



## 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, 2001

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:

Title of Each Class	Name of Each Exchange On Which Registered
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. [X]

Aggregate market value of voting stock of the Registrant held by non-affiliates as of February 15, 2002 (Common Stock): approximately \$73,441,600,000.

Number of shares of common stock outstanding as of February 15, 2002: 1,124,012,174.

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

Registrant's Document	Parts Into Which Incorporated
Annual Report to Shareholders for fiscal year ended December 31, 2001	Parts I, II, and IV
Proxy Statement dated March 4, 2002	Part III

## 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. Operations of our animal health business segment 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 26 other countries. Our products are sold in approximately 160 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 diagnose, 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 products include:

Neuroscience products, our largest-selling product group, including Zyprexa®, a product for the treatment of schizophrenia and acute bipolar mania; Prozac®, indicated for the treatment of depression and, in many countries, for bulimia and obsessive-compulsive disorder; the Darvon® line of analgesic products; Permax®, a treatment for Parkinson’s disease; and Sarafem™, for the treatment of pre-menstrual dysphoric disorder;

Endocrine products, including Humulin®, human insulin produced through recombinant DNA technology; Humalog® and Humalog Mix 75/25®, rapid-acting injectable human insulin analogs of recombinant DNA origin; Iletin®, animal-source insulin; Actos®, an oral agent for Type 2 diabetes that is manufactured and sold by a unit of Takeda Chemical Industries, Ltd. of Japan (“Takeda”) and co-promoted by us in the U.S. and certain other countries and sold by us alone in other countries; Evista®, an oral agent for the prevention and treatment of osteoporosis in post-menopausal women; and Humatrope®, human growth hormone produced by recombinant DNA technology;

Anti-infectives, including the oral antibiotics Ceclor®, Dynabac®, Keflex®, Keftab®, and Lorabid®, used in the treatment of a wide range of bacterial infections; Vancocin® HCl, an injectable antibiotic used primarily to treat staphylococcal infections; and the injectable antibiotics Nebcin®, Tazidime®, Kefurox®, and Kefzol®, used to treat a wide range of bacterial infections in the hospital setting;

Oncology products, including Gemzar®, indicated for treatment of pancreatic cancer and, in combination with other agents, for treatment of non-small-cell lung cancer; Oncovin®, indicated for treatment of acute leukemia and, in combination with other oncolytic agents, for treatment of several different types of advanced cancers; Velban®, used in a variety of cancers; and Eldisine®, indicated for treatment of acute childhood leukemia resistant to other drugs;

Animal health products, including Tylan®, an antibiotic used to control certain diseases in cattle, swine, and poultry and to improve feed efficiency and growth; 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; and Paylean®, a leanness and performance enhancer for swine;

Cardiovascular agents, including ReoPro®, a monoclonal antibody product developed and manufactured by Centocor, Inc. (a unit of Johnson & Johnson) and co-marketed by Centocor and us for use as an adjunct to percutaneous coronary intervention (“PCI”), including patients undergoing angioplasty, atherectomy or stent placement; Xigris™, a novel biotech agent to treat adults with severe sepsis at high risk of death; Dobutrex®, an agent for cardiac decompensation; and Cynt™, marketed outside the United States for treatment of hypertension; and

An antiulcer agent, Axid®.

## **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 approximately 35 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 Corporation, Cardinal Health, Inc., and McKesson Corporation – each accounted for between 19 and 23 percent of our consolidated net sales in 2001. No other distributor accounted for more than 10 percent of consolidated net sales. We also sell pharmaceutical products directly to the United States government and other manufacturers, but those sales are not material.

We promote our major pharmaceutical products in the United States through sales representatives who call upon physicians, wholesalers, hospitals, managed-care organizations, retail pharmacists, and other health care professionals. To support our sales representatives’ efforts, 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 dedicated to product lines or practice areas, such as primary care, neuroscience, diabetes care, critical care, cardiovascular, endocrinology, and oncology. We have entered into licensing arrangements under which other companies market certain products manufactured by the Company, such as Axid, Lorabid, and Permax.

Large purchasers of pharmaceuticals, such as managed-care groups and government 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 Company 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.

## **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 Catalytica, Inc. (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.

The majority of our sales abroad are of products manufactured wholly or in part abroad. However, a principal source of active ingredients for those manufactured products continues to be our facilities in the United States.

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. Consequently, 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 can 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 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 standard of intellectual property protection for pharmaceuticals varies widely. While many countries have reasonably strong patent laws, other countries currently provide little or no effective protection for inventions or other intellectual property rights. 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 possible that changes to this agreement will be made in the future that will diminish or further delay its implementation in developing countries. It is too soon to assess how much, if at all, we will benefit commercially from these changes.

When a product patent expires, the patent holder often loses effective market exclusivity for the product. This can result in very substantial reductions in sales of the formerly patented product, particularly in the United States. However, in some cases the innovator company can obtain additional commercial benefits through manufacturing trade secrets; later-expiring patents on processes, uses, or formulations; trademark use; or marketing exclusivity that may be available under pharmaceutical regulatory laws.

#### Our Intellectual Property Portfolio

We consider patent protection for certain products, processes, and uses—particularly that relating to Zyprexa, Gemzar, Humalog, Evista, Actos, ReoPro, Xigris and Axid—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 Axid, 2002; Zyprexa, 2011; Humalog, 2013; and ReoPro, 2015. The Gemzar compound patent in the U.S. expires in 2010, but a 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 can provide us exclusivity in the United States until at least 2012. We are in the process of extending the U.S. compound patent on the active ingredient in Evista, but, even if extended, this patent will expire substantially before 2012. In the United States, Actos will be protected by a compound patent through the duration of our co-promotion agreement, which runs 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 until at least 2015.

The United States compound patent covering Prozac expired in 2001. We hold another patent for the method of use of Prozac's active ingredient which expires in December 2003, but the patent claim to that use was ruled invalid by the U.S. Court of Appeals for the Federal Circuit. Generic competition for Prozac entered the U.S. market in August, 2001, resulting in a very rapid and substantial decline in U.S. Prozac sales. Outside the United States, Prozac patents generally either have expired or will expire over the next several years.

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 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. For example, the loss of the 2003 patent on Prozac described above was the result of a Paragraph IV patent challenge. Also, in 2001 we successfully defeated a Paragraph IV challenge to our patents covering Axid. In 2001, two generic drug manufacturers, Zenith Goldline Pharmaceuticals, Inc. (“Zenith”) and Dr. Reddy’s Laboratories, Ltd. (“Reddy”) filed ANDAs challenging our Zyprexa patents under Paragraph IV certifications. We filed separate suits against Zenith and Reddy seeking rulings that the patent challenges are without merit. For more information on the Zyprexa patent litigation, see Part 1, Item 3, Legal Proceedings.

Proposals have been introduced in Congress to amend various aspects of Hatch-Waxman. In general, the proposals appear to be principally designed to encourage more Paragraph IV challenges to innovator patents. We cannot predict whether any changes will be made or what impact they would have on our business.

## 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 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 and processes with therapeutic or cost advantages, our products can be subject to progressive price reductions or decreased volume of sales, or both. New products that we introduce usually 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 manufacture the products efficiently and to market them effectively 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 outmoded from time to time as a result of products or processes developed by our competitors.

### **Government Regulation**

Our operations are regulated extensively by the federal government, to some extent by state governments, and in varying degrees by foreign governments. The Federal Food, Drug, and Cosmetic Act, other federal statutes and regulations, various state statutes and regulations, and laws and regulations of foreign governments govern to varying degrees the testing, approval, production, labeling, distribution, post-market surveillance, advertising, dissemination of information, and promotion of our products. 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 products are extensively regulated in all major world markets. In addition, our operations are subject to complex federal, state, local, and foreign environmental and occupational safety laws and regulations. We anticipate that the laws and regulations affecting the manufacture 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.

In the United States, the Omnibus Budget Reconciliation Act of 1990 requires us to provide rebates to state governments on their purchases of certain of our products under state Medicaid programs. In addition, a model waiver program has been created administratively that allows states to expand the Medicaid drug benefit to include low-income Medicare beneficiaries. 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, discounts and rebates, restrictions on physician prescription levels, restrictions on reimbursement, compulsory licenses and generic substitution.

In the U.S., branded pharmaceutical products are subject to increasing pricing pressures, which could be significantly affected by the current national debate over Medicare reform as well as by actions by individual states to reduce pharmaceutical costs for Medicaid patients, seniors, and the uninsured and underinsured. Many proposals now being considered at the federal and state levels and, in some cases, implemented at the state level, would result in government agencies demanding discounts and rebates from pharmaceutical companies that may expressly or implicitly create price controls on prescription drugs. For example, at the federal level, the administration has proposed modifying the Medicaid rebate calculation. While this change requires congressional action, it would lead to a significant increase in our Medicaid rebate liability. At the state level, examples include Florida and Michigan, which have begun to implement supplemental rebates and restricted formularies in their Medicaid programs. While legal challenges to these and other state programs have been mounted, it is unknown at this time if the courts will allow them 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 whether such proposals will be adopted or 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 and likely intensify 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 or 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 2001, we employed approximately 7,600 people in pharmaceutical and animal health research and development activities, including a substantial number of physicians, scientists holding graduate or postgraduate degrees, and highly skilled technical personnel. We expended \$1.78 billion on research and development activities in 1999, \$2.02 billion in 2000, and \$2.24 billion in 2001.

We concentrate our pharmaceutical research and development efforts in six therapeutic categories: central nervous system and related diseases; endocrine diseases, including diabetes and osteoporosis; cancer; cardiovascular diseases; infectious diseases; and inflammation. However, we remain opportunistic; therefore, we selectively pursue promising leads in other therapeutic areas. We are actively engaged in biotechnology research programs involving recombinant DNA, proteins, and genomics (the development of therapeutics through identification of disease-causing genes and their cellular function). In addition to discovering and developing new chemical entities, we look for ways to expand the value of existing products through new uses and formulations that can provide additional benefits to patients.

To supplement our internal efforts, we collaborate with independent research organizations, 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 new 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.

We also conduct extensive work in the animal sciences, including animal nutrition and physiology and veterinary medicine. Certain of our research and development activities relating to pharmaceutical products may be applicable to animal health products. An example is the search for agents that will cure infectious disease.

Drug development is time-consuming, expensive, and risky. On average, only one out of many thousands of chemical compounds discovered by researchers proves to be both medically effective and safe enough to become an approved medicine. The process from discovery to regulatory approval can take more than twelve years. Drug candidates can fail at any stage of the process, and even late-stage product 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 pharmaceutical compounds and indications in all stages of development. Among our new investigational compounds in the later stages of development are potential therapies for osteoporosis, male erectile dysfunction, depression, attention deficit/hyperactivity disorder, various cancers, stress urinary incontinence, diabetic complications, and genital herpes. Further, we are studying many other drug candidates in the earlier stages of development.

We are also developing new uses and formulations for many of our important products, such as Zyprexa, Gemzar, ReoPro, and Evista.

### **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 the total commitment to quality in all parts of our operations, including research and development, purchasing, facilities planning, manufacturing, and distribution. We have developed 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.

As a result of plant inspections in early 2001, the FDA informed us of a number of observations and issued a warning letter regarding our adherence to current Good Manufacturing Practices (cGMP). In response, we have been implementing comprehensive, companywide improvements in our manufacturing operations. In November 2001, following a reinspection of the manufacturing facilities, the FDA noted additional observations, primarily relating to computer system validation, manufacturing process reviews, and data handling. We have responded to the FDA relative to these observations and have met with agency officials to discuss our plans to address the issues raised. Approval of new products will depend on resolution of all manufacturing issues to the agency's satisfaction. The timeline for resolution of these issues is difficult to predict. A manufacturer subject to a warning letter that fails to correct cGMP deficiencies to the agency's satisfaction could be subject to interruption of production, delays in NDA approvals, recalls, seizures, fines, and other penalties. If we were to experience an extended delay in new-product approvals because of these regulatory issues, it could have a material adverse effect on our consolidated results of operations but would be unlikely to have a material adverse effect on our financial position or liquidity.

### **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 15, 2002, 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. There is no understanding between any executive officer and any other person pursuant to which the executive officer was selected.

Name	Age	Offices
Sidney Taurel	53	Chairman of the Board (since January 1999), President and Chief Executive Officer (since June 1998), and a Director
Charles E. Golden	55	Executive Vice President and Chief Financial Officer (since March 1996) and a Director
John C. Lechleiter, Ph.D.	48	Executive Vice President, Pharmaceutical Products and Corporate Development (since January 2001)
Gerhard N. Mayr	55	Executive Vice President, Pharmaceutical Operations (since October 1999)
August M. Watanabe, M.D.	60	Executive Vice President, Science and Technology (since February 1996) and a Director
Rebecca O. Kendall	54	Senior Vice President and General Counsel (since June 1998)
Pedro P. Granadillo	54	Senior Vice President (since June 1998)

### Employees

At the end of 2001, we employed approximately 41,100 people, including approximately 19,100 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 2001 Annual Report at page 31 under "Segment Information" (page 14 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. In addition, the contribution of any particular product to net income is not necessarily the same as its contribution to consolidated net sales. This is due to several factors, including the introduction of new products by us and by other manufacturers.

### Financial Information Relating to Foreign and Domestic Operations

You can find financial information relating to foreign and domestic operations in our 2001 Annual Report at page 31 under "Segment Information" (page 14 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.

## **Item 2. Properties**

Our principal domestic and international executive offices are located in Indianapolis. At December 31, 2001, 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 9.7 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 also lease sales offices in a number of cities located in the United States and abroad.

We own production and distribution facilities in 17 countries outside the United States and Puerto Rico, containing an aggregate of approximately 4.3 million square feet of floor space. Major production sites include facilities in the United Kingdom, France, Ireland, Spain, Brazil, Italy, 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 4.0 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 612,000 square feet.

We believe that none of our properties is subject to any encumbrance, easement, or other restriction that would detract materially from its value or impair its use in the operation of the business. The buildings we own are of varying ages and in good condition.

## **Item 3. Legal Proceedings**

### **Zyprexa Patent Litigation**

In February 2001, we were notified that Zenith Goldline Pharmaceuticals, Inc. ("Zenith") had submitted an abbreviated new drug application ("ANDA") seeking permission to market a generic version of Zyprexa in various dosage forms several years prior to the expiration of our U.S. patents for the product, alleging that the patents are invalid or not infringed. On April 2, 2001, we filed suit against Zenith in federal district court in Indianapolis seeking a ruling that Zenith's challenge to the U.S. compound patent (expiring in 2011) is without merit. In May 2001, we were notified that Dr. Reddy's Laboratories, Ltd. ("Reddy") had also filed an ANDA covering two dosage forms, alleging that the patents are invalid or not infringed. On June 26, 2001, we filed a similar patent infringement suit against Reddy in federal district court in Indianapolis. Thereafter, in January 2002, Reddy filed an ANDA for additional dosage forms and in February 2002, we filed an infringement suit in the same court based on Reddy's later ANDA. The cases are in the preliminary stages. We believe that the generic manufacturers' patent 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 there can be 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.

### **Prozac Patent Litigation**

Beginning in 1995, several generic manufacturers filed ANDAs for generic forms of Prozac in various dosage forms, challenging our U.S. patents. Beginning in 1996, we filed suit against those manufacturers seeking rulings that our patents are valid and enforceable. On May 30, 2001, the Court of Appeals for the Federal Circuit held that our method of use patent, expiring in late 2003, was invalid. Thereafter, generic fluoxetine entered the U.S. market in early August 2001, resulting in a very rapid and substantial

decline in Prozac sales. On October 16, 2001, we filed a petition for a writ of certiorari seeking review of the decision by the U.S. Supreme Court. On January 14, 2002, our petition was denied, bringing the litigation to an end.

#### **Other Matters**

We are currently a defendant in a variety of product liability litigation lawsuits involving primarily diethylstilbestrol (“DES”) and Prozac. In approximately 115 actions, including several with multiple claimants, plaintiffs seek to recover damages on behalf of children or grandchildren of women who ingested DES during pregnancy. In another approximately 15 actions, plaintiffs seek to recover damages as a result of the ingestion of Prozac.

In March 1996, the U.S. Federal Trade Commission (“FTC”) commenced a non-public antitrust investigation focusing on the pharmaceutical industry practice of providing discounts or rebates to managed-care organizations and certain other purchasers. We have responded to two subpoenas from the FTC requesting production of certain documents and other discovery responses. We believe that all of our actions have been lawful and proper and are cooperating with the investigation.

The FTC has instituted an industrywide study into what it describes as “the use of agreements between and among pharmaceutical companies, and any other strategies, that may delay generic drug competition throughout the United States since January 1, 1991.” In April 2001, we received an order from the FTC for the production of documents and other information in connection with the agency’s investigation. The FTC has indicated that orders are being issued to approximately 100 pharmaceutical companies. We are cooperating with the agency and we believe that all of our actions have been lawful and proper.

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 believe that we are not the only pharmaceutical company to receive such a request. We are cooperating with the inquiry and we believe that all of our practices have been lawful and proper.

In December 2001, we were named as a defendant along with many other pharmaceutical manufacturers in a lawsuit in federal district court for the district of Massachusetts that purports to be nationwide class action on behalf of consumers of certain prescription drugs. The suit claims in general that as a result of alleged improprieties in the manufacturers’ calculation and reporting of average wholesale prices for purposes of Medicare reimbursement, the consumers overpaid their portion of the cost of the drugs. In February 2002, we were named as a defendant along with many other manufacturers in a similar suit brought in state court in Montana by the attorney general of Montana on behalf of consumers of certain prescription drugs in that state. We believe that all of our practices in this regard have been lawful and proper and that these suits are without merit.

We are also a defendant in other litigation, including product liability and patent suits, of a character we regard as normal to our business.

While it is not possible to predict or determine the outcome of the legal actions and investigations pending against us, we believe that except as referred to above with respect to the Zyprexa patent litigation, the costs associated with 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.

#### **Item 4. Submission of Matters to a Vote of Security Holders**

During the fourth quarter of 2001, no matters were submitted to a vote of security holders.

#### **Part II**

#### **Item 5. Market For the Company's Common Stock and Related Stockholder Matters**

You can find information relating to the principal market for our common stock and related stockholder matters, in our 2001 Annual Report under "Selected Quarterly Data (unaudited)," at page 32 (page 15 of Exhibit 13), and "Selected Financial Data (unaudited)," at page 33 (page 16 of Exhibit 13). That information is incorporated in this Report by reference.

You can find information concerning sales of equity options and other equity derivatives related to repurchases of Lilly stock in Note 9 to the consolidated financial statements, pages 41-42 of our 2001 Annual Report (pages 25-26 of Exhibit 13). All those transactions were exempt from registration under Section 4(2) of the Securities Act of 1933. No public offering or public solicitation was used in the offering of those securities. The transactions were privately negotiated, and all offerees and purchasers were accredited investors and/or qualified institutional buyers.

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

You can find selected financial data for each of our five most recent fiscal years in our 2001 Annual Report under "Selected Financial Data (unaudited)," at page 33 (page 16 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 2001 Annual Report (found at pages 1-8 of Exhibit 13):

- "Review of Operations—Operating Results—2001" (pages 19-20 and 22)
- "Review of Operations—Operating Results—2000" (pages 22-24)
- "Review of Operations—Financial Condition" (pages 24-25)
- "Review of Operations—Critical Accounting Policies" (page 25)
- "Review of Operations—Other Matters" (pages 25-26)
- "Review of Operations—Financial Expectations for 2002 and 2003" (page 26-27)
- "Review of Operations—Legal and Environmental Matters" (page 27)
- "Review of Operations—Private Securities Litigation Reform Act of 1995 – a Caution Concerning Forward-Looking Statements" (page 27)

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

**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 2001 Annual Report at “Review of Operations – Financial Condition” at pages 24-25 (page 5 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 2001 Annual Report at pages 21 and 28-30 (Consolidated Statements of Income, Consolidated Balance Sheets, Consolidated Statements of Cash Flows, and Consolidated Statements of Comprehensive Income), page 31 (Segment Information), and pages 34-46 (Notes to Consolidated Financial Statements) (together, pages 9-14 and 17-32 of Exhibit 13). You can find the Report of Independent Auditors at page 47 of the Annual Report (page 34 of Exhibit 13). All of the above information is incorporated in this Report by reference.

Also incorporated by reference is information on quarterly results of operations, which can be found in our 2001 Annual Report under “Selected Quarterly Data (unaudited),” at page 32 (page 15 of Exhibit 13).

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

None.

**Part III****Item 10. Directors and Executive Officers of the Company**

You can find information relating to our Board of Directors in our Proxy Statement dated March 4, 2002, under “Board of Directors” at pages 5-8, and information relating to our executive officers at pages 8-9 of this Form 10-K under “Executive Officers of the Company.” All of that information is incorporated in this Report by reference.

