

United States
Securities and Exchange Commission
Washington, D.C. 20549

Form 10-K

Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
for the fiscal year ended December 31, 2008

Commission file number 001-06351

Eli Lilly and Company

An Indiana corporation I.R.S. employer identification no. 35-0470950
Lilly Corporate Center, Indianapolis, Indiana 46285
(317) 276-2000

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

<u>Title of Each Class</u>	<u>Name of Each Exchange On Which Registered</u>
Common Stock (no par value)	New York Stock Exchange
6.57% Notes Due January 1, 2016	New York Stock Exchange
7-1/8% Notes Due June 1, 2025	New York Stock Exchange
6.77% Notes Due January 1, 2036	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act: None

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

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes No

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months, and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant's knowledge, in the definitive proxy statement incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company
(Do not check if a smaller reporting company)

Indicate by check mark whether the Registrant is a shell company as defined in Rule 12b-2 of the Act: Yes No

Aggregate market value of the common equity held by non-affiliates computed by reference to the price at which the common equity was last sold as of the last business day of the Registrant's most recently completed second fiscal quarter (Common Stock): approximately \$46,687,100,000

Number of shares of common stock outstanding as of February 13, 2009: 1,149,015,882

Portions of the Registrant's Proxy Statement to be filed on or about March 9, 2009 have been incorporated by reference into Part III of this report.

Part I

Item 1. Business

Eli Lilly and Company (the “Company” or “Registrant”, which may be referred to as “we”, “us”, or “our”) was incorporated in 1901 in Indiana to succeed to the drug manufacturing business founded in Indianapolis, Indiana, in 1876 by Colonel Eli Lilly. We discover, develop, manufacture, and sell products in one significant business segment – pharmaceutical products. We also have an animal health business segment, whose operations are not material to our financial statements. We manufacture and distribute our products through owned or leased facilities in the United States, Puerto Rico, and 25 other countries. Our products are sold in approximately 135 countries.

Most of the products we sell today were discovered or developed by our own scientists, and our success depends to a great extent on our ability to continue to discover and develop innovative new pharmaceutical products. We direct our research efforts primarily toward the search for products to prevent and treat human diseases. We also conduct research to find products to treat diseases in animals and to increase the efficiency of animal food production.

Products

Our products include:

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

- *Zyprexa*[®], for the treatment of schizophrenia, acute mixed or manic episodes associated with bipolar I disorder, and bipolar maintenance
- *Cymbalta*[®], for the treatment of major depressive disorder, diabetic peripheral neuropathic pain, generalized anxiety disorder, and in the United States for the management of fibromyalgia
- *Strattera*[®], for the treatment of attention-deficit hyperactivity disorder in children, adolescents and adults
- *Prozac*[®], for the treatment of major depressive disorder, obsessive-compulsive disorder, bulimia nervosa and panic disorder
- *Symbyax*[®], for the treatment of bipolar depression

Endocrinology products, including:

- *Humalog*[®], *Humalog Mix 75/25*[®], and *Humalog Mix 50/50*[™], for the treatment of diabetes
- *Humulin*[®], for the treatment of diabetes
- *Byetta*[®], for the treatment of type 2 diabetes
- *Actos*[®], for the treatment of type 2 diabetes
- *Evista*[®], for the prevention and treatment of osteoporosis in postmenopausal women and for the reduction of the risk of invasive breast cancer in postmenopausal women with osteoporosis and postmenopausal women at high risk for invasive breast cancer
- *Forteo*[®], for the treatment of osteoporosis in postmenopausal women and men at high risk for fracture
- *Humatrope*[®], for the treatment of human growth hormone deficiency and idiopathic short stature

Oncology products, including:

- *Gemzar*[®], for the treatment of pancreatic cancer; in combination with other agents, for the treatment of metastatic breast cancer, non-small cell lung cancer and advanced or recurrent ovarian cancer; and in the European Union for the treatment of bladder cancer

- *Alimta*[®], for the first-line treatment, in combination with another agent, of non-small cell lung cancer for patients with non-squamous histology; for the second-line treatment of non-small cell lung cancer; and in combination with another agent, for the treatment of malignant pleural mesothelioma
- *Erbix*[®], a product of ImClone Systems Incorporated, joined our oncology product portfolio upon our acquisition of ImClone in late November 2008. Erbitux is indicated both as a single agent and with other chemotherapy agents for the treatment of certain types of colorectal cancers and as a single agent or in combination with radiation therapy for head and neck cancers.

Cardiovascular products, including:

- *Cialis*[®], for the treatment of erectile dysfunction
- *Efient*[®], for the prevention of atherothrombotic events in patients with acute coronary syndromes undergoing percutaneous coronary intervention, was approved in February 2009 in the European Union. The drug is undergoing final regulatory review in the United States, where it would be marketed as *Effient*[®].
- *ReoPro*[®], for use as an adjunct to percutaneous coronary intervention (“PCI”), including patients undergoing angioplasty, atherectomy or stent placement
- *Xigris*[®], for the treatment of adults with severe sepsis at high risk of death

Animal health products, including:

- *Rumensin*[®], a cattle feed additive that improves feed efficiency and growth and also controls and prevents coccidiosis
- *Tylan*[®], an antibiotic used to control certain diseases in cattle, swine, and poultry
- *Micotil*[®], *Pulmotil*[®], and *Pulmotil AC*[®], antibiotics used to treat respiratory disease in cattle, swine, and poultry, respectively
- *Paylean*[®] and *Optaflexx*[®], leanness and performance enhancers for swine and cattle, respectively
- *Posilac*[®], a protein supplement to improve milk productivity in dairy cows. We acquired the worldwide rights to Posilac from Monsanto Company in August 2008.
- *Coban*[®], *Monteban*[®], and *Maxiban*[®], anticoccidial agents for use in poultry
- *Apralan*[®], an antibiotic used to control enteric infections in calves and swine
- *Surmax*[®] (sold as *Maxus*[®] in some countries), a performance enhancer for swine and poultry
- *Elector*[®], a parasiticide for use on cattle and premises
- Two products for dogs: *Comfortis*[™], the first FDA-approved, chewable tablet that kills fleas and prevents flea infestations on dogs; and *Reconcile*[™], for treatment of canine separation anxiety in conjunction with behavior modification training

Other pharmaceuticals, including:

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

Marketing

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

Pharmaceuticals – United States

In the United States, we distribute pharmaceutical products principally through independent wholesale distributors, with some sales directly to pharmacies. Our marketing policy is designed to assure that products and relevant medical information are immediately available to physicians, pharmacies, hospitals, public and private payers, and appropriate health care professionals throughout the country. Three wholesale distributors in the United States – AmerisourceBergen Corporation, Cardinal Health, Inc., and McKesson Corporation – each accounted for between 12 and 16 percent of our worldwide consolidated net sales in 2008. No other distributor accounted for more than 10 percent of consolidated net sales. We also sell pharmaceutical products directly to the United States government and other manufacturers, but those sales are not material.

We promote our major pharmaceutical products in the United States through sales representatives who call upon physicians and other health care professionals. We advertise in medical and drug journals, distribute literature and samples of certain products to physicians, and exhibit at medical meetings. In addition, we advertise certain products directly to consumers in the United States and we maintain web sites with information about all our major products. Divisions of our sales force are assigned to therapeutic areas, such as neuroscience, diabetes, osteoporosis, and oncology. We supplement our employee sales force with contract sales organizations as appropriate to leverage our own resources and the strengths of our partners in various markets.

Large purchasers of pharmaceuticals, such as managed-care groups, government agencies, and long-term care institutions, account for a significant portion of total pharmaceutical purchases in the United States. We maintain special business groups to service wholesalers, managed-care organizations, government and long-term care institutions, hospitals, and certain retail pharmacies. In response to competitive pressures, we have entered into arrangements with a number of these organizations providing for discounts or rebates on one or more Lilly products.

Pharmaceuticals – Outside the United States

Outside the United States, we promote our pharmaceutical products primarily through sales representatives. While the products marketed vary from country to country, neuroscience products constitute the largest single group in total sales. Distribution patterns vary from country to country. In most countries, we maintain our own sales organizations. In some countries, however, we market our products through independent distributors.

Pharmaceutical Marketing Collaborations

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

- Cymbalta is co-promoted in the United States by Quintiles Transnational Corp. and is co-promoted or co-marketed outside the U.S. (except Japan) by Boehringer Ingelheim GmbH.
- Evista is marketed in major European markets by Daiichi Sankyo Europe GmbH, a subsidiary of Daiichi Sankyo Co., Ltd. of Japan.
- We co-promote Byetta with Amylin Pharmaceuticals, Inc. in the United States and Puerto Rico, and we have exclusive marketing rights in other territories.
- Erbitux is marketed in North America by Bristol-Myers Squibb. We co-promote Erbitux in North America. Outside North America, Erbitux is commercialized by Merck KGaA. We receive royalties from Bristol-Myers Squibb and Merck KGaA.
- Efient will be co-promoted with us in major European markets by Daiichi Sankyo Europe GmbH. Assuming regulatory approvals, Daiichi Sankyo will also co-promote the product with us in the United States, Brazil, Mexico, China and several other Asian countries. Daiichi Sanko retains sole marketing rights in Japan, and we retain sole marketing rights in Canada, Australia, Russia and certain other countries.

Animal Health Products

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

Competition

Our pharmaceutical products compete with products manufactured by many other companies in highly competitive markets throughout the world. Our animal health products compete on a worldwide basis with products of animal health care companies as well as pharmaceutical, chemical, and other companies that operate animal health divisions or subsidiaries.

Important competitive factors include 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 or delivery systems with therapeutic or cost advantages, our products can be subject to progressive price reductions, decreased volume of sales, or both. Most new products that we introduce must compete with other products already on the market or products that are later developed by competitors. Manufacturers of generic pharmaceuticals 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 pharmaceutical 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 versions of our products. Increasingly, to obtain favorable reimbursement and formulary positioning with government payers, managed care and pharmacy benefits management organizations, we must demonstrate that our products offer not only medical benefits but also cost advantages as compared with other forms of care.

We believe our long-term competitive position depends upon our success in discovering and developing (either alone or in collaboration with others) innovative, cost-effective products that serve unmet medical needs, together with our ability to continuously improve the productivity of our discovery, development, manufacturing, marketing and support operations in a highly competitive environment. There can be no assurance that our research and development efforts will result in commercially successful products or that our products or processes will not become uncompetitive from time to time as a result of products or processes developed by our competitors.

Patents, Trademarks, and Other Intellectual Property Rights

Overview

Intellectual property protection is, in the aggregate, material to our ability to successfully commercialize our life sciences innovations. We own, have applied for, or are licensed under, a large number of patents, both in the United States and in other countries, relating to products, product uses, formulations, and manufacturing processes. There is no assurance that the patents we are seeking will be granted or that the patents we have been granted would be found valid and enforceable if challenged. Moreover, patents relating to particular products, uses, formulations, or processes do not preclude other manufacturers from employing alternative processes or from marketing alternative products or formulations that might successfully compete with our patented products. In addition, from time to time, competitors or other third parties assert claims that our activities infringe patents or other intellectual property rights held by them, or allege a third-party right of ownership in our existing intellectual property.

Outside the United States, the adequacy and effectiveness of intellectual property protection for pharmaceuticals varies widely. Under the Trade-Related Aspects of Intellectual Property Agreement (TRIPs) administered by the World Trade Organization (WTO), over 140 countries have now agreed to provide non-discriminatory protection for most pharmaceutical inventions and to assure that adequate and effective rights are available to all patent owners. Because of TRIPs transition provisions, dispute resolution mechanisms, and substantive

limitations, it is still too soon to assess when and 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 a severe and rapid decline in sales of the formerly patented product, particularly in the United States. However, in some cases the innovator company may achieve exclusivity beyond the expiry of the product patent through manufacturing trade secrets, later-expiring patents on methods of use or formulations, or data-based exclusivity that may be available under pharmaceutical regulatory laws.

Some of our products, including Erbitux, Forteo, ReoPro, and Xigris, are biological products, or biologics. Additionally, many of the potential products in our research pipeline are biologics. Currently, generic versions of biologics cannot be approved under U.S. law. Competitors seeking approval of biologics must file their own safety and efficacy data, and address the challenges of biologics manufacturing, which involves more complex and costly processes than those of traditional pharmaceutical operations. However, the law could change in the future to allow generic biologics. Even in the absence of new legislation, the U.S. Food and Drug Administration (FDA) is taking steps toward allowing generic versions of certain biologics.

Our Intellectual Property Portfolio

We consider intellectual property protection for certain products, processes, and uses – particularly those products discussed below – to be important to our operations. For many of our products, in addition to the compound patent we hold other patents on manufacturing processes, formulations, or uses that may extend exclusivity beyond the expiration of the product patent.

The most relevant U.S. patent protection, together with expected expiration, for our major marketed products is as follows:

- *Alimta* is protected by a compound patent (2016).
- *Byetta* is protected by a patent covering its use in treating type 2 diabetes (2017).
- *Cialis* is protected by compound and use patents (2017).
- *Cymbalta* is protected by a compound patent (2013).
- *Evista* is protected by patents on the treatment and prevention of osteoporosis (2012 and 2014), and its dosage form (2017). *Evista* for use in breast cancer risk reduction is protected by orphan drug exclusivity (2014).
- *Gemzar* is protected by a compound patent (2010) and a patent covering its antineoplastic use (2013).
- *Humalog* is protected by a compound patent (2013).
- *Strattera* is protected by a patent covering its use in treating attention deficit-hyperactivity disorder (2016).
- *Zyprexa* is protected by a compound patent (2011).

Worldwide, we sell all of our major products under trademarks that we consider in the aggregate to be important to our operations. Trademark protection varies throughout the world, with protection continuing in some countries as long as the mark is used, and in other countries as long as it is registered. Registrations are normally for fixed but renewable terms.

Patent Licenses

Most of our important products were discovered in our own laboratories and are not subject to significant license agreements. Two of our larger products, *Cialis* and *Alimta*, are subject to patent assignments or licenses granted to us by others.

- The compound patent for *Cialis* is the subject of a license agreement with Glaxo SmithKline which assigns to us exclusively all rights in the compound. The agreement calls for royalties of a single-digit percentage

of net sales. The agreement is not subject to termination by Glaxo for any reason other than a material breach by Lilly of the royalty obligation, after a substantial cure period.

- The compound patent for Alimta is the subject of a license agreement with Princeton University, granting us an irrevocable exclusive worldwide license to the compound patents for the lives of the patents in the respective territories. The agreement calls for royalties of a single-digit percentage of net sales. The agreement is not subject to termination by Princeton for any reason other than a material breach by Lilly of the royalty obligation, after a substantial cure period. Alimta is also the subject of a worldwide, nonexclusive license to certain compound and process patents owned by Takeda Pharmaceutical Company Limited. The agreement calls for royalties of a single-digit percentage of net sales in countries covered by a relevant patent. The agreement is subject to termination for material default and failure to cure by Lilly and in the event that Lilly becomes bankrupt or insolvent.

Patent Challenges

In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as “Hatch-Waxman,” made a complex set of changes to both patent and new-drug-approval laws. Before Hatch-Waxman, no drug could be approved without providing the FDA complete safety and efficacy studies, *i.e.*, a complete New Drug Application (NDA). Hatch-Waxman authorizes the FDA to approve generic versions of innovative pharmaceuticals (other than biologics) without such information by filing an Abbreviated New Drug Application (ANDA). In an ANDA, the generic manufacturer must demonstrate only “bioequivalence” between the generic version and the NDA-approved drug – not safety and efficacy.

Absent a patent challenge, the FDA cannot approve an ANDA until after the innovator’s patents expire. However, after the innovator has marketed its product for four years, a generic manufacturer may file an ANDA alleging that one or more of the patents listed in the innovator’s NDA are invalid or not infringed. This allegation is commonly known as a “Paragraph IV certification.” The innovator must then file suit against the generic manufacturer to protect its patents. The FDA is then prohibited from approving the generic company’s application for a 30- to 42-month period (which can be shortened or extended by the trial court judge hearing the patent challenge). If one or more of the NDA-listed patents are challenged, the first filer of a Paragraph IV certification may be entitled to a 180-day period of market exclusivity over all other generic manufacturers.

In recent years, generic manufacturers have used Paragraph IV certifications extensively to challenge patents on a wide array of innovative pharmaceuticals, and we expect this trend to continue. In addition, generic companies have shown an increasing willingness to launch “at risk,” *i.e.*, after receiving ANDA approval but before final resolution of their patent challenge. We are currently in litigation with numerous generic manufacturers arising from their Paragraph IV certifications on Alimta, Cymbalta, Evista, Gemzar, and Strattera. For more information on these, see Part II, Item 7, “Management’s Discussion and Analysis – Legal and Regulatory Matters.”

Outside the United States, the legal doctrines and processes by which pharmaceutical patents can be challenged vary widely. In recent years, we have experienced an increase in patent challenges from generic manufacturers in many countries outside the United States, and we expect this trend to continue. For more information on significant patent challenges outside the United States, see Part II, Item 7, “Management’s Discussion and Analysis – Legal and Regulatory Matters.”

Government Regulation

Regulation of Our Operations

Our operations are regulated extensively by numerous national, state and local agencies. The lengthy process of laboratory and clinical testing, data analysis, manufacturing development, and regulatory review necessary for required governmental approvals is extremely costly and can significantly delay product introductions in a given market. Promotion, marketing, manufacturing, and distribution of pharmaceutical and animal health products are extensively regulated in all major world markets. We are required to conduct extensive post-marketing surveillance of the safety of the products we sell. In addition, our operations are subject to complex

federal, state, local, and foreign laws and regulations concerning the environment, occupational health and safety, and privacy. The laws and regulations affecting the manufacture and sale of current products and the discovery, development and introduction of new products will continue to require substantial scientific and technical effort, time, and expense and significant capital investment.

Of particular importance is the FDA in the United States. Pursuant to the Federal Food, Drug, and Cosmetic Act, the FDA has jurisdiction over all of our products and administers requirements covering the testing, safety, effectiveness, manufacturing, quality control, distribution, labeling, marketing, advertising, dissemination of information and post-marketing surveillance of our pharmaceutical products. The FDA, along with the U.S. Department of Agriculture (USDA), also regulates our animal health products. The U.S. Environmental Protection Agency also regulates some animal health products. In 2007, Congress passed the Food and Drug Administration Amendments Act (FDAAA) of 2007, which imposes additional requirements for drug development and commercialization and provides the FDA with further authorities and resources, particularly in the area of drug safety.

The FDA extensively regulates all aspects of manufacturing quality under its current Good Manufacturing Practices (cGMP) regulations. In recent years, we have made, and we continue to make, substantial investments of capital and operating expenses to implement comprehensive, company-wide improvements in our manufacturing, product and process development, and quality operations to ensure sustained cGMP compliance. However, in the event we fail to adhere to cGMP requirements in the future, we could be subject to interruptions in production, fines and penalties, and delays in new product approvals.

Outside the United States, our products and operations are subject to similar regulatory requirements, notably by the European Medicines Agency (EMA) in the European Union and the Ministry of Health, Labor and Welfare (MHLW) in Japan. Specific regulatory requirements vary from country to country.

The marketing, promotional, and pricing practices of pharmaceutical manufacturers, as well as the manner in which manufacturers interact with purchasers and prescribers, are subject to various other federal and state laws, including the federal anti-kickback statute and the False Claims Act and state laws governing kickbacks, false claims, unfair trade practices, and consumer protection. These laws are administered by, among others, the Department of Justice, the Office of Inspector General of the Department of Health and Human Services, the Federal Trade Commission, the Office of Personnel Management and state attorneys general. Over the past several years, the FDA, the Department of Justice, and many of these other agencies have increased their enforcement activities with respect to pharmaceutical companies and increased the inter-agency coordination of enforcement activities. Over this period, several claims brought by these agencies against Lilly and other companies under these and other laws have resulted in corporate criminal sanctions and very substantial civil settlements. See Part I, Item 3, "Legal Proceedings," and Part II, Item 7, "Management's Discussion and Analysis – Legal and Regulatory Matters," for information about currently pending and recently resolved marketing and promotional practices investigations involving Lilly, including information regarding a Corporate Integrity Agreement entered into by Lilly in connection with the resolution of a U.S. federal marketing practices investigation and certain related state investigations involving Zyprexa.

It is possible that we could become subject to additional administrative and legal proceedings and actions, which could include claims for civil penalties (including treble damages under the False Claims Act), criminal sanctions, and administrative remedies, including exclusion from federal health care programs. It is possible that an adverse outcome in pending or future actions could have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

Regulations Affecting Pharmaceutical Pricing and Reimbursement

In the United States, we are required to provide rebates to state governments on their purchases of certain of our products under state Medicaid programs. Other cost containment measures have been adopted or proposed by federal, state, and local government entities that provide or pay for health care. In most international markets, we operate in an environment of government-mandated cost containment programs, which may include price controls, reference pricing, discounts and rebates, restrictions on physician prescription levels, restrictions on reimbursement, compulsory licenses, health economic assessments, and generic substitution.

