options |
|----------------------------------|---|--|
| Unexercised at January 1, 2002 | 67,098 | \$ 60.60 |
| Granted | 14,133 | 74.33 |
| Exercised | (3,357) | 21.18 |
| Forfeited | (1,819) | 70.95 |
| Unexercised at December 31, 2002 | 76,055 | 64.65 |
| Granted | 14,361 | 57.36 |
| Exercised | (4,379) | 22.65 |
| Forfeited | (4,047) | 70.03 |
| Unexercised at December 31, 2003 | 81,990 | 65.36 |
| Granted | 19,578 | 71.26 |
| Exercised | (4,145) | 28.45 |
| Forfeited | (3,765) | 70.46 |
| Unexercised at December 31, 2004 | 93,658 | 68.02 |

The following table summarizes information concerning outstanding and exercisable options at December 31, 2004 (shares in millions, contractual life in years):

| Range of Exercise Prices | Options Outstanding | | | Options Exercisable | |
|--------------------------------|-----------------------|--|---|-----------------------|---|
| | Number Outstanding | Weighted- Average Remaining Contractual Life | Weighted- Average Exercise Price | Number Exercisable | Weighted- Average Exercise Price |
| \$1-\$25 | 4.2 | 1.1 | \$ 22.53 | 4.2 | 22.53 |
| \$25-\$55 | 2.9 | 2.9 | 38.29 | 2.6 | 36.31 |
| \$55-\$65 | 17.0 | 6.6 | 59.33 | 5.2 | 62.39 |
| \$65-\$75 | 47.3 | 6.4 | 72.36 | 29.4 | 71.97 |
| \$75-\$95 | 22.3 | 6.5 | 77.96 | 12.7 | 79.38 |

Shares exercisable at December 31, 2004, 2003, and 2002, were 54.1 million, 48.7 million, and 44.6 million, respectively.

As noted above, 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 0.4 million shares were issued in 2002. No shares were issued in 2003 or 2004, and approximately 0.8 million shares will be issued in 2005.

At December 31, 2004, additional options, performance awards, or restricted stock grants may be granted under the 2002 Lilly Stock Plan for not more than 58.1 million shares.

Note 8: Other Assets and Other Liabilities

Our sundry assets include our capitalized computer software, prepaid retiree health benefit (Note 12), goodwill and other intangible assets (Note 1), long-term deferred income tax assets (Note 11), estimated insurance recoveries from our product litigation and environmental contingencies (Note 13), and a variety of other items. The increase in sundry assets is primarily attributable to an increase in capitalized computer software and prepaid retiree health benefits.

Our other current liabilities include our deferred income from our collaboration and out-licensing arrangements, other taxes, interest payable, deferred income tax liabilities, and a variety of other items. Major contributors to the increase in other current liabilities are interest payable, deferred income tax liabilities, and other taxes payable.

Our other noncurrent liabilities include the accrued liabilities from our pension and retiree health plans (Note 12), deferred income from our collaboration and out-licensing arrangements, product liability litigation and environmental accruals (Note 13), and a variety of other items. The decrease in other noncurrent liabilities is primarily attributable to a decrease in deferred income from collaboration and out-licensing arrangements offset by an increase to accrued liabilities from our pension and retiree health plans.

None of the components of sundry assets exceeds 5 percent of total assets, and none of the components of other current liabilities or other noncurrent liabilities exceeds 5 percent of current or total liabilities, respectively.

Note 9: Shareholders' Equity

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

| | Additional Paid-in Capital | Retained Earnings | Deferred Costs—ESOP | Common Stock in Treasury | |
|--|-------------------------------|----------------------|------------------------|--------------------------|----------|
| | | | | Shares (in thousands) | Amount |
| Balance at January 1, 2002 | \$ 2,610.0 | \$ 7,411.2 | \$ (129.1) | 985 | \$ 107.4 |
| Net income | | 2,707.9 | | | |
| Cash dividends declared per share: \$1.27 | | (1,370.7) | | | |
| Retirement of treasury shares | (393.9) | | | (4,677) | (396.8) |
| Purchase for treasury | | | | 4,532 | 389.2 |
| Issuance of stock under employee stock plans | 131.8 | | | 168 | 9.7 |
| ESOP transactions | 13.8 | | 5.8 | | |
| Reclassification | 248.3 | (248.3) | | | |
| Balance at December 31, 2002 | 2,610.0 | 8,500.1 | (123.3) | 1,008 | 109.5 |
| Net income | | 2,560.8 | | | |
| Cash dividends declared per share: \$1.36 | | (1,465.4) | | | |
| Retirement of treasury shares | (289.1) | | | (3,180) | (291.2) |
| Purchase for treasury | | | | 2,976 | 276.8 |
| Issuance of stock under employee stock plans | 150.4 | | | 148 | 9.1 |
| ESOP transactions | 13.6 | | 4.7 | | |
| Reclassification | 125.1 | (125.1) | | | |
| Balance at December 31, 2003 | 2,610.0 | 9,470.4 | (118.6) | 952 | 104.2 |
| Net income | | 1,810.1 | | | |
| Cash dividends declared per share: \$1.45 | | (1,555.9) | | | |
| Retirement of treasury shares | (17.4) | | | (271) | (17.6) |
| Issuance of stock under employee stock plans | 163.7 | | | 262 | 17.2 |
| ESOP transactions | 13.2 | | 6.7 | | |
| Acquisition of AME | 349.9 | | | | |
| Balance at December 31, 2004 | \$ 3,119.4 | \$ 9,724.6 | \$ (111.9) | 943 | \$ 103.8 |



As of December 31, 2004, we have purchased \$2.08 billion of our announced \$3.0 billion share repurchase program. During 2004, we did not repurchase any stock pursuant to this program. We acquired approximately 3.0 million and 4.5 million shares in 2003 and 2002, respectively, under our share repurchase program. As previously disclosed, in connection with the share repurchase program, we entered into agreements to purchase shares of our stock. During the second quarter of 2003, we satisfied all our remaining obligations under the agreements.

We have 5 million authorized shares of preferred stock. As of December 31, 2004 and 2003, no preferred stock has been issued.

We have funded an employee benefit trust with 40 million shares of Lilly common stock to provide a source of funds to assist us in meeting our obligations under various employee benefit plans. The funding had no net impact on shareholders' equity as we consolidated the employee benefit trust. The cost basis of the shares held in the trust was \$2.64 billion and is shown as a reduction in shareholders' equity, which offsets the resulting increases of \$2.61 billion in additional paid-in capital and \$25 million in common stock. 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 2004, 2003, or 2002.

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 million of third-party debt, repayment of which was guaranteed by us (see Note 6). 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.

Under a Shareholder Rights Plan adopted in 1998, all shareholders receive, along with each common share owned, a preferred stock purchase right entitling them to purchase from the company one one-thousandth of a share of Series B Junior Participating Preferred Stock (the Preferred Stock) at a price of \$325. The rights are exercisable only after the Distribution Date, which is generally the 10th business day after the date of a public announcement that a person (the Acquiring Person) has acquired ownership of 15 percent or more of our common stock. We may redeem the rights for \$.005 per right, up to and including the Distribution Date. The rights will expire on July 28, 2008, unless we redeem them earlier.