**Item 11. Executive Compensation**

You can find information on executive compensation in the Proxy Statement under “Directors’ Compensation” and “Executive Compensation” at pages 14-21. 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**

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 23 and 24. That information is incorporated in this Report by reference.

**Item 13. Certain Relationships and Related Transactions**

None.

**Part IV**

**Item 14. Exhibits, Financial Statement Schedules, and Reports on Form 8-K**

**(a)1. Financial Statements**

The following consolidated financial statements of the Company and its subsidiaries, included in our 2001 Annual Report at the pages indicated in parentheses, are incorporated by reference in Item 8:

- Consolidated Statements of Income—Years Ended December 31, 2001, 2000, and 1999 (page 21) (page 9 of Exhibit 13)
- Consolidated Balance Sheets—December 31, 2001 and 2000 (page 28) (pages 10-11 of Exhibit 13)
- Consolidated Statements of Cash Flows—Years Ended December 31, 2001, 2000, and 1999 (page 29) (page 12 of Exhibit 13)
- Consolidated Statements of Comprehensive Income—Years Ended December 31, 2001, 2000, and 1999 (page 30) (page 13 of Exhibit 13)
- Segment Information (page 31) (page 14 of Exhibit 13)
- Notes to Consolidated Financial Statements (pages 34-46) (pages 17-32 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	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
4.3	Form of Standard Multiple-Series Indenture Provisions dated, and filed with the Securities and Exchange Commission on, February 1, 1991
4.4	Form of Fiscal and Paying Agency Agreement dated February 7, 1995, between Eli Lilly and Company and Citibank, N.A., Fiscal and Paying Agent, including forms of Notes, relating to 8-3/8% Notes Due February 7, 2005 <sup>1</sup>
4.5	Form of Indenture with respect to Capital Securities dated August 5, 1999 between Lilly del Mar, Inc. and Citibank, N.A., as Trustee <sup>1</sup>
4.6	Form of Resetable Coupon Capital Security due 2029 of Lilly del Mar, Inc. <sup>1</sup>
4.7	Form of Floating Rate Capital Security due 2029 of Lilly del Mar, Inc. <sup>1</sup>
4.8	Form of Fiscal Agency Agreement dated March 22, 2001, between Eli Lilly and Company and Citibank, N.A., Fiscal Agent, relating to Puttable Reset Securities PURS <sup>SM</sup> due March 22, 2011 <sup>1</sup>
4.9	Form of Puttable Reset Securities PURS <sup>SM</sup> due March 22, 2011 <sup>1</sup>
4.10	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, 2031 <sup>1</sup>
4.11	Form of Resetable Floating Rate Debt Security due May 15, 2031 <sup>1</sup>
10.1	1989 Lilly Stock Plan, as amended <sup>2</sup>
10.2	1994 Lilly Stock Plan, as amended <sup>2</sup>
10.3	1998 Lilly Stock Plan, as amended <sup>2</sup>
10.4	The Lilly Deferred Compensation Plan, as amended <sup>2</sup>
10.5	The Lilly Directors' Deferral Plan, as amended <sup>2</sup>
10.6	The Eli Lilly and Company EVA <sup>®</sup> Bonus Plan, as amended <sup>2,3</sup>
10.7	Eli Lilly and Company Change in Control Severance Pay Plan for Select Employees, as amended <sup>2</sup>

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

<sup>2</sup> Indicates management contract or compensatory plan.

<sup>3</sup> EVA<sup>®</sup> is a registered trademark of Stern Stewart & Co.

- 10.8 Letter agreement dated September 17, 2001 between the company and Sidney Taurel, Chairman, President, and Chief Executive Officer, concerning Mr. Taurel's request that his base salary for 2002 be reduced to \$1.00<sup>2</sup>
- 12. Computation of Ratio of Earnings from Continuing Operations to Fixed Charges
- 13. Annual Report to Shareholders for the Year Ended December 31, 2001 (portions incorporated by reference into this Form 10-K)
- 21. List of Subsidiaries
- 23. Consent of Independent Auditors
- 99. Cautionary Statement under Private Securities Litigation Reform Act of 1995 — "Safe Harbor" for Forward-Looking Disclosures

**(b) Reports on Form 8-K**

The Company filed no reports on Form 8-K during the fourth quarter of 2001.

**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 25, 2002

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below on March 25, 2002 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 F. W. Bischoff</u> _____ SIR WINFRIED F. W. BISCHOFF	Director
<u>s/Martin S. Feldstein</u> _____ MARTIN S. FELDSTEIN, Ph.D.	Director

**Signature**

**Title**

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s/George M. C. Fisher

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Director

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GEORGE M. C. FISHER

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s/Karen N. Horn

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Director

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KAREN N. HORN, Ph.D.

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s/Alfred G. Gilman

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Director

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ALFRED G. GILMAN, M.D., Ph.D.

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s/Franklyn G. Prendergast

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Director

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

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s/Kathi P. Seifert

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Director

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KATHI P. SEIFERT

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s/August M. Watanabe

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Director

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AUGUST M. WATANABE, M.D.

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s/Alva O. Way

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Director

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ALVA O. WAY

**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 to the Company's Report on Form 10-Q for the quarter ended September 30, 1998
3.2	By-laws	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 Norwest Bank Minnesota, N. A., as Successor Rights Agent	Incorporated by reference from Exhibit 1 to the Company's Report on Form 8-K filed July 23, 1998
4.2	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, Registration No. 33-38347
4.3	Form of Standard Multiple-Series Indenture Provisions dated, and filed with the Securities and Exchange Commission on February 1, 1991	Incorporated by reference from Exhibit 4.2 to the Company's Registration Statement on Form S-3, Registration No. 33-38347
4.4	Form of Fiscal and Paying Agency Agreement dated February 7, 1995, between Eli Lilly and Company and Citibank, N.A., Fiscal and Paying Agent, including forms of Notes, relating to 8-3/8% Notes Due February 7, 2005	*
4.5	Form of Indenture with respect to Capital Securities dated August 5, 1999, between Lilly del Mar, Inc. and Citibank, N.A., as Trustee	*

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Exhibit		Location
4.6	Form of Resettable Coupon Capital Security due 2029 of Lilly del Mar, Inc.	*
4.7	Form of Floating Rate Capital Security due 2029 of Lilly del Mar, Inc.	*
4.8	Form of Fiscal Agency Agreement dated March 22, 2001, between Eli Lilly and Company and Citibank, N.A., Fiscal Agent, relating to Puttable Reset Securities PURS <sup>SM</sup> due March 22, 2011	*
4.9	Form of Puttable Reset Securities PURS <sup>SM</sup> due March 22, 2011	*
4.10	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, 2031	*
4.11	Form of Resettable Floating Rate Debt Security due May 15, 2031	*
10.1	1989 Lilly Stock Plan, as amended	Incorporated by reference from Exhibit 10.1 to the Company's report on Form 10-K for the year ended December 31, 2000
10.2	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
10.3	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

Exhibit		Location
10.4	The Lilly Deferred Compensation Plan, as amended	Attached
10.5	The Lilly Directors' Deferral Plan, as amended	Incorporated by reference from Exhibit 10.5 to the Company's Report on Form 10-K for the year ended December 31, 1999
10.6	The Eli Lilly and Company EVA® Bonus Plan, as amended	Attached
10.7	Eli Lilly and Company Change in Control Severance Pay Plan for Select Employees, as amended	Incorporated by reference from Exhibit 10.3 to the Company's Report on Form 10-Q for the quarter ended September 30, 2001
10.8	Letter Agreement dated September 17, 2001 between the Company and 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
12.	Computation of Ratio of Earnings to Fixed Charges	Attached
13.	Annual Report to Shareholders for the Year Ended December 31, 2001 (portions incorporated by reference in this Form 10-K)	Attached
21.	List of Subsidiaries	Attached
23.	Consent of Independent Auditors	Attached
99.	Cautionary Statement Under Private Securities Litigation Reform Act of 1995 — "Safe Harbor" for Forward-Looking Disclosures	Attached

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

THE LILLY DEFERRED COMPENSATION PLAN  
(As Amended and Restated as of August 1, 1994)

SECTION 1. ESTABLISHMENT OF THE PLAN.

There is hereby established for the benefit of Participants an unfunded plan of voluntarily deferred compensation known as "The Lilly Deferred Compensation Plan."

SECTION 2. DEFINITIONS.

When used in the Plan, the following terms shall have the definitions set forth in this Section 2:

2.1. Base Salary. The term "Base Salary" means the base salary to which a management employee is entitled for services rendered to the Company as a management employee.

2.2. Base Salary Year. The term "Base Salary Year" means each calendar year in which Base Salary deferred under the Plan is earned by a Participant.

2.3. Beneficiary. The term "Beneficiary" means the beneficiary or beneficiaries (including any contingent beneficiary or beneficiaries) designated pursuant to subsection 6.2 hereof.

2.4. Board of Directors. The term "Board of Directors" means the Board of Directors of Eli Lilly and Company.

2.5. Bonus. The term "Bonus" means the payment to which an Eligible Employee is entitled pursuant to the Contingent Compensation Plan, the Senior Executive Bonus Plan or the

Lilly Executive Bonus Plan (the EVA Bonus Plan) of the Company or any other similar compensation plan as may from time to time be designated by the Committee.

2.6. Bonus Year. The term "Bonus Year" means each calendar year in which a Bonus deferred under the Plan is earned by a Participant.

2.7. Committee. The term "Committee" means the committee designated in subsection 9.1 hereof to administer the Plan.

2.8. Company. The term "Company" means Eli Lilly and Company and its affiliates and subsidiaries.

2.9. Company Credit. The term "Company Credit" means an amount computed and credited annually to Participants' accounts hereunder at a rate that is two percent (2%) above the rate that the Treasurer of Lilly determines was the prime rate of interest charged by Chemical Bank, New York, New York (the "Bank") on loans made on the immediately preceding December 15 or, if the Bank was closed on December 15, the last day preceding December 15 on which the Bank was open for business.

2.10. Disability. The term "Disability" means a condition that the Committee determines (i) is attributable to sickness, injury, or disease and (ii) renders a Participant incapable of engaging in any activity for remuneration or profit commensurate with the Participant's education, experience, and training.

2.11. Eligible Employee. The term "Eligible Employee" means a management employee of the Company who is

designated by the Committee as eligible to defer a Bonus earned in the following year.

2.12. Lilly. The term "Lilly" means Eli Lilly and Company.

2.13. Participant. The term "Participant" means an Eligible Employee who has elected to defer all or part of a Bonus pursuant to the Plan in accordance with Section 3.1 hereof or an SEC Executive Officer who has elected to defer all or part of Base Salary pursuant to the Plan in accordance with Section 3.2 hereof.

2.14. Plan. The term "Plan" means "The Lilly Deferred Compensation Plan" as set forth herein and as it may be amended from time to time.

2.15. Retirement. The term "Retirement" means the first day of the month next following the Participant's last day of work for the Company, but only if such first day of the month occurs on or after the first to occur of (i) the day on which the Participant attains age 65 or (ii) the day on which the Participant is eligible to commence receiving a monthly retirement benefit under a funded, defined benefit retirement plan maintained by the Company and covering the Participant.

2.16. SEC Executive Officers. The term "SEC Executive Officers" shall mean those officers and employees from time to time designated as Executive Officers for purposes of the proxy statement and Form 10-K.

SECTION 3. PARTICIPATION.

3.1. Bonuses. Prior to the beginning of each Bonus Year, the Committee shall select those Eligible Employees who may elect to defer Bonuses pursuant to the Plan. Upon selection by the Committee and before the beginning of the applicable Bonus Year, an Eligible Employee may defer the receipt of a Bonus pursuant to the Plan by filing a written election with the Committee, in a form satisfactory to the Committee, that

- (i) defers payment of a designated amount (of One Thousand Dollars (\$1,000) or more) or percentage of the Bonus, if any, to be earned in the Bonus Year, and
- (ii) specifies the payment option selected by the Participant pursuant to subsection 6.1 hereof.

The amount deferred may not exceed the amount of the Bonus. Except as provided in subsections 6.1 and 6.3 hereof, any election made pursuant to this Section 3 (including any election made pursuant to paragraphs (i) and (ii), above) with respect to a Bonus Year shall be irrevocable when made.

Selection of an Eligible Employee for deferral of a Bonus during one year does not confer upon the Eligible Employee a right to defer Bonuses for subsequent years. The Eligible Employees who shall be permitted to defer Bonuses pursuant to the Plan shall be selected annually by the Committee. If an Eligible Employee is also an SEC Executive Officer as of the beginning of the Bonus Year, the Eligible Employee may also defer the receipt of Base Salary as provided in Section 3.2.

3.2. Base Salary. Subject to the right of the Committee to limit deferrals described below, prior to the beginning of each Compensation Year, an SEC Executive Officer may defer the receipt of up to one hundred percent (100%) of Base Salary pursuant to the Plan by filing a written election with the Committee, in a form satisfactory to the Committee, that

- (i) defers payment of a designated amount of One Thousand Dollars (\$1,000) or more or a percentage of Base Salary, and
- (ii) specifies the payment option selected by the Participant pursuant to subsection 6.1 hereof.

The amount deferred may not exceed the amount of Base Salary. Except as provided in subsections 6.1 and 6.3 hereof, any election made pursuant to this Section 3 (including any election made pursuant to paragraphs (i) and (ii), above) with respect to a Bonus Year shall be irrevocable when made and shall not be affected by the Participant's ceasing to be an SEC Executive Officer after the beginning of the Bonus Year.

The Committee reserves the right to limit the amount of Deferrals of Base Salary to assure that the Company has sufficient funds to cover taxes, benefit payments, and other necessary and appropriate deductions.

#### SECTION 4. INDIVIDUAL ACCOUNT.

The Treasurer of Lilly shall maintain an account in the name of

each Participant. In the year following the Bonus Year or Base Salary Year, each Participant's account shall be credited, as of the first day of the month in which Bonuses or Base Salary are paid, with the amount that the Participant has elected to defer hereunder. Each Participant shall be given an annual statement, as of December 31 of each year, showing for each year (i) the amount of Bonuses or Base Salary deferred and (ii) the amount of the Company Credit to the Participant's account.

#### SECTION 5. ACCRUAL OF COMPANY CREDIT.

The Treasurer of Lilly shall determine the applicable annual rate of Company Credit on or before December 31 of each calendar year. This rate shall be effective for the following calendar year. The Company Credit shall accrue monthly, at one-twelfth of the applicable annual rate, on all amounts credited to the Participant's account, including the Company Credits for prior years. The Company Credit shall not accrue on any amount distributed to the Participant (or to the Participant's Beneficiary) during the month for which the accrual is determined, except where an amount is distributed to a Beneficiary in the month of the Participant's death. The Company Credit for each year shall be credited to each Participant's account as of December 31 of that year and shall be compounded annually.

#### SECTION 6. PAYMENT.

6.1. Payment Options. The Participant shall select a payment election from the payment options described below. A Participant may elect that his final payment election control over all prior payment elections. The payment option selected by a Participant shall provide for payment

to the Participant of the amount credited to the Participant's account in

- (i) a lump sum in January of the second calendar year following the calendar year in which the Participant's employment terminates by reason of Retirement or Disability; or
- (ii) annual installments over a period of two to ten years commencing in January of the second calendar year following the calendar year in which the Participant's employment terminates by reason of Retirement or Disability;

provided, that in no event shall a lump sum be paid or installment payments begin under any payment option before the first January that begins after any Bonus that has been deferred under the payment option has been determined. The Company shall pay the aggregate amounts deferred, together with a proportionate part of the aggregate Company Credit accrued to the date (or dates) of payment, in the manner and on the date(s) specified by the Participant. If a payment option described in paragraph (i), above, has been elected, the amount of the lump sum shall be equal to the amount credited to the Participant's account as of the December 31 next preceding the date of the payment. If the payment option described in paragraph (ii), above, has been elected, the amount of each installment shall be equal to the amount credited to the Participant's account as of the December 31 next preceding the date of the installment payment divided by the number of installment payments that have not yet been made. If the Participant fails to elect a payment option, the amount credited to the Participant's account shall be distributed in a lump sum in accordance with the payment

option described in paragraph (i), above. If the amount credited to the Participant's account is less than \$25,000 at any time following the year in which the Participant's employment terminates by reason of Retirement or Disability, the Committee, in its sole discretion, may pay out the amount credited to the Participant's account in a lump sum.

6.2. Payment upon Death. Within a reasonable period of time following the death of a Participant, the balance in the Participant's account shall be paid in a lump sum to the Participant's Beneficiary. For purposes of this subsection 6.2, the balance in the Participant's account shall be determined as of the date of payment. A Participant may designate the Beneficiary, in writing, in a form acceptable to the Committee, and filed with the Committee before the Participant's death. A Participant may, before the Participant's death, revoke a prior designation of Beneficiary and may also designate a new Beneficiary without the consent of the previously designated Beneficiary, provided that such revocation and new designation (if any) are in writing, in a form acceptable to the Committee, and filed with the Committee before the Participant's death. If the Participant does not designate a Beneficiary, or if no designated Beneficiary survives the Participant, any amount not distributed to the Participant during the Participant's life shall be paid to the Participant's estate in a lump sum in accordance with this subsection 6.2.

6.3. Resignation or Dismissal. Within a reasonable time following termination of a Participant's employment by resignation or dismissal, the balance in the Participant's account shall be paid in a lump sum to the Participant. For purposes of this subsection 6.3, the balance in the

Participant's account shall be determined as of a date determined by the Committee in its sole discretion.

6.4. Payment on Unforeseeable Emergency. The Administrator may, in its sole discretion, direct payment to a Participant of all or of any portion of the Participant's Account balance, notwithstanding an election under Section 6.1. above, at any time that it determines that such Participant has an unforeseeable emergency and then only to the extent reasonably necessary to meet the emergency. For purposes of this rule, "unforeseeable emergency" means severe financial hardship to the Participant resulting from a sudden and unexpected illness or accident of the Participant or of a dependent of the Participant, loss of the Participant's property due to casualty, or other similar extraordinary and unforeseeable circumstances arising as a result of events beyond the control of the Participant. The circumstances that will constitute an unforeseeable emergency will depend upon the facts of each case, but, in any case, payment may not be made to the extent that such hardship is or may be relieved --

- (i) Through reimbursement or compensation by insurance or otherwise,
- (ii) By liquidation of the Participant's assets, to the extent the liquidation of such assets would not itself cause severe financial hardship, or
- (iii) By cessation of deferrals under the Plan.

Examples of what are not considered to be unforeseeable emergencies include the need to send a Participant's child to college or the desire to purchase a home.

6.5. Cash Payments. All payments under the Plan shall be made in cash.

SECTION 7. PROHIBITION AGAINST TRANSFER.

The right of a Participant to receive payments under the Plan may not be transferred except by will or applicable laws of descent and distribution. A Participant may not assign, sell, pledge, or otherwise transfer any amount to which he is entitled hereunder prior to transfer or payment thereof to the Participant.

SECTION 8. PARTICIPANT'S RIGHTS UNSECURED.

The Plan is unfunded. The right of any Participant to receive payments under the Plan shall be an unsecured claim against the general assets of the Company.

SECTION 9. ADMINISTRATION.

9.1. Committee. The Plan shall be administered by the Compensation and Management Development Committee of the Board of Directors, the members of which shall be selected by the Board of Directors from among its members. No member of the Committee may be a salaried employee of the Company.

9.2. Powers of the Committee. The Committee's powers shall include, but not be limited to, the power

- (i) to select Eligible Employees for participation in the Plan,

- (ii) to interpret the terms and provisions of the Plan and to determine any and all questions arising under the Plan, including, without limitation, the right to remedy possible ambiguities, inconsistencies, or omissions by a general rule or particular decision,
- (iii) to adopt rules consistent with the Plan, and
- (iv) to limit the deferrals of SEC Executive Officers to assure that the Company has sufficient funds to cover taxes, benefit payments, and other necessary or appropriate deductions.

9.3. Finality of Committee Determinations. Determinations by the Committee and any interpretation, rule, or decision adopted by the Committee under the Plan or in carrying out or administering the Plan shall be final and binding for all purposes and upon all interested persons, their heirs, and personal representatives.

9.4. Claims Procedures. Any person making a claim for benefits hereunder shall submit the claim in writing to the Committee. If the Committee denies the claim in whole or in part, it shall issue to the claimant a written notice explaining the reason for the denial and identifying any additional information or documentation that might enable the claimant to perfect the claim. The claimant may, within 60 days of receiving a written notice of denial, submit a written request for reconsideration to the Committee, together with a written explanation of the basis of the request. The Committee shall consider any such

request and shall provide the claimant with a written decision together with a written explanation thereof. All interpretations, determinations, and decisions of the committee in respect of any claim shall be final and conclusive.

9.5. Withholding. The Company shall have the right to deduct from all payments hereunder any taxes required by law to be withheld from such payments. The recipients of such payments shall bear all taxes on amounts paid under the Plan to the extent that no taxes are withheld thereon, irrespective of whether withholding is required.