In the U.S., the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA), took effect in 2006, providing a prescription drug benefit for seniors under the Medicare program, known as Medicare Part D. Pricing to manufacturers for drugs covered by the program is currently established through competitive negotiations between the manufacturers and private payers. However, various measures have been proposed that would allow or require the federal government to negotiate Medicare Part D drug prices directly with manufacturers. In addition, various proposals have been introduced that would increase the rebates we pay to the government. See Part II, Item 7, "Management's Discussion and Analysis – Executive Overview – Legal, Regulatory, and Other Matters," for more discussion of MMA and other federal healthcare cost containment measures. At the state level, budget pressures are causing various states to impose cost-control measures such as higher rebates and more restrictive formularies.

International operations are also generally subject to extensive price and market regulations, and there are many proposals for additional cost-containment measures, including proposals that would directly or indirectly impose additional price controls, limit access to or reimbursement for our products, or reduce the value of our intellectual property protection.

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

Research and Development

Our commitment to research and development dates back more than 100 years. Our research and development activities are responsible for the discovery and development of most of the products we offer today. We invest heavily in research and development because we believe it is critical to our long-term competitiveness. At the end of 2008, we employed approximately 8,600 people in pharmaceutical and animal health research and development activities, including a substantial number of physicians, scientists holding graduate or postgraduate degrees, and highly skilled technical personnel. Our research and development expenses were \$3.13 billion in 2006, \$3.49 billion in 2007, and \$3.84 billion in 2008.

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

To supplement our internal efforts, we collaborate with others, including educational institutions and research-based pharmaceutical and biotechnology companies, and we contract with others for the performance of research in their facilities. We use the services of physicians, hospitals, medical schools, and other research organizations worldwide to conduct clinical trials to establish the safety and effectiveness of our products. We actively seek out investments in external research and technologies that hold the promise to complement and strengthen our own research efforts. These investments can take many forms, including licensing arrangements, co-development and co-marketing agreements, co-promotion arrangements, joint ventures, and acquisitions.

Drug development is time-consuming, expensive, and risky. On average, only one out of many thousands of chemical compounds discovered by researchers proves to be both medically effective and safe enough to become an approved medicine. The process from discovery to regulatory approval can take 12 to 15 years or longer. Drug candidates can fail at any stage of the process, and even late-stage drug candidates sometimes fail to receive regulatory approval or commercial success. Even after approval and launch of a product, we expend considerable resources on post-marketing surveillance and clinical studies. We believe our investments in research, both internally and in collaboration with others, have been rewarded by the number of new

compounds and new indications for existing compounds that we have in all stages of development. Among our new investigational compounds in the later stages of development are potential therapies for acute coronary syndromes, diabetes, osteoporosis, and cancer. Further, we are studying many other drug candidates in the earlier stages of development, including compounds targeting cancers, diabetes, obesity, musculoskeletal disorders, lipid abnormalities, Alzheimer's disease, schizophrenia, multiple sclerosis, depression, sleep disorders, pain and migraine, attention-deficit hyperactivity disorder (ADHD), alcoholism, and autoimmune disorders including rheumatoid arthritis. At present we have approximately 60 drug candidates across all stages of clinical development. We are also developing new uses and formulations for many of these compounds as well as our currently marketed products, such as Alimta, Byetta, Cialis, Cymbalta, Erbitux, Forteo, Gemzar, and Zyprexa.

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, Byetta is manufactured by third-party suppliers to Amylin. In the event one of these suppliers was unable to provide the materials or product, we generally have sufficient inventory to supply the market until an alternative source of supply can be implemented. However, in the event of an extended failure of a supplier, it is possible that we could experience an interruption in supply until we established new sources or, in some cases, implemented alternative processes.

Our primary bulk manufacturing occurs at three sites in Indiana as well as locations in Ireland, Puerto Rico, and the United Kingdom. Finishing operations, including labeling and packaging, take place at a number of sites throughout the world.

We seek to design and operate our manufacturing facilities and maintain inventory in a way that will allow us to meet all expected product demand while maintaining flexibility to reallocate manufacturing capacity to improve efficiency and respond to changes in supply and demand. However, pharmaceutical production processes are complex, highly regulated, and vary widely from product to product. Shifting or adding manufacturing capacity can be a very lengthy process requiring significant capital expenditures and regulatory approvals. Accordingly, if we were to experience extended plant shutdowns or extraordinary unplanned increases in demand, we could experience an interruption in supply of certain products or product shortages until production could be resumed or expanded.

Quality Assurance

Our success depends in great measure upon customer confidence in the quality of our products and in the integrity of the data that support their safety and effectiveness. Product quality arises from a total commitment to quality in all parts of our operations, including research and development, purchasing, facilities planning, manufacturing, and distribution. We have implemented quality-assurance procedures relating to the quality and integrity of scientific information and production processes.

Control of production processes involves rigid specifications for ingredients, equipment, facilities, manufacturing methods, packaging materials, and labeling. We perform tests at various stages of production processes and on the final product to assure that the product meets all regulatory requirements and our standards. These tests may involve chemical and physical chemical analyses, microbiological testing, testing in animals, or a combination. Additional assurance of quality is provided by a corporate quality-assurance group that monitors existing pharmaceutical and animal health manufacturing procedures and systems in the parent company, subsidiaries and affiliates, and third-party suppliers.

Executive Officers of the Company

The following table sets forth certain information regarding our executive officers. All executive officers except Mr. Azar 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 20, 2009, 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
John C. Lechleiter, Ph.D.	55	Chairman (since January 2009), President (since October 2005), Chief Executive Officer (since April 2008) and a Director
Robert A. Armitage	60	Senior Vice President and General Counsel (since January 2003)
Alex M. Azar II	41	Senior Vice President, Corporate Affairs and Communications (since June 2007). From 2005 to 2007, Azar served as Deputy Secretary of the U.S. Department of Health and Human Services (HHS). From 2001 to 2005, he served HHS as General Counsel.
Bryce D. Carmine	57	Executive Vice President, Marketing and Sales (since April 2008)
Frank M. Deane, Ph.D.	59	President, Manufacturing Operations (since June 2007)
Anthony J. Murphy, Ph.D.	58	Senior Vice President, Human Resources (since June 2005)
Steven M. Paul, M.D.	58	Executive Vice President, Science and Technology (since July 2003)
Derica W. Rice	44	Senior Vice President and Chief Financial Officer (since May 2006)
Gino Santini	52	Senior Vice President, Corporate Strategy and Business Development (since June 2007)

Employees

At the end of 2008, we employed approximately 40,500 people, including approximately 19,600 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 Part II, Item 8 of this Form 10-K, “Segment Information.” That information is incorporated here by reference.

The relative contribution of any particular product to our consolidated net sales changes from year to year. This is due to several factors, including the introduction of new products by us and by other manufacturers and the introduction of generic pharmaceuticals upon patent expirations. In addition, margins vary for our different products due to various factors, including differences in the cost to manufacture and market the products, the value of the products to the marketplace, and government restrictions on pricing and reimbursement. Our major product sales are generally not seasonal.

Financial Information Relating to Foreign and Domestic Operations

You can find financial information relating to foreign and domestic operations in Part II, Item 8 of this Form 10-K, “Segment Information.” That information is incorporated here by reference.

To date, our overall operations abroad have not been significantly deterred by local restrictions on the transfer of funds from branches and subsidiaries located abroad, including the availability of dollar exchange. We cannot predict what effect these restrictions or the other risks inherent in foreign operations, including possible nationalization, might have on our future operations or what other restrictions may be imposed in the future. In addition, changing currency values can either favorably or unfavorably affect our financial position and results of operations. We actively manage foreign exchange risk through various hedging techniques including the use of foreign currency contracts.

Available Information on Our Web Site

We make available through our company web site, free of charge, our company filings with the Securities and Exchange Commission (SEC) as soon as reasonably practicable after we electronically file them with, or furnish them to, the SEC. The reports we make available include our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements, registration statements, and any amendments to those documents. The company web site link to our SEC filings is <http://investor.lilly.com/edgar.cfm>.

In addition, the Corporate Governance portion of our web site includes our corporate governance guidelines, board and committee information (including committee charters), and our articles of incorporation and by-laws. The link to our corporate governance information is <http://investor.lilly.com/corp-gov.cfm>.

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

Item 1A: Risk Factors; Cautionary Statement Regarding Forward Looking Statements

In addition to the other information contained in this Form 10-K, the following risk factors should be considered carefully in evaluating our company. It is possible that our business, financial condition, liquidity or results of operations could be materially adversely affected by any of these risks.

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

- *Pharmaceutical research and development is very costly and highly uncertain.* There are many difficulties and uncertainties inherent in new product research and development and the introduction of new products. There is a high rate of failure inherent in the research to develop new drugs. To bring a pharmaceutical compound from the discovery phase to market typically takes a decade or more and costs over \$1 billion. Failure can occur at any point in the process, including late in the process after significant funds have been invested. As a result, there is a significant risk that funds invested in research programs will not generate financial returns. New product candidates that appear promising in development may fail to reach the market or may have only limited commercial success because of efficacy or safety concerns, inability to obtain necessary regulatory approvals, limited scope of approved uses, difficulty or excessive costs to manufacture, or infringement of the patents or intellectual property rights of others. Delays and uncertainties in the FDA approval process and the approval processes in other countries can result in delays in product launches and lost market opportunity. In recent years, FDA review times have increased substantially and fewer new drugs are being approved. In addition, it can be very difficult to predict sales growth rates of new products.

- *We face intense competition.* We compete with large number of multinational pharmaceutical companies, biotechnology companies and generic pharmaceutical companies. To compete successfully, we must continue to deliver to the market innovative, cost-effective products that meet important medical needs. Our product sales can be adversely affected by the introduction by competitors of branded products that are perceived as superior by the marketplace, by generic versions of our branded products, and by generic versions of other products in the same therapeutic class as our branded products. See Item 1, “Business – Competition,” for more details.
- *Our long-term success depends on intellectual property protection.* Our long-term success depends on our ability to continually discover, develop, and commercialize innovative new pharmaceutical products. Without strong intellectual property protection, we would be unable to generate the returns necessary to support the enormous investments in research and development, capital, and other expenditures required to bring new drugs to the market. Several major products will lose intellectual property protection in the U.S. in the next decade beginning in late 2011. Several of these products will lose intellectual property protection in various countries outside the U.S. even before then. See Item 1, “Business – Patents, Trademarks, and Other Intellectual Property Protection,” for more details.

Intellectual property protection varies throughout the world and is subject to change over time. In the U.S., the Hatch-Waxman Act provides generic companies powerful incentives to seek to invalidate our patents; as a result, we expect that our U.S. patents on major products will be routinely challenged, and there can be no assurance that our patents will be upheld. See Item 1, “Business – Patents, Trademarks, and Other Intellectual Property Protection,” for more details. We are increasingly facing generic manufacturer challenges to our patents outside the U.S. as well. In addition, competitors or other third parties may claim that our activities infringe patents or other intellectual property rights held by them. If successful, such claims could result in our being unable to market a product in a particular territory or being required to pay damages for past infringement or royalties on future sales.

- *Our business is subject to increasing government price controls and other health care cost containment measures.* Government health care cost-containment measures can significantly affect our sales and profitability. In many countries outside the United States, government agencies strictly control, directly or indirectly, the prices at which our products are sold. In the United States, we are subject to substantial pricing pressures from state Medicaid programs and private insurance programs and pharmacy benefit managers, including those operating under the Medicare Part D pharmaceutical benefit. Many federal and state legislative proposals would further negatively affect our pricing and/or reimbursement for our products. We expect pricing pressures from both governments and private payers inside and outside the United States to become more severe. See Item I, “Business – Regulations Affecting Pharmaceutical Pricing and Reimbursement,” for more details.
- *Pharmaceutical products can develop unexpected safety or efficacy concerns.* Unexpected safety or efficacy concerns can arise with respect to marketed products, leading to product recalls, withdrawals, or declining sales, as well as costly product liability claims.
- *We depend on key products for most of our revenues, cash flows, and earnings.* Zyprexa sales of \$4.70 billion represented 23 percent of our revenues in 2008, and Cymbalta sales of \$2.70 billion constituted 13 percent of our 2008 revenues. Six other products – Humalog, Gemzar, Cialis, Alimta, Evista, and Humulin – each contributed more than \$1 billion in revenues in 2008. If these or other key products were to become subject to a problem such as loss of patent protection, materially adverse changes in prescription growth rates, unexpected side effects, regulatory proceedings, material product liability litigation, publicity affecting doctor or patient confidence, or pressure from competitive products, the adverse impact on our revenues, cash flows and earnings could be significant.
- *Regulatory compliance problems could be damaging to the company.* The marketing, promotional, and pricing practices of pharmaceutical manufacturers, as well as the manner in which manufacturers interact with purchasers, prescribers, and patients, are subject to extensive regulation. Many companies, including Lilly, have been subject to claims related to these practices asserted by federal and state governmental authorities and private payers and consumers. These claims have resulted in substantial expense and other

significant consequences to the company. It is possible other products could become subject to investigation and that the outcome of these matters could include criminal charges and fines, penalties, or other monetary or nonmonetary remedies. In particular, See Item 7, “Management’s Discussion and Analysis – Legal and Regulatory Matters,” for the discussions of the U.S. sales and marketing practices investigations. In addition, regulatory issues concerning compliance with current Good Manufacturing Practice (cGMP) regulations for pharmaceutical products can lead to product recalls and seizures, interruption of production leading to product shortages, and delays in the approvals of new products pending resolution of the cGMP issues. We are now operating under a Corporate Integrity Agreement with the Office of Inspector General of the U.S. Department of Health and Human Services that requires us to maintain comprehensive compliance programs governing our research, manufacturing, and sales and marketing of pharmaceuticals. Material failures to comply with the Agreement could result in severe sanctions to the company. See Item 1, “Business – Regulation of our Operations,” for more details.

- *We face many product liability claims today, and future claims will be largely self-insured.* We are subject to a substantial number of product liability claims involving primarily Zyprexa, DES, and thimerosal, and because of the nature of pharmaceutical products, it is possible that we could become subject to large numbers of product liability claims for other products in the future. See Item 7, “Management’s Discussion and Analysis – Legal and Regulatory Matters,” and Item 3, “Legal Proceedings,” for more information on our current product liability litigation. In the past few years, we have experienced difficulties in obtaining product liability insurance due to a very restrictive insurance market. Therefore, for substantially all our currently marketed products we have been and expect that we will continue to be largely self-insured for future product liability losses. In addition, there is no assurance that we will be able to fully collect from our insurance carriers on past claims.
- *Manufacturing difficulties could lead to product supply problems.* Pharmaceutical manufacturing is complex and highly regulated. Manufacturing difficulties can result in product shortages, leading to lost sales. See Item 1, “Business – Raw Materials and Product Supply,” for more details.
- *The current volatility in financial markets could adversely affect the cost and availability of financing.* Although the current contraction of the credit markets has not yet materially affected our borrowing costs or flexibility, if there is additional significant contraction of the markets, it could adversely affect our ability to obtain short-term or long-term financing at reasonable rates.
- *A prolonged economic downturn could adversely affect our business and operating results.* While pharmaceuticals have not generally been sensitive to overall economic cycles, a prolonged economic downturn coupled with rising unemployment (and a corresponding increase in the uninsured and underinsured population) could lead to decreased utilization of drugs, affecting our sales volume. Declining tax revenues attributable to the downturn may increase the pressure on governments to reduce healthcare spending, leading to increasing government efforts to control drug prices. In addition, a prolonged economic downturn could have an adverse impact on our investment portfolio, which could lead to the recognition of losses on our corporate investments and increased benefit expense related to our pension investments. Also, if our customers, suppliers or collaboration partners experience financial difficulties, we could experience slower customer collections, greater bad debt expense, and performance defaults by suppliers or collaboration partners.
- *We face other risks to our business and operating results.* Our business is subject to a number of other risks and uncertainties, including:
 - Economic factors over which we have no control, including changes in inflation, interest rates and foreign currency exchange rates can affect our results of operations.
 - Changes in tax laws, including laws related to the remittance of foreign earnings or investments in foreign countries with favorable tax rates, and settlements of federal, state, and foreign tax audits, can affect our net income.

- Changes in accounting standards promulgated by the Financial Accounting Standards Board, the Securities and Exchange Commission, and the Emerging Issues Task Force can affect reported results.
- Our results can also be affected by internal factors, such as changes in business strategies and the impact of restructurings, asset impairments, technology acquisition and disposition transactions, and business combinations.

We undertake no duty to update forward-looking statements.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our principal domestic and international executive offices are located in Indianapolis. At December 31, 2008, we owned 15 production and distribution facilities in the United States and Puerto Rico. Together with the corporate administrative offices, these facilities contain an aggregate of approximately 15.6 million square feet of floor area dedicated to production, distribution, and administration. Major production sites include Indianapolis, Clinton, and Lafayette, Indiana; two sites in Puerto Rico; Branchburg, New Jersey; and Augusta, Georgia.

We own production and distribution facilities in 15 countries outside the United States and Puerto Rico, containing an aggregate of approximately 3.9 million square feet of floor space. Major production sites include facilities in France, Ireland, Spain, Brazil, Italy, and the United Kingdom. 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 3.4 million square feet and are located primarily in Indianapolis, with smaller sites in San Diego and New York City. In October 2008 we sold our Greenfield, Indiana research facility to Covance Inc. Our major research and development facilities abroad are located in United Kingdom, Canada, Singapore, and Spain, and contain an aggregate of approximately 350,000 square feet.

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

Item 3. Legal Proceedings

We are a party to various currently pending legal actions, government investigations, and environmental proceedings, and we anticipate that such actions could be brought against us in the future. The most significant of these matters are described below or, as noted, in Part II, Item 7, "Management's Discussion and Analysis – Legal and Regulatory Matters." While it is not possible to determine the outcome of the legal actions, investigations and proceedings brought against us, we believe that, except as otherwise specifically noted in Part II, Item 7, the resolution of all such matters will not have a material adverse effect on our consolidated financial position or liquidity, but could possibly be material to our consolidated results of operations in any one accounting period.

Legal Proceedings Described in Management's Discussion and Analysis

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

- The U.S. patent litigation involving Alimta, Cymbalta, Evista, Gemzar, and Xigris
- The patent litigation outside the U.S. involving Zyprexa

- The investigations by the U.S. Attorney for the Eastern District of Pennsylvania and various state attorneys general relating to our U.S. sales, marketing, and promotional practices
- The Zyprexa product liability and related litigation, including claims brought on behalf of state Medicaid agencies and private healthcare payers

That information is incorporated into this Item by reference.

Other Patent Litigation

Strattera: Actavis Elizabeth LLC (Actavis), Glenmark Pharmaceuticals Inc., USA (Glenmark), Sun Pharmaceutical Industries Limited (Sun), Sandoz Inc. (Sandoz), Mylan Pharmaceuticals Inc. (Mylan), Teva Pharmaceuticals USA, Inc. (Teva), Apotex Inc. (Apotex), Aurobindo Pharma Ltd. (Aurobindo), Synthron Laboratories, Inc. (Synthron), and Zydus Pharmaceuticals, USA, Inc. (Zydus) each submitted an ANDA seeking permission to market generic versions of Strattera prior to the expiration of our relevant U.S. patent (expiring in 2017), and alleging that this patent is invalid. We filed a lawsuit against Actavis in the United States District Court for the District of New Jersey in August 2007, and added Glenmark, Sun, Sandoz, Mylan, Teva, Apotex, Aurobindo, Synthron, and Zydus as defendants in September 2007. In December 2007, Zydus agreed to entry of a consent judgment in which Zydus conceded the validity and enforceability of the patent and agreed to a permanent injunction. In June 2008, Glenmark agreed to entry of a permanent injunction, enjoining it from selling a generic product prior to the expiration of the U.S. patent. Also in June 2008, Synthron notified us that it has withdrawn its ANDA and agreed to a stipulated dismissal of all outstanding claims. For the remaining defendants, trial is anticipated as early as December 2009.

Evista: In June 2005, Dr. Alan Schreiber filed a lawsuit against us in the United States District Court for the Eastern District of Pennsylvania raising a number of claims, including patent infringement, misappropriation of trade secrets, breach of contract, and unjust enrichment, and seeking a declaration for inventorship of Lilly's Evista method-of-use patents. After the original lawsuit was filed, the University of Pennsylvania was added as a plaintiff. This matter was settled in December 2008. The settlement did not have a material impact on our consolidated results of operations, liquidity, or financial position.