The rights plan provides that, if an Acquiring Person acquires 15 percent or more of our outstanding common stock and our redemption right has expired, generally each holder of a right (other than the Acquiring Person) will have the right to purchase at the exercise price the number of shares of our common stock that have a value of two times the exercise price.

Alternatively, if, in a transaction not approved by the board of directors, we are acquired in a business combination transaction or sell 50 percent or more of our assets or earning power after a Distribution Date, generally each holder of a right (other than the Acquiring Person) will have the right to purchase at the exercise price the number of shares of common stock of the acquiring company that have a value of two times the exercise price.

At any time after an Acquiring Person has acquired 15 percent or more but less than 50 percent of our outstanding common stock, the board of directors may exchange the rights (other than those owned by the Acquiring Person) for our common stock or Preferred Stock at an exchange ratio of one common share (or one one-thousandth of a share of Preferred Stock) per right.

Note 10: Earnings per Share

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

| | 2004 | 2003 | 2002 |
|--|------------|-----------------------|------------|
| | | (Shares in thousands) | |
| Income available to common shareholders | \$ 1,810.1 | \$ 2,560.8 | \$ 2,707.9 |
| Basic earnings per share | | | |
| Weighted-average number of common shares outstanding, including incremental shares | 1,083,887 | 1,076,547 | 1,076,922 |
| Basic earnings per share | \$ 1.67 | \$ 2.38 | \$ 2.51 |
| Diluted earnings per share | | | |
| Weighted-average number of common shares outstanding | 1,083,677 | 1,076,547 | 1,076,873 |
| Stock options and other incremental shares | 5,259 | 5,683 | 8,215 |
| Weighted-average number of common shares outstanding—diluted | 1,088,936 | 1,082,230 | 1,085,088 |
| Diluted earnings per share | \$ 1.66 | \$ 2.37 | \$ 2.50 |

Note 11: Income Taxes

Following is the composition of income taxes:

| | 2004 | 2003 | 2002 |
|--|------------|----------|----------|
| Current | | | |
| Federal | \$ 47.6 | \$ 391.2 | \$ 140.1 |
| Foreign | 519.9 | 284.7 | 306.3 |
| State | (10.6) | (6.2) | (13.4) |
| | 556.9 | 669.7 | 433.0 |
| Deferred | | | |
| Federal | 175.2 | (112.9) | 366.1 |
| Foreign | (74.0) | 138.2 | (47.3) |
| State | 8.7 | 5.9 | (2.0) |
| | 109.9 | 31.2 | 316.8 |
| Unremitted earnings to be repatriated due to change in tax law | 465.0 | — | — |
| Income taxes | \$ 1,131.8 | \$ 700.9 | \$ 749.8 |

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

| | 2004 | 2003 |
|--|-----------------------|--------------|
| Deferred tax assets | | |
| Inventory | \$ 538.4 | \$ 411.8 |
| Other carryforwards | 492.5 | 411.7 |
| Sale of intangibles | 411.5 | 415.0 |
| Compensation and benefits | 320.7 | 275.9 |
| Tax credit carryforwards and carrybacks | 220.6 | 105.9 |
| Asset disposals | 165.3 | 21.0 |
| Asset purchases | 88.6 | 62.2 |
| Other | 476.8 | 506.5 |
| | 2,714.4 | 2,210.0 |
| Valuation allowances | (508.4) | (473.6) |
| Total deferred tax assets | 2,206.0 | 1,736.4 |
| Deferred tax liabilities | | |
| Prepaid employee benefits | (952.8) | (701.5) |
| Property and equipment | (681.3) | (564.5) |
| Unremitted earnings to be repatriated due to change in tax law | (465.0) | — |
| Unremitted earnings | (327.4) | (204.6) |
| Other | (215.5) | (153.3) |
| Total deferred tax liabilities | (2,642.0) | (1,623.9) |
| Deferred tax (liabilities) assets—net | \$ (436.0) | \$ 112.5 |

At December 31, 2004, we had other carryforwards, primarily net operating loss carryforwards, for international and U.S. income tax purposes of \$364.1 million: \$228.4 million will expire within five years and \$86.4 million thereafter; \$49.3 million of the carryforwards will never expire. The primary component of the remaining portion of the deferred tax asset for other carryforwards is related to net operating losses for state income tax purposes that are fully reserved. We also have tax credit carryforwards and carrybacks of \$220.6 million available to reduce future income taxes; \$53.0 million will be carried back, \$66.0 million will expire after five years, and \$16.3 million of the tax credit carryforwards will never expire. The remaining portion of the tax credit carryforwards is related to state tax credits that are fully reserved.

Domestic and Puerto Rican companies contributed approximately 6 percent, 22 percent, and 28 percent in 2004, 2003, and 2002, respectively, to consolidated income before income taxes. We have a subsidiary operating in Puerto Rico under a tax incentive grant that begins to expire at the end of 2007.

On October 22, 2004, the President of the United States signed into law the American Jobs Creation Act of 2004 (AJCA), which creates a temporary incentive for U.S. corporations to repatriate undistributed income earned abroad by providing an 85 percent dividends received deduction for certain dividends from controlled foreign corporations. Although the deduction is subject to a number of limitations and uncertainty remains as to how to interpret certain provisions of the AJCA, we believe we have the information necessary to make an informed decision on the impact of the AJCA on our repatriation plans. Based on that decision, we plan to repatriate \$8.00 billion in incentive dividends, as defined in the AJCA, during 2005 and accordingly have recorded a related tax liability of \$465.0 million as of December 31, 2004.

At December 31, 2004, we had an aggregate of \$2.8 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 taxes at approximately the U.S. statutory rate. The amount of unremitted earnings for which no tax has been provided decreased substantially in 2004 due to the change in tax law described above, which caused us to change our previous plans to permanently reinvest a portion of those unremitted earnings.

Cash payments of income taxes totaled \$487.0 million, \$614.0 million, and \$864.0 million in 2004, 2003, and 2002, respectively. The higher cash payments of income taxes in 2002 are primarily attributable to the resolution of an IRS examination.