9.6. Incapacity. If the Committee determines that any person entitled to benefits under the Plan is unable to care for his or her affairs because of illness or accident, any payment due (unless a duly qualified guardian or other legal representative has been appointed) may be paid for the benefit of such person to such person's spouse, parent, brother, sister, or other party deemed by the Committee to have incurred expenses for such person.

9.7. Inability to Locate. If the Committee is unable to locate a person to whom a payment is due under the Plan for a period of twelve (12) months, commencing with the first day of the month as of which the payment becomes payable, the total amount payable to such person shall be forfeited.

9.8. Legal Holidays. If any day on (or on or before) which action under the Plan must be taken falls on a Saturday, Sunday, or legal holiday, such action may be taken on (or on

or before) the next succeeding day that is not a Saturday, Sunday, or legal holiday; provided, that this subsection 9.8 shall not permit any action that must be taken in one calendar year to be taken in any subsequent calendar year.

SECTION 10. NO EMPLOYMENT RIGHTS.

No provision of the Plan or any action taken hereunder by the Company, the Board of Directors, or the Committee shall give any person any right to be retained in the employ of the Company, and the right and power of the Company to dismiss or discharge any Participant is specifically reserved.

SECTION 11. AMENDMENT, SUSPENSION, AND TERMINATION.

The Board of Directors shall have the right to amend, suspend, or terminate the Plan at any time. The Committee shall also have the right to amend the Plan, except for subsection 9.1 hereof and this Section 11.

SECTION 12. APPLICABLE LAW.

The Plan shall be governed by, and construed in accordance with, the laws of the State of Indiana, except to the extent that such laws are preempted by Federal law.

SECTION 13. EFFECTIVE DATE.

This amendment and restatement of the Plan is effective as of August 1, 1994. Nothing herein shall invalidate or adversely affect any previous election, designation, deferral, or accrual in accordance with the terms of the Plan that were then in effect.

ELI LILLY AND COMPANY EVA BONUS PLAN

(As amended and restated effective January 1, 2002)

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ARTICLE I

BONUS PLAN STATEMENT OF PURPOSE AND SUMMARY

- 1.1 The purpose of the Plan is to provide a system of bonus compensation for selected employees of Eli Lilly and Company and subsidiaries which will promote the maximization of shareholder value over the long term, by linking performance incentives to increases in shareholder value. The Plan ties bonus compensation to Economic Value Added ("EVA"), and thereby rewards employees for long-term, sustained improvement in shareholder value. The Plan is intended to satisfy the requirements for providing "performance-based" compensation under Section 162(m) of the Internal Revenue Code.
- 1.2 EVA will be used as the performance measure of value creation. EVA reflects the benefits and costs of capital employment. Employees create economic value when the operating profits from a business exceed the capital charge associated with the capital assets employed.

ARTICLE II

DEFINITIONS OF CERTAIN TERMS

Unless the context requires a different meaning, the following terms shall have the following meanings:

- 2.1 "Company" means Eli Lilly and Company and its subsidiaries.
- 2.2 "Committee" means the Compensation Committee, the members of which shall be selected by the Board of Directors of Eli Lilly and Company from among its members. Each Committee member shall, at all times while serving, satisfy the requirements of an "outside director" within the meaning of Section 162(m).
- 2.3 "Participant" means any employee of the Company designated by the Committee as a participant in the Plan with respect to any Plan Year. In its discretion, the Committee may designate Participants either on an individual basis or by determining that all employees in specified job categories, classifications or levels shall be Participants.
- 2.4 "Plan" means this Eli Lilly and Company EVA Bonus Plan.
- 2.5 "Plan Year" means the applicable calendar year.
- 2.6 "Retirement" means the cessation of employment upon the attainment of at least eighty age and benefit years of service points, as determined by the provisions of The Lilly Retirement Plan as amended from time to time, assuming eligibility to participate in that plan.
- 2.7 "Disability" means the time at which a Participant becomes eligible for a payment under The Lilly Extended Disability Plan, assuming eligibility to participate in that plan.

2.8 "Section 162(m)" means Section 162(m) of the Internal Revenue Code of 1986, as amended.

2.9 "Section 162(m) Participant" means a Participant who, in the determination of the Committee, is or may in the future become a "covered employee" under Section 162(m).

### ARTICLE III

#### DEFINITION AND COMPONENTS OF EVA

The following terms set forth the calculation of EVA and the components of calculating EVA. The calculation of EVA for a Plan Year is used in determining the bonuses earned by Participants under the Plan, as set forth in Article IV.

3.1 "Economic Value Added" or "EVA" means the excess NOPAT that remains after subtracting the Capital Charge.

3.2 "Net Operating Profit After Tax" or "NOPAT" means the after tax operating earnings of the Company for the Plan Year. NOPAT is determined by adding net sales plus other net income and subtracting the following: cost of goods sold, marketing and administrative expenses (excluding goodwill amortization and interest expense), amortization of research and development, taxes (excluding the tax benefit of interest expense) and amounts associated with discontinued operations.

3.3 "Capital Charge" means the deemed opportunity cost of employing capital for the Company. The Capital Charge is calculated by multiplying Operating Capital times Operating Cost of Capital (OC\*) and Cash Capital times Non-operating Cost of Capital (NOC\*), then summing the two products.

3.4 "Operating Capital" means the net investment employed in the operations of the Company produced by operations. Operating Capital is calculated by adding together current assets (excluding cash and short-term marketable securities), net property, plant and equipment, gross goodwill, net intangibles, other assets, and capitalized research and development, and the present value of operating leases, and subtracting the following: non-interest bearing liabilities and capital associated with discontinued operations.

3.5 "Cash Capital" means the aggregate balances of any cash plus short-term marketable securities.

3.6 "Cost of Operating Capital" or "OC\*" is the percentage calculated from the weighted average of Cost of Debt and Cost of Equity. Cost of Operating Capital for each Plan Year is determined by the Chief Financial Officer and approved by the Committee.

3.7 "Cost of Non-operating Capital" or "NOC\*" is the after-tax opportunity cost of capital associated with Cash Capital, as deemed appropriate for Cash Capital by the Chief Financial Officer and approved by the Committee.

- 3.8 "Cost of Debt" capital is the marginal long-term borrowing rate adjusted for the credit rating of the Company times (one minus the tax rate).
- 3.9 "Cost of Equity" capital is the risk-free rate plus (beta times the market risk premium). For this purpose, the risk-free rate, the beta and the market risk premium are determined by the Chief Financial Officer and approved by the Committee.

#### ARTICLE IV

##### DEFINITION AND COMPUTATION OF THE EVA BONUS

Bonuses earned under the Plan for a Plan Year are determined based on a comparison of actual EVA to the "Target EVA" for the year, which is established as described below to motivate improvement in EVA from year to year. The result of this comparison is adjusted by a "Leverage Factor" measuring the volatility of industry EVA returns. The factor produced is referred to as the "Bonus Multiple," which is multiplied by the Participant's applicable "Target Bonus" amount established for the year to produce the actual bonus earned. This amount, referred to as the "Declared Bonus," is credited to the Participant's "Bonus Bank" balance and paid out in the manner provided below.

- 4.1 Target Bonus. The Target Bonus Award will be determined by the Committee on a basis that takes into consideration a Participant's salary grade level, job responsibilities as well as past and expected future job performance. Target Bonus Awards for a particular Plan Year are expressed as a percentage of annual base salary as in effect on the fixed annual merit date in that Plan Year or on the first day of the Plan Year if there is no merit date in a given Plan Year. Early in the Plan Year, each Participant (except executive officers and Section 162(m) Participants) will receive three Target Bonus Awards to correspond with each of the three performance ratings. The actual Target Bonus used to calculate the Declared Bonus will be determined by the individual's performance rating for the given Plan Year as determined by the individual's supervision, except as otherwise provided in Article V. Executive officers (as determined in accordance with regulations under the Securities Exchange Act of 1934) and Section 162(m) Participants shall receive a single Target Bonus Award.

The Target Bonus will be based on the currency in which the highest portion of base pay is regularly paid. The Committee shall determine the appropriate foreign exchange conversion methodology in its discretion.

- 4.2 Declared Bonus. A Declared Bonus is the applicable Target Bonus times the Bonus Multiple.
- 4.3 Bonus Multiple. The Bonus Multiple is Actual EVA less Target EVA (positive or negative), divided by the Leverage Factor, plus one. In years in which the Bonus Multiple is equal to or less than zero, the Target Bonus used to calculate the Declared Bonus will be the Target Bonus associated with the "Successful" or middle performance rating.
- 4.4 Bonus Bank. All bonus payments are made from the Bonus Bank. Each Participant's beginning Bonus Bank balance in his/her first year of participation is zero. The Bonus Bank

is increased or decreased for any Plan Year by the amount of Declared Bonus. If the available Bonus Bank balance after the inclusion of the Declared Bonus is positive, the Participant will be paid from such balance up to the applicable Target Bonus Award, plus one third of any such balance that remains after subtracting the Target Bonus Award from the available Bonus Bank balance. If the available Bonus Bank balance is zero or negative, no payment will occur. After any payment as calculated above, the beginning Bonus Bank balance for the subsequent Plan Year shall be as follows:

- (a) Any positive balance shall be carried forward as the new beginning Bonus Bank balance.
- (b) Any negative balance resulting from a negative Bonus Multiple shall be carried forward as the new beginning (negative) Bonus Bank balance; provided, however, that not later than 90 days after the commencement of a Plan Year, the Committee may determine in its discretion that, with respect to that particular Plan Year, in the event a Declared Bonus for the Plan Year would result in a negative beginning Bonus Bank balance for the subsequent Plan Year, such Bonus Bank balance would be reset at zero.
- (c) If the Bonus Bank balance has been completely depleted because of a Bonus Multiple between zero and 1.0, the new beginning Bonus Bank balance shall be zero.

4.5 Target EVA. The Target EVA for each year will be calculated as follows:

Target EVA = Prior Year's Actual EVA + Expected Improvement

4.6 Expected Improvement. The Expected Improvement is the additional EVA amount determined by the Committee that is used to assure that a minimum level of improvement is achieved in order to earn target awards.

4.7 Leverage Factor. The Leverage Factor determines the rate of change in bonuses as EVA surpasses or falls short of Target EVA, determined by the Committee from an evaluation of the long term volatility of industry returns.

4.8 Section 162(m) Requirements, Bonus Maximum. In the case of Section 162(m) Participants, all determinations necessary for computing Declared Bonuses for a Plan Year, including establishment of all components of the EVA calculation and of the Target Bonus percentages, shall be made by the Committee not later than 90 days after the commencement of the Plan Year. As and to the extent required by Section 162(m), the terms of a Declared Bonus for a Section 162(m) Participant must state, in terms of an objective formula or standard, the method of computing the amount of compensation payable to the Section 162(m) Participant, and must preclude discretion to increase the amount of compensation payable that would otherwise be due under the terms of the award. Notwithstanding anything elsewhere in the Plan to the contrary, the maximum amount of the Declared Bonus that may be paid from the Bonus Bank to a Section 162(m) Participant during any one calendar year shall be \$5 million.

ARTICLE V

PLAN ADMINISTRATION

- 5.1 Time of Payment. Payment from the Bonus Bank will be made before April 1 of the year following the Plan Year.
- 5.2 Certification of Results. Before any amount is paid under the Plan, the Committee shall certify in writing the calculation of EVA for the Plan Year and the satisfaction of all other material terms of the calculation of the Declared Bonus.
- 5.3 New Hires and New Participants. New hires or individuals promoted who are first selected for participation by the Committee effective on a date other than January 1 will participate on a pro-rata basis in their first year of participation, based on the Declared Bonus determined for the Plan Year, pro-rated for that period of the year during which the Participant was selected for participation in the Plan. Any such Participant's Target Bonus Award for that Plan Year will be determined, as applicable, based on his or her annual base salary as in effect on (i) the fixed annual merit date in that Plan Year, (ii) January 1 in years when there is no merit date in that Plan Year, or (iii) on the date of hire or promotion if hired or promoted after the fixed annual merit date in that Plan Year. For purposes of pro-rating, the individual's performance rating at the end of the Plan Year will apply to the entire Plan Year. Notwithstanding the foregoing, in the case of any Section 162(m) Participant who is first selected by the Committee to participate in the Plan after January 1 of a Plan Year, such Participant's Declared Bonus may be determined, at the discretion of the Committee exercised at the time such participation begins, in a manner that complies with the requirements for "performance-based compensation" under Section 162(m).
- 5.4 Promotions of Existing Participants. If an existing Participant is promoted effective on a date other than January 1 to a position that is rated global job level ("G-level") G-6 or above but is not an executive officer or Section 162(m) Participant, he/she will receive a Declared Bonus that is pro-rated based on a proration calculation methodology to be determined by the vice president responsible for human resources in his or her discretion. Such methodology will address the date of the promotion, base salary(ies), Target Bonus percentage(s), and performance rating(s). Such vice president will also have discretion to pro-rate, using the same or a different methodology, in the case of promotions of existing Participants to positions with a G-level lower than G-6. If an existing Participant is promoted effective on a date other than January 1 to an executive officer and/or Section 162(m) Participant position, he/she will receive a Declared Bonus that is pro-rated according to time based on the date of promotion and the Target Bonus percentage and base salary applicable to each such position.
- 5.5 Termination of Employment. If a Participant ceases employment with the Company on or before the last day of a Plan Year for reasons other than Retirement, Disability or death, the Participant shall receive no Declared Bonus for that Plan Year, and his/her Bonus Bank balance shall be forfeited. The Committee may make complete or partial exceptions to this rule, in its sole discretion, and, with respect to employees other than executive officers, may delegate to the vice president responsible for human resources the authority to make such

exceptions. Notwithstanding the foregoing, with respect to the Declared Bonus for a Section 162(m) Participant, any such termination of employment shall result in payment of a bonus based on the Declared Bonus determined for the Plan Year but pro-rated for the period of the year prior to such event, subject to the Committee's discretion to forfeit all or any portion of such bonus, and the Bonus Bank balance shall be forfeited as well.

- 5.6 Demotions. If an existing Participant who is not an executive officer or Section 162(m) participant is demoted to a non-global job level ("G level") position or to a lower G-level position on a date other than January 1, he/she will receive a Declared Bonus that may be pro-rated based on a prorated calculation methodology to be determined by the vice president responsible for human resources in his or her discretion. Such methodology will address the date of the demotion, base salary(ies), Target Bonus percentage(s), and performance rating(s). If an executive officer and/or Section 162(m) Participant is demoted to a lower G-level position on a date other than January 1, he/she will receive a Declared Bonus that is pro-rated according to time based on the date of demotion and the Target Bonus percentage and base salary applicable to each such position.
- 5.7 Leave of Absence. If a Participant is on an approved leave of absence from employment during part of a Plan Year, the Participant shall receive a Declared Bonus for the Plan Year based on the Declared Bonus determined for the full Plan Year but pro-rated for the period of the year that the Participant was actively employed by the Company, subject to the Committee's discretion to forfeit all or any portion of such bonus. For purposes of pro-rating, the Participant's last performance rating (interim or annual) before commencement of the leave will be used to determine the Declared Bonus. A Participant who is on an approved leave of absence for an entire Plan Year will not receive a Declared Bonus for that Plan Year. The Participant will retain his Bonus Bank balance if he returns to employment immediately following the approved period of leave of absence.
- 5.8 Retirement, Disability or Death. If a Participant ceases employment with the Company on or before the last day of the Plan Year because of Retirement, Disability or death, the Participant or personal representative, as the case may be, shall receive into his or her Bonus Bank before April 1 of the next year a Declared Bonus based on the Declared Bonus determined for the Plan Year but pro-rated for that period of the Plan Year during which the Participant was an active employee of the Company. For purposes of pro-rating, the Participant's last performance rating (interim or annual) before termination of employment will be used to determine the Declared Bonus. Following payment of such bonus in accordance with Section 4.4, any remaining positive Bonus Bank balance shall be paid.
- 5.9 Plan Participation. A Participant may not participate in this Plan for any portion of a Plan Year for which he/she is entitled to receive payment under the Eli Lilly and Company Contingent Compensation Plan, The Eli Lilly and Company Premier Rewards Plan, or such other bonus program of the Company or a subsidiary or affiliate of the Company as may be specifically designated by the Committee or its designee. Such Participants will participate in this Plan on a pro-rata basis, based on the Declared Bonus for the Plan Year, pro-rated for that period of the year during which the Participant participated in this Plan. Alternatively, the Committee or its designee may determine that the Participant who is eligible to

participate in such other plan may continue to participate in this Plan but with reduced Target Bonus Awards for any period during which the Participant is also participating in such other plan.

- 5.10 Forfeiture Events. Notwithstanding any other provision of this Plan to the contrary, the Committee may, in its sole discretion, upon the occurrence of a Forfeiture Event (as defined below), forfeit all or any portion of a Participant's Declared Bonus and Bonus Bank balance and terminate such Participant's future participation in the Plan. For purposes hereof, a "Forfeiture Event" shall mean the occurrence of one or more of the following events with respect to a Participant: (i) the termination or forced resignation from employment of the Participant for "misconduct" (as defined in the Company's Employee Information Handbook), (ii) any violation by the Participant of The Red Book: Standards of Business Conduct that is detrimental to the Company, (iii) any breach of a noncompetition, nonsolicitation, nondisclosure or other restrictive covenant that may apply by written agreement between the Company and the Participant or (iv) Participant's having engaged in any other activity that, in the judgment of the Committee, is detrimental to the business, affairs or reputation of the Company (including, without limitation, engaging in any criminal activity). Except with respect to executive officers, the Committee may delegate the authority granted under this section to the vice president responsible for human resources.

## ARTICLE VI

### GENERAL PROVISIONS

- 6.1 Withholding of Taxes. The Company shall have the right to withhold the amount of taxes which in the sole determination of the Company are required to be withheld under law with respect to any amount due or payable under the Plan.
- 6.2 Expenses. All expenses and costs in connection with the adoption and administration of the Plan shall be borne by the Company.
- 6.3 No Prior Right or Offer, No Right to Future Participation. Participation in the Plan for Plan Years is determined from year-to-year by the Committee in its sole discretion. Except and until expressly granted pursuant to the Plan, nothing in the Plan shall be deemed to give any employee any contractual or other right to participate in the benefits of the Plan. No award to any such Participant in any Plan Year shall be deemed to create a right to receive any award or to participate in the benefits of the Plan in any subsequent Plan Year.
- 6.4 Rights Personal to Employee. Any rights provided to an employee under the Plan shall be personal to such employee, shall not be transferable, except by will or pursuant to the laws of descent or distribution, and shall be exercisable during his/her lifetime, only by such employee, or a court-appointed guardian for the employee.
- 6.5 Non-Allocation of Award. In the event of a suspension of the Plan in any Plan Year, as described in Section 11.1, no awards under the Plan for the Plan Year during which such

suspension occurs shall affect the calculation of awards for any subsequent period in which the Plan is continued.

## ARTICLE VII

### LIMITATIONS

- 7.1 No Continued Employment. Neither the establishment of the Plan nor the grant of an award thereunder shall be deemed to constitute an express or implied contract of employment of any Participant for any period of time or in any way abridge the rights of the Company to determine the terms and conditions of employment or to terminate the employment of any employee with or without notice or cause at any time.
- 7.2 No Vested Rights. Except as expressly provided herein, no employee or other person shall have any claim of right (legal, equitable, or otherwise) to any award, allocation, or distribution or any right, title, or vested interest in any amounts in his/her Target Bonus or Bonus Bank and no officer or employee of the Company or any other person shall have any authority to make representations or agreements to the contrary.
- 7.3 Non-alienation. No interest conferred herein to a Participant shall be assignable or subject to claim by a Participant's creditors. Except as provided in Subsection 6.1, no Participant or other person shall have any right or power, by draft, assignment, or otherwise, to mortgage, pledge or otherwise encumber in advance any payment under the Plan, and every attempted draft, assignment, or other disposition of any interest or payment under this Plan shall be absolutely void.

## ARTICLE VIII

### COMMITTEE AUTHORITY

- 8.1 Authority to Interpret and Administer. Except as otherwise expressly provided herein, full power and authority to interpret and administer this Plan shall be vested in the Committee. The Committee may from time to time make such decisions and adopt such rules and regulations for implementing the Plan as it deems appropriate for any Participant under the Plan. Except as to Participants who are treated by the Company as executive officers of the Company for federal securities law reporting purposes (including any Section 162(m) Participant), the Committee may delegate in writing to officers or employees of the Company the power and authority granted by this Section 8.1 to interpret and administer this Plan. Any decision taken by the Committee or officer or employee to whom authority has been delegated, arising out of or in connection with the construction, administration, interpretation and effect of the Plan shall be final, conclusive and binding upon all Participants and any person claiming under or through Participants.
- 8.2 Adjustments for Significant Events. Prior to the beginning of a Plan Year, the Committee may specify with respect to Declared Bonuses for the Plan Year that EVA will be

determined before the effects of acquisitions, divestitures, restructurings or changes in corporate capitalization, accounting changes, and/or events that are treated as extraordinary items for accounting purposes; provided that such adjustments shall be made only to the extent permitted by Section 162(m) in the case of Section 162(m) Participants.