Cialis: In July 2005, Vanderbilt University filed a lawsuit in the United States District Court in Delaware against ICOS Corporation seeking to add three of its scientists as co-inventors on the Cialis compound and method-of-use patents. In January 2009, the district court judge ruled in our favor, declining to add any of these scientists as an inventor on either patent. The plaintiff may appeal this ruling. We believe these claims are without legal merit and expect to prevail in any appeal of this litigation; however, it is not possible to determine the outcome. An unfavorable final outcome could have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

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

Other Product Liability Litigation

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

In approximately 50 U.S. actions involving approximately 75 claimants, plaintiffs seek to recover damages on behalf of children or grandchildren of women who were prescribed DES during pregnancy.

We have been named as a defendant in approximately 210 actions in the U.S., involving approximately 285 claimants, brought in various state courts and federal district courts on behalf of children with autism or other

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

Other Marketing Practices Investigations

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

In February 2006, we reached a settlement of an investigation by the Office of Consumer Litigation, Department of Justice, related to our marketing and promotional practices and physician communications with respect to Evista. As part of the settlement, we agreed to plead guilty to one misdemeanor violation of the Food, Drug, and Cosmetic Act. The plea was for the off-label promotion of Evista during 1998. The government did not charge the company with any unlawful intent, nor do we acknowledge any such intent. In connection with the overall settlement, we paid a total of \$36.0 million. In addition, as part of the settlement, a civil consent decree requires us to continue to have a compliance program and to undertake a set of defined corporate integrity obligations related to Evista for five years.

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

Shareholder Derivative Litigation

In 2007, the company received two demands from shareholders that the board of directors cause the company to take legal action against current and former directors and others for allegedly causing damage to the company through improper marketing of Evista, Prozac, and Zyprexa. In accordance with procedures established under the Indiana Business Corporation Law (Ind. Code § 23-1-32), the board has appointed a committee of independent persons to consider the demands and determine what action, if any, the company should take in response. Since January 2008, we have been served with seven shareholder derivative lawsuits: *Lambrecht, et al. v. Taurel, et al.*, filed January 17, 2008, in the United States District Court for the Southern District of Indiana; *Staehr et al. v. Eli Lilly and Company et al.*, filed March 27, 2008, in Marion County Superior Court in Indianapolis, Indiana; *Waldman et al., v. Eli Lilly and Company et al.*, filed February 11, 2008, in the United States District Court for the Eastern District of New York; *Solomon v. Eli Lilly and Company et al.*, filed March 27, 2008, in Marion County Superior Court in Indianapolis, Indiana; *Robbins v. Taurel, et al.*, filed April 9, 2008, in the United States District Court for the Eastern District of New York; *City of Taylor General Employees Retirement System v. Taurel, et al.*, filed April 15, 2008, in the United States

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

Employee Litigation

In April 2006, three former employees and one current employee filed a putative class action against the company in the U.S. District Court for the Southern District of Indiana (*Welch, et al. v. Eli Lilly and Company*, filed April 20, 2006) alleging racial discrimination. Plaintiffs have since amended their complaint twice, adding to the lawsuit a total of 154 individual plaintiffs as well as the national and local chapters of the National Association for the Advancement of Colored People (NAACP). Under the current schedule, the plaintiffs are to file their class certification motion in March 2009. We believe this lawsuit is without merit and are prepared to defend against it vigorously.

We have also been named as a defendant in a lawsuit filed in the U.S. District Court for the Northern District of New York (*Schaefer-LaRose, et al.*, filed November 14, 2006) claiming that our pharmaceutical sales representatives should have been categorized as “non-exempt” rather than “exempt” employees, and claiming that the company owes them back wages for overtime worked, as well as penalties, interest, and attorneys fees. Other pharmaceutical industry participants face identical lawsuits. The case was transferred to the U.S. District Court for the Southern District of Indiana in August 2007. In February 2008, the Indianapolis court conditionally certified a nationwide opt-in collective action under the Fair Labor Standards Act of all current and former employees who served as a Lilly pharmaceutical sales representative at any time from November 2003 to the present. As of the close of the opt-in period, fewer than 400 of the over 7,500 potential plaintiffs elected to participate in the lawsuit. We believe this lawsuit is without merit and are prepared to defend against it vigorously.

We have been named in a lawsuit brought by the Labor Attorney for 15th Region in the Labor Court of Paulinia, State of Sao Paulo, alleging possible harm to employees and former employees caused by exposure to heavy metals. We have also been named in approximately 50 lawsuits filed in the same court by individual former employees making similar claims. We believe these lawsuits are without merit and are prepared to defend against them vigorously.

Other Matters

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

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

Between 2003 and 2005, various municipalities in New York sued us and many other pharmaceutical manufacturers, claiming in general that as a result of alleged improprieties by the manufacturers in the calculation and reporting of average wholesale prices for purposes of Medicaid reimbursement, the municipalities overpaid their portion of the cost of pharmaceuticals. The suits seek monetary and other relief, including civil penalties and treble damages. Similar suits were filed against us and many other manufacturers by the States of Mississippi, Iowa, Utah, and Kansas. These suits are pending either in the U.S. District Court for the District of Massachusetts or in various state courts. All of these suits are in early stages or discovery is ongoing.

During 2004 we, along with several other pharmaceutical companies, were named in a consolidated lawsuit in California state court brought on behalf of consumers alleging that the conduct of pharmaceutical companies in preventing commercial importation of prescription drugs from outside the United States violated antitrust laws. The case sought restitution for alleged overpayments for pharmaceuticals and an injunction against the allegedly violative conduct. Summary judgment was granted to us and the other defendants. In July 2008, the California Court of Appeals affirmed that decision. The California Supreme Court has accepted plaintiff's appeal, and we expect it to be heard later this year.

In July 2008, we received a request from the Civil Division of the United States Department of Justice requesting the production of documents related to nominal pricing. We are cooperating in this matter.

We previously received requests for information about Zyprexa from the offices of Representative Henry Waxman, former Chair of the House Committee on Oversight and Government Reform, and Senator Charles Grassley, ranking member of the Senate Finance Committee. We also received a request from Representative Waxman's office for information about drug pricing under Medicare Part D. We are cooperating with these requests.

Along with over 100 other pharmaceutical companies operating in Europe, we have received a questionnaire from the European Commission as part of its ongoing inquiry into whether pharmaceutical companies have improperly blocked or created artificial barriers to pharmaceutical innovation or market entry of medicines through the misuse of patent rights, settlement of patent claims, litigation, or other means. We are cooperating with this request.

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

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

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

During the fourth quarter of 2008, no matters were submitted to a vote of security holders.

Part II

Item 5. Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

You can find information relating to the principal market for our common stock and related stockholder matters at Part II, Item 8 under "Selected Quarterly Data (unaudited)" and "Selected Financial Data (unaudited)." That information is incorporated here by reference.

The following table summarizes the activity related to repurchases of our equity securities during the fourth quarter ended December 31, 2008:

Period	Total Number of Shares Purchased (a) (in thousands)	Average Price Paid per Share (b)	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs (c)	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs (d) (Dollars in millions)
October 2008	4	\$ 33.47	—	\$419.2
November 2008	2	32.34	—	419.2
December 2008	—	—	—	419.2
Total	6	—	—	—

The amounts presented in columns (a) and (b) above represent purchases of common stock related to employee stock option exercises. The amounts presented in columns (c) and (d) in the above table represent activity related to our \$3.00 billion share repurchase program announced in March 2000. As of December 31, 2008, we have purchased \$2.58 billion related to this program.

Item 6. Selected Financial Data

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

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

Review of Operations

EXECUTIVE OVERVIEW

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

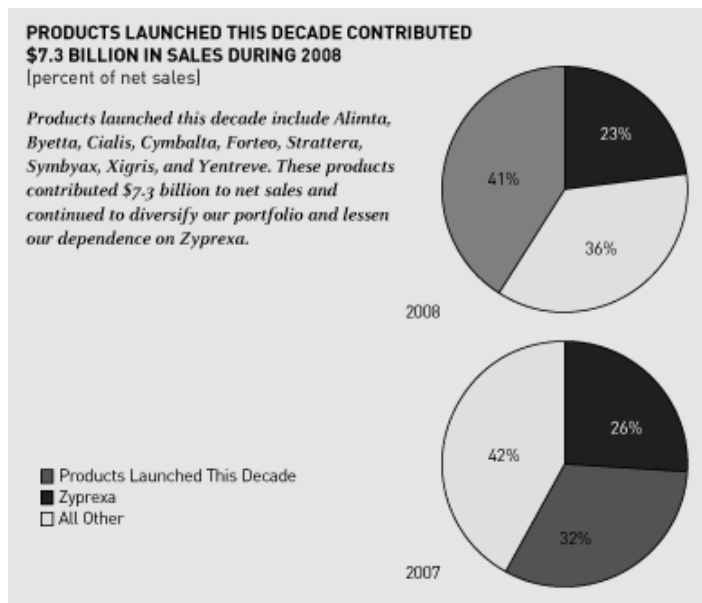
Financial Results

We achieved worldwide sales growth of 9 percent, which was primarily driven by volume increases in several key products. The favorable impact of foreign exchange rates on cost of sales contributed to an improvement in gross margin. Marketing, selling, and administrative expenses grew at the same rate as sales, driven by pre-launch activities associated with prasugrel, marketing costs associated with Cymbalta and Evista, the impact of foreign exchange rates, and increased litigation-related expenses; while our investment in research and development grew 10 percent. We completed our acquisition of ImClone Systems Inc. (ImClone), resulting in a significant charge of \$4.69 billion for acquired in-process research and development (IPR&D) and reached resolution on government investigations related to our past U.S. marketing and promotional practices for Zyprexa, resulting in an additional charge of \$1.48 billion. We incurred tax expense of \$764.3 million, despite a loss before income taxes of \$1.31 billion, primarily caused by the non-deductibility of the ImClone IPR&D charge and the partial deductibility of the Zyprexa investigation settlements. Accordingly, earnings decreased \$5.02 billion, to a net loss of \$2.07 billion, and earnings per share decreased \$4.60, to a loss of \$1.89 per share, in 2008 as compared with net income of \$2.95 billion, or earnings per share of \$2.71 in 2007. Net income comparisons between 2008 and 2007 are affected by the impact of the following significant items (see Notes 3, 5, 12, and 14 to the consolidated financial statements for additional information):

2008

Acquisitions (Note 3)

- We recognized charges totaling \$4.73 billion (pretax) associated with the acquisition of ImClone, which decreased earnings per share by \$4.46. These amounts include an IPR&D charge of \$4.69 billion (pretax). The remaining net expenses are related to ImClone’s operating results subsequent to the acquisition, incremental interest costs, and amortization of the intangible asset associated with Erbitux. We also incurred IPR&D charges of \$28.0 million (pretax) associated with the acquisition of SGX Pharmaceuticals, Inc. (SGX), which decreased earnings per share by \$.03.
- We incurred IPR&D charges associated with licensing arrangements with BioMS Medical Corp. (BioMS) and TransPharma Medical Ltd. totaling \$122.0 million (pretax), which decreased earnings per share by \$.07.



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

- We recognized asset impairments, restructuring, and other special charges totaling \$497.0 million (pretax), which decreased earnings per share by \$.30. A similar charge of \$57.1 million (pretax), which decreased earnings per share by \$.04, was included in cost of sales. These charges were primarily associated with the sale of our Greenfield, Indiana site, the termination of the AIR[®] Insulin program, and strategic exit activities related to manufacturing operations.
- We recorded charges of \$1.48 billion (pretax) related to the federal and state Zyprexa investigations led by the U.S. Attorney for the Eastern District of Pennsylvania (EDPA), as well as the resolution of a multi-state investigation regarding Zyprexa involving 32 states and the District of Columbia, which decreased earnings per share by \$1.20.

Other (Note 12)

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

2007

Acquisitions (Note 3)

- We incurred IPR&D charges associated with the acquisitions of ICOS Corporation (ICOS), Hypnion, Inc. (Hypnion), and Ivy Animal Health, Inc. (Ivy), totaling \$631.6 million (pretax), which decreased earnings per share by \$.57.
- We incurred IPR&D charges associated with our licensing arrangements with Glenmark Pharmaceuticals Limited India, MacroGenics, Inc., and OSI Pharmaceuticals, totaling \$114.0 million (pretax), which decreased earnings per share by \$.06.

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

- We recognized asset impairments, restructuring, and other special charges of \$190.6 million (pretax), which decreased earnings per share by \$.12. These charges were primarily associated with previously announced strategic decisions affecting manufacturing and research facilities.
- We incurred a special charge following a settlement with one of our insurance carriers over Zyprexa product liability claims, which led to a reduction of our expected product liability insurance recoveries, and other product liability charges. This resulted in a charge totaling \$111.9 million (pretax), which decreased earnings per share by \$.09.

Late-Stage Pipeline Developments and Business Development Activity

Our long-term success depends, to a great extent, on our ability to continue to discover and develop innovative pharmaceutical products and acquire or collaborate on compounds currently in development by other biotechnology or pharmaceutical companies. There were a number of late-stage pipeline developments and business development transactions within the past year, including:

Pipeline

- We, along with our partner Daiichi Sankyo Company Limited, are seeking from the U.S. Food and Drug Administration (FDA) approval for prasugrel as a treatment for patients with acute coronary syndrome being managed with percutaneous coronary intervention. The Cardiovascular and Renal Drugs Advisory Committee of the FDA reviewed prasugrel during a hearing and unanimously recommended it for approval. The FDA will consider the recommendation as it continues its review and makes its final decision.
- Prasugrel was approved for marketing by the European Commission under the trade name Efient in February 2009 for the prevention of atherothrombotic events in patients with acute coronary syndromes undergoing percutaneous coronary intervention.
- We received a complete response letter from the FDA for olanzapine long-acting injection (LAI) for acute and maintenance treatment of schizophrenia in adults. We are continuing to work with the agency on the new drug application (NDA). The FDA does not require any additional clinical trials for the continued review of the NDA. Per the agency's request, we are preparing a proposed Risk Evaluation and Mitigation Strategy, which will be submitted in the near future. In addition, olanzapine long-acting injection was approved by the European Commission under the trade name Zypadhera™.
- We withdrew our supplemental NDA from the FDA for Cymbalta for the management of chronic pain. We plan to resubmit the application in the first half of 2009, adding data from a recently completed study in chronic osteoarthritis pain of the knee.
- The FDA approved Alimta, in combination with cisplatin, as a first-line treatment for locally advanced and metastatic non-small cell lung cancer (NSCLC) for patients with nonsquamous histology. The European health authorities also approved Alimta, in combination with cisplatin, as a first-line treatment for non-small cell lung cancer patients with other than predominantly squamous cell histology.
- We submitted tadalafil as a treatment for pulmonary arterial hypertension (PAH) to regulatory authorities in the U.S., Europe, and Japan.
- The FDA approved Cymbalta for the management of fibromyalgia, a chronic pain disorder. In addition, the European Commission approved Cymbalta for the treatment of generalized anxiety disorder (GAD).
- We, along with our partner Amylin Pharmaceuticals, Inc. (Amylin), submitted Byetta as a monotherapy treatment for type 2 diabetes to the FDA.
- The European Commission approved a new indication for Forsteo® for the treatment of osteoporosis associated with sustained, systemic glucocorticoid therapy in women and men at increased risk for fracture. We have also received an approvable letter from the FDA for Forteo for the same indication.

- We terminated development of our AIR Insulin program, which was being conducted in collaboration with Alkermes, Inc. The program had been in Phase III clinical development as a potential treatment for type 1 and type 2 diabetes. This decision was not a result of any observations during AIR Insulin trials relating to the safety of the product, but rather was a result of increasing uncertainties in the regulatory environment and a thorough evaluation of the evolving commercial and clinical potential of the product compared to existing medical therapies.

Business Development

- We acquired all of the outstanding shares of ImClone for a total purchase price of approximately \$6.5 billion. This strategic combination will offer both targeted therapies and oncolytic agents along with an oncology pipeline spanning all phases of clinical development. It also expands our biotechnology capabilities.
- We entered into a license and a supply arrangement with United Therapeutics Corporation related to the U.S. commercialization rights for the PAH indication of tadalafil. We received an upfront payment of \$150.0 million in exchange for exclusive rights to commercialize tadalafil for PAH in the U.S., as well as for a product manufacturing and supply arrangement. As part of this arrangement, we acquired a \$150.0 million equity position in the company. The indication is currently under review by the FDA.
- We acquired the worldwide rights to the dairy cow supplement Posilac, as well as the product's supporting operations, from Monsanto Company (Monsanto) for an upfront payment of \$300.0 million, as well as contingent consideration based on future Posilac sales. The acquisition of Posilac provides us with a product that complements those of our animal health product line.
- We sold our Greenfield Laboratories site in Greenfield, Indiana, to Covance Inc. We also signed a 10-year service agreement, under which Covance will assume responsibility for our toxicology testing and other R&D support activities at the site.
- We acquired SGX for approximately \$64 million in cash. The acquisition allows us to integrate SGX's structure-guided drug discovery platform into our drug discovery efforts. It also gives us access to FAST™, SGX's fragment-based, protein structure guided drug discovery technology, and to a portfolio of preclinical oncology compounds focused on a number of kinase targets.
- We entered into a licensing and development agreement with TransPharma Medical Ltd. (TransPharma) to acquire rights to its product and related drug delivery system for the treatment of osteoporosis. The product, which is administered transdermally using TransPharma's proprietary technology, is currently in Phase II clinical testing.
- We entered into an agreement with an affiliate of TPG-Axon Capital (TPG) for the Phase III development of our two lead molecules for the treatment of Alzheimer's disease. This agreement provides TPG with success-based milestones and royalties in exchange for clinical trial funding.
- We entered into a licensing and development agreement with BioMS whereby we acquired exclusive worldwide rights to a multiple sclerosis (MS) compound. The compound is currently being evaluated in two pivotal Phase III clinical trials in secondary progressive MS.

Legal, Regulatory, and Other Matters

In March 2004, we were notified by the U.S. Attorney's office for the EDPA that it had commenced an investigation relating to our U.S. marketing and promotional practices for Zyprexa, Prozac, and Prozac Weekly™. In October 2008, we announced that we were in advanced discussions to resolve the ongoing investigations led by the EDPA, and we recorded a charge of \$1.42 billion. In January 2009, we announced that the discussions had been successfully concluded, and that we settled the Zyprexa-related federal claims, as well as similar Medicaid-related claims of states which decide to participate in the settlement.

Beginning in August 2006, we received civil investigative demands or subpoenas from the attorneys general of a number of states under various state consumer protection laws seeking documents pertaining to Zyprexa. In

October 2008, we reached a settlement with 32 states and the District of Columbia, under which we paid \$62.0 million.

In December 2008, the Federal Supreme Court (BGH) in Germany re-established our Zyprexa patent that had been declared invalid in 2007 by the German Federal Patent Court. As a result of this ruling, generic olanzapine has been withdrawn from the German market as of the beginning of 2009.

We continue to reach agreements with claimants' attorneys involved in U.S. Zyprexa product liability litigation to settle claims against us relating to the medication. Approximately 120 claims remain.

In the third quarter of 2008, we initiated a strategic review of our Tippecanoe manufacturing facility in Lafayette, Indiana. Options being considered for this site include continuing operations with a revised site mission, exploring opportunities to sell the facility, and ceasing operations altogether. The review is expected to last six to twelve months. No final decisions have been made at this time; however, depending on the decision, we could record significant charges.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) continues to provide an effective prescription drug benefit under the Medicare program (known as Medicare Part D). Various measures have been discussed and/or passed in both the U.S. House of Representatives and U.S. Senate that would impose additional pricing pressures on our products, including proposals to legalize the importation of prescription drugs and either allow, or require, the Secretary of Health and Human Services to negotiate drug prices within Medicare Part D directly with pharmaceutical manufacturers. Additionally, various proposals have been introduced that would increase the rebates we pay on sales to Medicaid patients or impose additional rebates on sales to patients who receive their medicines through Medicare Part D. Uncertainty exists surrounding the new administration and Congress and the impact any government decisions or programs will have on the pharmaceutical industry. In addition, many states are facing substantial budget difficulties due to the downturn in the economy and are expected to seek aggressive cuts or other offsets in healthcare spending. We expect pricing pressures at the federal and state levels to become more severe, which could have a material adverse effect on our consolidated results of operations.

International operations also are generally subject to extensive price and market regulations, and there are many proposals for additional cost-containment measures, including proposals that would directly or indirectly impose additional price controls or reduce the value of our intellectual property protection.