Following is a reconciliation of the effective income tax rate applicable to income before income taxes:

| | 2004 | 2003 | 2002 |
|---|---------------|--------|--------|
| United States federal statutory tax rate | 35.0% | 35.0% | 35.0% |
| Add (deduct) | | | |
| International operations, including Puerto Rico | (19.1) | (15.7) | (12.6) |
| Additional repatriation due to change in tax law | 15.8 | — | — |
| Non-deductible acquired in-process research and development | 4.3 | — | — |
| General business credits | (1.3) | (0.7) | (0.7) |
| Sundry | 3.8 | 2.9 | — |
| Effective income tax rate | 38.5% | 21.5% | 21.7% |

Note 12: Retirement Benefits

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

| | Defined Benefit Pension Plans | | Retiree Health Benefit Plans | |
|---|-------------------------------|------------|------------------------------|----------|
| | 2004 | 2003 | 2004 | 2003 |
| Change in benefit obligation | | | | |
| Benefit obligation at beginning of year | \$ 4,703.1 | \$ 3,988.2 | \$ 1,039.6 | \$ 911.6 |
| Service cost | 238.8 | 195.4 | 47.6 | 38.2 |
| Interest cost | 286.4 | 267.2 | 62.5 | 60.4 |
| Actuarial loss | 39.7 | 105.8 | 161.2 | 17.6 |
| Benefits paid | (259.4) | (250.5) | (71.5) | (75.5) |
| Reduction in discount rate, foreign currency exchange rate changes, and other adjustments | 182.1 | 397.0 | 149.0 | 87.3 |
| Benefit obligation at end of year | 5,190.7 | 4,703.1 | 1,388.4 | 1,039.6 |
| Change in plan assets | | | | |
| Fair value of plan assets at beginning of year | 3,721.9 | 3,177.4 | 553.9 | 415.0 |
| Actual return on plan assets | 494.6 | 580.2 | 58.7 | 75.3 |
| Employer contribution | 784.0 | 153.4 | 204.3 | 139.1 |
| Benefits paid | (257.3) | (247.6) | (71.5) | (75.5) |
| Foreign currency exchange rate changes and other adjustments | 54.6 | 58.5 | — | — |
| Fair value of plan assets at end of year | 4,797.8 | 3,721.9 | 745.4 | 553.9 |
| Funded status | (392.9) | (981.2) | (643.0) | (485.7) |
| Unrecognized net actuarial loss | 2,339.7 | 2,296.5 | 979.5 | 728.2 |
| Unrecognized prior service cost (benefit) | 66.0 | 72.0 | (116.9) | (132.6) |
| Net amount recognized | \$ 2,012.8 | \$ 1,387.3 | \$ 219.6 | \$ 109.9 |

Amounts recognized in the consolidated balance sheet consisted of

| | | | | |
|--|-------------------|------------|-----------------|----------|
| Prepaid pension | \$ 2,253.8 | \$ 1,613.3 | \$ 310.4 | \$ 192.3 |
| Accrued benefit liability | (464.4) | (445.0) | (90.8) | (82.4) |
| Accumulated other comprehensive loss before income taxes | 223.4 | 219.0 | — | — |
| Net amount recognized | \$ 2,012.8 | \$ 1,387.3 | \$ 219.6 | \$ 109.9 |

| (Percents) | Defined Benefit Pension Plans | | Retiree Health Benefit Plans | |
|---|-------------------------------|------|------------------------------|------|
| | 2004 | 2003 | 2004 | 2003 |
| Weighted-average assumptions as of December 31 | | | | |
| Discount rate for benefit obligation | 5.9 | 6.2 | 6.0 | 6.2 |
| Discount rate for net benefit costs | 6.2 | 6.8 | 6.2 | 6.9 |
| Rate of compensation increase for benefit obligation | 5.6 | 5.3 | — | — |
| Rate of compensation increase for net benefit costs | 5.3 | 5.3 | — | — |
| Expected return on plan assets for net benefit costs | 9.20 | 9.27 | 9.25 | 9.25 |

In evaluating the expected return on plan assets, we have considered our historical assumptions compared with actual results, an analysis of current market conditions, asset allocations, and the views of leading financial advisers and economists. Our plan assets in our U.S. defined benefit pension and retiree health plans comprise approximately 85 percent of our worldwide benefit plan assets. Including the investment losses due to overall market conditions in 2001 and 2002, our 10- and 20-year annualized rate of return on our U.S. defined benefit pension plans and retiree health benefit plan was approximately 10.3 percent and 11.9 percent, respectively, as of December 31, 2004. Health-care-cost trend rates were assumed to increase at an annual rate of 10 percent in 2005, decreasing 1 percent per year to 6 percent in 2009 and thereafter.

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

| | Defined Benefit Pension Plans | Retiree Health Benefit Plans |
|-----------|-------------------------------|------------------------------|
| 2005 | \$ 246.4 | \$ 83.4 |
| 2006 | 249.3 | 89.5 |
| 2007 | 255.2 | 95.2 |
| 2008 | 263.6 | 100.5 |
| 2009 | 272.2 | 105.2 |
| 2010-2014 | 1,551.8 | 594.9 |

The total accumulated benefit obligation for our defined benefit pension plans was \$4.55 billion and \$3.96 billion at December 31, 2004 and 2003, 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 \$1.33 billion and \$0.78 billion, respectively, as of December 31, 2004, and \$4.70 billion and \$3.72 billion, respectively, as of December 31, 2003.

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

| Components of net periodic benefit cost | Defined Benefit Pension Plans | | | Retiree Health Benefit Plans | | |
|---|-------------------------------|-----------------|----------------|------------------------------|----------------|----------------|
| | 2004 | 2003 | 2002 | 2004 | 2003 | 2002 |
| Service cost | \$ 238.8 | \$ 195.4 | \$ 170.2 | \$ 47.6 | \$ 38.2 | \$ 34.0 |
| Interest cost | 286.4 | 267.2 | 254.3 | 62.5 | 60.4 | 64.5 |
| Expected return on plan assets | (402.2) | (382.7) | (398.0) | (60.2) | (53.6) | (50.8) |
| Amortization of prior service cost | 7.3 | 11.9 | 16.1 | (15.6) | (15.6) | (0.7) |
| Recognized actuarial loss | 99.7 | 52.4 | 21.9 | 57.8 | 50.6 | 36.0 |
| Net periodic benefit cost | \$ 230.0 | \$ 144.2 | \$ 64.5 | \$ 92.1 | \$ 80.0 | \$ 83.0 |

If the health-care-cost trend rates were to be increased by one percentage point each future year, the December 31, 2004, accumulated postretirement benefit obligation would increase by 13.9 percent and the aggregate of the service cost and interest cost components of the 2004 annual expense would increase by 14.5 percent. A one-percentage-point decrease in these rates would decrease the December 31, 2004, accumulated postretirement benefit obligation by 12.2 percent and the aggregate of the 2004 service cost and interest cost by 12.6 percent.

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 \$75.5 million, \$72.9 million, and \$41.7 million for the years 2004, 2003, and 2002, 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 2004, 2003, and 2002 were not significant.



Our U.S. defined benefit pension and retiree health benefit plan investment allocation strategy currently comprises approximately 85 percent to 95 percent growth investments and 5 percent to 15 percent fixed-income investments. Within the growth investment classification, the plan asset strategy encompasses equity and equity-like instruments that are expected to represent approximately 75 percent of our plan asset portfolio of both public and private market investments. The largest component of these equity and equity-like instruments is public equity securities that are well diversified and invested in U.S. and international small-to-large companies. The remaining portion of the growth investment classification is represented by other alternative growth investments.