8.3 Financial And Accounting Terms. Except as otherwise provided, financial and accounting terms, including terms defined herein, shall be determined by the Committee in accordance with generally accepted accounting principles and as derived from the audited consolidated financial statements of the Company, prepared in the ordinary course of business.

8.4 Section 162(m) Deferrals. To the extent that, notwithstanding the terms of the Plan, the Company's tax deduction for remuneration in respect of the payment of bonuses under the Plan to a Section 162(m) Participant would be disallowed under Section 162(m) by reason of the fact that such Participant's applicable employee remuneration, as defined in Section 162(m), either exceeds or, if such bonus were paid, would exceed the \$1,000,000 limitation in Section 162(m), any such excess (as determined by the Committee in its sole discretion) shall be automatically deferred under the terms of The Lilly Deferred Compensation Plan. Payment of any deferred amounts shall be made to the Participant in the first year thereafter that the Company's tax deduction in respect of the payment would not be disallowed under Section 162(m).

#### ARTICLE IX

##### NOTICE

9.1 Any notice to be given to the Company or Committee pursuant to the provisions of the Plan shall be in writing and directed to Secretary, Eli Lilly and Company, Lilly Corporate Center, Indianapolis, IN 46285.

#### ARTICLE X

##### EFFECTIVE DATE

10.1 This Plan, as amended and restated herein, shall be effective for the Plan Year commencing January 1, 2002. The terms of this restated plan shall apply to Declared Bonuses earned in 2002 and future Plan Years. All Declared Bonuses earned in Plan Years prior to 2002 shall be payable in accordance with the terms of the Plan as in effect for the year to which the Declared Bonus relates. The final Plan Year of this Plan, unless amended or terminated by the Board (or the Committee) and approved by the stockholders to the extent provided in Article XI, shall be the 2007 Plan Year.

ARTICLE XI

AMENDMENTS AND TERMINATION

- 11.1 This Plan may be amended, suspended or terminated at any time at the discretion of the Board of Directors of Eli Lilly and Company, and may, except for this Section 11.1, be amended at any time by the Committee. Solely to the extent deemed necessary or advisable by the Board (or the Committee) for purposes of complying with Section 162(m), the Board (or the Committee) may seek the approval of any such amendment by the Company's stockholders. Any such approval shall be by the affirmative votes of a majority of the stockholders of the Company present, or represented, and entitled to vote at a meeting duly held in accordance with applicable state law and the Articles of Incorporation and By-laws of the Company. The material terms of EVA must be disclosed to and reapproved by the stockholders of the Company no later than the Company's annual meeting of stockholders that occurs in the year 2003.

ARTICLE XII

APPLICABLE LAW

- 12.1 This Plan shall be governed by and construed in accordance with the provisions of the laws of the State of Indiana without regard to the conflicts-of-law principles of Indiana.

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,				
	2001	2000	1999	1998	1997
Consolidated pretax income from continuing operations before extraordinary item	\$ 3,552.1	\$ 3,858.7	\$ 3,245.4	\$ 2,665.0	\$ 2,901.1
Interest from continuing operations and other fixed charges	208.1	225.4	213.1	198.3	253.1
Less interest capitalized during the period from continuing operations	(61.5)	(43.1)	(29.3)	(17.0)	(20.4)
Earnings	\$ 3,698.7	\$ 4,041.0	\$ 3,429.2	\$ 2,846.3	\$ 3,133.8
Fixed charges(1)	\$ 208.1	\$ 225.4	\$ 213.2	\$ 200.5	\$ 256.8
Ratio of earnings to fixed charges	17.8	17.9	16.1	14.2	12.2

(1) Fixed charges include interest from continuing operations for all years presented and preferred stock dividends for 1997 through 1999.

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### EXHIBIT 13.

Appendix to Exhibit 13

Deferred Compensation Plan, as amended

EVA Bonus Plan, as amended

Computation of Ratio of Earnings

Annual Report to Shareholders

List of Subsidiaries

Consent of Independent Auditors

Cautionary Statement

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### EXHIBIT 13. ANNUAL REPORT TO SHAREHOLDERS FOR THE YEAR ENDED DECEMBER 31, 2001

#### REVIEW OF OPERATIONS

#### OPERATING RESULTS— 2001

##### SUMMARY

Net income was \$2.78 billion, or \$2.55 per share, in 2001 and \$3.06 billion, or \$2.79 per share, in 2000. Comparisons between 2001 and 2000 are made difficult by the impact of several unusual items that are reflected in the company's operating results for both years. Excluding these unusual items, which are discussed further below, net income for 2001 and 2000 would have been \$3.01 billion, or \$2.76 per share, and \$2.90 billion, or \$2.65 per share, respectively. This represents an increase in net income and earnings per share of 4 percent. The 2001 increases are attributed to growth in sales, offset, in part, by operating expenses (as defined below) increasing at a rate greater than sales growth.

##### UNUSUAL ITEMS

As noted above, several unusual items are reflected in the company's operating results for 2001 and 2000. These transactions are summarized as follows (see Notes 3, 4, and 7 to the consolidated financial statements for additional information).

##### 2001

- Pretax charges of \$190.5 million for acquired in-process research and development related to collaboration arrangements with Isis Pharmaceuticals, Inc. (Isis); Minnesota Mining and Manufacturing Company (3M); and Bioprojet, Société Civile de Recherche (Bioprojet), in the third and fourth quarters of 2001, which decreased earnings per share by approximately \$.05 in the third quarter and \$.06 in the fourth quarter of 2001
- Pretax charges of \$121.4 million associated with asset impairments and other site charges in the third quarter of 2001 due to actions taken as a result of the recent assessment of the company's worldwide manufacturing capacity, which decreased earnings per share by approximately \$.07 in the third quarter of 2001
- An extraordinary charge of \$45.2 million (\$29.4 million net of income taxes) from the repurchase of higher interest rate debt in the third and fourth quarters of 2001, which decreased earnings per share by approximately \$.02 in the third quarter and \$.01 in the fourth quarter of 2001

##### 2000

- A gain of \$214.4 million on the sale of the company's interest in Kinetra LLC to WebMD Corporation (WebMD) and the subsequent sale of WebMD stock, which increased earnings per share by approximately \$.20 in the first quarter of 2000
- Approximately \$91 million in additional product sales in 1999 as a result of year-2000-related wholesaler buying that normally would have been realized during the first quarter of 2000, which increased earnings per share by approximately \$.06 in the fourth quarter of 1999 and reduced earnings per share by the same amount in the first quarter of 2000

##### SALES

The company's reported worldwide sales for 2001 increased 6 percent, to \$11.54 billion. Worldwide sales for 1999 included approximately \$91 million of sales relating to year-2000 wholesaler buying that normally would have been recognized in 2000. Adjusting for the impact of year-2000 wholesaler buying, sales growth for 2001 would have been 5 percent. Sales growth was led by Zyprexa, a treatment for schizophrenia and related psychoses; diabetes care products; Gemzar, an oncolytic product; and Evista, an osteoporosis treatment and prevention agent. Sales in the U.S. increased 5 percent, to \$7.36 billion. Sales outside the U.S. increased 8 percent, to \$4.18 billion. Both worldwide and U.S. sales growth was offset, in part, by decreased sales of Prozac, an antidepressant, and anti-infectives. The decrease in Prozac sales was primarily due to the entrance of generic fluoxetine in the U.S. market in early August 2001. Excluding Prozac, the company's worldwide and U.S. sales increased 17 percent and 22 percent, respectively. Worldwide sales reflected volume growth of 8 percent and a 1 percent increase in global selling prices, partially offset by a 2 percent decrease in exchange rates. (Percentages do not add due to rounding.)

Zyprexa had worldwide sales of \$3.09 billion in 2001, representing an increase of 31 percent. Sales in the U.S. increased 29 percent, to \$2.18 billion. Zyprexa's sales continued to experience strong growth in the face of an additional competitive product in the U.S. Sales outside the U.S. increased 38 percent, to \$910.5 million, benefiting, in part, from the launch of Zyprexa in Japan during the second quarter of 2001.

Diabetes care products, composed primarily of Humulin®, the company's biosynthetic human insulin; Humalog, the company's insulin analog; and Actos, an oral agent for the treatment of type 2 diabetes, had worldwide revenues of \$2.13 billion in 2001.

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representing an increase of 21 percent. Diabetes care revenues in the U.S. increased 27 percent, to \$1.37 billion. Diabetes care revenues outside the U.S. increased 12 percent, to \$764.8 million. Humulin had worldwide sales of \$1.06 billion, representing a decrease of 5 percent due to the continued shift by patients to Humalog and Humalog mixture products and to increased competition. Humulin sales in the U.S. decreased 6 percent, to \$578.5 million. Humulin sales outside the U.S. decreased 3 percent, to \$482.2 million. Humalog had worldwide sales of \$627.8 million, representing an increase of 79 percent. The company received service revenues of \$360.6 million in 2001, an increase of 62 percent, relating to sales of Actos. Actos is manufactured and sold in the U.S. by Takeda Chemical Industries, Ltd., and is copromoted by Takeda and the company.

Prozac, Prozac Weekly, and Sarafem™, a treatment for premenstrual dysphoric disorder (collectively “fluoxetine product(s)”) had combined worldwide sales of \$1.99 billion, representing a decrease of 23 percent. This full-year result included a 66 percent decline in the fourth quarter of 2001. Fluoxetine product sales in the U.S. decreased 26 percent, to \$1.66 billion, primarily due to generic competition for Prozac beginning in early August 2001. Fluoxetine product sales outside the U.S. decreased 3 percent, to \$330.1 million, primarily due to continuing generic competition. For additional information on the expected financial impact of generic competition, see the “Financial Expectations for 2002 and 2003” section.

Gemzar had worldwide sales of \$722.9 million in 2001, representing an increase of 29 percent. Sales in the U.S. increased 32 percent, to \$417.4 million. Sales outside the U.S. increased 26 percent, to \$305.5 million.

Evista had worldwide sales of \$664.8 million in 2001, representing an increase of 27 percent. Sales in the U.S. increased 21 percent, to \$526.1 million. U.S. sales growth slowed in the second half of the year primarily due to increased competition. Sales outside the U.S. increased 58 percent, to \$138.7 million, primarily due to the launch of Evista as a treatment for postmenopausal osteoporosis in a number of European countries during the second quarter of 2000.

ReoPro® had worldwide sales of \$431.4 million in 2001, representing an increase of 3 percent. Sales in the U.S. decreased 1 percent, to \$312.3 million, due to continued competition. Sales outside the U.S. increased 16 percent, to \$119.1 million.

At the end of November 2001, the company received approval from the U.S. Food and Drug Administration (FDA) and launched Xigris™, a treatment for adult severe sepsis patients at high risk of death. Initial Xigris sales were \$21.2 million in 2001.

Anti-infectives had worldwide sales of \$749.5 million in 2001, representing a decrease of 16 percent, due to continuing competitive pressures. Cefaclor and Keflex® accounted for the majority of the decline. Sales in the U.S. of anti-infectives decreased 32 percent, to \$128.9 million. Sales outside the U.S. decreased 12 percent, to \$620.6 million.

Animal health products had worldwide sales of \$686.1 million in 2001, representing an increase of 3 percent. Sales in the U.S. increased 5 percent, to \$323.2 million. Sales outside the U.S. remained flat at \$362.9 million.

The company’s payments under federally mandated Medicaid rebate programs reduced 2001 sales by approximately \$475.0 million compared with approximately \$464.0 million in 2000.

### GROSS MARGIN, COSTS, AND EXPENSES

The 2001 gross margin improved to 81.3 percent of sales compared with 81.1 percent for 2000. This increase was attributed primarily to favorable changes in product mix due to growth in sales of higher margin products, such as Zyprexa, Gemzar, Evista, and diabetes care products. The decline in sales of Prozac, also a higher margin product, partially offset these gross margin increases.

Operating expenses (the aggregate of research and development and marketing and administrative expenses) increased 8 percent in 2001. Investment in research and development expenses increased 11 percent, to \$2.24 billion, as the company continued to invest in its promising product pipeline. Marketing and administrative expenses increased 6 percent. Expansion of the worldwide sales force and increased marketing efforts in support of the company’s growth products and upcoming product launches offset a slight decline in administrative expenses. The growth rates of both research and development expenses and marketing and administrative expenses were diminished by reduced incentive compensation expenses resulting from lower growth in earnings.

During 2001, the company recorded \$190.5 million for acquired in-process research and development charges related to collaboration arrangements with Isis, 3M, and Bioprojet. The compounds acquired in these collaboration agreements are in the development phase and no alternative future uses were identified.

Net other income for 2001 was \$280.7 million, an increase of \$12.8 million, excluding the gain on the sale of Kinetra LLC in 2000. The increase was primarily due to an increase in interest income.

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The company's effective tax rate for 2001 was 20.9 percent compared with 20.8 percent for 2000. Excluding the unusual items discussed previously, the effective tax rate was 22.0 percent for both years. See Note 11 to the consolidated financial statements for additional information.

### OPERATING RESULTS – 2000

#### SUMMARY

Net income was \$3.06 billion, or \$2.79 per share, in 2000 and \$2.72 billion, or \$2.46 per share, in 1999. Comparisons between 2000 and 1999 are made difficult by the impact of several unusual items that are reflected in the company's operating results for both years. Excluding these unusual items, which are discussed further below, net income for 2000 and 1999 would have been \$2.90 billion, or \$2.65 per share, and \$2.52 billion, or \$2.28 per share, respectively. This represents an increase in net income and earnings per share of 15 percent and 16 percent, respectively. The 2000 increases are attributed to growth in sales, improved gross margin, and increased interest income, offset by increases in operating expenses at a rate greater than sales growth. Earnings per share also benefited from a decrease in the number of shares outstanding as a result of the share repurchase plan.

#### UNUSUAL ITEMS

As noted above, several unusual items are reflected in the company's operating results for 2000 and 1999. The unusual items relating to 2000 are summarized under "Operating Results – 2001." The 1999 unusual items are summarized as follows (see Notes 3, 4, 5, and 13 to the consolidated financial statements for additional information).

- A pretax gain of \$110.0 million in settlement of litigation with Biochimica Opos S.p.A., which increased earnings per share by approximately \$.06 in the fourth quarter of 1999
- A pretax charge of \$26.0 million associated with the decommissioning of manufacturing facilities and other site charges, which decreased earnings per share by approximately \$.02 in the fourth quarter of 1999
- A pretax gain of \$67.8 million on the sale of U.S. and Puerto Rican Lorabid® marketing rights, which increased earnings per share by approximately \$.05 in the third quarter of 1999
- A pretax gain of \$165.6 million (\$174.3 million net of an income tax benefit) on the sale of PCS, the company's health-care-management subsidiary, which increased earnings per share by approximately \$.16 in the first quarter of 1999
- A pretax charge of \$150.0 million as the result of a contribution to Eli Lilly and Company Foundation, which decreased earnings per share by approximately \$.09 in the first quarter of 1999
- A pretax charge of \$61.4 million associated with the impairment of certain manufacturing assets, which decreased earnings per share by approximately \$.04 in the first quarter of 1999

#### SALES

The company's reported worldwide sales for 2000 increased 9 percent, to \$10.86 billion. Worldwide sales for 1999 included approximately \$91 million of sales relating to year-2000 wholesaler buying that normally would have been recognized in 2000. Adjusting for the impact of year-2000 wholesaler buying, sales growth for 2000 would have been 10 percent. Sales growth was led by Zyprexa, diabetes care products, Evista, and Gemzar. Sales in the U.S. increased 12 percent, to \$7.00 billion. Sales outside the U.S. increased 2 percent, to \$3.86 billion. Worldwide sales reflected volume growth of 11 percent, partially offset by a 2 percent decrease in exchange rates while prices remained flat.

Fluoxetine products had combined worldwide sales of \$2.57 billion, representing a decrease of 2 percent. Sales in the U.S. increased 7 percent, to \$2.23 billion. The U.S. sales comparison benefited, in part, from wholesaler inventory reductions in 1999. Fluoxetine product sales outside the U.S. decreased 35 percent, to \$341.0 million, primarily due to continuing generic competition in the U.K.

Zyprexa had worldwide sales of \$2.35 billion in 2000, representing an increase of 25 percent. Sales in the U.S. increased 23 percent, to \$1.69 billion. Sales in 2000 benefited from the FDA approval of Zyprexa for the treatment of acute mania associated with bipolar disorder in the first quarter of 2000. Sales outside the U.S. increased 28 percent, to \$659.3 million.

Diabetes care products, composed primarily of Humulin, Humalog, and Actos, had worldwide revenues of \$1.76 billion in 2000, representing an increase of 22 percent. Diabetes care revenues in the U.S. increased 21 percent, to \$1.08 billion. Diabetes care revenues outside the U.S. increased 22 percent, to \$685.8 million. Humulin had worldwide sales of \$1.11 billion, representing an increase of 2 percent. Humulin sales in the U.S. decreased 6 percent, to \$617.4 million, largely as a result of patients shifting to Humalog and Humalog mixture products. Humulin sales outside the U.S. increased 15 percent, to \$497.0 million. Humalog had worldwide sales of \$350.2 million, representing an increase of 56 percent. Sales of Humalog benefited from the U.S. launch of Humalog Mix75/25™ Pen in the first quarter of 2000. The company received service revenues of \$223.0 million in 2000 relating to sales of Actos.

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Gemzar had worldwide sales of \$559.3 million in 2000, representing an increase of 23 percent. Sales in the U.S. increased 20 percent, to \$315.9 million. Sales outside the U.S. increased 27 percent, to \$243.3 million.

Evista had worldwide sales of \$521.5 million in 2000, representing an increase of 60 percent. Sales in the U.S. increased 52 percent, to \$433.8 million. Increases in sales in the U.S. were due, in part, to the FDA approval of Evista for the treatment of postmenopausal osteoporosis in the U.S., which was granted in September 1999. Sales outside the U.S. increased 115 percent, to \$87.7 million.

ReoPro had worldwide sales of \$418.1 million in 2000, representing a decrease of 7 percent. Sales in the U.S. decreased 12 percent, to \$315.1 million. Sales outside the U.S. increased 15 percent, to \$102.9 million. The decline in sales was due to increased competition in the U.S.

Anti-infectives had worldwide sales of \$894.3 million in 2000, representing a decrease of 13 percent, due to continuing competitive pressures. Cefaclor and Lorabid accounted for the majority of the decline. Sales in the U.S. decreased 12 percent, to \$189.4 million. Sales outside the U.S. decreased 13 percent, to \$704.9 million.

Animal health products had worldwide sales of \$668.5 million in 2000, representing an increase of 6 percent. Sales in the U.S. increased 8 percent, to \$307.5 million. Sales outside the U.S. increased 5 percent, to \$360.9 million. The increases were balanced across the product line.

The company's payments under federally mandated Medicaid rebate programs reduced 2000 sales by approximately \$464.0 million compared with approximately \$352.5 million in 1999.

### GROSS MARGIN, COSTS, AND EXPENSES

The 2000 gross margin improved to 81.1 percent of sales compared with 79.0 percent for 1999. This increase was attributed primarily to favorable changes in product mix due to growth in sales of newer products and, to a lesser extent, increased production volume.

Operating expenses increased 16 percent in 2000. Research and development expenses increased 13 percent, to \$2.02 billion, as the company continued to invest in both the early and late stages of its internal product pipeline and external collaborations. Marketing and administrative expenses increased 17 percent primarily due to sales force expansions and increased marketing efforts to support the company's newer products.

Net other income for 2000 was \$267.9 million, an increase of \$142.8 million, excluding the gain on the sale of Kinetra LLC, the gains from the litigation settlement, the sale of Lorabid marketing rights, and a charge for the contribution to Eli Lilly and Company Foundation in 1999. The increase was primarily due to an increase in interest income.

The company's effective tax rate for 2000 was 20.8 percent compared with 21.5 percent for 1999. Excluding the unusual items discussed previously, the effective tax rate for both 2000 and 1999 was 22.0 percent. See Note 11 to the consolidated financial statements for additional information.

### FINANCIAL CONDITION

As of December 31, 2001, cash, cash equivalents, and short-term investments totaled approximately \$3.73 billion compared with \$4.62 billion at December 31, 2000. The decrease in cash was primarily due to cash generated from operations and from issuances of debt being more than offset by the purchase of investments, dividends paid, share repurchases, and capital expenditures. The company acquired approximately 7.2 million shares, for approximately \$595.8 million, during 2001 pursuant to its previously announced \$3 billion share repurchase program. The company has now completed \$1.41 billion of purchases in connection with that program.