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

Product	Year Ended December 31, 2008			Year Ended December 31, 2007 Total	Percent Change from 2007
	U.S. ¹	Outside U.S.	Total		
(Dollars in millions)					
Zyprexa	\$ 2,202.5	\$ 2,493.6	\$ 4,696.1	\$ 4,761.0	(1)
Cymbalta	2,253.8	443.3	2,697.1	2,102.9	28
Humalog	1,008.4	727.4	1,735.8	1,474.6	18
Gemzar	734.8	985.0	1,719.8	1,592.4	8
Cialis ²	539.0	905.5	1,444.5	1,143.8	26
Alimta	561.9	592.8	1,154.7	854.0	35
Animal health products	537.3	556.0	1,093.3	995.8	10
Evista	700.5	375.1	1,075.6	1,090.7	(1)
Humulin	380.9	682.3	1,063.2	985.2	8
Forteo	489.9	288.8	778.7	709.3	10
Strattera	437.8	141.7	579.5	569.4	2
Other pharmaceutical products	1,087.6	1,252.1	2,339.7	2,354.4	(1)
Total net sales	\$10,934.4	\$ 9,443.6	\$20,378.0	\$ 18,633.5	9

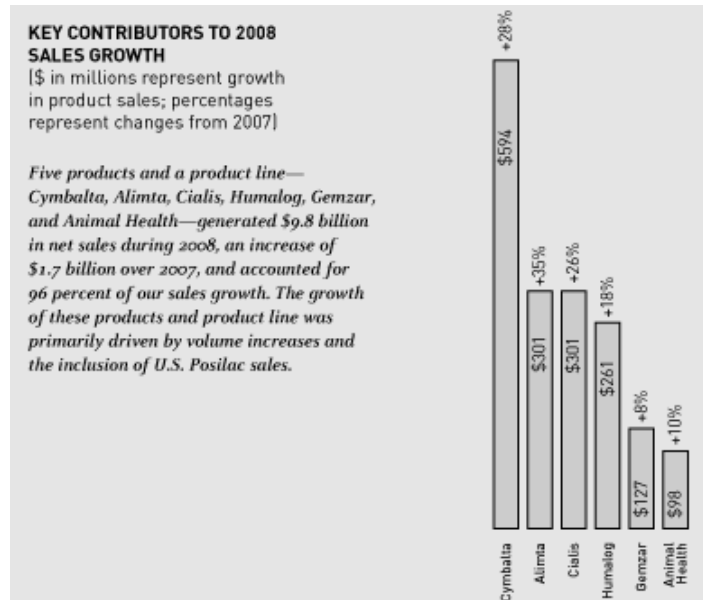
¹ U.S. sales include sales in Puerto Rico.

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

OPERATING RESULTS — 2008

Sales

Our worldwide sales for 2008 increased 9 percent, to \$20.38 billion, driven primarily by growth of Cymbalta, Cialis, Alimta, Humalog, and Gemzar. Worldwide sales volume increased 5 percent, while foreign exchange rates contributed 3 percent, and selling prices contributed 2 percent. (Numbers do not add due to rounding.) Sales in the U.S. increased 8 percent, to \$10.93 billion, driven primarily by increased sales of Cymbalta, Humalog, Cialis, and Alimta. Sales outside the U.S. increased 11 percent, to \$9.44 billion, driven primarily by the sales growth of Alimta, Cialis, Cymbalta, and Humalog.



Zyprexa, our top-selling product, is a treatment for schizophrenia, acute mixed or manic episodes associated with bipolar I disorder, and bipolar maintenance. Zyprexa sales in the U.S. decreased 1 percent in 2008, driven by lower demand, partially offset by higher prices. Sales outside the U.S. decreased 1 percent, driven by decreased demand and to a lesser extent, lower prices, partially offset by the favorable impact of foreign exchange rates. Demand outside the U.S. was unfavorably impacted by generic competition in Germany and Canada. As noted previously, generic olanzapine has been withdrawn from the German market as of the beginning of 2009.

Sales of Cymbalta, a product for the treatment of major depressive disorder, diabetic peripheral neuropathic pain, generalized anxiety disorder, and fibromyalgia, increased 23 percent in the U.S., driven by increased demand and, to a lesser extent, higher prices. Sales outside the U.S. increased 66 percent, driven by increased demand and, to a lesser extent, the favorable impact of foreign exchange rates and higher prices. Higher demand outside the U.S. reflects increased demand in established markets as well as recent launches in new markets.

Sales of Humalog, our injectable human insulin analog for the treatment of diabetes, increased 14 percent in the U.S., driven by increased demand and higher prices. Sales outside the U.S. increased 24 percent, driven by increased demand and, to a lesser extent, the favorable impact of foreign exchange rates.

Sales of Gemzar, a product approved to fight various cancers, increased 10 percent in the U.S., driven by increased demand and higher prices. Sales outside the U.S. increased 7 percent, driven primarily by the favorable impact of foreign exchange rates and, to a lesser extent, increased demand, partially offset by lower prices. We will likely face increased generic competition in certain markets outside the U.S. in 2009.

Our sales of Cialis, a treatment for erectile dysfunction, increased 27 percent in the U.S., driven by increased demand and higher prices. Sales outside the U.S. increased 26 percent, driven by increased demand and, to a lesser extent, the favorable impact of foreign exchange rates and higher prices. Total worldwide sales of Cialis increased 19 percent to \$1.44 billion in 2008 as compared to \$1.22 billion in 2007. This includes \$72.7 million of sales in the Lilly ICOS joint-venture territories for the 2007 period prior to the acquisition of ICOS.

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

Sales of Evista, a product for the prevention and treatment of osteoporosis in postmenopausal women and for risk reduction of invasive breast cancer in postmenopausal women with osteoporosis and postmenopausal women at high risk for invasive breast cancer, decreased 1 percent in the U.S., driven by decreased demand, partially offset by higher prices. Sales outside the U.S. decreased 2 percent, driven by lower demand and lower prices, partially offset by the favorable impact of foreign exchange rates. As described in Legal and Regulatory Matters, Evista is the subject of a Hatch-Waxman patent challenge by Teva Pharmaceuticals USA, Inc. (Teva), which has received tentative approval of its Abbreviated New Drug Application (ANDA) from the FDA. Unless the current stay on Teva's approved ANDA remains in force or Teva is preliminarily enjoined from markets if the stay is lifted, it is possible that Teva could choose to launch before the current action against Teva is concluded. Such a launch could have a material adverse impact on our future consolidated results of operations.

Sales of Humulin, an injectable human insulin for the treatment of diabetes, increased 4 percent in the U.S., driven by higher prices. Sales outside the U.S. increased 10 percent, driven by the favorable impact of foreign exchange rates and increased demand.

Sales of Forteo, an injectable treatment for osteoporosis in postmenopausal women and men at high risk for fracture, decreased 1 percent in the U.S., driven by decreased demand, partially offset by higher prices. Sales outside the U.S. increased 34 percent, driven by increased demand and, to a lesser extent, the favorable impact of foreign exchange rates.

Sales of Strattera, a treatment for attention-deficit hyperactivity disorder in children, adolescents, and adults, decreased 6 percent in the U.S., driven by decreased demand, partially offset by higher prices. Sales outside the U.S. increased 35 percent, driven primarily by increased demand.

Worldwide sales of Byetta, an injectable product for the treatment of type 2 diabetes that we market with Amylin, increased 16 percent to \$751.4 million during 2008. We report as revenue our 50 percent share of Byetta's gross margin in the U.S., 100 percent of Byetta sales outside the U.S., and our sales of Byetta pen delivery devices to Amylin. Our revenues increased 20 percent to \$396.1 million in 2008.

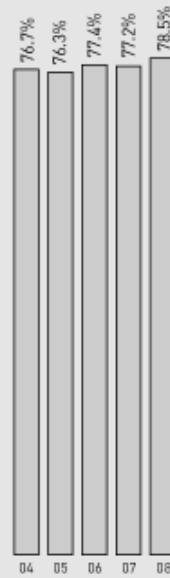
Animal health product sales in the U.S. increased 12 percent, driven by the inclusion of U.S. Posilac sales since the date of acquisition. Sales outside the U.S. increased 8 percent, driven by increased demand and, to a lesser extent, the favorable impact of foreign exchange rates.

Gross Margin, Costs, and Expenses

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

GROSS MARGIN
[percent of net sales]

Gross margin as a percent of net sales increased by 1.3 percentage points to 78.5 percent in 2008, due primarily to the favorable impact of foreign exchange rates.



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

RESEARCH AND DEVELOPMENT INVESTMENT INCREASING
[\$ millions, percent of net sales]

Research and development expenditures increased by 10 percent, to \$3.8 billion, in 2008 due to increases in late-stage clinical trial and discovery research costs. This sustained level of investment in research and development enabled us to move 17 drug candidates into human clinical trials in 2008, unprecedented in Lilly's history, supporting our commitment to develop best-in-class and first-in-class medicines to provide answers that matter for our customers.



Acquired IPR&D charges related to the acquisitions of ImClone and SGX, as well as our in-licensing arrangements with BioMS and TransPharma, were \$4.84 billion in 2008 as compared to \$745.6 million in

2007. We recognized asset impairments, restructuring, and other special charges of \$1.97 billion in 2008, as compared to \$302.5 million in 2007. The 2008 charges were primarily associated with the resolution of Zyprexa investigations with the U.S. Attorney for the EDPA and multiple states. See Notes 3, 5 and 14 to the consolidated financial statements for additional information.

Other — net decreased \$148.1 million, to a net expense of \$26.1 million. This line item consists of interest expense, interest income, the after-tax operating results of the Lilly ICOS joint venture, and all other miscellaneous income and expense items.

- Interest expense for 2008 was essentially flat at \$228.3 million. The impact of lower interest rates on our debt was substantially offset by lower capitalized interest due to lower construction-in-progress balances and increased interest expense due to the financing of the ImClone acquisition.
- Interest income for 2008 decreased \$4.6 million, to \$210.7 million, as lower interest rates were partially offset by higher cash balances.
- The Lilly ICOS joint venture income prior to the 2007 acquisition was \$11.0 million. Subsequent to the acquisition, all activity related to ICOS is included in our consolidated financial results.
- Net other miscellaneous items decreased \$132.5 million to a loss of \$8.5 million, primarily as a result of lower outlicensing income and increased net losses on investment securities in 2008 (the majority of which consisted of unrealized losses).

We incurred tax expense of \$764.3 million in 2008, despite having a loss before income taxes of \$1.31 billion. Our net loss was driven by the \$4.69 billion acquired IPR&D charge for ImClone and the \$1.48 billion Zyprexa investigation settlements. The IPR&D charge was not tax deductible, and only a portion of the Zyprexa investigation settlements was deductible. In addition, we recorded tax expense associated with the ImClone acquisition, as well as a discrete income tax benefit of \$210.3 million for the resolution of the IRS audit. The effective tax rate was 23.8 percent in 2007. See Note 12 to the consolidated financial statements for additional information.

OPERATING RESULTS — 2007

Financial Results

We achieved worldwide sales growth of 19 percent. This growth was primarily driven by volume increases in a number of key products, with a significant portion of this increase in volume resulting from the acquisition of ICOS. Our additional investments in marketing and selling expenses in support of key products, primarily Cymbalta and the diabetes care products, contributed to this sales growth and enabled us to increase our investment in research and development 11 percent in 2007. While cost of sales and operating expenses in the aggregate grew at approximately the same rate as sales, other — net decreased and the effective tax rate increased. As a result, net income and earnings per share increased 11 percent, to \$2.95 billion, or \$2.71 per share, in 2007 as compared with \$2.66 billion, or \$2.45 per share, in 2006. Net income comparisons between 2007 and 2006 are affected by the impact of significant items that are reflected in our financial results. The significant items for 2007 are summarized in the Executive Overview. The 2006 items are summarized as follows (see Notes 5 and 14 to the consolidated financial statements for additional information):

- We recognized asset impairments, restructuring, and other special charges of \$450.3 million (pretax) in the fourth quarter, which decreased earnings per share by \$.31 (Note 5).
- In the fourth quarter, we incurred a charge related to Zyprexa product liability litigation matters of \$494.9 million (pretax), or \$.42 per share (Notes 5 and 14).

Sales

Our worldwide sales for 2007 increased 19 percent, to \$18.63 billion, driven primarily by the inclusion of Cialis since our January 29, 2007 acquisition of ICOS and sales growth of Cymbalta, Zyprexa, Alimta, Gemzar, and Humalog. Worldwide sales volume increased 12 percent, while selling prices and foreign

exchange rates each increased sales by 3 percent. (Numbers do not add due to rounding.) Sales in the U.S. increased 18 percent, to \$10.15 billion, driven primarily by increased sales of Cymbalta, Zyprexa, Alimta, and Byetta, and the inclusion of Cialis. Sales outside the U.S. increased 20 percent, to \$8.49 billion, driven primarily by the inclusion of Cialis, and sales growth of Zyprexa, Alimta, Gemzar, and Cymbalta.

The following table summarizes our net sales activity in 2007 compared with 2006:

Product	Year Ended December 31, 2007			Year Ended December 31, 2006	Percent Change from 2006
	U.S. ¹	Outside U.S.	Total	Total	
(Dollars in millions)					
Zyprexa	\$ 2,236.0	\$ 2,525.0	\$ 4,761.0	\$ 4,363.6	9
Cymbalta	1,835.6	267.3	2,102.9	1,316.4	60
Gemzar	670.0	922.4	1,592.4	1,408.1	13
Humalog	888.0	586.6	1,474.6	1,299.5	13
Cialis ²	423.8	720.0	1,143.8	215.8	NM
Evista	706.1	384.6	1,090.7	1,045.3	4
Animal health products	480.9	514.9	995.8	875.5	14
Humulin	365.2	620.0	985.2	925.3	6
Alimta	448.0	406.0	854.0	611.8	40
Forteo	494.1	215.2	709.3	594.3	19
Strattera	464.6	104.8	569.4	579.0	(2)
Humatrope	213.6	227.2	440.8	415.6	6
Actos	150.8	219.8	370.6	448.5	(17)
Byetta	316.5	14.2	330.7	219.0	51
Other pharmaceutical products	452.3	760.0	1,212.3	1,373.3	(12)
Total net sales	\$10,145.5	\$ 8,488.0	\$18,633.5	\$ 15,691.0	19

NM — Not meaningful

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

² Prior to the acquisition of ICOS, the Cialis sales shown in the table above represent results only in the territories in which we marketed Cialis exclusively. The remaining sales relate to the joint-venture territories of Lilly ICOS LLC (North America, excluding Puerto Rico, and Europe). Our share of the joint-venture territory sales, net of expenses and income taxes, is reported in other — net in our consolidated statements of operations. Subsequent to the acquisition, all Cialis product sales are reported in our net sales.

Zyprexa sales in the U.S. increased 6 percent in 2007, driven by higher net selling prices, partially offset by lower demand. Sales outside the U.S. increased 12 percent, driven by the favorable impact of foreign exchange rates and increased demand.

Sales of Cymbalta increased 58 percent in the U.S., driven primarily by strong demand. Sales outside the U.S. increased 70 percent, driven by increased demand and the favorable impact of foreign exchange rates.

Sales of Gemzar increased 10 percent in the U.S., driven by higher prices and increased demand. Sales outside the U.S. increased 16 percent, driven by increased demand and the favorable impact of foreign exchange rates.

Sales of Humalog increased 9 percent in the U.S., driven by higher prices and increased demand. Sales outside the U.S. increased 20 percent, driven by increased demand and the favorable impact of foreign exchange rates, partially offset by declining prices.

Total worldwide sales of Cialis were \$1.22 billion and \$971.0 million during 2007 and 2006, respectively. This includes \$72.7 million of sales in the Lilly ICOS joint-venture territories for the 2007 period prior to the acquisition of ICOS. Worldwide sales grew 25 percent in 2007. U.S. sales increased 20 percent in 2007, driven by increased demand and higher prices. Sales outside the U.S. increased 28 percent in 2007, driven by increased demand, the favorable impact of foreign exchange rates, and higher prices.

Sales of Evista increased 6 percent in the U.S., driven by higher prices. Sales outside the U.S. increased 1 percent, driven by the favorable impact of foreign exchange rates, partially offset by lower prices and lower demand.

Sales of Humulin decreased 1 percent in the U.S., driven by lower demand, partially offset by higher prices. Sales outside the U.S. increased 11 percent, driven by increased demand and the favorable impact of foreign exchange rates, partially offset by lower prices.

Sales of Alimta increased 28 percent in the U.S., driven by increased demand and, to a lesser extent, higher prices. Sales outside the U.S. increased 55 percent, driven by increased demand and, to a lesser extent, the favorable impact of foreign exchange rates.

Sales of Forteo increased 19 percent in the U.S., driven by higher net selling prices. U.S. sales growth benefited from access to medical coverage through the Medicare Part D program and decreased utilization of our U.S. patient assistance program and, to a lesser extent, increased demand. Sales outside the U.S. increased 21 percent, driven by increased demand and the favorable impact of foreign exchange rates.

Sales of Strattera decreased 9 percent in the U.S., as a result of decreased demand. Sales outside the U.S. increased 50 percent, driven by increased demand and the favorable impact of foreign exchange rates.

Our revenues from Actos decreased 46 percent in the U.S. Sales outside the U.S. increased 30 percent, driven primarily by increased demand and, to a lesser extent, the favorable impact of foreign exchange rates.

Worldwide sales of Byetta increased 51 percent to \$650.2 million during 2007. Our revenues increased 51 percent to \$330.7 million in 2007.

Animal health product sales in the U.S. increased 18 percent, driven by increased demand, the acquisition of Ivy Animal Health, and new companion-animal product launches. Sales outside the U.S. increased 10 percent, driven by the favorable impact of foreign exchange rates and increased demand.

Gross Margin, Costs, and Expenses

The 2007 gross margin decreased to 77.2 percent of sales compared with 77.4 percent for 2006. This decrease was primarily due to the expense resulting from the amortization of the intangible assets acquired in the ICOS acquisition, the unfavorable impact of foreign exchange rates, and production volumes growing at a slower rate than sales, offset partially by manufacturing expenses growing at a slower rate than sales.

Operating expenses (the aggregate of research and development and marketing, selling, and administrative expenses) increased 19 percent in 2007. Investment in research and development increased 11 percent, to \$3.49 billion. In addition to the acquisition of ICOS, this increase was due to increases in discovery research and late-stage clinical trial costs. Marketing, selling, and administrative expenses increased 25 percent in 2007, to \$6.10 billion. This increase was largely due to the impact of the ICOS acquisition, as well as increased marketing and selling expenses in support of key products, primarily Cymbalta and the diabetes care products, and the unfavorable impact of foreign exchange rates.

Acquired IPR&D charges were \$745.6 million in 2007 and related to the acquisitions of ICOS, Hypnion, and Ivy, as well as our licensing arrangements with OSI, MacroGenics, and Glenmark. We incurred asset impairments, restructuring, and other special charges of \$302.5 million in 2007 as compared to \$945.2 million in 2006. See Notes 3, 5 and 14 to the consolidated financial statements for additional information.

Other — net decreased \$115.8 million, to income of \$122.0 million. This line item consists of interest expense, interest income, the after-tax operating results of the Lilly ICOS joint venture, and all other miscellaneous income and expense items.

- Interest expense for 2007 decreased \$9.8 million, to \$228.3 million. This decrease is a result of lower average debt balances in 2007 compared to 2006.
- Interest income for 2007 decreased \$46.6 million, to \$215.3 million, due to lower cash balances in 2007 compared to 2006.

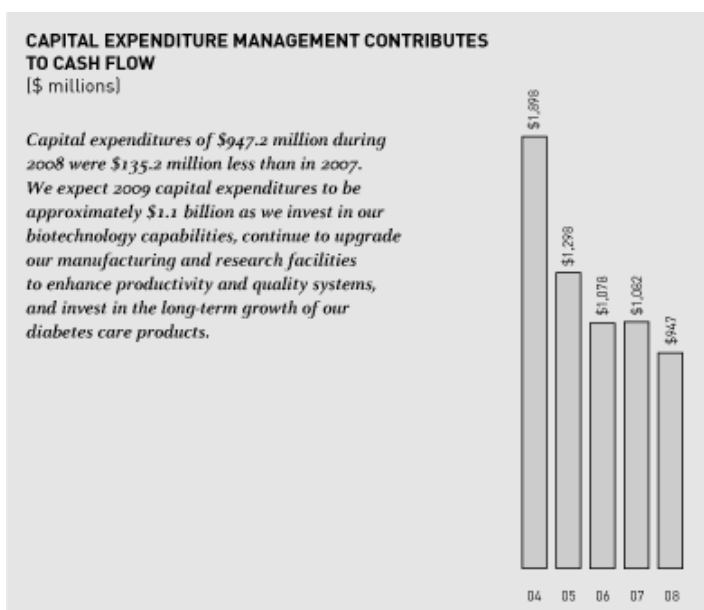
- The Lilly ICOS joint-venture income was \$11.0 million in 2007 as compared to \$96.3 million in 2006, due to the acquisition of ICOS on January 29, 2007.
- Net other miscellaneous income items increased \$6.3 million to \$124.0 million.