Our defined benefit pension plan and retiree health plan asset allocations as of December 31 are as follows:

| (Percents) | Percentage of Pension Plan Assets | | Percentage of Retiree Health Plan Assets | |
|---|--------------------------------------|------|---|------|
| | 2004 | 2003 | 2004 | 2003 |
| Asset Category | | | | |
| Equity securities and equity-like instruments | 74 | 79 | 78 | 81 |
| Debt securities | 9 | 8 | 10 | 12 |
| Real estate | 1 | 2 | 1 | 1 |
| Other | 16 | 11 | 11 | 6 |
| Total | 100 | 100 | 100 | 100 |

In 2005, we expect to contribute approximately \$30 million to our defined benefit pension plans to satisfy minimum funding requirements for the year. In addition, we expect to contribute approximately \$75 million of additional discretionary funding in 2005 to our defined benefit plans. We also expect to contribute approximately \$100 million of discretionary funding to our postretirement health benefit plans during 2005.

Note 13: Contingencies

Three generic pharmaceutical manufacturers, Zenith Goldline Pharmaceuticals, Inc. (Zenith), Dr. Reddy's Laboratories, Ltd. (Reddy), and Teva Pharmaceuticals (Teva), have submitted abbreviated new drug applications (ANDAs) seeking permission to market generic versions of Zyprexa in various dosage forms several years prior to the expiration of our U.S. patents for the product, alleging that our patents are invalid, unenforceable, or not infringed. We filed suit against the three companies in the U.S. District Court for the Southern District of Indiana seeking a ruling that the challenges to our compound patent (expiring in 2011) are without merit. The cases have been consolidated. A trial before a district court judge in Indianapolis was held in January and February of 2004, and we are awaiting the court's decision. Regardless of the trial court ruling, we anticipate that appeals will follow. If we are unsuccessful at the trial court level, we cannot predict whether any of the generic companies would launch generic versions of Zyprexa prior to a final resolution of any appeals. We believe that the generic manufacturers' claims are without merit and we expect to prevail in this litigation. However, it is not possible to predict or determine the outcome of this litigation and, accordingly, we can provide no assurance that we will prevail. An unfavorable outcome would have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

In October 2002, we were notified that Barr Laboratories, Inc. (Barr), had submitted an ANDA with the FDA seeking permission to market a generic version of Evista several years prior to the expiration of our U.S. patents covering the product, alleging that the patents are invalid or not infringed. In November 2002, we filed suit against Barr in the U.S. District Court for the Southern District of Indiana seeking a ruling that Barr's challenges to our patents claiming the methods of use and pharmaceutical form (expiring from 2012 to 2017) are without merit. Recently, Barr has also asserted that the method of use patents are unenforceable. On September 28, 2004, the U.S. Patent and Trademark Office issued to us a new patent (expiring in 2017) directed to pharmaceutical compositions containing raloxifene. Barr has challenged this patent, alleging that the patent is invalid, unenforceable, or will not be infringed. This patent has been added to the lawsuit. The suit is in discovery and the trial is now scheduled to begin in February 2006. While we believe that Barr's claims are without merit and we expect to prevail, it is not possible to predict or determine the outcome of the litigation. Therefore, we can provide no assurance that we will prevail. An unfavorable outcome could have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

In July 2002, we received a grand jury subpoena for documents from the Office of Consumer Litigation, U.S. Department of Justice, related to our marketing and promotional practices and physician communications with respect to Evista. We received subpoenas seeking additional documents in July 2003, July 2004, and August 2004.

We continue to cooperate with the government and have provided a broad range of information concerning our U.S. marketing and promotional practices, including documents relating to communications with physicians and the remuneration of physician consultants and advisers. Based upon advanced discussions with the government to resolve this matter, which commenced in the fourth quarter of 2004, we have expensed \$36.0 million, which we believe will be sufficient to resolve the matter.

In March 2004, the office of the U.S. Attorney for the Eastern District of Pennsylvania advised us that it has commenced a civil investigation related to our U.S. marketing and promotional practices with respect to Zyprexa, Prozac, and Prozac Weekly. We are cooperating with the U.S. Attorney in this investigation and are providing a broad range of documents and information related to the investigation, including documents relating to communications with physicians and the remuneration of physician consultants and advisers. It is possible that other Lilly products could become subject to this investigation and that the outcome of this matter could include criminal charges and fines and/or civil penalties. We cannot predict or determine the outcome of this matter or reasonably estimate the amount or range of amounts of any fines or penalties that might result from an adverse outcome. It is possible, however, that an adverse outcome could have a material adverse impact on our consolidated results of operations, liquidity, and financial position. We have implemented and continue to review and enhance a broadly based compliance program that includes comprehensive compliance-related activities designed to ensure that our marketing and promotional practices, physician communications, and remuneration of health care professionals comply with promotional laws and regulations.

We have been named in approximately 140 product liability cases in the United States involving approximately 360 claimants alleging a variety of injuries from the use of Zyprexa. Most of the cases allege that the product caused or contributed to diabetes or high blood-glucose levels. The lawsuits seek substantial compensatory and punitive damages and typically accuse us of inadequately testing for and warning about side effects of Zyprexa. Many of the lawsuits also allege that we improperly promoted the drug. We are vigorously defending these suits. All the federal cases, involving approximately 330 claimants, have been or will be transferred to The Honorable Jack Weinstein in the Federal District Court for the Eastern District of New York for consolidated and coordinated pretrial proceedings. Two cases requesting certification of nationwide class actions on behalf of those who allegedly suffered injuries from the administration of Zyprexa were filed in the Federal District Court for the Eastern District of New York on April 16, 2004, and May 19, 2004, respectively. The cases seek damages for alleged personal injuries and also seek compensation for medical monitoring of individuals who have taken Zyprexa. A lawsuit was also filed that requests a class action on behalf of Iowa residents who took Zyprexa, and that case has been transferred to the federal court in New York. In addition, we have entered into agreements with various plaintiffs' counsel halting the running of the statutes of limitation (tolling agreements) with respect to more than 3,050 individuals who do not have lawsuits on file and may or may not eventually file suits. This provides counsel additional time to evaluate the potential claims. In exchange, the individuals have agreed not to file suits in state courts, and the Plaintiffs Steering Committee agreed to dismiss the personal injury claims in the two pending nationwide class actions. The class action claims seeking medical monitoring for Zyprexa patients are not affected by this agreement.

In December 2004, we were served with two lawsuits brought in state court in Louisiana on behalf of the Louisiana Department of Health and Hospitals, alleging that Zyprexa caused or contributed to diabetes or high blood-glucose levels and that we improperly promoted the drug. In these actions, which we have removed to federal court, the Department of Health and Hospitals seeks to recover the costs it paid for Zyprexa through Medicaid and other drug benefit programs and the costs the department alleges it has incurred and will incur to treat Zyprexa-related illnesses.

In early 2005, we were served with four lawsuits seeking class action status in Canada on behalf of patients who took Zyprexa. The allegations in these suits are similar to those in the litigation pending in the United States.