Total debt at December 31, 2001, was \$3.42 billion, an increase of \$600.4 million, primarily due to the issuance of \$250 million of one-year resettable notes in March 2001, \$250 million of 30-year debt in May 2001, \$400 million of five-year notes in July 2001, and \$249.5 million of seven-year debt in November 2001. This issuance of debt was partially offset by the repurchase of \$401.2 million of higher interest rate debt, which resulted in an extraordinary charge of \$45.2 million (\$29.4 million net of income taxes), and additional repayment of short-term debt.

Capital expenditures of \$884.0 million during 2001 were \$206.1 million more than in 2000 as the company continued to invest in manufacturing and research and development initiatives and related infrastructure. The company expects near-term capital expenditures to increase significantly from 2001 levels.

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Dividends of \$1.12 per share were paid in 2001, an increase of 8 percent from the \$1.04 per share paid in 2000. In the fourth quarter of 2001, effective for the first-quarter dividend in 2002, the quarterly dividend was increased to \$.31 per share (11 percent increase), resulting in an indicated annual rate for 2002 of \$1.24 per share. The year 2001 was the 117th consecutive year in which the company made dividend payments and the 34th consecutive year in which dividends have been increased.

The company believes that cash generated from operations, along with available cash and cash equivalents, will be sufficient to fund most of the company's operating needs, including debt service, share repurchases, capital expenditures, and dividends in 2002. The company will issue additional debt in 2002 to fund the remaining cash requirements. The company believes that, if necessary, amounts available through existing commercial paper programs should be adequate to fund maturities of short-term borrowings. The company's commercial paper program is also currently backed by \$2.03 billion of committed bank credit facilities. Various risks and uncertainties, including those discussed in the "Other Matters" and "Financial Expectations for 2002 and 2003" sections, may affect the company's operating results and cash generated from operations.

In the normal course of business, operations of the company are exposed to fluctuations in interest rates and currency values. These fluctuations can vary the costs of financing, investing, and operating. The company addresses 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.

The company's primary interest rate risk exposure results from changes in short-term U.S. dollar interest rates. In an effort to manage interest rate exposures, the company strives 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 the company's overall interest rate exposure at December 31, 2001 and 2000, 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, 2001 and 2000, respectively, would have no material impact on earnings, cash flows, or fair values of interest rate risk-sensitive instruments over a one-year period.

The company's foreign currency risk exposure results from fluctuating currency exchange rates, primarily the strengthening of the U.S. dollar against the Japanese yen and the euro. The company faces transactional currency exposures that arise when its foreign subsidiaries (or the company itself) enter into transactions, generally on an intercompany basis, denominated in currencies other than their local currency. The company also faces currency exposure that arises from translating the results of its global operations to the U.S. dollar at exchange rates that have fluctuated from the beginning of the period. The company uses forward contracts and purchased options to manage its foreign currency exposures. Company 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 the company's derivative financial instruments outstanding at December 31, 2001 and 2000, a hypothetical 10 percent change in exchange rates (primarily against the U.S. dollar) as of December 31, 2001 and 2000, 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.

### CRITICAL ACCOUNTING POLICIES

To understand the company's financial statements, it is important to understand its accounting policies. In preparing the financial statements in accordance with generally accepted accounting principles (GAAP), management must often 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. 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 made by the company, there may also be other estimates or assumptions that are reasonable; however, the company believes that given current facts and circumstances, it is unlikely that applying any such other reasonable judgment would cause a material adverse effect on the company's consolidated results of operations, financial position, or liquidity for the periods presented in this report.

The company's most critical accounting policies include sales rebates and discounts and their impact on revenue recognition; licensing arrangements, including milestone recognition and acquired in-process research and development; product litigation liabilities; pension benefit costs; recoverability of deferred tax assets; and other contingencies.

Sales rebate and discount accruals, the largest of which relates to Medicaid rebates, are established in the same period the related sales are recorded and are included in other current liabilities. The accruals are based on estimates of the proportion of sales that will be subject to rebates and discounts. A 5 percent change in the Medicaid rebate accrual assumptions would lead to an approximate \$9 million effect on the statement of operations before income taxes (Note 1).

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Licensing milestone income is recorded in other income and recognized upon the occurrence of the event requiring the milestone payment (Note 1).

Acquired in-process research and development costs are recognized at the time of acquisition if the regulatory agency has not yet approved the acquired technology or compound and there is no alternative future use. Licensing milestone expense is generally recognized when the event requiring payment of the milestone occurs (Notes 1 and 3).

Product litigation liabilities and other contingencies are based upon judgments and probabilities. Due in part to the insurance coverage currently in effect, a reasonable change in product litigation liability assumptions would not have a material effect on consolidated results of operations (Note 13).

Pension benefit costs include assumptions for the discount rate, expected return on plan assets, and the health-care-cost trend rates. See Note 12 for a discussion of these assumptions and how a change in these assumptions could affect the company's results of operations.

The company has recorded valuation allowances related to deferred tax assets primarily from net operating loss carryforwards. The company has not assumed future taxable income or tax planning strategies in the jurisdictions associated with these carryforwards. Implementation of tax planning strategies in these jurisdictions could lead to additional income recognition. If it were determined that 5 percent of these carryforwards currently reserved for could be utilized, the company would recognize approximately \$17 million additional net income (Notes 1 and 11).

## OTHER MATTERS

In mid-2001, Lilly ICOS LLC, a joint venture between ICOS Corporation and the company, submitted to the FDA a New Drug Application (NDA) for Cialis to treat erectile dysfunction.

In the fourth quarter of 2001, the company filed with the FDA an NDA for the use of atomoxetine, a treatment for attention-deficit hyperactivity disorder (ADHD) in children, adolescents, and adults. If approved for use, atomoxetine would be the first nonstimulant and the first new type of medication for the treatment of ADHD in more than 30 years.

Also in the fourth quarter of 2001, the company submitted to the FDA an NDA for duloxetine for the treatment of depression. Clinical trials suggest that duloxetine's clinical profile may enable it to address a number of unmet medical needs in the antidepressant market.

On March 29, 2001, the company received an approvable letter from the FDA for Zyprexa IntraMuscular for the treatment of agitation associated with schizophrenia, bipolar mania, and dementia. Approval is contingent upon successful completion of manufacturing inspections. On October 6, 2001, the company received an approvable letter from the FDA for the use of Fortéo in postmenopausal women and men with osteoporosis. Approval is contingent upon labeling negotiations, agreement on measures to ensure appropriate use of the product, and successful completion of manufacturing inspections.

As a result of preapproval plant inspections for those two products in early 2001, the FDA informed the company of a number of observations and issued the company a warning letter regarding its adherence to current Good Manufacturing Practices (cGMP) regulations. In response, the company has been implementing comprehensive, companywide improvements in its manufacturing operations. In November 2001, following a reinspection of the manufacturing facilities for Zyprexa IntraMuscular and Fortéo, the FDA noted additional observations, primarily relating to computer system validation, manufacturing process reviews, and data handling. The company has responded to the FDA relative to these observations and has met with agency officials to discuss its plans to address the issues raised. Approval of new products, including Zyprexa IntraMuscular, Fortéo, and others in the near-term pipeline, such as Cialis, atomoxetine, and duloxetine for depression, will depend on resolution of all manufacturing issues to the agency's satisfaction. The timeline for resolution of these issues is difficult to predict. A manufacturer subject to a warning letter that fails to correct cGMP deficiencies to the agency's satisfaction could be subject to interruption of production, delays in NDA approvals, recalls, seizures, fines, and other penalties.

In the U.S., many pharmaceutical products are subject to increasing pricing pressures, which could be significantly affected by the current national debate over Medicare reform as well as by actions by individual states to reduce pharmaceutical costs for Medicaid and other programs. Many proposals now being considered at the federal and state levels and, in some cases, implemented at the state level, may result in government agencies demanding discounts from pharmaceutical companies that may expressly or implicitly create price controls on prescription drugs. In addition, managed care organizations, institutions, and other government agencies continue to seek price discounts. International operations are also generally subject to extensive price and market regulations. As a result, it is expected that pressures on pharmaceutical pricing will continue.

## FINANCIAL EXPECTATIONS FOR 2002 AND 2003

As noted previously, in early August 2001, generic fluoxetine was introduced in the U.S. market. As a result, sales of Prozac have experienced a very steep decline and further declines are expected beginning in February 2002 when the number of generic sellers of fluoxetine is no longer restricted under the federal Hatch-Waxman Act of 1984. Prozac sales in the U.S. have historically represented a significant portion of the company's overall sales, accounting for approximately 20 percent in 2000. While the Prozac decline is expected to significantly affect results of operations for the 12 months following August 2001, its impact on the company's consolidated financial position or liquidity is not expected to be material due to the growth of the company's newer products including Zyprexa, Humalog, Gemzar, Evista, Actos, and Xigris.

The company currently expects low-to-mid single-digit sales growth for 2002. Several key products are expected to contribute to this growth, including Zyprexa, Gemzar, Evista, diabetes care products, and Xigris. Growth in all these products is anticipated to more than offset the decline of Prozac sales and anti-infectives. The company also plans a number of new-product approvals, including Fortéo, Cialis, atomoxetine, and duloxetine for depression, and the introduction of a new formulation, Zyprexa IntraMuscular.

Gross margins as a percent of sales are expected to decline in 2002 approximately 1 percentage point as a result of the decline in Prozac sales. The company anticipates marketing and administrative expenses will grow at least in the mid-single digits. Research and development expenses are expected to grow in the low-single digits. Nonoperating income is expected to contribute approximately \$100 million in 2002. The effective tax rate is expected to remain at approximately 22 percent for the full year, absent unusual items.

As a result of the above, excluding any unusual items, the company anticipates earnings per share for 2002 to be in the range of \$2.70 to \$2.80. The company continues to expect a decline in earnings per share for the first half of 2002 followed by a return to earnings growth for the second half. For the first quarter of 2002, excluding unusual items, the company expects earnings per share to be in the range of \$.56 to \$.58. For 2003, the company is targeting high-teen earnings-per-share growth, excluding unusual items.

Actual results could differ materially and will depend on, among other things, the timing, number of entrants, and pricing strategies of generic fluoxetine competitors; the continuing growth of the company's other currently marketed products; developments with competitive products; the timing and scope of regulatory approvals, including the necessary FDA approvals of manufacturing operations in connection with pending NDAs; the timing and success of new-product launches; foreign exchange rates; and the impact of state, federal, and foreign government pricing and reimbursement measures. The company undertakes no duty to update these forward-looking statements.

## LEGAL AND ENVIRONMENTAL MATTERS

In February 2001, the company was notified that Zenith Goldline Pharmaceuticals, Inc. ("Zenith"), had submitted an Abbreviated New Drug Application (ANDA) under the federal Hatch-Waxman Act of 1984 seeking permission to market a generic version of Zyprexa in various dosage forms prior to the expiration of the company's U.S. patents for the product, alleging that the patents are invalid or not infringed. On April 2, 2001, the company filed suit against Zenith in federal district court in Indianapolis seeking a ruling that Zenith's challenge to the U.S. compound patent (expiring in 2011) is without merit. In May 2001, the company was notified that Dr. Reddy's Laboratories Ltd. ("Reddy") had also filed an ANDA covering two dosage forms, alleging that the patents are invalid or not infringed. On June 26, 2001, the company filed suit against Reddy in federal district court in Indianapolis seeking a ruling that Reddy's patent challenge is without merit. In January 2002, the company was notified that Reddy had supplemented its ANDA to include the remaining dosage forms. The company believes that the generic manufacturers' patent claims are without merit and expects to prevail in this litigation. However, it is not possible to predict or determine the outcome of this litigation and accordingly there can be no assurance that the company will prevail. An unfavorable outcome could have a material adverse impact on the company's consolidated results of operations, liquidity, and financial position.

Several generic manufacturers filed ANDAs for generic forms of Prozac in various dosage forms, challenging the company's patents under the Hatch-Waxman Act. On May 30, 2001, the Court of Appeals for the Federal Circuit held that the company's 2003 method of use patent was invalid. Generic fluoxetine entered the U.S. market in early August 2001. On January 14, 2002, the U.S. Supreme Court denied a petition filed by the company seeking review of the decision, bringing the litigation to a close.

The company is a defendant in numerous product liability suits involving primarily two products, diethylstilbestrol (DES) and Prozac. See Note 13 to the consolidated financial statements for further information on those matters.

The company's worldwide operations are subject to complex and changing environmental and health and safety laws and regulations, which will continue to require capital investment and operational expenses. The company has also been designated a potentially responsible party with respect to fewer than 10 sites under the federal environmental law commonly known as Superfund. For more information on those matters, see Note 13 to the consolidated financial statements.

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The company is nearing completion of an examination by the Internal Revenue Service (IRS) for tax years 1996 and 1997. Discussions between the company and the IRS are currently under way related to one remaining issue.

While it is not possible to predict or determine the outcome of the patent, product liability, or other legal actions brought against the company or the ultimate cost of environmental matters or the resolution of the examination by the IRS, the company believes that, except as noted above with respect to the patent litigation, the costs associated with all such matters will not have a material adverse effect on its 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, the company cautions investors that any forward-looking statements or projections made by the company, 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, and other factors that may affect the company's operations and prospects are discussed above and in Exhibit 99 to the company's most recent report on Forms 10-Q and 10-K filed with the Securities and Exchange Commission.

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

Year Ended December 31	2001	2000	1999
Net sales	\$11,542.5	\$10,862.2	\$10,002.9
Cost of sales	2,160.2	2,055.7	2,098.0
Research and development	2,235.1	2,018.5	1,783.6
Marketing and administrative	3,417.4	3,228.3	2,757.6
Acquired in-process research and development (Note 3)	190.5	—	—
Asset impairment and other site charges (Note 4)	121.4	—	87.4
Interest expense	146.5	182.3	183.8
Other income—net	(280.7)	(481.3)	(152.9)
	<u>7,990.4</u>	<u>7,003.5</u>	<u>6,757.5</u>
Income from continuing operations before income taxes and extraordinary item	3,552.1	3,858.7	3,245.4
Income taxes (Note 11)	742.7	800.9	698.7
Income from continuing operations before extraordinary item	<u>2,809.4</u>	<u>3,057.8</u>	<u>2,546.7</u>
Income from discontinued operations, net of tax (Note 5)	—	—	174.3
Extraordinary item, net of tax (Note 7)	(29.4)	—	—
Net income	<u>\$ 2,780.0</u>	<u>\$ 3,057.8</u>	<u>\$ 2,721.0</u>
Earnings per share – basic (Note 10)			
Income from continuing operations before extraordinary item	\$ 2.61	\$ 2.83	\$ 2.34
Income from discontinued operations	—	—	.16
Extraordinary item	(.03)	—	—
Net income	<u>\$ 2.58</u>	<u>\$ 2.83</u>	<u>\$ 2.50</u>
Earnings per share – diluted (Note 10)			
Income from continuing operations before extraordinary item	\$ 2.58	\$ 2.79	\$ 2.30
Income from discontinued operations	—	—	.16
Extraordinary item	(.03)	—	—
Net income	<u>\$ 2.55</u>	<u>\$ 2.79</u>	<u>\$ 2.46</u>

See notes to consolidated financial statements.

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

December 31	2001	2000
<b>Assets</b>		
<i>Current Assets</i>		
Cash and cash equivalents	\$ 2,702.3	\$ 4,114.9
Short-term investments	1,028.7	503.3
Accounts receivable, net of allowances of \$88.5 (2001) and \$115.3 (2000)	1,406.2	1,630.7
Other receivables	289.0	335.4
Inventories	1,060.2	883.1
Deferred income taxes (Note 11)	223.3	269.5
Prepaid expenses	229.2	206.1
Total current assets	6,938.9	7,943.0
<i>Other Assets</i>		
Prepaid pension (Note 12)	1,102.8	1,032.5
Investments	2,710.9	395.7
Sundry	1,149.1	1,143.0
	4,962.8	2,571.2
<i>Property and Equipment</i>	4,532.4	4,176.6
	<b>\$16,434.1</b>	<b>\$14,690.8</b>

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Consolidated Balance Sheets  
ELI LILLY AND COMPANY AND SUBSIDIARIES  
(Dollars in millions) – Con't.

December 31	2001	2000
<b>Liabilities and Shareholders' Equity</b>		
<i>Current Liabilities</i>		
Short-term borrowings (Note 7)	\$ 286.3	\$ 184.3
Accounts payable	624.1	661.9
Employee compensation	381.9	468.3
Dividends payable	341.0	315.4
Income taxes payable (Note 11)	2,319.5	2,200.2
Other liabilities	1,250.2	1,130.6
Total current liabilities	5,203.0	4,960.7
<i>Other Liabilities</i>		
Long-term debt (Note 7)	3,132.1	2,633.7
Other noncurrent liabilities	995.0	1,049.5
	4,127.1	3,683.2
Commitments and contingencies (Note 13)	—	—
<i>Shareholders' Equity</i> (Notes 8 and 9)		
Common stock – no par value		
Authorized shares: 3,200,000,000		
Issued shares: 1,124,333,530 (2001) and 1,126,567,407 (2000)	702.7	704.4
Additional paid-in capital	2,610.0	2,610.0
Retained earnings	7,411.2	6,223.2
Employee benefit trust	(2,635.0)	(2,635.0)
Deferred costs – ESOP	(129.1)	(135.0)
Accumulated other comprehensive loss (Note 14)	(748.4)	(611.2)
	7,211.4	6,156.4
Less cost of common stock in treasury		
2001 – 984,781 shares		
2000 – 1,007,235 shares	107.4	109.5
	7,104.0	6,046.9
	\$16,434.1	\$14,690.8

See notes to consolidated financial statements.

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Consolidated Statements of Cash Flows  
 ELI LILLY AND COMPANY AND SUBSIDIARIES  
 (Dollars in millions)

Year Ended December 31	2001	2000	1999
<b>Cash Flows From Operating Activities</b>			
Net income	\$ 2,780.0	\$ 3,057.8	\$ 2,721.0
<b>Adjustments To Reconcile Net Income to Cash Flows From Operating Activities</b>			
Depreciation and amortization	454.9	435.8	439.7
Change in deferred taxes	273.8	(442.7)	27.1
Gain on sale of Kinetra (2000) and PCS (1999), net of tax	—	(214.4)	(174.3)
Acquired in-process research and development, net of tax	123.8	—	—
Asset impairment and other site charges, net of tax	78.9	—	58.1
Other, net	27.6	117.3	96.6
	<u>3,739.0</u>	<u>2,953.8</u>	<u>3,168.2</u>
Changes in operating assets and liabilities			
Receivables – (increase) decrease	167.5	(165.4)	(179.0)
Inventories – (increase) decrease	(184.2)	9.8	16.9
Other assets – increase	(81.1)	(210.5)	(88.8)
Accounts payable and other liabilities – increase (decrease)	20.4	1,143.8	(174.9)
	<u>(77.4)</u>	<u>777.7</u>	<u>(425.8)</u>
<b>Net Cash Provided by Operating Activities</b>	<b>3,661.6</b>	<b>3,731.5</b>	<b>2,742.4</b>
<b>Cash Flows From Investing Activities</b>			
Purchase of property and equipment	(884.0)	(677.9)	(528.3)
Disposals of property and equipment	31.6	5.1	78.3
Proceeds from sale of investments	319.0	983.9	216.1
Purchase of investments	(3,061.7)	(1,233.2)	(162.8)
Purchase of in-process research and development	(159.6)	—	—
Proceeds from sale of PCS	—	—	1,600.0
Other, net	(210.1)	(134.4)	(116.6)
	<u>(3,964.8)</u>	<u>(1,056.5)</u>	<u>1,086.7</u>
<b>Net Cash Provided by (Used in) Investing Activities</b>	<b>(3,964.8)</b>	<b>(1,056.5)</b>	<b>1,086.7</b>
<b>Cash Flows From Financing Activities</b>			
Dividends paid	(1,207.2)	(1,126.0)	(1,000.5)
Purchase of common stock and other capital transactions	(545.7)	(1,052.8)	(1,453.0)
Issuances under stock plans	109.5	178.4	187.5
Net change in short-term borrowings	102.0	(203.0)	(139.4)
Proceeds from issuance of long-term debt	901.3	1.1	843.5
Repayments of long-term debt	(408.6)	(27.2)	(13.5)
	<u>(1,048.7)</u>	<u>(2,229.5)</u>	<u>(1,575.4)</u>
<b>Net Cash Used for Financing Activities</b>	<b>(1,048.7)</b>	<b>(2,229.5)</b>	<b>(1,575.4)</b>
Effect of exchange rate changes on cash	(60.7)	(31.0)	(49.0)
Net increase (decrease) in cash and cash equivalents	(1,412.6)	414.5	2,204.7
Cash and cash equivalents at beginning of year	4,114.9	3,700.4	1,495.7
	<u>\$ 2,702.3</u>	<u>\$ 4,114.9</u>	<u>\$ 3,700.4</u>
<b>Cash and cash equivalents at end of year</b>	<b>\$ 2,702.3</b>	<b>\$ 4,114.9</b>	<b>\$ 3,700.4</b>

See notes to consolidated financial statements.