We incurred tax expense of \$923.8 million in 2007, resulting in an effective tax rate of 23.8 percent, compared with 22.1 percent for 2006. The effective tax rates for 2007 and 2006 were affected primarily by the nondeductible ICOS and Hynion IPR&D charges of \$594.6 million in 2007, and the product liability charges of \$494.9 million in 2006. The tax effect of the product liability charge was less than our effective tax rate, as the tax benefit was calculated based upon existing tax laws in the countries in which we reasonably expect to deduct the charge. See Note 12 to the consolidated financial statements for additional information.

FINANCIAL CONDITION

As of December 31, 2008, cash, cash equivalents, and short-term investments totaled \$5.93 billion compared with \$4.83 billion at December 31, 2007. Cash flow from operations in 2008 of \$7.30 billion and net proceeds from the issuance of debt of \$4.41 billion exceeded the total of the net cash paid for corporate acquisitions of \$6.08 billion, dividends paid of \$2.06 billion, purchases of property and equipment of \$947.2 million, and net purchases of noncurrent investments of \$815.1 million.

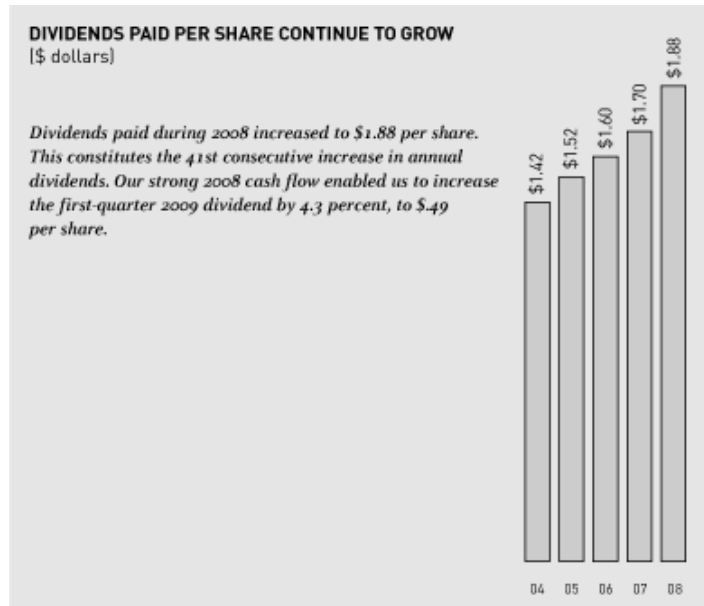
Capital expenditures of \$947.2 million during 2008 were \$135.2 million less than in 2007. We expect 2009 capital expenditures to be approximately \$1.1 billion as we invest in our biotechnology capabilities, continue to upgrade our manufacturing and research facilities to enhance productivity and quality systems, and invest in the long-term growth of our diabetes care products.



Total debt as of December 31, 2008 increased \$5.45 billion, to \$10.46 billion, reflecting the commercial paper we issued in November 2008 primarily to finance our acquisition of ImClone, offset by long-term debt repayments and paydown of commercial paper with cash and cash equivalents on hand. Our current debt ratings from Standard & Poor's and Moody's are at AA and A1, respectively.

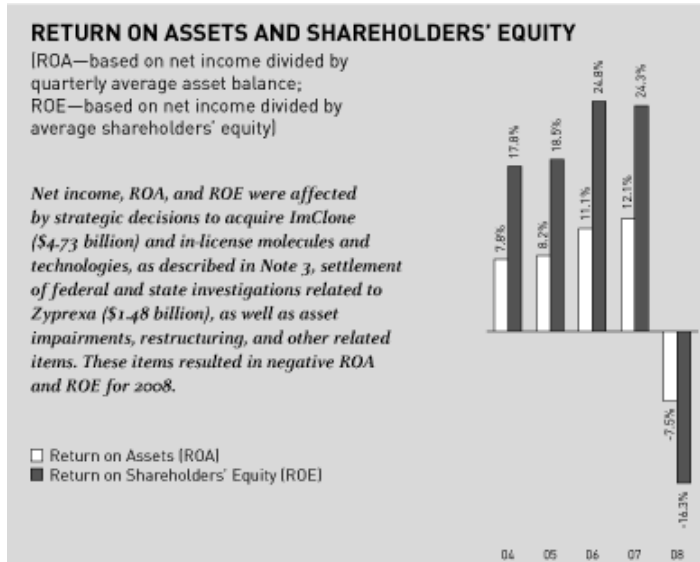
Dividends of \$1.88 per share were paid in 2008, an increase of 11 percent from 2007. In the fourth quarter of 2008, effective for the first-quarter dividend in 2009, the quarterly dividend was increased to \$.49 per share (a 4.3 percent increase), resulting in an indicated annual rate for 2009 of \$1.96 per share. The year 2008 was the

124th consecutive year in which we made dividend payments and the 41st consecutive year in which dividends have been increased.



In recent months, global economic conditions have deteriorated. Triggered by the liquidity crisis in the capital markets, the implications have become more widespread, resulting in higher unemployment and declines in real consumer spending. In addition, many financial institutions have tightened lines of credit, reducing funding available for near-term economic growth. Pharmaceutical consumption has traditionally been relatively unaffected by economic downturns; however, an extended downturn could lead to a decline in overall prescriptions corresponding with the growth of the uninsured and underinsured population in the U.S. In addition, both private and public health care payers are facing heightened fiscal challenges due to the economic slowdown and are taking aggressive steps to reduce the costs of care, including pressures for increased pharmaceutical discounts and rebates and efforts to drive greater use of generic drugs. We continue to monitor the potential near-term impact of prescription trends, the credit worthiness of our wholesalers and other customers and suppliers, the decline of health insurance coverage in the overall population, and the federal government's involvement in the economic crisis.

We believe that cash generated from operations, along with available cash and cash equivalents, will be sufficient to fund our normal operating needs, including debt service, capital expenditures, costs associated with litigation and government investigations, and dividends in 2009. We believe that amounts accessible through existing commercial paper markets should be adequate to fund short-term borrowings. Our access to credit markets has not been adversely affected by the recent illiquidity in the market because of the high credit quality of our short- and long-term debt. In 2009, we intend to fund payments required in connection with the EDPA settlements, and to further reduce outstanding commercial paper with cash and cash equivalents on hand, cash generated from operations, and the issuance of longterm debt. We currently have \$1.24 billion of unused committed bank credit facilities, \$1.20 billion of which backs our commercial paper program. Additionally, in November 2008, we obtained a one-year short-term revolving credit facility in the amount of \$4.00 billion as back-up, alternative financing. Various risks and uncertainties, including those discussed in the Financial Expectations for 2009 section, may affect our operating results and cash generated from operations.



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

Our primary interest rate risk exposure results from changes in short-term U.S. dollar interest rates. In an effort to manage interest rate exposures, we strive to achieve an acceptable balance between fixed and floating rate debt positions and may enter into interest rate derivatives to help maintain that balance. Based on our overall interest rate exposure at December 31, 2008 and 2007, 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, 2008 and 2007, respectively, would have no material impact on earnings, cash flows, or fair values of interest rate risksensitive instruments over a one-year period.

Our foreign currency risk exposure results from fluctuating currency exchange rates, primarily the U.S. dollar against the euro and the Japanese yen, and the British pound against the euro. We face transactional currency exposures that arise when we enter into transactions, generally on an intercompany basis, denominated in currencies other than the local currency. We also face currency exposure that arises from translating the results of our global operations to the U.S. dollar at exchange rates that have fluctuated from the beginning of the period. We may use forward contracts and purchased options to manage our foreign currency exposures. Our policy outlines the minimum and maximum hedge coverage of such exposures. Gains and losses on these derivative positions offset, in part, the impact of currency fluctuations on the existing assets, liabilities, commitments, and anticipated revenues. Considering our derivative financial instruments outstanding at December 31, 2008 and 2007, a hypothetical 10 percent change in exchange rates (primarily against the U.S. dollar) as of December 31, 2008 and 2007, respectively, would have no material impact on earnings, cash flows, or fair values of foreign currency rate risk-sensitive instruments over a one-year period. These calculations do not reflect the impact of the exchange gains or losses on the underlying positions that would be offset, in part, by the results of the derivative instruments.

Off-Balance Sheet Arrangements and Contractual Obligations

We have no off-balance sheet arrangements that have a material current effect or that are reasonably likely to have a material future effect on our financial condition, changes in financial condition, revenues or expenses,

results of operations, liquidity, capital expenditures, or capital resources. We acquire and collaborate on assets still in development and enter into research and development arrangements with third parties that often require milestone and royalty payments to the third party contingent upon the occurrence of certain future events linked to the success of the asset in development. Milestone payments may be required contingent upon the successful achievement of an important point in the development life cycle of the pharmaceutical product (e.g., approval of the product for marketing by the appropriate regulatory agency or upon the achievement of certain sales levels). If required by the arrangement, we may have to make royalty payments based upon a percentage of the sales of the pharmaceutical product in the event that regulatory approval for marketing is obtained. Because of the contingent nature of these payments, they are not included in the table of contractual obligations.

Individually, these arrangements are not material in any one annual reporting period. However, if milestones for multiple products covered by these arrangements would happen to be reached in the same reporting period, the aggregate charge to expense could be material to the results of operations in any one period. These arrangements often give us the discretion to unilaterally terminate development of the product, which would allow us to avoid making the contingent payments; however, we are unlikely to cease development if the compound successfully achieves clinical testing objectives. We also note that, from a business perspective, we view these payments as positive because they signify that the product is successfully moving through development and is now generating or is more likely to generate cash flows from sales of products.

Our current noncancelable contractual obligations that will require future cash payments are as follows (in millions):

	Payments Due by Period				
	Total	Less Than 1 Year	1-3 Years	3-5 Years	More Than 5 Years
Long-term debt, including interest payments ¹	\$ 8,205.5	\$ 595.8	\$ 387.0	\$ 881.2	\$ 6,341.5
Capital lease obligations	41.3	13.1	17.0	5.2	6.0
Operating leases	335.3	90.8	141.4	73.6	29.5
Purchase obligations ²	7,923.0	5,976.3	723.5	388.5	834.7
Other long-term liabilities reflected on our balance sheet ³	1,088.8	—	316.7	185.0	587.1
Other ⁴	157.1	157.1	—	—	—
Total	\$ 17,751.0	\$ 6,833.1	\$ 1,585.6	\$ 1,533.5	\$ 7,798.8

¹ Our long-term debt obligations include both our expected principal and interest obligations and our interest rate swaps. We used the interest rate forward curve at December 31, 2008 to compute the amount of the contractual obligation for interest on the variable rate debt instruments and swaps.

² We have included the following:

- Purchase obligations, consisting primarily of all open purchase orders at our significant operating locations as of December 31, 2008. Some of these purchase orders may be cancelable; however, for purposes of this disclosure, we have not distinguished between cancelable and noncancelable purchase obligations.
- Contractual payment obligations with each of our significant vendors, which are noncancelable and are not contingent.

³ We have included long-term liabilities consisting primarily of our nonqualified supplemental pension funding requirements and deferred compensation liabilities. We excluded liabilities for unrecognized tax benefits of \$906.2 million, as we cannot reasonably estimate the timing of future cash outflows associated with those liabilities.

⁴ This category comprises primarily minimum pension funding requirements.

The contractual obligations table is current as of December 31, 2008. We expect the amount of these obligations to change materially over time as new contracts are initiated and existing contracts are completed, terminated, or modified.

APPLICATION OF CRITICAL ACCOUNTING POLICIES

In preparing our financial statements in accordance with generally accepted accounting principles (GAAP), we must often make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses, and related disclosures. Some of those judgments can be subjective and complex, and consequently actual results could differ from those estimates. For any given individual estimate or assumption we make, it is possible that other people applying reasonable judgment to the same facts and circumstances could develop different estimates. We believe that, given current facts and circumstances, it is unlikely that applying any such other reasonable judgment would cause a material adverse effect on our consolidated results of operations, financial position, or liquidity for the periods presented in this report. Our most critical accounting policies have been discussed with our audit committee and are described below.

Revenue Recognition and Sales Return, Rebate, and Discount Accruals

We recognize revenue from sales of products at the time title of goods passes to the buyer and the buyer assumes the risks and rewards of ownership. For more than 90 percent of our sales, this is at the time products are shipped to the customer, typically a wholesale distributor or a major retail chain. The remaining sales, which are outside the U.S., are recorded at the point of delivery. Provisions for returns, rebates, and discounts are established in the same period the related sales are recorded.

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

We establish sales return accruals for anticipated product returns. We record the return amounts as a deduction to arrive at our net sales. Once the product is returned, it is destroyed. Consistent with SFAS 48, Revenue Recognition When Right of Return Exists, we estimate a reserve when the sales occur for future product returns related to those sales. This estimate is primarily based on historical return rates as well as specifically identified anticipated returns due to known business conditions and product expiry dates. Actual product returns have been approximately one percent of our net sales over the past three years and have not fluctuated significantly as a percent of sales.

We establish sales rebate and discount accruals in the same period as the related sales. The rebate and discount amounts are recorded as a deduction to arrive at our net sales. Sales rebates and discounts that require the use of judgment in the establishment of the accrual include Medicaid, managed care, Medicare, chargebacks, long-term-care, hospital, patient assistance programs, and various other government programs. We base these accruals primarily upon our historical rebate and discount payments made to our customer segment groups and the provisions of current rebate and discount contracts.

The largest of our sales rebate and discount amounts are rebates associated with sales covered by Medicaid. In determining the appropriate accrual amount, we consider our historical Medicaid rebate payments by product as a percentage of our historical sales as well as any significant changes in sales trends, an evaluation of the current Medicaid rebate laws and interpretations, the percentage of our products that are sold to Medicaid recipients, and our product pricing and current rebate and discount contracts. Although we accrue a liability for Medicaid rebates at the time we record the sale (when the product is shipped), the Medicaid rebate related

to that sale is typically paid up to six months later. Because of this time lag, in any particular period our rebate adjustments may incorporate revisions of accruals for several periods.

Most of our rebates outside the U.S. are contractual or legislatively mandated and are estimated and recognized in the same period as the related sales. In some large European countries, government rebates are based on the anticipated pharmaceutical budget deficit in the country. A best estimate of these rebates, updated as governmental authorities revise budgeted deficits, is recognized in the same period as the related sale. If our estimates are not reflective of the actual pharmaceutical budget deficit, we adjust our rebate reserves.

We believe that our accruals for sales returns, rebates, and discounts are reasonable and appropriate based on current facts and circumstances. Sales returns, federally mandated Medicaid rebate and state pharmaceutical assistance programs (Medicaid) and Medicare rebates reduced sales by \$1.03 billion, \$738.8 million, and \$704.8 million in 2008, 2007, and 2006, respectively. A 5 percent change in the sales return, Medicaid, and Medicare rebate amounts we recognized in 2008 would lead to an approximate \$52 million effect on our income before income taxes. As of December 31, 2008, our sales returns, Medicaid, and Medicare rebate liability was \$618.5 million.

Our global rebate and discount liabilities are included in sales rebates and discounts on our consolidated balance sheet. Our global sales return liability is included in other current liabilities and other noncurrent liabilities on our consolidated balance sheet. Approximately 80 percent and 78 percent of our global sales return, rebate, and discount liability resulted from sales of our products in the U.S. as of December 31, 2008 and 2007, respectively. The following represents a roll-forward of our most significant U.S. returns, rebate, and discount liability balances, including Medicaid (in millions):

	<u>2008</u>	<u>2007</u>
Sales return, rebate, and discount liabilities, beginning of year	\$ 693.5	\$ 614.5
Reduction of net sales due to sales returns, discounts, and rebates ¹	1,864.9	1,404.0
Cash payments of discounts and rebates	(1,751.8)	(1,325.0)
Sales return, rebate, and discount liabilities, end of year	<u>\$ 806.5</u>	<u>\$ 693.5</u>

¹ Adjustments of the estimates for these returns, rebates, and discounts to actual results were less than 0.1 percent of net sales for each of the years presented.

Product Litigation Liabilities and Other Contingencies

Product litigation liabilities and other contingencies are, by their nature, uncertain and are based upon complex judgments and probabilities. The factors we consider in developing our product litigation liability reserves and other contingent liability amounts include the merits and jurisdiction of the litigation, the nature and the number of other similar current and past litigation cases, the nature of the product and the current assessment of the science subject to the litigation, and the likelihood of settlement and current state of settlement discussions, if any. In addition, we accrue for certain product liability claims incurred, but not filed, to the extent we can formulate a reasonable estimate of their costs. We estimate these expenses based primarily on historical claims experience and data regarding product usage. We accrue legal defense costs expected to be incurred in connection with significant product liability contingencies when probable and reasonably estimable.

We also consider the insurance coverage we have to diminish the exposure for periods covered by insurance. In assessing our insurance coverage, we consider the policy coverage limits and exclusions, the potential for denial of coverage by the insurance company, the financial condition of the insurers, and the possibility of and length of time for collection. In the past few years, we have experienced difficulties in obtaining product liability insurance due to a very restrictive insurance market. Therefore, for substantially all of our currently marketed products, we have been and expect that we will continue to be completely self-insured for future product liability losses. In addition, there is no assurance that we will be able to fully collect from our insurance carriers in the future.

The litigation accruals and environmental liabilities and the related estimated insurance recoverables have been reflected on a gross basis as liabilities and assets, respectively, on our consolidated balance sheets.

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

Pension and Retiree Medical Plan Assumptions

Pension benefit costs include assumptions for the discount rate, retirement age, and expected return on plan assets. Retiree medical plan costs include assumptions for the discount rate, retirement age, expected return on plan assets, and health-care-cost trend rates. These assumptions have a significant effect on the amounts reported. In addition to the analysis below, see Note 13 to the consolidated financial statements for additional information regarding our retirement benefits.

Periodically, we evaluate the discount rate and the expected return on plan assets in our defined benefit pension and retiree health benefit plans. In evaluating these assumptions, we consider many factors, including an evaluation of the discount rates, expected return on plan assets, and health-care-cost trend rates of other companies; our historical assumptions compared with actual results; an analysis of current market conditions and asset allocations (approximately 88 percent to 92 percent of which are growth investments); and the views of leading financial advisers and economists. We use an actuarially determined, company-specific yield curve to determine the discount rate. In evaluating our expected retirement age assumption, we consider the retirement ages of our past employees eligible for pension and medical benefits together with our expectations of future retirement ages.

We believe our pension and retiree medical plan assumptions are appropriate based upon the above factors. If the health-care-cost trend rates were to be increased by one percentage point each future year, the aggregate of the service cost and interest cost components of the 2008 annual expense would increase by approximately \$27 million. A one-percentage-point decrease would lower the aggregate of the 2008 service cost and interest cost by approximately \$21 million. If the 2008 discount rate for the U.S. defined benefit pension and retiree health benefit plans (U.S. plans) were to be changed by a quarter percentage point, income before income taxes would change by approximately \$26 million. If the 2008 expected return on plan assets for U.S. plans were to be changed by a quarter percentage point, income before income taxes would change by approximately \$17 million. If our assumption regarding the 2008 expected age of future retirees for U.S. plans were adjusted by one year, our income before income taxes would be affected by approximately \$28 million. The U.S. plans represent approximately 83 percent of the total accumulated postretirement benefit obligation and approximately 84 percent of total plan assets at December 31, 2008.

Impairment of Long-Lived Assets

We review the carrying value of long-lived assets (both intangible and tangible) for potential impairment on a periodic basis and whenever events or changes in circumstances indicate the carrying value of an asset may not be recoverable. We determine impairment by comparing the projected undiscounted cash flows to be generated by the asset to its carrying value. If an impairment is identified, a loss is recorded equal to the excess of the asset's net book value over its fair value, and the cost basis is adjusted. The estimated future cash flows, based on reasonable and supportable assumptions and projections, require management's judgment. Actual results could vary from these estimates.