The number of product liability lawsuits and tolled claims relating to Zyprexa continues to increase, and we cannot predict at this time the additional number of lawsuits and claims that may be asserted. As noted, we are vigorously defending this litigation. However, product litigation of this type is inherently unpredictable, with the risk of excessive verdicts not justified by the evidence. Accordingly, it is possible that the ultimate resolution of the Zyprexa product liability litigation could have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

We have been named as a defendant in numerous product liability lawsuits involving primarily diethylstilbestrol (DES), thimerosal, and Zyprexa. With respect to current claims, we have accrued for our estimated exposures to the extent they are both probable and estimable based on the information available to us. In addition, we have accrued for certain 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 expect the cash amounts related to the accruals to be paid out over the next several years. A portion of

the costs associated with defending and disposing of these suits is covered by insurance. We estimate insurance recoverables based on existing deductibles, coverage limits, and the existing and projected future level of insolvencies among the insurance carriers.

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, taking 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 reached a settlement with our liability insurance carriers providing for coverage for certain environmental liabilities.

The litigation accruals and environmental liabilities have been reflected in our consolidated balance sheet at the gross amount of approximately \$258.4 million at December 31, 2004. Estimated insurance recoverables of approximately \$70.9 million at December 31, 2004, have been reflected as assets in the consolidated balance sheet.

While it is not possible to predict or determine the outcome of the patent, product liability, or other legal actions brought against us or the ultimate cost of environmental matters, we believe that, except as noted previously with respect to the U.S. Zyprexa and Evista patent litigation, the Zyprexa, Prozac, and Prozac Weekly marketing and promotional practices investigation, and the Zyprexa product liability litigation, 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 the consolidated results of operations in any one accounting period.

Note 14: Other Comprehensive Income (Loss)

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

| | Foreign Currency Translation Gains (Losses) | Unrealized Gains (Losses) on Securities | Minimum Pension Liability Adjustment | Effective Portion of Cash Flow Hedges | Accumulated Other Comprehensive Income (loss) |
|--------------------------------------|--|--|---|--|--|
| Beginning balance at January 1, 2004 | \$ 116.7 | \$ 42.5 | \$ (144.2) | \$ (175.1) | \$ (160.1) |
| Other comprehensive income (loss) | 434.7 | (18.2) | (2.8) | (35.0) | 378.7 |
| Balance at December 31, 2004 | \$ 551.4 | \$ 24.3 | \$ (147.0) | \$ (210.1) | \$ 218.6 |

The amounts above are net of income taxes. The income taxes related to other comprehensive income were not significant, as income taxes were generally not provided for foreign currency translation.

The unrealized gains (losses) on securities is net of reclassification adjustments of \$9.8 million, \$37.4 million, and \$11.3 million, net of tax, in 2004, 2003, and 2002, respectively, for net realized gains on sales of securities included in net income. The effective portion of cash flow hedges is net of reclassification adjustments of \$23.1 million and \$27.2 million, net of tax, in 2004 and 2003, respectively, for realized losses on foreign currency options and \$15.6 million, \$14.2 million, and \$6.5 million, net of tax, in 2004, 2003, and 2002, 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 Report on Internal Control Over Financial Reporting

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 as well as for establishing and maintaining adequate internal control over financial reporting. 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.

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. The design, monitoring, and revision of internal accounting control systems involve, among other things, management's judgments with respect to the relative cost and expected benefits of specific control measures. 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 also 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 controls over financial reporting were effective as of December 31, 2004.

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 agree, in writing, to a financial code of ethics, which further reinforces their fiduciary responsibilities.

The financial statements and internal control over financial reporting 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) and evaluate management's assessment and evidence about whether internal control over financial reporting was designed and operating effectively. Ernst & Young's attestation with respect to the fairness of presentation of the statements, management's assessment, and the effectiveness of internal control over financial reporting (see attestation reports on pages 50 and 51) are included in our annual report. Ernst & Young reports directly to the audit committee of the board of directors.

Our audit committee comprises five nonemployee members of the board of directors, all of whom are independent from our company. The committee charter, which is published in the proxy statement, outlines the members' roles and responsibilities and is consistent with the recently 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.

Sidney Taurel
Chairman of the Board, President, and Chief Executive Officer

Charles E. Golden
Executive Vice President and Chief Financial Officer
February 14, 2005

Report of Independent Registered Public Accounting Firm

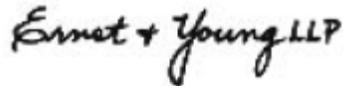
Board of Directors and Shareholders Eli Lilly and Company

We have audited the accompanying consolidated balance sheets of Eli Lilly and Company and subsidiaries as of December 31, 2004 and 2003, and the related consolidated statements of income, cash flows, and comprehensive income for each of the three years in the period ended December 31, 2004. 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, 2004 and 2003, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2004, 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), the effectiveness of Eli Lilly and Company and subsidiaries' internal control over financial reporting as of December 31, 2004, 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 14, 2005 expressed an unqualified opinion thereon.

The signature of Ernst & Young LLP is written in a cursive, handwritten style in black ink.

Indianapolis, Indiana
February 14, 2005

Report of Independent Registered Public Accounting Firm

Board of Directors and Shareholders Eli Lilly and Company

We have audited management's assessment, included in the accompanying Management's Report on Internal Control Over Financial Reporting, that Eli Lilly and Company and subsidiaries maintained effective internal control over financial reporting as of December 31, 2004, 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. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the company's internal control over financial reporting based on our audit.

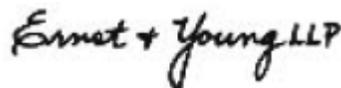
We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, 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, management's assessment that Eli Lilly and Company and subsidiaries maintained effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, Eli Lilly and Company and subsidiaries maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the 2004 consolidated financial statements of Eli Lilly and Company and subsidiaries and our report dated February 14, 2005 expressed an unqualified opinion thereon.

The signature of Ernst & Young LLP is written in a cursive, handwritten style in black ink.

Indianapolis, Indiana
February 14, 2005

Graphs in Annual Report to Shareholders
for the Year Ended December 31, 2004

Set forth below, converted to tabular format, are the graphs contained in the paper format of the Company's Annual Report to Shareholders that are contained in Exhibit 13.

Graph #1— (Contained in Chairman's letter to shareholders) Growth in Established and Newer Products

(\$ millions)

| | 2000 | 2001 | 2002 | 2003 | 2004 |
|--|---------|---------|---------|---------|---------|
| Newly Launched Growth Products <i>Strattera, Cialis, Forteo, Xigris, Cymbalta, Yentreve, Symbyax, and Alimta</i> | — | 21.2 | 108.4 | 669.5 | 1,547.9 |
| Other Established Growth Products <i>Humalog, Gemzar, Evista, and Actos</i> | 1,654.0 | 2,376.1 | 2,922.4 | 3,396.2 | 3,781.6 |
| Zyprexa | 2,349.5 | 3,086.6 | 3,688.9 | 4,276.9 | 4,419.8 |
| Prozac/Sarafem/Prozac Weekly | 2,559.1 | 1,990.0 | 733.7 | 645.1 | 559.0 |
| Other | 4,299.6 | 4,068.6 | 3,624.1 | 3,594.8 | 3,549.6 |

Combined net sales of the company's established growth and newer products – Actos, Evista, Gemzar, Humalog, Alimta, Cialis, Cymbalta, Forteo, Strattera, Symbyax, Xigris, Yentreve, and Zyprexa – increased by 17 percent over 2003, representing \$9.7 billion, or 70 percent of total net sales, compared with \$8.3 billion, or 66 percent in 2003. Zyprexa sales as a percentage of total net sales decreased from 34 percent in 2003 to 32 percent in 2004.