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Consolidated Statements of Comprehensive Income  
ELI LILLY AND COMPANY AND SUBSIDIARIES  
(Dollars in millions)

Year Ended December 31	2001	2000	1999
Net income	\$2,780.0	\$3,057.8	\$2,721.0
Other comprehensive income (loss)			
Foreign currency translation adjustments	(83.8)	(170.7)	(177.7)
Net unrealized gains (losses) on securities (Note 14)	47.7	(20.5)	27.8
Minimum pension liability adjustment	(95.6)	(33.6)	(26.7)
Effective portion of cash flow hedges	(42.0)	—	—
Other comprehensive loss before income taxes	(173.7)	(224.8)	(176.6)
Provision for income taxes related to other comprehensive loss items	36.5	20.0	—
Other comprehensive loss	(137.2)	(204.8)	(176.6)
Comprehensive income	\$2,642.8	\$2,853.0	\$2,544.4

See notes to consolidated financial statements.

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## ELI LILLY AND COMPANY AND SUBSIDIARIES

(Dollars in millions)

The company operates 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.

<b>Year Ended December 31</b>	<b>2001</b>	<b>2000</b>	<b>1999</b>
<b>Net sales – to unaffiliated customers</b>			
Neurosciences	\$ 5,328.2	\$ 5,157.6	\$ 4,729.3
Endocrinology	3,103.5	2,583.5	2,075.5
Anti-infectives	749.5	894.3	1,022.3
Oncology	739.1	580.5	486.1
Animal health	686.1	668.5	627.8
Cardiovascular	593.4	587.9	637.6
Other pharmaceutical	342.7	389.9	424.3
<b>Net sales</b>	<b>\$11,542.5</b>	<b>\$10,862.2</b>	<b>\$10,002.9</b>
<b>Geographic Information</b>			
<b>Net sales – to unaffiliated customers<sup>1</sup></b>			
United States	\$ 7,364.3	\$ 7,002.9	\$ 6,226.4
Western Europe	1,953.1	1,773.9	1,888.0
Other foreign countries	2,225.1	2,085.4	1,888.5
	<b>\$11,542.5</b>	<b>\$10,862.2</b>	<b>\$10,002.9</b>
<b>Long-lived assets</b>			
United States	\$ 4,015.4	\$ 3,621.0	\$ 3,416.8
Western Europe	767.9	735.3	744.2
Other foreign countries	519.6	472.1	470.3
	<b>\$ 5,302.9</b>	<b>\$ 4,828.4</b>	<b>\$ 4,631.3</b>

<sup>1</sup> Net sales are attributed to the countries based on the location of the subsidiary making the sale.

The largest category of products is the neurosciences group, which includes Zyprexa, Prozac, Permax®, and Darvon®. Endocrinology products consist primarily of Humulin, Evista, Humalog, Actos, and Humatrope®. Anti-infectives include primarily Ceclor®, Vancocin®, Keflex, Nebcin®, and Lorabid®. Oncology products consist primarily of Gemzar. Animal health products include Tylan®, Rumensin®, Micotil®, Surmax®, Coban®, and other products for livestock and poultry. Cardiovascular products consist primarily of ReoPro, Xigris, and Dobutrex®. The other pharmaceutical product group includes primarily Axid® and other miscellaneous pharmaceutical products and services.

Most of the pharmaceutical products are distributed through wholesalers that serve physicians and other health care professionals, pharmacies, and hospitals. In 2001, the company's three largest wholesalers each accounted for between 19 percent and 23 percent of consolidated net sales. Further, they each accounted for between 11 percent and 14 percent of accounts receivable as of December 31, 2001. Animal health products are sold primarily to wholesale distributors.

The company's 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 taxes for the animal health business was approximately \$204 million, \$180 million, and \$165 million in 2001, 2000, and 1999, respectively.

The assets of the animal health business are intermixed with those of the pharmaceutical products business and are not separately determinable. Long-lived assets disclosed above consist of property and equipment and certain sundry assets.

The company is exposed to the risk of changes in social, political, and economic conditions inherent in foreign operations, and the company's results of operations and the value of its foreign assets are affected by fluctuations in foreign currency exchange rates.

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

2001	Fourth	Third	Second	First
Net sales	\$2,828.9	\$2,874.4	\$3,033.5	\$2,805.7
Cost of sales	566.7	549.0	522.2	522.3
Operating expenses	1,472.6	1,431.9	1,463.6	1,284.4
Acquired in-process research and development	100.0	90.5	—	—
Asset impairment and other site charges	—	121.4	—	—
Other income – net	(51.7)	(33.7)	(13.4)	(35.4)
Income before income taxes and extraordinary item	741.3	715.3	1,061.1	1,034.4
Net income	575.41	570.11	827.7	806.8
Earnings per share – basic	.53	.53	.77	.75
Earnings per share – diluted	.53	.52	.76	.74
Dividends paid per share	.28	.28	.28	.28
Common stock prices				
High	83.60	83.37	87.47	90.23
Low	74.73	73.65	73.15	71.83
2000	Fourth	Third	Second	First
Net sales	\$2,977.7	\$2,811.9	\$2,621.5	\$2,451.1
Cost of sales	565.2	490.1	491.7	508.7
Operating expenses	1,489.4	1,306.4	1,304.2	1,146.8
Other (income) expense – net	(60.6)	17.0	(28.5)	(226.9)
Income before income taxes	983.7	998.4	854.1	1,022.5
Net income	767.3	778.8	666.2	845.5
Earnings per share – basic	.71	.72	.62	.78
Earnings per share – diluted	.70	.71	.61	.77
Dividends paid per share	.26	.26	.26	.26
Common stock prices				
High	94.50	108.24	101.33	70.86
Low	80.64	67.18	64.13	54.34

The company's common stock is listed on the New York, London, Tokyo, and other stock exchanges.

<sup>1</sup> Extraordinary charges of \$12.8 million and \$16.6 million, net of a \$6.8 million and \$9.0 million income tax benefit, were recognized as a result of debt repurchased during the fourth quarter and third quarter of 2001, respectively.

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

	2001	2000	1999	1998	1997
<b>Operations</b>					
Net sales	\$ 11,542.5	\$ 10,862.2	\$ 10,002.9	\$ 9,236.8	\$ 7,987.7
Research and development	2,235.1	2,018.5	1,783.6	1,738.9	1,370.2
Other costs and expenses	5,755.3	4,985.0	4,973.9	4,832.9	4,348.2
Gain on sale of DowElanco	—	—	—	—	(631.8)
Income from continuing operations before taxes and extraordinary item	3,552.1	3,858.7	3,245.4	2,665.0	2,901.1
Income taxes	742.7	800.9	698.7	568.7	885.2
Income from:					
Continuing operations before extraordinary item	2,809.4	3,057.8	2,546.7	2,096.3	2,015.9
Discontinued operations	—	—	174.3	8.8	(2,401.0)
Net income (loss)	2,780.0 <sup>2</sup>	3,057.8	2,721.0	2,097.9 <sup>2</sup>	(385.1)
Income from continuing operations before extraordinary item as a percent of sales	24.3%	28.2%	25.5%	22.7%	25.2%
Per-share data – diluted:					
Income (loss) from:					
Continuing operations before extraordinary item	\$ 2.58	\$ 2.79	\$ 2.30	\$ 1.87	\$ 1.78
Discontinued operations	—	—	.16	.01	(2.12)
Net income (loss)	2.55 <sup>2</sup>	2.79	2.46	1.87 <sup>2</sup>	(.34)
Dividends declared per share	1.15	1.06	.95	.83	.76
Weighted-average number of shares outstanding – diluted (thousands)	1,090,793	1,097,725	1,106,055	1,121,486	1,130,579
<b>Financial Position</b>					
Current assets	\$ 6,938.9	\$ 7,943.0	\$ 7,055.5	\$ 5,406.8	\$ 5,320.7
Current liabilities	5,203.0	4,960.7	3,935.4	4,607.2	4,191.6
Property and equipment – net	4,532.4	4,176.6	3,981.5	4,096.3	4,101.7
Total assets	16,434.1	14,690.8	12,825.2	12,595.5	12,577.4
Long-term debt	3,132.1	2,633.7	2,811.9	2,185.5	2,326.1
Shareholders' equity	7,104.0	6,046.9	5,013.0	4,429.6	4,645.6
<b>Supplementary Data<sup>1</sup></b>					
Return on shareholders' equity	42.7%	55.3%	53.9%	46.2%	37.5%
Return on assets	18.0%	22.9%	21.3%	17.0%	15.4%
Capital expenditures	\$ 884.0	\$ 677.9	\$ 528.3	\$ 419.9	\$ 366.3
Depreciation and amortization	454.9	435.8	439.7	490.4	509.8
Effective tax rate	20.9%	20.8%	21.5%	21.3%	30.5% <sup>3</sup>
Number of employees	41,100	35,700	31,300	29,800	28,900
Number of shareholders of record	57,700	59,200	62,300	62,300	58,200

<sup>1</sup> All supplementary financial data have been computed using income from continuing operations except for capital expenditures and depreciation and amortization, which include amounts from discontinued operations. The number of employees reflects continuing operations, including controlled joint ventures.

<sup>2</sup> Reflects the impact of an extraordinary item in 2001 (see Note 7) and 1998.

<sup>3</sup> Excluding the impacts of the unusual transactions reflected in 1997, the effective tax rate would have been 24.1 percent.

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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 accounts of all wholly owned and majority-owned subsidiaries are included in the consolidated financial statements. All intercompany balances and transactions have been eliminated.

The preparation of financial statements in conformity with generally accepted accounting principles 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).

**Reclassifications:** Certain reclassifications have been made to prior-year amounts to conform with current-year presentation.

**Cash equivalents:** The company considers 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:** The company states all its inventories at the lower of cost or market. The company uses the last-in, first-out (LIFO) method for substantially all its inventories located in the continental United States, or approximately 51 percent of its total inventories. Other inventories are valued by the first-in, first-out (FIFO) method. Inventories at December 31 consisted of the following:

	2001	2000
Finished products	\$ 315.1	\$284.3
Work in process	489.6	380.6
Raw materials and supplies	264.9	230.1
	1,069.6	895.0
Reduction to LIFO cost	(9.4)	(11.9)
	<u>\$1,060.2</u>	<u>\$883.1</u>

**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 currently. Factors the company considers in making this evaluation include 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 initial cost adjusted for any other-than-temporary declines in fair value. The company owns no investments that are considered to be trading securities.

**Derivative financial instruments:** The company's 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, the company designates the instruments individually as either a fair value hedge or a cash flow hedge. Management reviews the correlation and effectiveness of its derivatives on a periodic 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.

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The company enters into foreign currency forward and option contracts to reduce the effect of fluctuating currency exchange rates (principally the Japanese yen and the euro). 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. The company 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, operations of the company are exposed to fluctuations in interest rates. These fluctuations can vary the costs of financing, investing, and operating. The company addresses 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 rates. The company's primary interest rate risk exposure results from changes in short-term U.S. dollar interest rates. In an effort to manage interest rate exposures, the company strives 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 the company's fixed rate debt or investments to a floating rate are designated as fair value hedges of the underlying debt. Interest rate swaps or collars that convert floating rate debt or investments to a fixed rate are designated as cash flow hedges. Interest expense on the debt is adjusted to include the payments made or received under the swap agreements.

**Goodwill and other intangibles:** Goodwill and other intangibles arising from acquisitions and research alliances are amortized over their estimated useful lives, ranging from 5-25 years, using the straight-line method. Goodwill and other intangibles are reviewed to assess recoverability when impairment indicators are present. Assets are considered to be impaired and are written down to fair value if expected future operating cash flows of the related assets are less than their carrying amounts. Fair value is the present value of the expected future cash flows of the related assets using a discount rate commensurate with the risk involved. Assets are grouped at the lowest level for which there are identifiable cash flows for purposes of impairment testing. Goodwill and other intangibles and the related allowances for amortization were \$191.3 million and \$98.2 million, respectively, at December 31, 2001, and \$233.2 million and \$117.8 million, respectively, at December 31, 2000, and are included in sundry assets in the consolidated balance sheets. Upon adoption of Statement of Financial Accounting Standards (SFAS) 142, "Goodwill and Other Intangible Assets," effective in January 2002, amortization of goodwill and those intangible assets identified as having an indefinite life will cease. See Note 2 for additional information.

**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 5 to 18 years for equipment).

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

	2001	2000
Land	\$ 99.8	\$ 103.5
Buildings	2,593.1	2,395.1
Equipment	4,776.8	4,638.5
Construction in progress	945.7	647.6
	8,415.4	7,784.7
Less allowances for depreciation	3,883.0	3,608.1
	\$4,532.4	\$4,176.6

Depreciation expense related to continuing operations for 2001, 2000, and 1999 was \$414.9 million, \$393.5 million, and \$406.7 million, respectively. Approximately \$61.5 million, \$43.1 million, and \$29.0 million of interest costs were capitalized as part of property and equipment in 2001, 2000, and 1999, respectively. Total rental expense for all leases related to continuing operations, including contingent rentals (not material), amounted to approximately \$207.1 million, \$172.3 million, and \$154.9 million for 2001, 2000, and 1999, 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:** Revenue from sales of products is recognized 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 and are included in other current liabilities. Revenue from copromotion services is recognized at the time the copromotion partner records sales. Income

received from milestone payments is recorded in other income and is recognized upon the occurrence of the event requiring the milestone payment.

**Acquired in-process research and development:** 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 is expensed as incurred. Licensing milestone expense is generally recognized 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.

**Earnings per share:** Basic earnings per share are calculated based on the weighted-average number of outstanding common shares and incremental shares. Diluted earnings per share are calculated based on the weighted-average number of outstanding common shares plus the effect of dilutive stock options and other incremental shares.

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

The company adopted SFAS 133, "Accounting for Derivative Instruments and Hedging Activities," as amended on January 1, 2001. The statement requires the company to recognize all derivatives on the balance sheet at fair value. Derivatives that are not hedges must be adjusted to fair value through income. If the derivative is a hedge, depending on the nature of the hedge, changes in the fair value of derivatives will either be offset against the change in fair value of the hedged assets, liabilities, or firm commitments through earnings or recognized in other comprehensive income until the hedged item is recognized in earnings. Hedge ineffectiveness, the amount by which the change in the value of a hedge does not exactly offset the change in the value of the hedged item, will be immediately recognized in earnings. The adoption of SFAS 133 on January 1, 2001, did not have a material effect on the consolidated results of operations or financial position of the company, as it increased other income by less than \$1 million and decreased other comprehensive income by approximately \$15 million.

In 2001, the Financial Accounting Standards Board (FASB) issued SFAS 141, "Business Combinations," and SFAS 142, "Goodwill and Other Intangible Assets." SFAS 141 applies to all business combinations with a closing date after June 30, 2001, and effectively eliminates the pooling-of-interests method of accounting and further clarifies the recognition of intangible assets separately from goodwill.

SFAS 142 applies to all acquired intangible assets. Upon adoption, goodwill and other identifiable intangible assets with an indefinite useful life will not be amortized but are required to be tested for impairment at least annually. Identifiable intangible assets will be amortized when their useful life is determined to no longer be indefinite. The company will adopt this statement effective as of January 1, 2002, and does not expect that this statement will have a material impact on its consolidated financial position or results of operations.

In 2001, the 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 period. In addition, the 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 asset. The company will adopt SFAS 143 on January 1, 2003, and does not expect that this statement will have a material impact on its consolidated financial position or results of operations.

In 2001, the FASB issued SFAS 144, "Accounting for the Impairment or Disposal of Long-Lived Assets." SFAS 144 significantly changes the criteria that would have to be met to classify an asset as held-for-sale. This statement also requires expected future operating losses from discontinued operations to be recorded in the period in which the losses are incurred (rather than as of the date management commits to a formal plan to dispose of a segment as presently required). In addition, more dispositions will qualify for discontinued operations treatment in the income statement. The company will adopt SFAS 144 effective as of January 1, 2002, and does not expect that this statement will have a material impact on its consolidated financial position or results of operations.

**Note 3: Collaborations and Dispositions**

In 2001, the company entered into significant collaboration arrangements with three companies. In August, the company licensed Isis Pharmaceuticals, Inc.'s non-small-cell lung cancer drug candidate and entered into an agreement regarding an ongoing research collaboration. In September, the company entered into a collaboration with Bioprojet, Société Civile de Recherche to jointly develop and commercialize a vasopeptidase inhibitor (fasidotril) for hypertension and chronic heart failure. In October, the company entered into a collaboration with Minnesota Mining and Manufacturing Company to jointly develop and commercialize an immune response modifier (resiquimod) for various forms of herpes. These compounds are in the development phase (late Phase II / early Phase III clinical trials) and no alternative future uses were identified. As with many late Phase II / early Phase III compounds, launch of the products, if successful, is not expected in the near term. The company's charge for acquired in-process research and development expense related to these arrangements totaled \$190.5 million.

During the first quarter of 2000, the company sold its interest in Kinetra LLC, a joint venture between the company and EDS, to WebMD Corporation (WebMD) in exchange for shares of WebMD common stock. A gain of \$214.4 million was recognized on the combined effect of the transaction and the subsequent sale of the majority of those shares of WebMD stock. The gain is included in other income in the consolidated statements of income.

During 1999, the company recognized a pretax gain of \$67.8 million on the sale of the U.S. and Puerto Rican marketing rights of the antibiotic Lorabid to King Pharmaceuticals, Inc. The gain has been included in other income in the consolidated statements of income. The company has an opportunity to receive additional payments if certain sales performance milestones are achieved.

**Note 4: Asset Impairment and Other Site Charges**

The company periodically assesses its worldwide manufacturing capacity to maximize the efficiency of its worldwide manufacturing operations. As a result of this strategic review, the company recognized asset impairments and other site charges totaling \$121.4 million in the third quarter of 2001. The charges principally consist of impairments of facilities and equipment that are expected to be disposed of or destroyed in 2002, termination of third-party manufacturing arrangements, and a plant closure in Taiwan. The impairment charges were necessary to adjust the carrying value of certain manufacturing assets to fair value. The fair value of the assets was estimated based upon anticipated future cash flows, discounted at a rate commensurate with the risk involved. Approximately \$18 million of this charge was for severance-related costs, which are expected to be fully expended by the end of the second quarter of 2002.

The company recognized asset impairments and other site charges totaling \$87.4 million in 1999. The impairment charges were necessary to adjust the carrying value of certain manufacturing assets to fair value. Approximately \$75.0 million of these charges were related to the decommissioning of manufacturing buildings and the related equipment, which resulted from the consolidation of certain manufacturing processes. The company plans to continue ownership of the vacated buildings although no planned future uses have been identified. The fair values of the facilities were estimated based upon anticipated future cash flows, discounted at a rate commensurate with the risk involved.

**Note 5: Discontinued Operations**

In January 1999, the company sold PCS, its health-care-management subsidiary, to Rite Aid Corporation for \$1.6 billion in cash. The transaction generated a gain of \$174.3 million (\$.16 per share), net of \$8.7 million tax benefit, in the first quarter of 1999.

**Note 6: Financial Instruments**

Financial instruments that potentially subject the company 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 the company's ongoing credit review procedures. The company places substantially all its interest-bearing investments with major financial institutions, in U.S. government securities, or with top-rated corporate issuers. In accordance with documented corporate policies, the company limits the amount of credit exposure to any one financial institution. The company is exposed to credit-related losses in the event of nonperformance by counterparties to financial instruments, but it does not expect any counterparties to fail to meet their obligations given their high credit ratings.

**Fair Value of Financial Instruments**

A summary of the company's outstanding financial instruments at December 31 follows:

	2001		2000	
	Carrying Amount	Fair Value	Carrying Amount	Fair Value
Short-term investments				
Debt securities	\$1,028.7	\$1,028.7	\$ 503.3	\$ 504.3
Noncurrent investments				
Marketable equity	179.6	179.6	79.8	90.1
Debt securities	1,983.7	1,984.1	266.2	271.2
Nonmarketable equity	12.7	12.7	7.5	7.5
Long-term debt, including current portion	3,144.3	3,258.1	2,796.6	2,861.7

The company determines fair values based on quoted market values where available or discounted cash flow analyses (principally long-term debt). The fair values of nonmarketable equity securities, which represent either equity investments in start-up technology companies or partnerships that invest in start-up technology companies, are estimated based on the fair value information provided by these ventures. The fair value and carrying amount of risk-management instruments were not material at December 31, 2001 and 2000. In addition to the financial instruments above, the company has an equity method investment in an investment company with a carrying amount of \$500.6 million at December 31, 2001. Approximately \$2.1 billion of the company's debt securities mature within five years.