Income Taxes

We prepare and file tax returns based on our interpretation of tax laws and regulations and record estimates based on these judgments and interpretations. In the normal course of business, our tax returns are subject to examination by various taxing authorities, which may result in future tax, interest, and penalty assessments by these authorities. Inherent uncertainties exist in estimates of many tax positions due to changes in tax law resulting from legislation, regulation, and/or as concluded through the various jurisdictions' tax court systems. We recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the

position. The tax benefits recognized in the financial statements from such a position are measured based on the largest benefit that has a greater than 50 percent likelihood of being realized upon ultimate resolution. The amount of unrecognized tax benefits is adjusted for changes in facts and circumstances. For example, adjustments could result from significant amendments to existing tax law and the issuance of regulations or interpretations by the taxing authorities, new information obtained during a tax examination, or resolution of an examination. We believe that our estimates for uncertain tax positions are appropriate and sufficient to pay assessments that may result from examinations of our tax returns. We recognize both accrued interest and penalties related to unrecognized tax benefits in income tax expense.

We have recorded valuation allowances against certain of our deferred tax assets, primarily those that have been generated from net operating losses and tax credit carryforwards in certain taxing jurisdictions. In evaluating whether we would more likely than not recover these deferred tax assets, we have not assumed any future taxable income or tax planning strategies in the jurisdictions associated with these carryforwards where history does not support such an assumption. Implementation of tax planning strategies to recover these deferred tax assets or future income generation in these jurisdictions could lead to the reversal of these valuation allowances and a reduction of income tax expense.

We believe that our estimates for the uncertain tax positions and valuation allowances against the deferred tax assets are appropriate based on current facts and circumstances. A 5 percent change in the amount of the uncertain tax positions and the valuation allowance would result in a change in net income of approximately \$43.2 million and \$42.3 million, respectively.

FINANCIAL EXPECTATIONS FOR 2009

For the full year of 2009, we expect earnings per share to be in the range of \$4.00 to \$4.25. We expect volume growth in sales again in 2009, driven by Cymbalta, Alimta, Cialis, Humalog, and the anticipated launches of prasugrel, as well as by the Elanco animal health division. However, the negative impact of weaker foreign currencies, worldwide pricing pressures, and the impact of generic competition in certain markets for Gemzar are anticipated to partially offset these positive impacts. As a result, we expect mid-single digit sales growth. We expect gross margin as a percent of net sales to increase, driven by the strengthening dollar. This increase could be more pronounced in the first half of 2009. Marketing, selling, and administrative expenses are expected to show flat to low-single digit growth. Research and development expenses are projected to grow in the low-double digits. Other — net is expected to be a net loss of between \$200 million and \$250 million. Capital expenditures are expected to be approximately \$1.1 billion, and we expect continued strong operating cash flow.

Actual results could differ materially and will depend on, among other things, the continuing growth of our currently marketed products; developments with competitive products; the timing and scope of regulatory approvals and the success of our new product launches; asset impairments, restructurings, and acquisitions of compounds under development resulting in acquired in-process research and development charges; foreign exchange rates and global macroeconomic conditions; changes in effective tax rates; wholesaler inventory changes; other regulatory developments, litigation, and government investigations; and the impact of governmental actions regarding pricing, importation, and reimbursement for pharmaceuticals. We undertake no duty to update these forward-looking statements.

LEGAL AND REGULATORY MATTERS

We are a party to various legal actions and government investigations. The most significant of these are described below. While it is not possible to determine the outcome of these matters, we believe that, except as specifically noted below, the resolution of all such matters will not have a material adverse effect on our consolidated financial position or liquidity, but could possibly be material to our consolidated results of operations in any one accounting period.

Patent Litigation

We are engaged in the following patent litigation matters brought pursuant to procedures set out in the Hatch-Waxman Act (the Drug Price Competition and Patent Term Restoration Act of 1984):

- *Cymbalta*: Sixteen generic drug manufacturers have submitted ANDAs seeking permission to market generic versions of Cymbalta prior to the expiration of our relevant U.S. patents (the earliest of which expires in 2013). Of these challengers, all allege non-infringement of the patent claims directed to the commercial formulation, and eight allege invalidity of the patent claims directed to the active ingredient duloxetine. Of the eight challengers to the compound patent claims, one further alleges invalidity of the claims directed to the use of Cymbalta for treating fibromyalgia, and one alleges the patent having claims directed to the active ingredient is unenforceable. Lawsuits have been filed in U.S. District Court for the Southern District of Indiana against Activis Elizabeth LLC; Aurobindo Pharma Ltd.; Cobalt Laboratories, Inc.; Impax Laboratories, Inc.; Lupin Limited; Sandoz Inc.; Sun Pharma Global, Inc.; and Wockhardt Limited, seeking rulings that the patents are valid, infringed, and enforceable. Answers to the complaints are pending.
- *Gemzar*: Sicor Pharmaceuticals, Inc. (Sicor), Mayne Pharma (USA) Inc. (Mayne), and Sun Pharmaceutical Industries Inc. (Sun) each submitted an ANDA seeking permission to market generic versions of Gemzar prior to the expiration of our relevant U.S. patents (compound patent expiring in 2010 and method-of-use patent expiring in 2013), and alleging that these patents are invalid. We filed lawsuits in the U.S. District Court for the Southern District of Indiana against Sicor (February 2006) and Mayne (October 2006 and January 2008), seeking rulings that these patents are valid and are being infringed. The suit against Sicor has been scheduled for trial in July 2009. Sicor's ANDAs have been approved by the FDA; however, Sicor must provide 90 days notice prior to marketing generic Gemzar to allow time for us to seek a preliminary injunction. Both suits against Mayne have been administratively closed, and the parties have agreed to be bound by the results of the Sicor suit. In November 2007, Sun filed a declaratory judgment action in the United States District Court for the Eastern District of Michigan, seeking rulings that our method-of-use and compound patents are invalid or unenforceable, or would not be infringed by the sale of Sun's generic product. This trial is scheduled for December 2009.
- *Alimta*: Teva Parenteral Medicines, Inc. (Teva) and APP Pharmaceuticals, LLC (APP) each submitted ANDAs seeking approval to market generic versions of Alimta prior to the expiration of the relevant U.S. patent (licensed from the Trustees of Princeton University and expiring in 2016), and alleging the patent is invalid. We, along with Princeton, filed lawsuits in the U.S. District Court for the District of Delaware against Teva and APP, seeking rulings that the compound patent is valid and infringed. Trial is scheduled for November 8, 2010.
- *Evista*: Barr Laboratories, Inc. (Barr) submitted an ANDA in 2002 seeking permission to market a generic version of Evista prior to the expiration of our relevant U.S. patents (expiring in 2012-2017) and alleging that these patents are invalid, not enforceable, or not infringed. In November 2002, we filed a lawsuit against Barr in the U.S. District Court for the Southern District of Indiana, seeking a ruling that these patents are valid, enforceable, and being infringed by Barr. Teva Pharmaceuticals USA, Inc. (Teva) has also submitted an ANDA seeking permission to market a generic version of Evista. In June 2006, we filed a similar lawsuit against Teva in the U.S. District Court for the Southern District of Indiana. The lawsuit against Teva is currently scheduled for trial beginning March 9, 2009, while no trial date has been set in the lawsuit against Barr. In April 2008, the FDA granted Teva tentative approval of its ANDA, but Teva's ability to market a generic product is subject to a statutory stay, which has been extended to expire on March 9, 2009. If the stay expires and the company cannot obtain preliminary relief from the court, Teva can launch its generic product, regardless of the status of the current litigation, but subject to our right to recover damages, should we prevail at trial.

We believe each of these Hatch-Waxman challenges is without merit and expect to prevail in this litigation. However, it is not possible to determine the outcome of this litigation, and accordingly, we can provide no assurance that we will prevail. An unfavorable outcome in any of these cases could have a material adverse impact on our future consolidated results of operations, liquidity, and financial position.

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

- In Canada, several generic pharmaceutical manufacturers have challenged the validity of our Zyprexa compound and method-of-use patent (expiring in 2011). In April 2007, the Canadian Federal Court ruled against the first challenger, Apotex Inc. (Apotex), and that ruling was affirmed on appeal in February 2008. In June 2007, the Canadian Federal Court held that an invalidity allegation of a second challenger, Novopharm Ltd. (Novopharm), was justified and denied our request that Novopharm be prohibited from receiving marketing approval for generic olanzapine in Canada. Novopharm began selling generic olanzapine in Canada in the third quarter of 2007. We sued Novopharm for patent infringement, and the trial began in November 2008. We expect the trial to run through the first quarter of 2009, with a decision in the second half of 2009. In November 2007, Apotex filed an action seeking a declaration of the invalidity of our Zyprexa compound and method-of-use patents, and no trial date has been set. We have brought similar actions against Pharmascience (August 2007), Sandoz (July 2007), Nu-Pharm (June 2008), Genpharm (June 2008) and Cobalt (January 2009); none of these suits has been scheduled for trial. Pharmascience has agreed to be bound by the outcome of the Novopharm suit, and, pending the outcome of the lawsuit, we have agreed not to take any further steps to prevent the company from coming to market with generic olanzapine tablets, subject to a contingent damages obligation should we be successful against Novopharm.
- In Germany, generic pharmaceutical manufacturers Egis-Gyogyszergyar and Neolab Ltd. challenged the validity of our Zyprexa compound and method-of-use patent (expiring in 2011). In June 2007, the German Federal Patent Court held that our patent is invalid. Generic olanzapine was launched by competitors in Germany in the fourth quarter of 2007. We appealed the decision to the German Federal Supreme Court and following a hearing in December 2008, the Supreme Court reversed the Federal Patent Court and found the patent to be valid. Following the decision of the Supreme Court, the generic companies either agreed to withdraw from the market or were subject to preliminary injunction. We are pursuing these companies for damages arising from infringement.
- We have received challenges in a number of other countries, including Spain, the United Kingdom (U.K.), France, and several smaller European countries. In Spain, we have been successful at both the trial and appellate court levels in defeating the generic manufacturers' challenges, but further legal challenge is now pending before the Commercial Court in Madrid. In the U.K., the generic pharmaceutical manufacturer Dr. Reddy's Laboratories (UK) Limited has challenged the validity of our Zyprexa compound and method-of-use patent (expiring in 2011). In October 2008, the Patents Court in the High Court, London ruled that our patent was valid. Dr. Reddy's appealed this decision, and a hearing date for the appeal has not been set.

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

Xigris and Evista: In June 2002, Ariad Pharmaceuticals, Inc., the Massachusetts Institute of Technology, the Whitehead Institute for Biomedical Research, and the President and Fellows of Harvard College in the U.S. District Court for the District of Massachusetts sued us, alleging that sales of two of our products, Xigris and Evista, were inducing the infringement of a patent related to the discovery of a natural cell signaling phenomenon in the human body, and seeking royalties on past and future sales of these products. On May 4, 2006, a jury in Boston issued an initial decision in the case that Xigris and Evista sales infringe the patent. The jury awarded the plaintiffs approximately \$65 million in damages, calculated by applying a 2.3 percent royalty to all U.S. sales of Xigris and Evista from the date of issuance of the patent through the date of trial. In addition, a separate bench trial with the U.S. District Court of Massachusetts was held in August 2006, on our contention that the patent is unenforceable and impermissibly covers natural processes. In June 2005, the United States Patent and Trademark Office (USPTO) commenced a reexamination of the patent, and in August 2007 took the position that the Ariad claims at issue are unpatentable, a position that Ariad continues to contest. In September 2007, the Court entered a final judgment indicating that Ariad's claims are patentable, valid, and enforceable, and finding damages in the amount of \$65 million plus a 2.3 percent royalty on net U.S. sales of Xigris and Evista since the time of the jury decision. However, the Court deferred the requirement to pay any damages until after all rights to appeal have been exhausted. We have appealed this

judgment. The Court of Appeals for the Federal Circuit heard oral arguments on the appeal on February 6, 2009. We believe that these allegations are without legal merit, that we will ultimately prevail on these issues, and therefore that the likelihood of any monetary damages is remote.

Government Investigations and Related Litigation

In March 2004, the Office of the U.S. Attorney for the EDPA advised us that it had commenced an investigation related to our U.S. marketing and promotional practices, including our communications with physicians and remuneration of physician consultants and advisors, with respect to Zyprexa, Prozac, and Prozac Weekly. In addition, the State Medicaid Fraud Control Units of more than 30 states coordinated with the EDPA in its investigation of any Medicaid-related claims relating to our marketing and promotion of Zyprexa. In January 2009, we announced that we reached resolution of this matter. As part of the resolution, we pled guilty to one misdemeanor violation of the Food, Drug, and Cosmetic Act and agreed to pay \$615.0 million. The misdemeanor plea is for the off-label promotion of Zyprexa in elderly populations as treatment for dementia, including Alzheimer's dementia, between September 1999 and March 2001. We have also entered into a settlement agreement resolving the federal civil claims, under which we will pay approximately \$438.0 million, although we do not admit to the allegations. We have also agreed to settle the civil investigations brought by the State Medicaid Fraud Control Units of the states that have coordinated with the EDPA in its investigation, and will make available a maximum amount of approximately \$362.0 million for payment to those states that agree to settle. The charge we recorded for this matter in the third quarter of \$1.42 billion will be sufficient to cover these payments. Also, as part of the settlement, we have entered into a corporate integrity agreement with the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS). This agreement will require us to maintain our compliance program and to undertake a set of defined corporate integrity obligations for five years. The agreement also provides for an independent third-party review organization to assess and report on the company's systems, processes, policies, procedures and practices.

In June 2005, we received a subpoena from the Office of the Attorney General, Medicaid Fraud Control Unit, of the State of Florida, seeking production of documents relating to sales of Zyprexa and our marketing and promotional practices with respect to Zyprexa. In September 2006, we received a subpoena from the California Attorney General's Office seeking production of documents related to our efforts to obtain and maintain Zyprexa's status on California's formulary, marketing and promotional practices with respect to Zyprexa, and remuneration of health care providers. We expect these matters to be resolved if Florida and California participate in the state component of the EDPA resolution.

Beginning in August 2006, we received civil investigative demands or subpoenas from the attorneys general of a number of states under various state consumer protection laws. Most of these requests became part of a multistate investigative effort coordinated by an executive committee of attorneys general. In October 2008, we reached a settlement with 32 states and the District of Columbia. While there is no finding that we have violated any provision of the state laws under which the investigations were conducted, we paid \$62.0 million and agreed to undertake certain commitments regarding Zyprexa for a period of six years, through consent decrees filed in the settling states. The 32 states participating in the settlement are: Alabama, Arizona, California, Delaware, Florida, Hawaii, Illinois, Indiana, Iowa, Kansas, Maine, Maryland, Massachusetts, Michigan, Missouri, Nebraska, Nevada, New Jersey, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Dakota, Tennessee, Texas, Vermont, Washington, and Wisconsin.

Product Liability and Related Litigation

We have been named as a defendant in a large number of Zyprexa product liability lawsuits in the U.S. and have been notified of many other claims of individuals who have not filed suit. The lawsuits and unfiled claims (together the "claims") allege a variety of injuries from the use of Zyprexa, with the majority alleging that the product caused or contributed to diabetes or high blood-glucose levels. The claims seek substantial compensatory and punitive damages and typically accuse us of inadequately testing for and warning about side effects of Zyprexa. Many of the claims also allege that we improperly promoted the drug. Almost all of the

federal lawsuits are part of a Multi-District Litigation (MDL) proceeding before The Honorable Jack Weinstein in the Federal District Court for the Eastern District of New York (MDL No. 1596).

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

- In June 2005, we reached an agreement in principle (and in September 2005 a final agreement) to settle more than 8,000 claims for \$690.0 million plus \$10.0 million to cover administration of the settlement.
- In January 2007, we reached agreements with a number of plaintiffs' attorneys to settle more than 18,000 claims for approximately \$500 million.

The 2005 settlement totaling \$700.0 million was paid during 2005. The January 2007 settlements were paid during 2007.

We are prepared to continue our vigorous defense of Zyprexa in all remaining claims. The U.S. Zyprexa product liability claims not subject to these agreements include approximately 105 lawsuits in the U.S. covering approximately 120 plaintiffs, of which about 80 cases covering about 90 plaintiffs are part of the MDL. No trials have been scheduled related to these claims.

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

Since the beginning of 2005, we have recorded aggregate net pretax charges of \$1.61 billion for Zyprexa product liability matters. The net charges, which take into account our actual insurance recoveries, covered the following:

- The cost of the Zyprexa product liability settlements to date; and
- Reserves for product liability exposures and defense costs regarding the known Zyprexa product liability claims and expected future claims to the extent we could formulate a reasonable estimate of the probable number and cost of the claims.

In December 2004, we were served with two lawsuits brought in state court in Louisiana on behalf of the Louisiana Department of Health and Hospitals, alleging that Zyprexa caused or contributed to diabetes or high blood-glucose levels, and that we improperly promoted the drug. These cases have been removed to federal court and are now part of the MDL proceedings in the Eastern District of New York (EDNY). In these actions, the Department of Health and Hospitals seeks to recover the costs it paid for Zyprexa through Medicaid and other drug-benefit programs, as well as the costs the department alleges it has incurred and will incur to treat Zyprexa-related illnesses. We have been served with similar lawsuits filed by the states of Alaska, Arkansas, Connecticut, Idaho, Minnesota, Mississippi, Montana, New Mexico, Pennsylvania, South Carolina, Utah, and West Virginia in the courts of the respective states. The Connecticut, Louisiana, Minnesota, Mississippi, Montana, New Mexico, and West Virginia cases are part of the MDL proceedings in the EDNY. The Alaska case was settled in March 2008 for a payment of \$15.0 million, plus terms designed to ensure, subject to certain limitations and conditions, that Alaska is treated as favorably as certain other states that may settle with us in the future over similar claims. The following cases have been set for trial in 2009: Connecticut in the EDNY in June, Pennsylvania in November, and South Carolina in August, in their respective states.

In 2005, two lawsuits were filed in the EDNY purporting to be nationwide class actions on behalf of all consumers and third-party payors, excluding governmental entities, which have made or will make payments for their members or insured patients being prescribed Zyprexa. These actions have now been consolidated into a single lawsuit, which is brought under certain state consumer protection statutes, the federal civil RICO statute, and common law theories, seeking a refund of the cost of Zyprexa, treble damages, punitive damages, and attorneys' fees. Two additional lawsuits were filed in the EDNY in 2006 on similar grounds. In September

2008, Judge Weinstein certified a class consisting of third-party payors, excluding governmental entities and individual consumers. We appealed the certification order, and Judge Weinstein's order denying our motion for summary judgment, in September 2008. In 2007, The Pennsylvania Employees Trust Fund brought claims in state court in Pennsylvania as insurer of Pennsylvania state employees, who were prescribed Zyprexa on similar grounds as described in the New York cases. As with the product liability suits, these lawsuits allege that we inadequately tested for and warned about side effects of Zyprexa and improperly promoted the drug. The Pennsylvania case is set for trial in October 2009.

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

In addition, we have been named as a defendant in numerous other product liability lawsuits involving primarily diethylstilbestrol (DES) and thimerosal. The majority of these claims are covered by insurance, subject to deductibles and coverage limits.

Because of the nature of pharmaceutical products, it is possible that we could become subject to large numbers of product liability and related claims for other products in the future. In the past few years, we have experienced difficulties in obtaining product liability insurance due to a very restrictive insurance market. Therefore, for substantially all of our currently marketed products, we have been and expect that we will continue to be completely self-insured for future product liability losses. In addition, there is no assurance that we will be able to fully collect from our insurance carriers in the future.

PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995 — A CAUTION CONCERNING FORWARD-LOOKING STATEMENTS

Under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, we caution investors that any forward-looking statements or projections made by us, including those made in this document, are based on management's expectations at the time they are made, but they are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Economic, competitive, governmental, technological, legal, and other factors that may affect our operations and prospects are discussed earlier in this section and our most recent report on Forms 10-Q and 10-K filed with the Securities and Exchange Commission. We undertake no duty to update forward-looking statements.

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 Part II, Item 7 at "Review of Operations – Financial Condition." That information is incorporated in this report by reference.

Item 8. Financial Statements and Supplementary Data

Consolidated Statements of Operations

ELI LILLY AND COMPANY AND SUBSIDIARIES	Year Ended December 31		
	2008	2007	2006
	(Dollars in millions, except per-share data)		
Net sales	\$20,378.0	\$18,633.5	\$15,691.0
Cost of sales	4,382.8	4,248.8	3,546.5
Research and development	3,840.9	3,486.7	3,129.3
Marketing, selling, and administrative	6,626.4	6,095.1	4,889.8
Acquired in-process research and development (Note 3)	4,835.4	745.6	—
Asset impairments, restructuring, and other special charges (Note 5)	1,974.0	302.5	945.2
Other — net, expense (income)	26.1	(122.0)	(237.8)
	21,685.6	14,756.7	12,273.0
Income (loss) before income taxes	(1,307.6)	3,876.8	3,418.0
Income taxes (Note 12)	764.3	923.8	755.3
Net income (loss)	\$ (2,071.9)	\$ 2,953.0	\$ 2,662.7
Earnings (loss) per share — basic and diluted (Note 11)	\$ (1.89)	\$ 2.71	\$ 2.45

See notes to consolidated financial statements.