Graph #2—(page 9 of Annual Report) Revenues

(\$ millions)

| Product | Amount |
|------------------------------|----------|
| Zyprexa | \$ 4,420 |
| Gemzar | 1,214 |
| Humalog | 1,102 |
| Evista | 1,013 |
| Humulin | 998 |
| Strattera | 667 |
| Prozac/Sarafem/Prozac Weekly | 559 |
| Actos | 453 |
| Humatrope | 430 |
| ReoPro | 363 |

We had 10 products in 2004 with annual net revenues in excess of \$300 million. Four of these products – Zyprexa, Gemzar, Humalog, and Evista – had net revenues in excess of \$1 billion in 2004. In addition, the combined efforts of Lilly and ICOS generated worldwide Cialis sales of \$552 million.

Graph #3—(page 12 of Annual Report) Thirteen Key Products Collectively Delivered 17 Percent Increase in Net Sales

(\$ millions; percentages represent changes from 2003)

| Established Key Products | 2004 Growth | 2003 Sales | Increase |
|---------------------------------------|-------------|------------|----------|
| Gemzar | \$ 193 | \$ 1,022 | 19% |
| Zyprexa | 143 | 4,277 | 3% |
| Evista | 91 | 922 | 10% |
| Humalog | 80 | 1,021 | 8% |
| Actos | 22 | 431 | 5% |
| Newly Launched Growth Products | | | |
| Strattera | 296 | 370 | 80% |
| Forteo | 173 | 65 | 265% |
| Alimta | 143 | 0 | NM |
| Cymbalta | 94 | 0 | NM |
| Symbyax | 70 | 0 | NM |
| Cialis | 57 | 74 | 78% |
| Xigris | 41 | 160 | 26% |
| Yentreve | 4 | 0 | NM |

The company's established key products — Gemzar, Zyprexa, Evista, Humalog, and Actos — grew \$528 million (7 percent) and generated \$8.2 billion of total net sales in 2004. In addition, sales of our newly launched growth products — Strattera, Forteo, Alimta, Cymbalta, Symbyax, Cialis (non-joint-venture territories), Xigris, and Yentreve — doubled, generating \$1.5 billion of net sales in 2004. We expect our newer products to approximate 20 percent of total sales in 2005. Combined, all our key products grew 17 percent.

Graph #4—(page 13 of Annual Report) Gross Margin

(as a percent of total net sales)

| Year | Percent |
|------|---------|
| 00 | 81.1% |
| 01 | 81.3% |
| 02 | 80.4% |
| 03 | 78.7% |
| 04 | 76.7% |

Gross margin as a percent of sales decreased by 2.0 percentage points to 76.7 percent. This decline was primarily due to continued investment in our manufacturing technical capabilities and capacity and the impact of foreign exchange rates, offset partially by a favorable product mix due to growth in higher margin products such as Gemzar, Strattera, Forteo, and the newly launched Alimta.

Graph #5—(page 13 of Annual Report) Research and Development

(\$ millions; percent of net sales)

| Year | Amount | Percent |
|------|--------|---------|
| 95 | 1,042 | 16.0 |
| 96 | 1,190 | 17.0 |
| 97 | 1,370 | 17.2 |
| 98 | 1,739 | 18.8 |
| 99 | 1,784 | 17.8 |
| 00 | 2,019 | 18.6 |
| 01 | 2,235 | 19.4 |
| 02 | 2,149 | 19.4 |
| 03 | 2,350 | 18.7 |
| 04 | 2,691 | 19.4 |

Research and development expenditures increased by 15 percent, to \$2.7 billion, in 2004 due to increased clinical trial and development expenses and increased incentive compensation and benefits expenses, partially offset by reimbursements for research activities from our collaboration partners. At 19 percent of net sales, we continue to be a leader in our industry peer group in proportion of revenue reinvested in research and development. This significant financial investment in our pipeline of products supports our commitment to develop best-in-class and first-in-class medicines to provide answers for the unmet medical

needs of our customers.

Graph #6—(page 16 of Annual Report) Capital Expenditures

(\$ millions)

| Year | Amount |
|------|---------|
| 00 | 677.9 |
| 01 | 884.0 |
| 02 | 1,130.9 |
| 03 | 1,706.6 |
| 04 | 1,898.1 |

Capital expenditures increased 11 percent from 2003. The continued heavy investment supported various manufacturing and research and development initiatives and related infrastructure. We expect near-term capital expenditures to remain approximately the same as 2004 levels while we continue to prepare for the long-term growth of our diabetes care and other products, as well as increased research and development activities.

Graph #7—(page 18 of the Annual Report) Return on Shareholders' Equity

(based on income from continuing operations divided by average shareholders' equity)

| Year | Percent |
|------|---------|
| 95 | 26.1% |
| 96 | 28.2% |
| 97 | 37.5% |
| 98 | 46.0% |
| 99 | 53.9% |
| 00 | 55.3% |
| 01 | 42.3% |
| 02 | 35.2% |
| 03 | 28.4% |
| 04 | 17.5% |

Return on shareholders' equity declined in 2004, to 17.5 percent. This decline is primarily attributable to additional tax expense associated with the anticipated repatriation of earnings as the result of the American Jobs Creation Act and charges related to both acquired in-process research and development and restructuring activities. In addition, we made substantial investments in our manufacturing operations and research and development activities.

Graph #8—(page 18 of the Annual Report) Dividends Paid Per Share

(dollars)

| Year | Amount |
|------|--------|
| 00 | 1.04 |
| 01 | 1.12 |
| 02 | 1.24 |
| 03 | 1.34 |
| 04 | 1.42 |

Dividends paid during 2004 increased to \$1.42 per share. This constitutes the 37th consecutive increase in annual dividends. The company also continues this tradition into 2005 by declaring a first-quarter 2005 dividend of \$.38 per share, a 7 percent increase over first-quarter 2004. This record clearly reflects our continued commitment to delivering outstanding shareholder value.