At December 31, 2001 and 2000, the gross unrealized holding gains on available-for-sale securities were \$65.6 million and \$24.3 million, respectively, and the gross unrealized holding losses were \$8.5 million and \$14.9 million, respectively. The proceeds from sales of available-for-sale securities totaled \$262.1 million, \$773.8 million, and \$56.2 million in 2001, 2000, and 1999, respectively. Purchases of available-for-sale securities were \$3.23 billion, \$443.0 million, and negligible in 2001, 2000, and 1999, respectively. Realized gains on sales of available-for-sale securities were \$14.1 million, \$71.6 million, and \$25.0 million in 2001, 2000, and 1999, respectively. Realized losses on sales of available-for-sale securities were \$0.1 million, \$16.5 million, and negligible in 2001, 2000, and 1999, respectively. The net adjustment to unrealized gains and losses on available-for-sale securities increased (decreased) other comprehensive income by \$34.3 million, (\$12.3) million, and \$18.6 million in 2001, 2000, and 1999, respectively.

During the year ended December 31, 2001, 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.

The company expects to reclassify approximately \$21.6 million of pretax net gains on cash flow hedges from accumulated other comprehensive loss to earnings during 2002.

**Note 7: Borrowings**

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

	2001	2000
6.57 to 7.13 percent notes (due 2016-2036)	\$ 787.4	\$1,000.0
5.50 to 8.38 percent notes (due 2001-2006)	711.4	650.0
Floating rate capital securities (due 2029)	525.0	525.0
Floating rate bonds (due 2008-2031)	505.0	—
8.38 percent eurodollar bonds (due 2005)	150.0	150.0
Resettable coupon capital securities (due 2029)	300.0	300.0
6.55 percent ESOP debentures (due 2017)	96.6	97.6
Other, including capitalized leases	68.9	74.0
	3,144.3	2,796.6
Less current portion	12.2	162.9
	\$3,132.1	\$2,633.7

In May 2001, the company issued \$250 million of 30-year floating rate bonds. The variable interest rate is at LIBOR (1.97 percent at December 31, 2001) for the first three years and will adjust every six months after the first three years to reflect the company's six-month credit spread. The interest accumulates over the life of the bonds and is payable upon maturity. The company has an option to begin periodic interest payments any time after the first three years. At the time of option exercise, the company would owe all previously accrued interest on the bonds. In addition, in 2001, the company issued \$400.0 million of 5.50 percent notes due July 2006 and \$249.5 million of floating rate bonds due October 2008.

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In 1999, the company issued \$525.0 million floating rate capital securities and \$300.0 million adjustable rate capital securities. These capital securities are subordinated to the notes, bonds, and debentures listed above. The floating rate capital securities pay cumulative interest at an annual rate equal to LIBOR plus a predetermined spread, reset quarterly. The rates at December 31, 2001 and 2000, were 3.41 percent and 7.95 percent, respectively. The securities may be redeemed any time on or after August 5, 2004, for a defined redemption price. The resettable coupon capital securities pay cumulative interest at an annual rate of 7.72 percent until August 1, 2004. At this date and every fifth anniversary thereafter, the interest rate will be reset equal to the weekly average interest rate of U.S. treasury securities having an index maturity of five years for the week immediately preceding the reset date plus a predetermined spread. The securities may be redeemed on August 1, 2004, and anytime thereafter for a defined redemption price.

The 6.55 percent Employee Stock Ownership Plan (ESOP) debentures are obligations of the ESOP but are shown on the consolidated balance sheet because they are guaranteed by the company. The principal and interest on the debt are funded by contributions from the company 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.

In 2001, the company repurchased \$188.6 million of 8.38 percent notes due in 2006, \$14.0 million of 6.77 percent notes due in 2036, and \$198.6 million of 7.13 percent notes due in 2025. As a result of this debt repurchase, the company recognized an extraordinary charge of \$29.4 million, net of a \$15.8 million income tax benefit.

The aggregate amounts of maturities on long-term debt for the next five years are as follows: 2002, \$12.2 million; 2003, \$211.2 million; 2004, \$8.4 million; 2005, \$156.4 million; and 2006, \$514.1 million.

At December 31, 2001 and 2000, short-term borrowings included \$274.1 million and \$21.4 million, respectively, of notes payable to banks. Included in short-term borrowings are \$250 million of 4.25 percent one-year resettable notes issued in March 2001. The notes have a final maturity of 10 years. Annually, the notes will be remarketed or redeemed by the company at the option of the underwriter. At December 31, 2001, unused committed lines of credit totaled approximately \$2.02 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.

The company has converted substantially all fixed rate debt to floating rates through the use of interest rate swaps.

Cash payments of interest on borrowings totaled \$133.7 million, \$195.9 million, and \$170.6 million in 2001, 2000, and 1999, respectively.

### **Note 8: 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 3 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 the company's common stock. The number of performance award shares actually issued varies depending upon the achievement of certain earnings targets. In general, performance awards vest 100 percent at the end of the second fiscal year following the grant date.

The company issued a grant under the GlobalShares program in both 2001 and 1999. Essentially all employees were given an option to buy 125 shares in the 2001 grant and 100 shares in the 1999 grant of the company's stock at a price equal to the fair market value of the company's stock on the date of the grant. Options to purchase approximately 4.3 million and 2.8 million shares were granted as part of the program in 2001 and 1999, respectively. Individual grants generally become exercisable on or after the third anniversary of the grant date and have a term of 10 years.

In the fourth quarter of 2000, the company changed the timing of the annual option grant to management from the fourth quarter to the first quarter of the following year. This resulted in a reduction in options granted in 2000. The company also issued a special stock option grant in 2001 to global management and all employees in the U.S. and Puerto Rico. This option grant was designed to retain and motivate employees affected by the compensation changes due to the Prozac patent expiration. Options to purchase approximately 10.0 million shares were granted as part of this program at a price equal to the fair market value on the date of the grant. Approximately 7.3 million of these options vest in 2002 with the remainder vesting in 2003.

The company has elected to follow Accounting Principles Board (APB) Opinion 25, "Accounting for Stock Issued to Employees," and related interpretations in accounting for its stock options and performance awards. Under APB 25, because the exercise price of the company's employee stock options equals the market price of the underlying stock on the date of grant, no compensation expense is recognized. Total compensation expense for stock-based performance awards reflected in income on a pretax basis was \$13.9 million, \$88.3 million, and \$117.1 million in 2001, 2000, and 1999, respectively. However, SFAS 123, "Accounting for Stock-Based Compensation," requires presentation of pro forma information as if the company had accounted for

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its 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. Under the fair value method, the company's net income and earnings per share would have been as follows:

	2001	2000	1999
Net income	\$2,569.6	\$2,969.3	\$2,639.6
Earnings per share – diluted	2.36	2.70	2.39

The weighted-average per-share fair value of the individual options and performance awards granted during 2001, 2000, and 1999 were as follows on the date of grant:

	2001	2000	1999
Employee stock options	\$26.59	\$29.25	\$20.27
Performance awards	78.86	93.06	66.50

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

	2001	2000	1999
Dividend yield	1.80%	2.26%	2.73%
Volatility	33.10%	32.70%	25.20%
Risk-free interest rate	4.58%	5.02%	6.15%
Forfeiture rate	0	0	0
Expected life	7 years	7 years	7 years

Stock option activity during 1999-2001 is summarized below:

	Shares of Common Stock Attributable to Options (in thousands)	Weighted-Average Exercise Price of Options
Unexercised at January 1, 1999	52,953	\$32.35
Granted	12,494	68.22
Exercised	(10,849)	19.04
Forfeited	(875)	50.46
Unexercised at December 31, 1999	53,723	43.08
Granted	1,315	86.75
Exercised	(9,242)	22.33
Forfeited	(671)	64.97
Unexercised at December 31, 2000	45,125	48.28
Granted	26,883	76.10
Exercised	(4,298)	26.72
Forfeited	(612)	71.20
Unexercised at December 31, 2001	67,098	60.60

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The following table summarizes information concerning outstanding and exercisable options at December 31, 2001 (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
\$10 - \$25	13.11	2.86	18.62	13.11	18.62
\$25 - \$65	8.20	5.40	52.24	8.17	52.20
\$65 - \$70	9.13	7.79	66.38	.58	66.38
\$70 - \$75	24.52	8.38	74.09	13.31	74.19
\$75 - \$95	12.14	9.66	80.01	.01	82.13

Shares exercisable at December 31, 2001, 2000, and 1999 were 35.2 million, 26.1 million, and 29.9 million, respectively.

As noted above, the number of shares ultimately issued pursuant to the performance award program is dependent upon the earnings achieved during the vesting period. Pursuant to this plan, approximately 0.8 million shares, 1.2 million shares, and 2.2 million shares were issued in 2001, 2000, and 1999, respectively. At December 31, 2001, plan participants had the right to receive up to 2.1 million additional shares (reduced to the extent necessary to satisfy payroll tax withholdings), contingent upon earnings achieved.

At December 31, 2001, additional options, performance awards, or restricted stock grants may be granted under the 1998 Lilly Stock Plan and the Lilly GlobalShares Stock Plan for not more than 16.5 million shares and 2.0 million shares, 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, 1999	\$ —	\$ 4,228.8	\$(146.9)	995	\$ 109.0
Net income		2,721.0			
Cash dividends declared per share: \$.95		(1,030.5)			
Retirement of treasury shares	(1,488.4)			(19,689)	(1,500.8)
Purchase for treasury				19,147	1,455.1
Issuance of stock under employee stock plans	530.6			542	45.7
ESOP transactions	20.8		7.0		
Other	3.3			(6)	(0.7)
Reclassification	933.7	(933.7)			
Balance at					
December 31, 1999	—	4,985.6	(139.9)	989	108.3
Net income		3,057.8			
Cash dividends declared per share: \$1.06		(1,158.4)			
Retirement of treasury shares	(1,117.6)			(15,256)	(1,126.9)
Purchase for treasury	34.3			14,794	1,089.8
Issuance of stock under employee stock plans	405.6			494	39.8
Issuance of stock for employee benefit trust	2,610.0				
ESOP transactions	16.7		4.9		
Other	(0.6)	(0.2)		(14)	(1.5)
Reclassification	661.6	(661.6)			
Balance at					
December 31, 2000	2,610.0	6,223.2	(135.0)	1,007	109.5
Net income		2,780.0			
Cash dividends declared per share: \$1.15		(1,232.8)			
Retirement of treasury shares	(581.8)			(7,368)	(586.7)
Purchase for treasury	(24.8)			7,176	571.0
Issuance of stock under employee stock plans	229.0			170	13.6
ESOP transactions	18.4		5.9		
Other	0.1	(0.1)			
Reclassification	359.1	(359.1)			
Balance at					
December 31, 2001	\$ 2,610.0	\$ 7,411.2	\$(129.1)	985	\$ 107.4

As of December 31, 2001, the company has purchased \$1.41 billion of its announced \$3.0 billion share repurchase program. A \$1.5 billion share repurchase program was completed in 1999. The company acquired approximately 7.2 million, 14.8 million, and 19.1 million shares in 2001, 2000, and 1999, respectively, pursuant to these programs.

In connection with the share repurchase program, the company has entered into agreements to purchase shares of the company's stock. As of December 31, 2001, the company has agreements to purchase up to approximately 6.0 million shares of company stock from an independent third party at various times through the expiration of the agreements in December 2003 at prices ranging from

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\$80 to \$100 per share. The number of shares to be purchased will be reduced ratably each quarter through the expiration of the agreements. In addition, as of December 31, 2001, equity forward and other derivative contracts, which provide for purchase of a total of approximately 2.1 million shares, remain outstanding at prices ranging from \$83 to \$98 per share with expiration dates ranging from May 2002 to November 2002. If the options are exercised, the contracts allow the company, at its option, to repurchase the shares for cash or deliver to the holder cash or shares for the difference between the contractual exercise price and the market price of the company's stock. The company's objective with the above agreements is to reduce the average price of repurchased shares.

The company has five million authorized shares of preferred stock. As of December 31, 2001 and 2000, no preferred stock has been issued.

In 2000, the company funded an employee benefit trust with 40 million shares of Lilly common stock to provide a source of funds to assist the company in meeting its obligations under various employee benefit plans. The funding had no net impact on shareholders' equity as the employee benefit trust is consolidated with the company. 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 the company and the trust are eliminated. Stock held by the trust is not considered outstanding in the computation of earnings per share.

The company has an ESOP as a funding vehicle for the existing employee savings plan. The ESOP used the proceeds of a loan from the company to purchase shares of common stock from the treasury. The ESOP issued \$200 million of third-party debt, repayment of which was guaranteed by the company (see Note 7). The proceeds were used to purchase shares of the company's 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 the company's 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 the company's common stock. The company may redeem the rights for \$.005 per right up to and including the Distribution Date. The rights will expire on July 28, 2008, unless redeemed earlier by the company.

The plan provides that, if an Acquiring Person acquires 15 percent or more of the outstanding common stock of the company and the company's 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 common stock of the company as have a value of two times the exercise price.

Alternatively, if, in a transaction not approved by the board of directors, the company is acquired in a business combination transaction or sells 50 percent or more of its 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 as 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 the company's outstanding common stock, the board of directors may exchange the rights (other than those owned by the Acquiring Person) for company 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 from continuing operations before extraordinary item:

	2001	2000	1999
	(Shares in thousands)		
Income from continuing operations before extraordinary item available to common shareholders	\$ 2,809.4	\$ 3,057.8	\$ 2,546.6
Basic earnings per share			
Weighted-average number of common shares outstanding, including incremental shares	1,077,497	1,081,559	1,087,652
Basic earnings per share from continuing operations before extraordinary item	\$ 2.61	\$ 2.83	\$ 2.34
Diluted earnings per share			
Weighted-average number of common shares outstanding	1,077,390	1,081,409	1,087,368
Stock options and other incremental shares	13,403	16,316	18,687
Weighted-average number of common shares outstanding — diluted	1,090,793	1,097,725	1,106,055
Diluted earnings per share from continuing operations before extraordinary item	\$ 2.58	\$ 2.79	\$ 2.30

**Note 11: Income Taxes**

Following is the composition of income taxes attributable to continuing operations before extraordinary item:

	2001	2000	1999
Current			
Federal	\$ 313.4	\$ 928.4	\$ 439.2
Foreign	247.9	322.4	260.4
State	16.6	(7.2)	(4.9)
	577.9	1,243.6	694.7
Deferred			
Federal	240.5	(81.2)	104.0
Foreign	34.6	(58.6)	22.4
State	0.2	0.9	2.7
	275.3	(138.9)	129.1
Utilization of capital loss carryforwards	(110.5)	(303.8)	(125.1)
Income taxes	\$ 742.7	\$ 800.9	\$ 698.7

Significant components of the company's deferred tax assets and liabilities as of December 31 are as follows:

	2001	2000
Deferred tax assets		
Sale of intangibles	\$ 416.4	\$ 230.6
Other carryforwards	341.8	450.4
Tax credit carryforwards and carrybacks	321.3	734.5
Compensation and benefits	230.2	109.0
Inventory	148.8	70.2
Capital loss carryforward	13.1	158.8
Other	399.6	378.6
	1,871.2	2,132.1
Valuation allowances	(332.2)	(408.0)
Total deferred tax assets	1,539.0	1,724.1
Deferred tax liabilities		
Property and equipment	(528.0)	(527.7)
Prepaid employee benefits	(474.0)	(429.2)
Unremitted earnings	(123.2)	(182.0)
Other	(19.4)	(29.2)
Total deferred tax liabilities	(1,144.6)	(1,168.1)
Deferred tax assets — net	\$ 394.4	\$ 556.0

At December 31, 2001, the company had other carryforwards for international and U.S. income tax purposes of \$201.2 million: \$161.2 million will expire within five years and \$32.3 million thereafter; \$7.7 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. The company also has tax credit carryforwards of \$321.3 million available to reduce future income taxes: \$2.5 million will expire within five years and \$261.6 million thereafter; \$57.2 million of the tax credit carryforwards will never expire.

Domestic and Puerto Rican companies contributed approximately 55 percent, 56 percent, and 56 percent in 2001, 2000, and 1999, respectively, to consolidated income from continuing operations before income taxes and extraordinary item. At December 31, 2001, the company had an aggregate of \$6.4 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 company has a subsidiary operating in Puerto Rico under a tax incentive grant that begins to expire at the end of 2007. Cash payments of income taxes totaled \$320.0 million, \$294.0 million, and \$252.0 million in 2001, 2000, and 1999, respectively.

Following is a reconciliation of the effective income tax rate applicable to income from continuing operations before extraordinary item:

	2001	2000	1999
United States federal statutory tax rate	35.0%	35.0%	35.0%
Add (deduct)			
International operations, including Puerto Rico	(13.9)	(12.9)	(7.5)
General business credits	(1.1)	(1.2)	(1.6)
Sundry	0.9	(0.1)	(4.4)
Effective income tax rate	20.9%	20.8%	21.5%

**Note 12: Retirement Benefits**

The change in benefit obligation, change in plan assets, funded status, and amounts recognized in the consolidated balance sheets at December 31 for the company's defined benefit pension and retiree health benefit plans were as follows:

	Defined Benefit Pension Plans		Retiree Health Benefits	
	2001	2000	2001	2000
<b>Change in benefit obligation</b>				
Benefit obligation at beginning of year	\$3,380.1	\$3,004.4	\$ 751.3	\$ 687.6
Service cost	156.0	130.1	28.7	23.2
Interest cost	242.4	219.6	53.8	49.6
Actuarial loss	88.5	144.3	135.6	51.4
Benefits paid	(218.0)	(179.8)	(64.7)	(61.5)
Foreign currency exchange rate changes and other adjustments	(50.3)	61.5	23.5	1.0
Benefit obligation at end of year	<u>3,598.7</u>	<u>3,380.1</u>	<u>928.2</u>	<u>751.3</u>
<b>Change in plan assets</b>				
Fair value of plan assets at beginning of year	3,732.1	3,532.0	349.2	332.1
Actual return on plan assets	(382.3)	138.7	(37.6)	(16.4)
Employer contribution	63.1	270.0	126.5	95.0
Benefits paid	(218.0)	(179.8)	(64.7)	(61.5)
Foreign currency exchange rate changes and other adjustments	(12.8)	(28.8)	—	—
Fair value of plan assets at end of year	<u>3,182.1</u>	<u>3,732.1</u>	<u>373.4</u>	<u>349.2</u>
Funded status	(416.6)	352.0	(554.8)	(402.1)
Unrecognized net actuarial loss	1,142.7	298.8	531.1	317.1
Unrecognized prior service cost (benefit)	208.5	227.2	0.1	(0.1)
Unrecognized net obligation at January 1, 1986	1.1	1.7	1.6	1.8
Net amount recognized	<u>\$ 935.7</u>	<u>\$ 879.7</u>	<u>\$ (22.0)</u>	<u>\$ (83.3)</u>
<b>Amounts recognized in the consolidated balance sheet consisted of</b>				
Prepaid pension	\$1,102.8	\$1,032.5	\$ 42.9	\$ —
Accrued benefit liability	(371.7)	(302.9)	(64.9)	(83.3)
Intangible asset	—	41.1	—	—
Accumulated other comprehensive income before income taxes	204.6	109.0	—	—
Net amount recognized	<u>\$ 935.7</u>	<u>\$ 879.7</u>	<u>\$ (22.0)</u>	<u>\$ (83.3)</u>

(Percents)	Defined Benefit Pension Plans		Retiree Health Benefits	
	2001	2000	2001	2000
Weighted-average assumptions as of December 31				
Discount rate	7.2	7.4	7.2	7.5
Expected return on plan assets	10.5	10.5	10.5	10.5
Rate of compensation increase	3.5-8.0	3.5-8.0	—	—

Health-care-cost trend rates were assumed to increase at an annual rate of 6.0 percent in 2002 and thereafter for all participants.

The projected benefit obligation, accumulated 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 \$778.3 million, \$673.0 million, and \$325.1 million, respectively, as of December 31, 2001, and \$736.8 million, \$616.8 million, and \$381.6 million, respectively, as of December 31, 2000.