Consolidated Balance Sheets

ELI LILLY AND COMPANY AND SUBSIDIARIES	December 31	
	2008	2007
	(Dollars in millions)	
Assets		
<i>Current Assets</i>		
Cash and cash equivalents	\$ 5,496.7	\$ 3,220.5
Short-term investments	429.4	1,610.7
Accounts receivable, net of allowances of \$97.4 (2008) and \$103.1(2007)	2,778.8	2,673.9
Other receivables (Note 9)	498.5	1,030.9
Inventories	2,493.2	2,523.7
Deferred income taxes (Note 12)	382.1	642.8
Prepaid expenses	374.6	613.6
Total current assets	<u>12,453.3</u>	<u>12,316.1</u>
<i>Other Assets</i>		
Prepaid pension (Note 13)	—	1,670.5
Investments (Note 6)	1,544.6	577.1
Goodwill and other intangibles — net (Note 3)	4,054.1	2,455.4
Sundry (Note 9)	2,534.3	1,280.6
	<u>8,133.0</u>	<u>5,983.6</u>
<i>Property and Equipment, net</i>	<u>8,626.3</u>	<u>8,575.1</u>
	<u>\$29,212.6</u>	<u>\$26,874.8</u>
Liabilities and Shareholders' Equity		
<i>Current Liabilities</i>		
Short-term borrowings and current maturities of long-term debt (Note 7)	\$ 5,846.3	\$ 413.7
Accounts payable	885.8	924.4
Employee compensation	771.0	823.8
Sales rebates and discounts	873.4	706.8
Dividends payable	536.8	513.6
Income taxes payable (Note 12)	229.2	238.4
Other current liabilities (Note 9)	3,967.2	1,816.1
Total current liabilities	<u>13,109.7</u>	<u>5,436.8</u>
<i>Other Liabilities</i>		
Long-term debt (Note 7)	4,615.7	4,593.5
Accrued retirement benefit (Note 13)	2,387.6	1,145.1
Long-term income taxes payable (Note 12)	906.2	1,196.7
Deferred income taxes (Note 12)	74.7	287.5
Other noncurrent liabilities (Note 9)	1,383.4	711.3
	<u>9,367.6</u>	<u>7,934.1</u>
Commitments and contingencies (Note 14)		
Shareholders' Equity (Notes 8 and 10)		
Common stock — no par value		
Authorized shares: 3,200,000,000		
Issued shares: 1,136,948,610 (2008) and 1,135,212,894 (2007)	711.1	709.5
Additional paid-in capital	3,976.6	3,805.2
Retained earnings	7,654.9	11,806.7
Employee benefit trust	(2,635.0)	(2,635.0)
Deferred costs — ESOP	(86.3)	(95.2)
Accumulated other comprehensive income (loss) (Note 15)	(2,786.8)	13.2
	<u>6,834.5</u>	<u>13,604.4</u>
Less cost of common stock in treasury		
2008 — 888,998 shares		
2007 — 899,445 shares	99.2	100.5
	<u>6,735.3</u>	<u>13,503.9</u>
	<u>\$29,212.6</u>	<u>\$26,874.8</u>

See notes to consolidated financial statements.

Consolidated Statements of Cash Flows

ELI LILLY AND COMPANY AND SUBSIDIARIES	Year Ended December 31		
	2008	2007	2006
	(Dollars in millions)		
Cash Flows From Operating Activities			
Net income (loss)	\$(2,071.9)	\$ 2,953.0	\$ 2,662.7
Adjustments To Reconcile Net Income To Cash Flows			
From Operating Activities			
Depreciation and amortization	1,122.6	1,047.9	801.8
Change in deferred taxes	442.6	60.7	346.8
Stock-based compensation expense	255.3	282.0	359.3
Acquired in-process research and development, net of tax	4,792.7	692.6	—
Other, net	406.5	172.1	600.6
	4,947.8	5,208.3	4,771.2
Changes in operating assets and liabilities, net of acquisitions			
Receivables — (increase) decrease	799.1	(842.7)	243.9
Inventories — (increase) decrease	84.8	154.3	(60.2)
Other assets — (increase) decrease	1,648.6	(355.8)	(43.0)
Accounts payable and other liabilities — increase (decrease)	(184.7)	990.4	(936.0)
	2,347.8	(53.8)	(795.3)
Net Cash Provided by Operating Activities	7,295.6	5,154.5	3,975.9
Cash Flows From Investing Activities			
Purchases of property and equipment	(947.2)	(1,082.4)	(1,077.8)
Disposals of property and equipment	25.7	32.3	65.2
Net change in short-term investments	957.6	(376.9)	1,247.5
Proceeds from sales and maturities of noncurrent investments	1,597.3	800.1	1,507.7
Purchases of noncurrent investments	(2,412.4)	(750.7)	(1,313.2)
Purchases of in-process research and development	(122.0)	(111.0)	—
Cash paid for acquisitions, net of cash acquired	(6,083.0)	(2,673.2)	—
Other, net	(284.8)	(166.3)	179.0
Net Cash Provided by (Used for) Investing Activities	(7,268.8)	(4,328.1)	608.4
Cash Flows From Financing Activities			
Dividends paid	(2,056.7)	(1,853.6)	(1,736.3)
Net change in short-term borrowings	5,060.5	(468.5)	(8.4)
Proceeds from issuance of long-term debt	0.1	2,512.6	—
Repayments of long-term debt	(649.8)	(1,059.5)	(2,781.5)
Purchases of common stock	—	—	(122.1)
Issuances of common stock under stock plans	—	24.7	59.6
Other, net	(8.1)	(0.6)	9.9
Net Cash Provided by (Used for) Financing Activities	2,346.0	(844.9)	(4,578.8)
Effect of exchange rate changes on cash and cash equivalents	(96.6)	129.7	97.1
Net increase in cash and cash equivalents	2,276.2	111.2	102.6
Cash and cash equivalents at beginning of year	3,220.5	3,109.3	3,006.7
Cash and Cash Equivalents at End of Year	\$ 5,496.7	\$ 3,220.5	\$ 3,109.3

See notes to consolidated financial statements.

Consolidated Statements of Comprehensive Income (Loss)

ELI LILLY AND COMPANY AND SUBSIDIARIES	Year Ended December 31		
	2008	2007	2006
	(Dollars in millions)		
Net income (loss)	\$(2,071.9)	\$2,953.0	\$2,662.7
Other comprehensive income (loss)			
Foreign currency translation gains (losses)	(766.1)	756.6	542.4
Net unrealized losses on securities	(190.6)	(11.4)	(3.2)
Minimum pension liability adjustment (Note 13)	—	—	(18.8)
Defined benefit pension and retiree health benefit plans (Note 13)	(2,941.2)	943.8	—
Effective portion of cash flow hedges	23.2	(0.1)	143.3
Other comprehensive income (loss) before income taxes	(3,874.7)	1,688.9	663.7
Provision for income taxes related to other comprehensive income (loss) items	1,074.7	(287.0)	(43.1)
Other comprehensive income (loss) (Note 15)	(2,800.0)	1,401.9	620.6
Comprehensive income (loss)	\$(4,871.9)	\$4,354.9	\$3,283.3

See notes to consolidated financial statements

Segment Information

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

ELI LILLY AND COMPANY AND SUBSIDIARIES	Year Ended December 31		
	2008	2007	2006
	(Dollars in millions)		
Net sales — to unaffiliated customers			
Neurosciences	\$ 8,371.5	\$ 7,851.0	\$ 6,728.5
Endocrinology	5,890.7	5,479.6	5,014.5
Oncology	2,874.5	2,446.4	2,020.2
Cardiovascular	1,882.7	1,624.1	730.4
Animal health	1,093.3	995.8	875.5
Other pharmaceuticals	265.3	236.6	321.9
Net sales	\$20,378.0	\$ 18,633.5	\$15,691.0
Geographic Information			
Net sales — to unaffiliated customers¹			
United States	\$10,934.4	\$10,145.5	\$ 8,599.2
Europe	5,334.9	4,731.8	3,804.0
Other foreign countries	4,108.7	3,756.2	3,287.8
	\$20,378.0	\$ 18,633.5	\$15,691.0
Long-lived assets			
United States	\$ 5,750.0	\$ 5,905.4	\$ 6,207.4
Europe	2,119.0	2,057.7	1,733.8
Other foreign countries	1,753.0	1,768.6	1,718.4
	\$ 9,622.0	\$ 9,731.7	\$ 9,659.6

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

The largest category of products is the neurosciences group, which includes Zyprexa, Cymbalta, Strattera, and Prozac. Endocrinology products consist primarily of Humalog, Humulin, Byetta, Actos, Evista, Forteo, and Humatrope. Oncology products consist primarily of Gemzar and Alimta. Cardiovascular products consist primarily of Cialis, ReoPro, and Xigris. Animal health products include Posilac, Tylan, Rumensin, Coban, and other products for livestock and poultry, and Comfortis and other products for companion animals. The other pharmaceuticals category includes anti-infectives, primarily Ceclor and Vancocin, and other miscellaneous pharmaceutical products and services.

Most of our pharmaceutical products are distributed through wholesalers that serve pharmacies, physicians and other health care professionals, and hospitals. In 2008, our three largest wholesalers each accounted for between 12 percent and 16 percent of consolidated net sales. Further, they each accounted for between 10 percent and 15 percent of accounts receivable as of December 31, 2008. Animal health products are sold primarily to wholesale distributors.

Our business segments are distinguished by the ultimate end user of the product: humans or animals. Performance is evaluated based on profit or loss from operations before income taxes. The accounting policies of the individual segments are substantially the same as those described in the summary of significant accounting policies in Note 1 to the consolidated financial statements. Income before income taxes for the animal health business was approximately \$192 million, \$173 million, and \$184 million in 2008, 2007, and 2006, respectively.

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

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

Selected Quarterly Data (unaudited)

ELI LILLY AND COMPANY AND SUBSIDIARIES

Fourth Third Second First
(Dollars in millions, except per-share data)

2008				
Net sales	\$ 5,210.5	\$5,209.5	\$5,150.4	\$4,807.6
Cost of sales	915.4	1,155.2	1,200.9	1,111.3
Operating expenses	2,785.9	2,602.2	2,651.6	2,427.6
Acquired in-process research and development	4,685.4	28.0	35.0	87.0
Asset impairments, restructuring, and other special charges	80.0	1,659.4	88.9	145.7
Other — net, expense (income)	81.2	(2.5)	(32.3)	(20.3)
Income (loss) before income taxes	(3,337.4)	(232.8)	1,206.3	1,056.3
Net income (loss) ¹	(3,629.4)	(465.6)	958.8	1,064.3
Earnings (loss) per share — basic and diluted	(3.31)	(.43)	.88	.97
Dividends paid per share	.47	.47	.47	.47
Common stock closing prices				
High	43.69	49.25	53.06	57.18
Low	29.91	43.92	45.61	47.81

2007				
Net sales	\$5,189.6	\$4,586.8	\$4,631.0	\$4,226.1
Cost of sales	1,272.8	1,054.6	998.9	922.5
Operating expenses	2,709.4	2,322.3	2,379.1	2,171.0
Acquired in-process research and development	89.0	—	328.1	328.5
Asset impairments, restructuring, and other special charges	98.2	81.3	—	123.0
Other — net, expense (income)	(32.1)	(49.8)	(1.8)	(38.3)
Income before income taxes	1,052.3	1,178.4	926.7	719.4
Net income	854.4	926.3	663.6	508.7
Earnings per share — basic and diluted	.78	.85	.61	.47
Dividends paid per share	.425	.425	.425	.425
Common stock closing prices				
High	59.47	58.44	60.56	54.99
Low	49.09	54.09	54.39	51.63

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

¹ We incurred tax expense of \$764.3 million in 2008, despite having a loss before income taxes of \$1.31 billion. Our net loss was driven by the \$4.69 billion acquired IPR&D charge for ImClone in the fourth quarter and the \$1.48 billion Zyprexa investigation settlements recorded in the third quarter. The IPR&D charge was not tax deductible, and only a portion of the Zyprexa investigation settlements was deductible. In addition, we recorded tax expense associated with the ImClone acquisition in the fourth quarter, as well as a discrete income tax benefit of \$210.3 million in the first quarter for the resolution of the IRS audit.

Selected Financial Data (unaudited)

ELI LILLY AND COMPANY AND SUBSIDIARIES

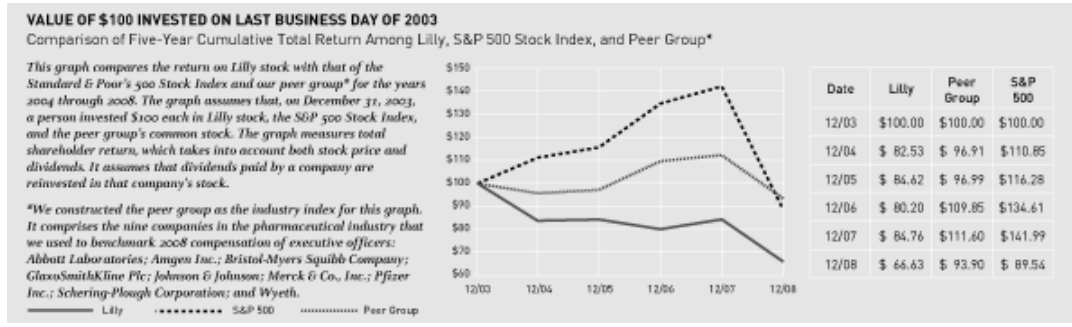
	2008	2007 ²	2006	2005	2004
(Dollars in millions, except net sales per employee and per-share data)					
Operations					
Net sales	\$ 20,378.0	\$ 18,633.5	\$ 15,691.0	\$ 14,645.3	\$ 13,857.9
Cost of sales	4,382.8	4,248.8	3,546.5	3,474.2	3,223.9
Research and development	3,840.9	3,486.7	3,129.3	3,025.5	2,691.1
Marketing, selling, and administrative	6,626.4	6,095.1	4,889.8	4,497.0	4,284.2
Other	6,835.5 ₄	926.1	707.4	931.1	716.8
Income (loss) before income taxes and cumulative effect of a change in accounting principle	(1,307.6)	3,876.8	3,418.0	2,717.5	2,941.9
Income taxes	764.3	923.8	755.3	715.9	1,131.8
Net income (loss)	(2,071.9)	2,953.0	2,662.7	1,979.6 ₁	1,810.1
Net income as a percent of sales	NM	15.8%	17.0%	13.5%	13.1%
Net income (loss) per share — diluted	(1.89)	2.71	2.45	1.81	1.66
Dividends declared per share	1.90	1.75	1.63	1.54	1.45
Weighted-average number of shares outstanding — diluted (thousands)	1,094,499	1,090,750	1,087,490	1,092,150	1,088,936
Financial Position					
Current assets	\$ 12,453.3	\$ 12,316.1	\$ 9,753.6	\$ 10,855.0	\$ 12,895.0
Current liabilities	13,109.7	5,436.8	5,254.0	5,884.8	7,762.2
Property and equipment — net	8,626.3	8,575.1	8,152.3	7,912.5	7,550.9
Total assets	29,212.6	26,874.8	22,042.4	24,667.8	24,954.0
Long-term debt	4,615.7	4,593.5	3,494.4	5,763.5	4,491.9
Shareholders' equity	6,735.3	13,503.9	10,820.2	10,631.4	10,759.4
Supplementary Data					
Return on shareholders' equity	(16.3)%	24.3%	24.8%	18.5%	17.8%
Return on assets	(7.5)%	12.1%	11.1%	8.2%	7.8%
Capital expenditures	\$ 947.2	\$ 1,082.4	\$ 1,077.8	\$ 1,298.1	\$ 1,898.1
Depreciation and amortization	1,122.6	1,047.9	801.8	726.4	597.5
Effective tax rate	NM ₃	23.8%	22.1%	26.3%	38.5%
Net sales per employee	\$ 504,000	\$ 459,000	\$ 378,000	\$ 344,000	\$ 311,000
Number of employees	40,450	40,600	41,500	42,600	44,500
Number of shareholders of record	39,800	41,700	44,800	50,800	52,400

NM — Not Meaningful

- 1 Reflects the impact of a cumulative effect of a change in accounting principle in 2005 of \$22.0 million, net of income taxes of \$11.8 million. The diluted earnings per share impact of this cumulative effect of a change in accounting principle was \$.02. The net income per diluted share before the cumulative effect of a change in accounting principle was \$1.83.
- 2 Reflects the ICOS acquisition, effective January 29, 2007. See Note 3 for additional information.
- 3 We incurred tax expense of \$764.3 million in 2008, despite having a loss before income taxes of \$1.31 billion. Our net loss was driven by the \$4.69 billion acquired IPR&D charge for ImClone and the \$1.48 billion

Zyprexa investigation settlements. The IPR&D charge was not tax deductible, and only a portion of the Zyprexa investigation settlements was deductible. In addition, we recorded tax expense associated with the ImClone acquisition, as well as a discrete income tax benefit of \$210.3 million for the resolution of the IRS audit.

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



Notes to Consolidated Financial Statements

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

Note 1: Summary of Significant Accounting Policies

Basis of presentation: The accompanying consolidated financial statements have been prepared in accordance with accounting practices generally accepted in the United States (GAAP). The accounts of all wholly owned and majority-owned subsidiaries are included in the consolidated financial statements. Where our ownership of consolidated subsidiaries is less than 100 percent, the outside shareholders' interests are reflected in other noncurrent liabilities. All intercompany balances and transactions have been eliminated.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses, and related disclosures at the date of the financial statements and during the reporting period. Actual results could differ from those estimates.

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

Cash equivalents: We consider all highly liquid investments with a maturity of three months or less from the date of purchase to be cash equivalents. The cost of these investments approximates fair value. Included in cash equivalents at December 31, 2008, is restricted cash of \$339.0 million related to the debt assumed with the ImClone acquisition, which is expected to be paid in the first quarter of 2009.

Inventories: We state all inventories at the lower of cost or market. We use the last-in, first-out (LIFO) method for the majority of our inventories located in the continental United States, or approximately 45 percent of our total inventories. Other inventories are valued by the first-in, first-out (FIFO) method. FIFO cost approximates current replacement cost. Inventories at December 31 consisted of the following:

	2008	2007
Finished products	\$ 771.0	\$ 653.4
Work in process	1,657.1	1,803.0
Raw materials and supplies	236.3	202.7
	2,664.4	2,659.1
Reduction to LIFO cost	(171.2)	(135.4)
	<u>\$ 2,493.2</u>	<u>\$ 2,523.7</u>

Investments: Substantially all of our investments in debt and marketable equity securities are classified as available-for-sale. Available-for-sale securities are carried at fair value with the unrealized gains and losses, net of tax, reported in other comprehensive income. Unrealized losses considered to be other-than-temporary are recognized in earnings. Factors we consider in making this evaluation include company-specific drivers of the decrease in fair value, status of projects in development, near-term prospects of the issuer, the length of time the value has been depressed, and the financial condition of the industry. We do not evaluate cost-method investments for impairment unless there is an indicator of impairment. We review these investments for indicators of impairment on a regular basis. Realized gains and losses on sales of available-for-sale securities are computed based upon specific identification of the initial cost adjusted for any other-than-temporary declines in fair value. Investments in companies over which we have significant influence but not a controlling interest are accounted for using the equity method with our share of earnings or losses reported in other — net. We own no investments that are considered to be trading securities.

Risk-management instruments: Our derivative activities are initiated within the guidelines of documented corporate risk-management policies and do not create additional risk because gains and losses on derivative

contracts offset losses and gains on the assets, liabilities, and transactions being hedged. As derivative contracts are initiated, we designate the instruments individually as either a fair value hedge or a cash flow hedge. Management reviews the correlation and effectiveness of our derivatives on a quarterly basis.

For derivative contracts that are designated and qualify as fair value hedges, the derivative instrument is marked to market with gains and losses recognized currently in income to offset the respective losses and gains recognized on the underlying exposure. For derivative contracts that are designated and qualify as cash flow hedges, the effective portion of gains and losses on these contracts is reported as a component of other comprehensive income and reclassified into earnings in the same period the hedged transaction affects earnings. Hedge ineffectiveness is immediately recognized in earnings. Derivative contracts that are not designated as hedging instruments are recorded at fair value with the gain or loss recognized in current earnings during the period of change.