Exhibit 21 — List of Subsidiaries and Affiliates

**The following are the subsidiaries and affiliated corporations of the Company at December 31, 2004.
Certain subsidiaries have been omitted as they are not significant in the aggregate.**

| | State or Jurisdiction of Incorporation or Organization |
|--|--|
| ELI LILLY AND COMPANY | Indiana |
| Eli Lilly International Corporation | Indiana |
| Lilly HK Finance I Limited | Hong Kong |
| Lilly HK Finance II Limited | Hong Kong |
| Eli Lilly Funding Partnership | Hong Kong |
| Eli Lilly Funding II Partnership | Hong Kong |
| Eli Lilly Holdings Ltd. | United Kingdom |
| Eli Lilly Group Limited | United Kingdom |
| Eli Lilly Group Pension Trustees Limited | United Kingdom |
| Eli Lilly and Company Limited | United Kingdom |
| Eli Lilly and Company (Ireland) Trustees Limited | Ireland |
| Lilly Pharma Holding GmbH | Germany |
| Lilly Deutschland GmbH | Germany |
| Lilly Pharma Fertigung & Distribution GmbH | Germany |
| Lilly Pharma Produktion GmbH & Co. KG | Germany |
| Lilly Forschung GmbH | Germany |
| Eli Lilly Ges.m.b.H. | Austria |
| Lilly GmbH | Germany |
| Eli Lilly Danmark A/S | Denmark |
| OY Eli Lilly Finland AB | Finland |
| Eli Lilly and Company (Ireland) Limited | Ireland |
| Eli Lilly Norge A.S. | Norway |
| Eli Lilly Sweden AB | Sweden |
| ELCO Insurance Company Limited | Bermuda |
| Lilly Turkey A.S. | Turkey |
| Eli Lilly Interamerica, Inc. | Indiana |
| Eli Lilly do Brasil Limitada | Brazil |
| Elanco Quimica Limitada | Brazil |
| Darilor Sociedad Anonima | Uruguay |
| Beirmirco Sociedad Anonima | Uruguay |
| Eli Lilly Interamerica Inc., y Compania Limitada | Chile |
| ELCO International Sales Corporation | U.S. Virgin Islands |
| Control Diabetes Services, Inc. | Indiana |
| STC Pharmaceuticals | Indiana |
| Integrated Medical Systems, Inc. | Colorado |

| ELI LILLY AND COMPANY (continued) | <u>State or Jurisdiction of Incorporation or Organization</u> |
|---|---|
| Lilly ICOS LLC | Delaware |
| Eli Lilly Finance, S.A. | Switzerland |
| Lilly Del Mar, Inc. | British Virgin Islands |
| Scienteur Corporation | Indiana |
| InnoCentive, Inc. | Delaware |
| Lilly Global Services, Inc. | Indiana |
| Applied Molecular Evolution | Delaware |
| Novasite Pharmaceuticals | Delaware |
| AME Torreview LLC | Delaware |
| Eli Lilly Funding Ltd. | Hong Kong |
| Dista, Inc. | Indiana |
| Eli Lilly Holding Company Ltd. | United Kingdom |
| Eli Lilly Holding GmbH | Germany |
| Eli Lilly Spain Holding ETVE, S.L. | Spain |
| Eli Lilly Nederland Holding B.V. | Netherlands |
| Eli Lilly and Company (Tawian), Inc. | Taiwan |
| Eli Lilly de Centro America, S.A. | Guatemala |
| Eli Lilly de Centro America, Sociedad Anonima | Costa Rica |
| Eli Lilly y Compania de Mexico, S.A. de C.V. | Mexico |
| Dista Mexicana, S.A. de C.V. | Mexico |
| Eli Lilly Industries, Inc. | Delaware |
| Del Sol Financial Services, Inc. | British Virgin Islands |
| Lilly del Caribe, Inc. | Cayman Islands |
| ELCO Dominicana, S.A. | Dominican Republic |
| Eli Lilly Asia, Inc. | Delaware |
| Eli Lilly Australia Pty. Limited | Australia |
| Eli Lilly Australia Custodian Pty. Limited | Australia |
| Eli Lilly and Company (N.Z.) Limited | New Zealand |
| Eli Lilly (NZ) Staff Benefits Custodian Limited | New Zealand |
| L E Heston Energy LLC | Delaware |

| ELI LILLY AND COMPANY (continued) | State or Jurisdiction of Incorporation or Organization |
|--|--|
| Eli Lilly de Mexico, S.A. de C.V. | Mexico |
| Lilly Systems Biology Pte. Ltd. | Singapore |
| Lilly Holdings, LLC | Delaware |
| Lilly Holdings GmbH | Austria |
| ELCO Management, Inc. | Delaware |
| Eli Lilly S.A. | Switzerland |
| Eli Lilly Export S.A. | Switzerland |
| Eli Lilly (Suisse) S.A. | Switzerland |
| Eli Lilly Vostok S.A., Geneva | Switzerland |
| Oldfields Financial Management S.A. | Switzerland |
| GEMS Services S.A. | Belgium |
| Eli Lilly Suzhou Pharmaceutical Co. Ltd. | China |
| Eli Lilly Nederland B.V. | Netherlands |
| ELCO Participation, sarl | France |
| Lilly France S.A.S. | France |
| ELSA France, S.A. | France |
| LICO sarl | France |
| Eli Lilly Benelux, S.A. | Belgium |
| Eli Lilly Italia S.p.A. | Italy |
| Dista-Produtos Quimicos & Farmaceuticos, LDA | Portugal |
| Lilly-Farma, Produtos Farmaceuticos, Lda. | Portugal |
| Vital Pharma Productos Farmaceuticos | Portugal |
| Elanco-Valquimica, S.A. | Spain |
| Dista, S.A. | Spain |
| Spaly Bioquimica, S.A. | Spain |
| Irisfarma S.A. | Spain |
| Lilly S.A. | Spain |
| Eli Lilly Nigeria Ltd. | Nigeria |
| Lilly Development Centre, S.A. | Belgium |
| Lilly Services, S.A. | Belgium |
| Lilly Clinical Operations S.A. | Belgium |
| Eli Lilly CR s.r.o. | Czech Republic |
| Eli Lilly Egypt | Egypt |
| ELCO Foreign Trade and Marketing SAE | Egypt |
| Pharmaserve-Lilly S.A.C.I. | Greece |
| Phrambrand, S.A.C.I. | Greece |
| PRAXICO Ltd. | Hungary |
| Lilly Hungaria KFT | Hungary |
| PaRxner B.V. | Netherlands |
| Eli Lilly (Philippines), Incorporated | Philippines |
| Eli Lilly and Company (India) Pvt. Ltd. | India |
| Eli Lilly Israel Ltd. | Israel |
| Dista Italia S.r.L. | Italy |

| | <u>State or Jurisdiction of Incorporation or Organization</u> |
|--|---|
| ELI LILLY AND COMPANY (continued) | |
| ELCO Management, Inc. (continued) | |
| Eli Lilly S.A. (continued) | |
| Eli Lilly Nederland B.V. (continued) | |
| Eli Lilly Japan K.K. | Japan |
| Lilly Korea Ltd. | Korea |
| Elanco Animal Health, Korea, Ltd. | Korea |
| Eli Lilly Malaysia Sdn. Bhd. | Malaysia |
| Eli Lilly Maroc, S.a.r.l. | Morocco |
| TDM B.V. | Netherlands |
| Eli Lilly Pakistan (Pvt.) Ltd. | Pakistan |
| Eli Lilly Polska Sp.z.o.o. (Ltd.) | Poland |
| Vitalia Pharma Sp.Z.o.o. | Poland |
| Eli Lilly Singapore Pte. Ltd. | Singapore |
| Lilly-NUS Centre for Clinical Pharmacology | Singapore |
| Eli Lilly (S.A.) (Proprietary) Limited | South Africa |
| Eli Lilly y Compania de Venezuela, S.A. | Venezuela |
| Dista Products & Compania Venezuela S.A. | Venezuela |
| Eli Lilly Regional Operations GmbH | Austria |
| Andean Technical Operations Center | Peru |
| Eli Lilly Asian Operations, Limited | Hong Kong |
| Dista Ilac Ticaret Ltd. Sti. | Turkey |
| Eli Lilly Slovakia s.r.o. | Slovakia |
| Eli Lilly Romania SRL | Romania |
| Lilly Pharma Ltd. | Russia |
| Elanco Trustees Limited | Ireland |
| Kinsale Financial Services, Ltd. | Ireland |
| ELGO Insurance Company Limited | Bermuda |
| E L Management LLC | Delaware / Canada |
| Eli Lilly Canada Inc. | Canada |
| Eli Lilly Denmark Holding ApS | Denmark |