Net pension and retiree health benefit expense included the following components related to continuing operations:

	Defined Benefit Pension Plans			Retiree Health Benefits		
	2001	2000	1999	2001	2000	1999
Components of net periodic benefit cost						
Service cost	\$ 156.0	\$ 130.1	\$ 127.7	\$ 28.7	\$ 23.2	\$ 16.8
Interest cost	242.4	219.6	193.7	53.8	49.6	41.5
Expected return on plan assets	(382.3)	(341.0)	(295.1)	(40.1)	(30.1)	(24.2)
Amortization of prior service cost	19.3	16.9	11.5	0.1	0.1	—
Recognized actuarial loss	9.8	5.9	3.7	23.6	21.9	17.6
Net periodic benefit cost	\$ 45.2	\$ 31.5	\$ 41.5	\$ 66.1	\$ 64.7	\$ 51.7

The assumed health-care trend rates, discount rates, and expected return on plan assets have a significant effect on the amounts reported. If the health-care trend rates were to be increased by one percentage point each future year, the December 31, 2001, accumulated postretirement benefit obligation would increase by 14 percent and the aggregate of the service cost and interest cost components of 2001 annual expense would increase by 16 percent. A one-percentage-point decrease in these rates would decrease the December 31, 2001, accumulated postretirement benefit obligation by 12 percent and the aggregate of the 2001 service cost and interest cost by 13 percent. If the discount rate were to be changed by a quarter percentage point, the net periodic benefit cost of the defined benefit pension plans would be changed by approximately \$3 million. If the expected return on plan assets were to be changed by a quarter percentage point, the net periodic benefit cost of the defined benefit pension plans would change by approximately \$8 million.

The company has defined contribution savings plans that cover its 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. Company contributions to the plan are based on employee contributions and the level of company match. Expenses under the plans related to continuing operations totaled \$39.3 million, \$65.2 million, and \$56.4 million for the years 2001, 2000, and 1999, respectively.

The company provides certain other postemployment benefits primarily related to disability benefits and accrues for the related cost over the service lives of employees. Expenses associated with these benefit plans in 2001, 2000, and 1999 were not significant.

**Note 13: Contingencies**

In February 2001, the company was notified that Zenith Goldline Pharmaceuticals, Inc. (“Zenith”), had submitted an Abbreviated New Drug Application (ANDA) under the Hatch-Waxman Act of 1984 seeking permission to market a generic version of Zyprexa in various dosage forms prior to the expiration of the company’s U.S. patents for the product, alleging that the patents are invalid or not infringed. On April 2, 2001, the company filed suit against Zenith in federal district court in Indianapolis seeking a ruling that Zenith’s challenge to the U.S. compound patent (expiring in 2011) is without merit. In May 2001, the company was notified that Dr. Reddy’s Laboratories Ltd. (“Reddy”) had also filed an ANDA covering two dosage forms, alleging that the patents are invalid or not infringed. On June 26, 2001, the company filed suit against Reddy in federal district court in Indianapolis seeking a ruling that Reddy’s patent challenge is without merit. In January 2002, the company was notified that Reddy had supplemented its ANDA to include the remaining dosage forms. The company believes that the generic manufacturers’ patent claims are without merit and expects to prevail in this litigation. However, it is not possible to predict or determine the outcome of this litigation and, accordingly, there can be no assurance that the company will prevail. An unfavorable outcome could have a material adverse impact on the company’s consolidated results of operations, liquidity, and financial position.

Several generic manufacturers filed ANDAs for generic forms of Prozac in various dosage forms, challenging the company’s patents under the Hatch-Waxman Act. On May 30, 2001, the Court of Appeals for the Federal Circuit held that the company’s 2003 method of use patent was invalid. Generic fluoxetine entered the U.S. market in early August 2001. On January 14, 2002, the U.S. Supreme Court denied a petition filed by the company seeking review of the decision, bringing the litigation to a close. Prozac sales in the U.S. have historically represented a significant portion of the company’s overall sales, accounting for approximately 20 percent in 2000.

The company has been named as a defendant in numerous product liability lawsuits involving primarily two products, diethylstilbestrol (DES) and Prozac. The company has accrued for its estimated exposure with respect to all current product liability claims. In addition, the company has accrued for certain claims incurred, but not filed, to the extent the company can formulate a reasonable estimate of their costs. The company’s estimates of these expenses are based primarily on historical claims experience and data regarding product usage. The company expects 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. The company’s estimate of insurance recoverables is based on existing deductibles, coverage limits, and the existing and projected future level of insolvencies among its insurance carriers.

Under the Comprehensive Environmental Response, Compensation, and Liability Act, commonly known as Superfund, the company has 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. The company also continues remediation of certain of its own sites. The company has 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. The company has reached a settlement with its primary liability insurance carrier and certain excess carriers providing coverage for certain environmental liabilities. Litigation seeking coverage from certain other excess carriers is ongoing.

The environmental liabilities and litigation accruals have been reflected in the company’s consolidated balance sheet at the gross amount of approximately \$132.4 million at December 31, 2001. Estimated insurance recoverables of approximately \$65.2 million at December 31, 2001 have been reflected as assets in the consolidated balance sheet.

The company is nearing completion of an examination by the Internal Revenue Service (IRS) for tax years 1996 and 1997. Discussions between the company and the IRS are currently under way related to one remaining issue.

In 1999, the company recognized a pretax gain of \$110.0 million as a result of a cash payment received in settlement of litigation with Biochimica Opos S.p.A. relating to the manufacture, sale, or distribution of cefaclor and certain other products made by Biochimica Opos S.p.A. The gain, which was recorded in other income, increased earnings per share by approximately \$.06 in 1999.

While it is not possible to predict or determine the outcome of the patent, product liability, or other legal actions brought against the company or the ultimate cost of environmental matters or the resolution of the examination by the IRS, the company believes that, except as noted above with respect to the patent litigation, the costs associated with all such matters will not have a material adverse effect on its 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:

	<u>Foreign Currency Translation</u>	<u>Unrealized Gains on Securities</u>	<u>Minimum Pension Liability Adjustment</u>	<u>Effective Portion of Cash Flow Hedges</u>	<u>Accumulated Other Comprehensive Loss</u>
Beginning balance at					
January 1, 2001	\$(546.3)	\$ 7.8	\$ (72.7)	\$ —	\$(611.2)
Adoption of SFAS 133	—	—	—	(15.0)	(15.0)
Other comprehensive income (loss)	(83.8)	34.3	(62.1)	(10.6)	(122.2)
Balance at					
December 31, 2001	\$(630.1)	\$42.1	\$(134.8)	\$(25.6)	\$(748.4)

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 \$12.3 million, \$43.9 million, and \$8.5 million, net of tax, in 2001, 2000, and 1999, respectively, for net realized gains on sales of securities included in net income. The effective portion of cash flow hedges is net of a reclassification adjustment of \$16.5 million, net of tax, in 2001 for realized gains on foreign currency options.

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.

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### Responsibility for Financial Statements

### Eli Lilly and Company and Subsidiaries

The consolidated financial statements and related notes have been prepared by management, who are responsible for their integrity and objectivity. 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. The other financial information in this annual report is consistent with that in the financial statements.

The company maintains internal accounting control systems that 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.

In addition to the system of internal accounting controls, the company maintains guidelines of company policy emphasizing proper overall business conduct, possible conflicts of interest, compliance with laws, and confidentiality of proprietary information. The guidelines are reviewed on a periodic basis with employees worldwide.

The financial statements have been audited by Ernst & Young LLP, independent auditors. Their responsibility is to examine the company's consolidated financial statements in accordance with generally accepted auditing standards in the United States and to express their opinion with respect to the fairness of presentation of the statements.

The members of the audit committee of the board of directors, none of whom are employees of the company, recommend independent auditors for appointment by the board of directors, review the services performed by the independent auditors, and receive and review the reports submitted by them. The audit committee meets several times during the year with management, the internal auditors, and the independent auditors to discuss audit activities, internal controls, and financial reporting matters. The internal auditors and the independent auditors have full and free access to the committee.

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

Charles E. Golden  
Executive Vice President and  
Chief Financial Officer

January 28, 2002

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Report of Independent Auditors

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, 2001 and 2000, and the related consolidated statements of income, cash flows, and comprehensive income for each of the three years in the period ended December 31, 2001. 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 auditing standards generally accepted in the 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, 2001 and 2000, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2001, in conformity with accounting principles generally accepted in the United States.

Ernst & Young LLP

Indianapolis, Indiana

January 28, 2002

Graphs in Annual Report to Shareholders  
for the Year Ended December 31, 2001

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—Five Newer Growth Products Accounted for 47 Percent of 2001 Net Sales

(\$ millions)

Year	Amount
97	\$ 7,987.7
98	9,236.8
99	10,002.9
00	10,862.2
01	11,542.5

Year	Prozac/Sarafem/Prozac Weekly	Anti-Infectives	Other	Best-in-Class Growth Products
97	32%	16%	40%	12%
98	30%	13%	35%	22%
99	26%	10%	35%	29%
00	24%	8%	31%	37%
01	17%	7%	29%	47%

Combined net sales of the company's best-in-class growth products-Zyprexa, Humalog, Gemzar, Evista and Actos-increased by 36 percent over 2000, representing \$5.5 billion, or 47 percent of total net sales, compared with 37 percent in 2000.

Graph #2—Five Newer Growth Products Collectively Delivered 36 Percent Increase

(\$ millions; percentages represent changes from 2000)

Product	Amount	Percent
Zyprexa	\$737.1	+31
Humalog	277.6	+79
Gemzar	163.6	+29
Evista	143.3	+27
Actos	137.6	+62

The company's five major growth products-Zyprexa, Humalog, Gemzar, Evista, and Actos-generated \$1.46 billion of incremental net sales and \$5.5 billion of total net sales in 2001. Combined, these products grew 36 percent for the year with Zyprexa, Humalog, and Gemzar growing at rates faster than 2000. During 2001, Zyprexa became the company's first product with net sales in excess of \$3 billion.

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Graph #3—Revenues

(\$ millions)

Product	Amount
Zyprexa	\$3,087
Prozac/Sarafem/Prozac Weekly	1,990
Humulin	1,061
Gemzar	723
Evista	665
Humalog	628
ReoPro	431
Actos	361
Humatrope	313
Axid	285
Ceclor	232
Vancocin	211

In total, 12 products spanning various therapeutic classes each had annual revenues in excess of \$200 million.

Graph #4—Gross Margin

(as a percent of total net sales)

Year	Amount
97	75.6%
98	78.2%
99	79.0%
00	81.1%
01	81.3%

Gross margin improved to 81.3 percent, primarily due to improvements in product mix in spite of the introduction of generic Prozac in 2001. This continued gross margin performance has enabled the company to aggressively fund investments in research and development and sales and marketing.

Graph #5—Research and Development

(\$ millions)

Year	Amount
97	\$1,370.2
98	1,738.9
99	1,783.6
00	2,018.5
01	2,235.1

Worldwide research and development expenditures increased 11 percent in 2001 in support of the company's strong pipeline. The company continues to invest heavily in research and development as these expenditures represented 19 percent of total net sales in both 2001 and 2000. The late-stage pipeline includes up to 10 potential new products for a wide range of serious, unmet medical needs that are expected to be launched during the period of 2002 through 2005.

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## Graph #6—Return on Shareholders' Equity

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

Year	Amount
97	37.5%
98	46.2%
99	53.9%
00	55.3%
01	42.7%

Return on shareholders' equity was lower in 2001 as the company invested in its robust pipeline and five best-in-class growth products at a rate faster than current-year sales growth, which was affected by the Prozac patent expiration.

## Graph #7—Capital Expenditures

(\$ millions)

Year	Amount
97	\$366.3
98	419.9
99	528.3
00	677.9
01	884.0

Capital expenditures increased 30 percent from 2000, primarily due to the increased support of various manufacturing and research initiatives and related infrastructure. The company expects near-term capital expenditures to increase from 2001 levels due to continuing investment in research and manufacturing capacity to support its growing product portfolio.

## Graph #8—Dividends Paid per Share

(dollars)

Year	Amount
97	\$0.74
98	0.80
99	0.92
00	1.04
01	1.12

Dividends paid during 2001 increased 8 percent over 2000. The year 2001 became the 34th consecutive year in which dividends were increased. The company has declared a first-quarter 2002 dividend of \$.31 per share, an 11 percent increase over 2001. The amount reflects the company's continued commitment to delivering shareholder value.

EXHIBIT 21-LIST OF SUBSIDIARIES AND AFFILIATES

The following are the subsidiaries and affiliated corporations of the Company at  
December 31, 2001

Certain subsidiaries have been omitted since they are not significant in the  
aggregate.

	State or Jurisdiction of Incorporation or Organization
-----	
ELI LILLY AND COMPANY	Indiana
Eli Lilly Interamerica, Inc.	Indiana
Eli Lilly do Brasil Limitada	Brazil
Elanco Quimica Limitada	Brazil
Eli Lilly Interamerica Inc., y Compania Limitada	Chile
STC Pharmaceuticals, Inc.	Indiana
Lilly ICOS L.L.C.	Delaware
Bounty Labs Corporation	Indiana
InnoCentive, LLC	Delaware
LE Hesten Energy, LLC	Delaware
Dista, Inc.	Indiana
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 de Mexico, S.A. de C.V.	Mexico
Eli Lilly Industries, Inc.	Delaware
Del Sol Financial Services, Inc.	British V.I.
Lilly del Caribe, Inc.	Cayman Isls.
Eli Lilly and Company (Taiwan), Inc.	Taiwan
Control Diabetes Services, Inc.	Indiana
Integrated Medical Systems, Inc.	Colorado
ELCO Dominicana, S.A.	Dominican Rep.
ELCO International Sales Corporation	Virgin Is.-US
Eli Lilly Finance S.A.	Switzerland
Lilly Del Mar, Inc.	British Virgin Islands
Lilly Global Services, Inc.	Indiana
Lilly Systems Biology PTE LTD	Singapore
Lilly Spain Holding ETVE, S.L.	Spain
Eli Lilly Nederland Holding B.V.	Netherlands
Eli Lilly Holding Company Ltd.	United Kingdom
Eli Lilly Holding GmbH	Germany

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aggregate.

	State or Jurisdiction of Incorporation or Organization -----
ELI LILLY AND COMPANY (Cont'd)	
Eli Lilly International Corporation	Indiana
ELCO Insurance Company, Ltd.	Bermuda
Eli Lilly Holdings Ltd	United Kingdom
Eli Lilly Group Limited	United Kingdom
Eli Lilly & Co. LTD.	United Kingdom
Dista Products Limited	United Kingdom
Eli Lilly & Co (Ireland) Trustee Limited	United Kingdom
Lilly Industries Limited	United Kingdom
Lilly Research Centre Limited	United Kingdom
Elanco Products Limited	United Kingdom
Creative Packaging Limited	United Kingdom
Greenfield Pharmaceuticals Limited	United Kingdom
Eli Lilly (Basingstoke) Limited	United Kingdom
Eli Lilly Leasing Limited	United Kingdom
Eli Lilly Group Pension Trustees Limited	United Kingdom
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 Norge A.S.	Norway
Eli Lilly & Co. (Ireland) Limited	Ireland
Eli Lilly Sweden AB	Sweden
Lilly Turkey A.S.	Turkey
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
Integrated Disease Management (NZ) Limited	New Zealand

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December 31, 2001

Certain subsidiaries have been omitted since they are not significant in the  
aggregate.

	State or Jurisdiction of Incorporation or Organization -----
ELI LILLY AND COMPANY (Cont'd)	
E L Management Incorporated	Delaware/Nova Scotia
Eli Lilly Canada Inc.	Canada
Eli Lilly S.A.	Switzerland
Eli Lilly Export S.A.	Switzerland
GEMS Services, S.A.	Belgium
Elanco Trustees Limited	Ireland
Kinsale Financial Services, Ltd.	Ireland
Eli Lilly (Suisse) S.A.	Switzerland
Eli Lilly Vostok SA, Geneva	Switzerland
Oldfields Financial Management S.A.	Switzerland
Eli Lilly Suzhou Pharmaceutical Company Limited	China
Eli Lilly Nederland B.V.	Netherlands
Lilly Development Centre S.A.	Belgium
Lilly Services S.A.	Belgium
Lilly Clinical Operations S.A.	Belgium
Eli Lilly CR s.r.o.	Czech Repub.
Eli Lilly Regional GmbH	Austria
Eli Lilly Egypt	Egypt
ELCO SAE	Egypt
PaRxner B.V.	Netherlands
Elco Participation, sarl	France
Lilly France S.A.S	France
Elsa France, S.A.	France
LICO sarl	France
Eli Lilly Italia S.p.A.	Italy
Eli Lilly Benelux, S.A.	Belgium
Dista-Produtos Quimicos & Farmaceuticos, LDA	Portugal
Lilly-Farma, Produtos Farmaceuticos, Lda.	Portugal
Vital Farma Productos Farmaceuticos	Portugal
Dista Italia S.r.l.	Italy
Pharmaserve - Lilly S.A.C.I.	Greece
Pharmabrand, S.A.C.I.	Greece
PRAXICO Ltd.	Hungary
Lilly Hungaria KFT	Hungary
Eli Lilly (Philippines), Incorporated	Philippines
Eli Lilly (India) Private Limited	India
Eli Lilly Israel Ltd.	Israel
Eli Lilly Japan K.K.	Japan
Chugai Lilly Clinical Research Co, LTD.	Japan

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December 31, 2001

Certain subsidiaries have been omitted since they are not significant in the  
aggregate.

	State or Jurisdiction of Incorporation or Organization -----
Eli Lilly Asian Operations, Limited	Hong Kong, PRC
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 BV	Netherlands
Andean Technical Operations Center	Peru
Lilly Pharma Ltd.	Russia
Eli Lilly Pakistan (Pvt.) Ltd.	Pakistan
Eli Lilly Polska Sp. z.o.o. (Ltd.)	Poland
Lilly Grodzisk Sp. z.o.o.	Poland
Vitalia Pharma Sp. Z.o.o.	Poland
Eli Lilly Asia Pacific Pte. Ltd.	Singapore
Lilly-NUS Centre for Clinical Pharmacology Pte. Ltd.	Singapore
Eli Lilly (S.A.) (Proprietary) Limited	South Africa
Elanco-Valquimica, S.A.	Spain
Dista, S.A.	Spain
Lilly, S.A.	Spain
Spaly Bioquimica, S.A.	Spain
Irisfarma S.A.	Spain
Eli Lilly Nigeria Ltd.	Nigeria
Eli Lilly y Compania de Venezuela, S.A.	Venezuela
Dista Products & Compania Venezuela S.A.	Venezuela

EXHIBIT 23. CONSENT OF INDEPENDENT AUDITORS

We consent to the incorporation by reference in this Annual Report (Form 10-K) of Eli Lilly and Company of our report dated January 28, 2002, included in the 2001 Annual Report to Shareholders of Eli Lilly and Company.

We also consent to the incorporation by reference in the following registration statements of our report dated January 28, 2002 with respect to the consolidated financial statements incorporated by reference in the 2001 Annual Report (Form 10-K) of Eli Lilly and Company:

Registration Statement No.	Type of Statement	Date
33-29482	S-8	June 23, 1989
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

ERNST & YOUNG LLP

Indianapolis, Indiana  
March 25, 2002

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 Company spokespersons based on then-current expectations of management. All forward-looking statements made by the Company 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. One can also identify them by the fact that they do not relate strictly to historical or current facts. These statements are likely to address the Company's growth strategy, financial results, regulatory issues, 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, including generic competition as patents on key products, such as Prozac, expire; pricing pressures, both in the U.S. and abroad, primarily from managed care groups and government agencies; and new patented products or expanded indications for existing products introduced by competitors, which can lead to declining demand for the Company's products.
- - Governmental factors, including federal, state and foreign laws and regulations that affect pharmaceutical pricing, such as Medicaid, Medicare, pharmaceutical importation laws, and other laws and regulations that could, directly or indirectly, impose governmental controls on the prices at which the Company's products are sold.
- - The difficulties and uncertainties inherent in new product development and the 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, 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, resulting in delays in product launches and lost market opportunity.
- - Regulatory issues concerning compliance with current good manufacturing practice (cGMP) regulations for pharmaceutical products, that can lead to product recalls and seizures, interruption of production, and delays in the approvals of new products pending resolution of the cGMP issues. In particular, see "Quality Assurance" at page 8 for a discussion of certain cGMP issues currently facing the Company.
- - Changes in inventory levels maintained by pharmaceutical wholesalers can cause reported sales for a particular period to differ significantly from underlying prescriber demand.
- - Economic factors over which the Company has no control, including changes in inflation, interest rates and foreign currency exchange rates, and overall economic conditions in volatile areas such as Latin America.
- - Unexpected safety or efficacy concerns arising with respect to marketed products, whether or not scientifically justified, leading to product recalls, withdrawals or declining sales.

- - Legal factors, including unanticipated litigation of product liability or other liability claims; antitrust and pricing litigation; environmental matters; and patent disputes with competitors that could preclude commercialization of products or negatively affect the profitability of existing products.
- - 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.
- - Changes in accounting standards promulgated by the Financial Accounting Standards Board, the Securities and Exchange Commission, and the American Institute of Certified Public Accountants which are adverse to the Company.
- - Internal factors such as changes in business strategies and the impact of restructurings, asset impairments, technology acquisition and disposition transactions, and business combinations.

The Company undertakes no duty to update forward-looking statements.