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in this Annual Report (Form 10-K) of Eli Lilly and Company of our reports dated February 14, 2005, with respect to the consolidated financial statements of Eli Lilly and Company, Eli Lilly and Company management's assessment of the effectiveness of internal control over financial reporting, and the effectiveness of internal control over financial reporting of Eli Lilly and Company, included in the 2004 Annual Report to Shareholders of Eli Lilly and Company.

We consent to the incorporation by reference in the following Registration Statements:

| Registration Statement No. | Type of Statement | Date |
|----------------------------|-------------------|---------------------|
| 33-37341 | S-8 | October 17, 1990 |
| 33-58466 | S-3 | February 17, 1993 |
| 33-50783 | S-8 | October 27, 1993 |
| 33-56141 | S-8 | October 24, 1994 |
| 333-02021 | S-8 | March 28, 1996 |
| 333-62015 | S-8 | August 21, 1998 |
| 333-66113 | S-8 | October 26, 1998 |
| 333-90397 | S-8 | November 5, 1999 |
| 333-35248 | S-3 | April 20, 2000 |
| 333-70308 | S-8 | September 27, 2001 |
| 333-104057 | S-8 | March 27, 2003 |
| 333-106478 | S-3/A | September 16, 2003; |

of our reports dated February 14, 2005, with respect to the consolidated financial statements of Eli Lilly and Company, Eli Lilly and Company management's assessment of the effectiveness of internal control over financial reporting, and the effectiveness of internal control over financial reporting of Eli Lilly and Company incorporated by reference in the 2004 Annual Report (Form 10-K) of Eli Lilly and Company.

/s/ Ernst & Young LLP

Ernst & Young LLP

Indianapolis, Indiana
March 4, 2005

CERTIFICATIONS

I, Sidney Taurel, chairman of the board, president, and chief executive officer, certify that:

1. I have reviewed this report on Form 10-K of Eli Lilly and Company;
 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;
 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
-

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

- a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
- b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 8, 2005

By: /s/ Sidney Taurel
Sidney Taurel
Chairman of the Board, President,
and Chief Executive Officer

CERTIFICATIONS

I, Charles E. Golden, executive vice president and chief financial officer, certify that:

1. I have reviewed this report on Form 10-K of Eli Lilly and Company;
 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;
 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
-

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

- a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
- b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 8, 2005

By: /s/ Charles E. Golden
Charles E. Golden
Executive Vice President
and Chief Financial Officer

Exhibit 32 Section 1350 Certification

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of Eli Lilly and Company, an Indiana corporation (the "Company"), does hereby certify that, to the best of their knowledge:

The Annual Report on Form 10-K for the year ended December 31, 2004 (the "Form 10-K") of the Company fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 and information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date March 8, 2005

/s/ Sidney Taurel

Sidney Taurel
Chairman of the Board, President, and
Chief Executive Officer

Date March 8, 2005

/s/ Charles E. Golden

Charles E. Golden
Executive Vice President and
Chief Financial Officer

EXHIBIT 99. Cautionary Statement Under Private Securities Litigation Reform Act of 1995 —
“Safe Harbor” for Forward-Looking Disclosures

Certain forward-looking statements are included in this Form 10-K and may be made by spokespersons based on then-current expectations of management. All forward-looking statements made by us are subject to risks and uncertainties. One can identify forward-looking statements by the use of words such as “expects,” “plans,” “will,” “estimates,” “forecasts,” “projects,” “believes,” “anticipates,” and other words of similar meaning. Forward-looking statements do not relate strictly to historical or current facts. They are likely to address our growth strategy, financial results, regulatory issues, and status of product approvals, development programs, litigation, and investigations.

Certain factors, including but not limited to those listed below, may cause actual results to differ materially from current expectations and historical results.

- Competitive factors can lead to declining demand for our products. These factors include new patented products or expanded indications for existing products introduced by competitors; generic competition as patents on key products expire; and pricing pressures, both in the U.S. and abroad.
- Government health care cost-containment measures can significantly affect our sales and profitability. These include federal, state, and foreign laws and regulations that negatively affect pharmaceutical pricing, such as Medicaid and Medicare; pharmaceutical importation laws; and other laws and regulations that, directly or indirectly, impose governmental controls on the prices at which our products are sold.
- There are many difficulties and uncertainties inherent in new product development and introduction of new products. 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. In addition, it can be very difficult to predict sales growth rates of new products.
- Delays and uncertainties in the FDA approval process and the approval processes in other countries can result in delays in product launches and lost market opportunity.
- Unexpected safety or efficacy concerns can arise with respect to marketed products, whether or not scientifically justified, leading to product recalls, withdrawals, or declining sales.
- Patent challenges, including challenges to our patents by generic pharmaceutical manufacturers under the Hatch-Waxman Act or patent infringement suits brought against us by other patent holders, can cause us to prematurely lose market exclusivity for, or preclude commercialization of, our products. In particular, see Part I, Item 3 for a discussion of Hatch-Waxman Act challenges to our patents for Zyprexa and Evista.
- Changes in inventory levels maintained by pharmaceutical wholesalers can cause reported sales for a particular period to differ significantly from underlying prescriber demand.
- Regulatory issues concerning compliance with current Good Manufacturing Practice (cGMP) regulations for pharmaceutical products can lead to product recalls and seizures, interruption of production, and delays in the approvals of new products pending resolution of the cGMP issues.

- Other legal factors, including product liability or other liability claims, marketing and promotional practices investigations, antitrust and pricing litigation, environmental matters, and privacy regulations can result in significant expense to the company. In particular, See Part I, Item 3 for the discussions of the U.S. marketing practices investigations and the Zyprexa product liability litigation.
- We have experienced difficulties in obtaining product liability insurance due to a very restrictive insurance market, and therefore will be largely 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 on past claims.
- 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 net income.
- Economic factors over which we have no control, including changes in inflation, interest rates and foreign currency exchange rates, and overall economic conditions in volatile areas can affect our results of operations.
- Changes in accounting standards promulgated by the Financial Accounting Standards Board, the Securities and Exchange Commission, the American Institute of Certified Public Accountants, and the Emerging Issues Task Force can affect reported results.
- Our results 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.

End of Filing

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