We may enter into foreign currency forward and option contracts to reduce the effect of fluctuating currency exchange rates (principally the euro, the British pound, and the Japanese yen). Foreign currency derivatives used for hedging are put in place using the same or like currencies and duration as the underlying exposures. Forward contracts are principally used to manage exposures arising from subsidiary trade and loan payables and receivables denominated in foreign currencies. These contracts are recorded at fair value with the gain or loss recognized in other — net. The purchased option contracts are used to hedge anticipated foreign currency transactions, primarily intercompany inventory activities expected to occur within the next year. These contracts are designated as cash flow hedges of those future transactions and the impact on earnings is included in cost of sales. We may enter into foreign currency forward contracts and currency swaps as fair value hedges of firm commitments. Forward and option contracts generally have maturities not exceeding 12 months.

In the normal course of business, our operations are exposed to fluctuations in interest rates. These fluctuations can vary the costs of financing, investing, and operating. We address a portion of these risks through a controlled program of risk management that includes the use of derivative financial instruments. The objective of controlling these risks is to limit the impact of fluctuations in interest rates on earnings. Our primary interest rate risk exposure results from changes in short-term U.S. dollar interest rates. In an effort to manage interest rate exposures, we strive to achieve an acceptable balance between fixed and floating rate debt and investment positions and may enter into interest rate swaps or collars to help maintain that balance. Interest rate swaps or collars that convert our fixed-rate debt or investments to a floating rate are designated as fair value hedges of the underlying instruments. Interest rate swaps or collars that convert floating rate debt or investments to a fixed rate are designated as cash flow hedges. Interest expense on the debt is adjusted to include the payments made or received under the swap agreements.

Goodwill and other intangibles: Goodwill is not amortized. All other intangibles arising from acquisitions and research alliances have finite lives and are amortized over their estimated useful lives, ranging from 5 to 20 years, using the straight-line method. The weighted-average amortization period for developed product technology is approximately 12 years. Amortization expense for 2008, 2007, and 2006 was \$193.4 million, \$172.8 million, and \$7.6 million before tax, respectively. The estimated amortization expense for each of the five succeeding years approximates \$280 million before tax, per year. Substantially all of the amortization expense is included in cost of sales. See Note 3 for further discussion of goodwill and other intangibles acquired in 2008 and 2007.

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

	2008	2007
Goodwill	\$ 1,167.5	\$ 745.7
Developed product technology — gross	3,035.4	1,767.5
Less accumulated amortization	(346.6)	(162.6)
Developed product technology — net	2,688.8	1,604.9
Other intangibles — gross	243.2	142.8
Less accumulated amortization	(45.4)	(38.0)
Other intangibles — net	197.8	104.8
Total intangibles — net	\$ 4,054.1	\$ 2,455.4

Goodwill and net other intangibles are reviewed to assess recoverability at least annually and when certain impairment indicators are present. No significant impairments occurred with respect to the carrying value of our goodwill or other intangible assets in 2008, 2007, or 2006.

Property and equipment: Property and equipment is stated on the basis of cost. Provisions for depreciation of buildings and equipment are computed generally by the straight-line method at rates based on their estimated useful lives (12 to 50 years for buildings and 3 to 18 years for equipment). We review the carrying value of long-lived assets for potential impairment on a periodic basis and whenever events or changes in circumstances indicate the carrying value of an asset may not be recoverable. Impairment is determined by comparing projected undiscounted cash flows to be generated by the asset to its carrying value. If an impairment is identified, a loss is recorded equal to the excess of the asset's net book value over its fair value, and the cost basis is adjusted.

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

	2008	2007
Land	\$ 219.0	\$ 180.0
Buildings	5,953.4	5,543.7
Equipment	8,045.2	7,454.9
Construction in progress	1,098.3	1,662.7
	15,315.9	14,841.3
Less allowances for depreciation	(6,689.6)	(6,266.2)
	\$ 8,626.3	\$ 8,575.1

Depreciation expense for 2008, 2007, and 2006 was \$731.7 million, \$682.3 million, and \$627.4 million, respectively. Approximately \$48.2 million, \$95.3 million, and \$106.7 million of interest costs were capitalized as part of property and equipment in 2008, 2007, and 2006, respectively. Total rental expense for all leases, including contingent rentals (not material), amounted to approximately \$327.4 million, \$294.2 million, and \$293.6 million for 2008, 2007, and 2006, respectively. Assets under capital leases included in property and equipment in the consolidated balance sheets, capital lease obligations entered into, and future minimum rental commitments are not material.

Litigation and environmental liabilities: Litigation accruals and environmental liabilities and the related estimated insurance recoverables are reflected on a gross basis as liabilities and assets, respectively, on our consolidated balance sheets. With respect to the product liability claims currently asserted against us, we have accrued for our estimated exposures to the extent they are both probable and estimable based on the information available to us. We accrue for certain product liability claims incurred but not filed to the extent we can formulate a reasonable estimate of their costs. We estimate these expenses based primarily on historical claims experience and data regarding product usage. Legal defense costs expected to be incurred in connection with significant product liability loss contingencies are accrued when probable and reasonably estimable. A

portion of the costs associated with defending and disposing of these suits is covered by insurance. We record receivables for insurance-related recoveries when it is probable they will be realized. These receivables are classified as a reduction of the litigation charges on the statement of income. We estimate insurance recoverables based on existing deductibles, coverage limits, our assessment of any defenses to coverage that might be raised by the carriers, and the existing and projected future level of insolvencies among the insurance carriers. However, for substantially all of our currently marketed products, we are completely self-insured for future product liability losses.

Revenue recognition: We recognize revenue from sales of products at the time title of goods passes to the buyer and the buyer assumes the risks and rewards of ownership. For more than 90 percent of our sales, this is at the time products are shipped to the customer, typically a wholesale distributor or a major retail chain. The remaining sales are recorded at the point of delivery. Provisions for returns, discounts, and rebates are established in the same period the related sales are recorded.

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

Royalty revenue from licensees, which are based on third-party sales of licensed products and technology, are recorded as earned in accordance with the contract terms when third-party sales can be reasonably measured and collection of the funds is reasonably assured. This royalty revenue is included in net sales.

Acquired research and development: We recognize as incurred the cost of directly acquiring assets to be used in the research and development process that have not yet received regulatory approval for marketing and for which no alternative future use has been identified. Once the product has obtained regulatory approval, we capitalize the milestones paid and amortize them over the period benefited. Milestones paid prior to regulatory approval of the product are generally expensed when the event requiring payment of the milestone occurs.

Other — net: Other — net consisted of the following:

	2008	2007	2006
Interest expense	\$ 228.3	\$ 228.3	\$ 238.1
Interest income	(210.7)	(215.3)	(261.9)
Joint venture income	—	(11.0)	(96.3)
Other	8.5	(124.0)	(117.7)
	<u>\$ 26.1</u>	<u>\$(122.0)</u>	<u>\$(237.8)</u>

The joint venture income represents our share of the Lilly ICOS LLC joint venture results of operations, net of income taxes. We acquired the outstanding ownership of the joint venture in January 2007 as a result of our acquisition of ICOS. See Note 3 for further discussion.

Income taxes: Deferred taxes are recognized for the future tax effects of temporary differences between financial and income tax reporting based on enacted tax laws and rates. Federal income taxes are provided on the portion of the income of foreign subsidiaries that is expected to be remitted to the United States and be taxable.

We recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The tax benefits recognized in the financial statements from such a position are measured based on the largest benefit that has a greater than 50 percent likelihood of being realized upon ultimate resolution.

Earnings per share: We calculate basic earnings per share based on the weighted-average number of outstanding common shares and incremental shares. We calculate diluted earnings per share based on the weighted-average number of outstanding common shares plus the effect of dilutive stock options and other incremental shares. See Note 11 for further discussion.

Stock-based compensation: We recognize the fair value of stock-based compensation as expense over the requisite service period of the individual grantees, which generally equals the vesting period. Under our policy all stock-based awards are approved prior to the date of grant. The Compensation Committee of the Board of Directors approves the value of the award and date of grant. Stock-based compensation that is awarded as part of our annual equity grant is made on a specific grant date scheduled in advance.

Reclassifications: Certain reclassifications have been made to the December 31, 2007 and 2006 consolidated financial statements and accompanying notes to conform with the December 31, 2008 presentation.

Note 2: Implementation of New Financial Accounting Pronouncements

In March 2008, the Financial Accounting Standards Board (FASB) issued Statement No. 161, Disclosures about Derivative Instruments and Hedging Activities, an amendment of FASB Statement No. 133 (SFAS 161). SFAS 161 applies to all derivative instruments and related hedged items accounted for under FASB Statement No. 133, Accounting for Derivative Instruments and Hedging Activities. This Statement requires entities to provide enhanced disclosures about how and why an entity uses derivative instruments, how derivative instruments and related hedged items are accounted for under Statement 133 and its related interpretations, and how derivative instruments and related hedged items affect an entity's financial position, results of operations, and cash flows. This Statement is effective for us January 1, 2009.

We adopted the provisions of Emerging Issues Task Force (EITF) Issue No. 07-3 (EITF 07-3), Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities, on January 1, 2008. Pursuant to EITF 07-3, nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities should be deferred and capitalized. Such amounts should be recognized as an expense when the related goods are delivered or services are performed, or when the goods or services are no longer expected to be received. This Issue is to be applied prospectively for contracts entered into on or after the effective date.

We adopted the provisions of FASB Statement No. 157 (SFAS 157), Fair Value Measurements, on January 1, 2008. SFAS 157 defines fair value, establishes a framework for measuring fair value in GAAP, and expands disclosures about fair value measurements. The implementation of this Statement was not material to our consolidated financial position or results of operations.

In December 2007, the FASB revised and issued Statement No. 141, Business Combinations (SFAS 141(R)). SFAS 141(R) changes how the acquisition method is applied in accordance with SFAS 141. The primary revisions to this Statement require an acquirer in a business combination to measure assets acquired, liabilities assumed, and any noncontrolling interest in the acquiree at the acquisition date, at their fair values as of that date, with limited exceptions specified in the Statement. This Statement also requires the acquirer in a business combination achieved in stages to recognize the identifiable assets and liabilities, as well as the noncontrolling interest in the acquiree, at the full amounts of their fair values (or other amounts determined in accordance with the Statement). Assets acquired and liabilities assumed arising from contractual contingencies as of the acquisition date are to be measured at their acquisition-date fair values, and assets or liabilities arising from all other contingencies as of the acquisition date are to be measured at their acquisition-date fair value, only if it is more likely than not that they meet the definition of an asset or a liability in FASB Concepts Statement No. 6, Elements of Financial Statements. This Statement significantly amends other Statements and authoritative guidance, including FASB Interpretation No. 4, Applicability of FASB Statement No. 2 to Business Combinations Accounted for by the Purchase Method, and now requires the capitalization of research and development assets acquired in a business combination at their acquisition-date fair values, separately from goodwill. SFAS No. 109, Accounting for Income Taxes, was also amended by this Statement to require the acquirer to recognize changes in the amount of its deferred tax benefits that are recognizable because of a business combination either in income from continuing operations in the period of the combination or directly

in contributed capital, depending on the circumstances. This Statement is effective for us for business combinations for which the acquisition date is on or after January 1, 2009.

In December 2007, in conjunction with SFAS 141(R), the FASB issued Statement No. 160, Accounting for Noncontrolling Interests. This Statement amends Accounting Research Bulletin No. 51, Consolidated Financial Statements (ARB 51), by requiring companies to report a noncontrolling interest in a subsidiary as equity in its consolidated financial statements. Disclosure of the amounts of consolidated net income attributable to the parent and the noncontrolling interest will be required. This Statement also clarifies that transactions that result in a change in a parent's ownership interest in a subsidiary that do not result in deconsolidation will be treated as equity transactions, while a gain or loss will be recognized by the parent when a subsidiary is deconsolidated. This Statement is effective for us January 1, 2009, and we do not anticipate the implementation will be material to our consolidated financial position or results of operations.

In December 2007, the FASB ratified the consensus reached by the EITF on Issue No. 07-1 (EITF 07-1), Accounting for Collaborative Arrangements. EITF 07-1 defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. This Issue is effective for us beginning January 1, 2009 and will be applied retrospectively to all prior periods presented for all collaborative arrangements existing as of the effective date. The implementation of this Issue will not be material to our consolidated financial position or results of operations.

We adopted the provisions of FASB Interpretation (FIN) No. 48, Accounting for Uncertainty in Income Taxes, on January 1, 2007. FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. See Note 12 for further discussion of the impact of adopting this Interpretation.

Note 3: Acquisitions

During 2008 and 2007, we acquired several businesses. These acquisitions were accounted for as business combinations under the purchase method of accounting. Under the purchase method of accounting, the assets acquired and liabilities assumed were recorded at their respective fair values as of the acquisition date in our consolidated financial statements. The determination of estimated fair value required management to make significant estimates and assumptions. The excess of the purchase price over the fair value of the acquired net assets, where applicable, has been recorded as goodwill. The results of operations of these acquisitions are included in our consolidated financial statements from the date of acquisition.

Most of these acquisitions included in-process research and development (IPR&D), which represented compounds, new indications, or line extensions under development that had not yet achieved regulatory approval for marketing. There are several methods that can be used to determine the estimated fair value of the IPR&D acquired in a business combination. We utilized the "income method," which applies a probability weighting to the estimated future net cash flows that are derived from projected sales revenues and estimated costs. These projections are based on factors such as relevant market size, patent protection, historical pricing of similar products, and expected industry trends. The estimated future net cash flows are then discounted to the present value using an appropriate discount rate. This analysis is performed for each project independently. In accordance with FIN 4, Applicability of FASB Statement No. 2 to Business Combinations Accounted for by the Purchase Method, these acquired IPR&D intangible assets totaling \$4.71 billion and \$340.5 million in 2008 and 2007, respectively, were expensed immediately subsequent to the acquisition because the products had no alternative future use. The ongoing activities with respect to each of these products in development are not material to our research and development expenses.

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

ImClone Acquisition

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

The acquisition has been accounted for as a business combination under the purchase method of accounting, resulting in goodwill of \$419.5 million. No portion of this goodwill is expected to be deductible for tax purposes.

Allocation of Purchase Price

We are currently determining the fair values of a significant portion of these net assets. The purchase price has been preliminarily allocated based on an estimate of the fair value of assets acquired and liabilities assumed as of the date of acquisition. The final determination of these fair values will be completed as soon as possible but no later than one year from the acquisition date. Although the final determination may result in asset and liability fair values that are different than the preliminary estimates of these amounts included herein, it is not expected that those differences will be material to our financial results.

Estimated Fair Value at November 24, 2008

Cash and short-term investments	\$ 982.9
Inventories	136.2
Developed product technology (Erbitux) ¹	1,057.9
Goodwill	419.5
Property and equipment	339.8
Debt assumed	(600.0)
Deferred taxes	(315.0)
Deferred income	(127.7)
Other assets and liabilities — net	(72.1)
Acquired in-process research and development	4,685.4
Total purchase price	<u>\$ 6,506.9</u>

¹ This intangible asset will be amortized on a straight-line basis through 2023 in the U.S. and 2018 in the rest of the world.

All of the estimated fair value of the acquired IPR&D is attributable to oncology-related products in development, including \$1.33 billion to line extensions for Erbitux. A significant portion (81 percent) of the remaining value of acquired IPR&D is attributable to two compounds in Phase III clinical testing and one compound in Phase II clinical testing, all targeted to treat various forms of cancers. The discount rate we used in valuing the acquired IPR&D projects was 13.5 percent, and the charge for acquired IPR&D of \$4.69 billion recorded in the fourth quarter of 2008, was not deductible for tax purposes.

Pro Forma Financial Information

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

	2008	2007
Net sales	\$ 20,801.8	\$ 19,051.4
Net income ¹	2,356.2	2,704.1
Earnings per share:		
Basic and diluted	2.15	2.48

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

The unaudited pro forma financial information above reflects the following:

- a reduction of the amortization of ImClone's deferred income of \$86.2 million (2008) and \$98.4 million (2007);
- the increase of amortization expense of \$78.8 million in 2008 and 2007 related to the estimated fair value of identifiable intangible assets from the purchase price allocation which are being amortized over their estimated useful lives through 2023 in the U.S. and through 2018 in the rest of the world. The change in depreciation expense related to the change in the estimated fair value of property and equipment from the book value at the time of the acquisition was not material;
- the adjustment to increase interest expense related to the debt incurred to finance the acquisition and the adjustment to decrease interest income related to the lost interest income on the cash used to purchase ImClone by a total of \$301.0 million in 2008 and 2007;
- the reduction of ImClone's income tax expense to provide for income taxes at the statutory tax rate and the adjustment to income taxes for pro forma adjustments at the statutory tax rate, totaling \$139.3 million (2008) and \$189.5 million (2007). This excludes the acquired IPR&D charge of \$4.69 billion, which was not tax deductible;
- certain reclassifications to conform to accounting policies and classifications that are consistent with our practices (e.g., ImClone's license fees and milestones were classified as other — net, rather than net sales).

Posilac

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

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

SGX Pharmaceuticals, Inc.

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

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

ICOS Corporation

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

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

We determined the following estimated fair values for the assets acquired and liabilities assumed as of the date of acquisition.

Estimated Fair Value at January 29, 2007

Cash and short-term investments	\$ 197.7
Developed product technology (Cialis) ¹	1,659.9
Tax benefit of net operating losses	404.1
Goodwill	646.7
Long-term debt assumed	(275.6)
Deferred taxes	(583.5)
Other assets and liabilities — net	(32.1)
Acquired in-process research and development	303.5
Total purchase price	<u>\$ 2,320.7</u>

¹ This intangible asset will be amortized over the remaining expected patent lives of Cialis in each country; patent expiry dates range from 2015 to 2017.

New indications for and formulations of the Cialis compound in clinical testing at the time of the acquisition represented approximately 48 percent of the estimated fair value of the acquired IPR&D. The remaining value of acquired IPR&D represented several other products in development, with no one asset comprising a significant portion of this value. The discount rate we used in valuing the acquired IPR&D projects was 20 percent, and the charge for acquired IPR&D of \$303.5 million recorded in the first quarter of 2007 was not deductible for tax purposes.

Other Acquisitions

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

The acquisition of Hypnion provided us with a broader and more substantive presence in the area of sleep disorder research and ownership of HY10275, a novel Phase II compound with a dual mechanism of action aimed at promoting better sleep onset and sleep maintenance. This was Hypnion's only significant asset. For this acquisition, we recorded an acquired IPR&D charge of \$291.1 million, which was not deductible for tax purposes. Because Hypnion was a development-stage company, the transaction was accounted for as an acquisition of assets rather than as a business combination and, therefore, goodwill was not recorded.

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

Product Acquisitions

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

In January 2008, our agreement with BioMS Medical Corp. to acquire the rights to its compound for the treatment of multiple sclerosis became effective. At the inception of this agreement, this compound was in the development stage (Phase III clinical trials) and had no alternative future use. As with many development-phase compounds, launch of the product, if approved, was not expected in the near term. The charge of \$87.0 million for acquired IPR&D related to this arrangement was included as expense in the first quarter of 2008 and is deductible for tax purposes.

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

In October 2007, we entered into a global strategic alliance with MacroGenics, Inc. (MacroGenics) to develop and commercialize teplizumab, a humanized anti-CD3 monoclonal antibody, as well as other potential next-generation anti-CD3 molecules for use in the treatment of autoimmune diseases. As part of the arrangement, we acquired the exclusive rights to the molecule, which was in the development stage (Phase II/III clinical trial for individuals with recent-onset type 1 diabetes) and had no alternative future use. As with many development-phase compounds, launch of the product, if approved, was not expected in the near term. The charge of \$44.0 million for acquired IPR&D was deductible for tax purposes and was included as expense in the fourth quarter of 2007.

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

for acquired IPR&D related to this arrangement was included as expense in the first quarter of 2007 and was deductible for tax purposes.

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

Note 4: Collaborations

We often enter into collaborative arrangements to develop and commercialize drug candidates. Collaborative activities might include research and development, marketing and selling (including promotional activities and physician detailing), manufacturing, and distribution. These collaborations often require milestone and royalty or profit share payments, contingent upon the occurrence of certain future events linked to the success of the asset in development, as well as expense reimbursements or payments to the third party. Each collaboration is unique in nature and our more significant arrangements are discussed below.

Erbitux

Prior to our acquisition, ImClone entered into several collaborations with respect to Erbitux, a product approved to fight cancer, while still in its development phase. The most significant collaborations operate in these geographic territories: the U.S., Japan, and Canada (Bristol-Myers Squibb); and worldwide except the U.S. and Canada (Merck KGaA). The agreements are expected to expire in 2018, upon which all of the rights with respect to Erbitux in the U.S. and Canada return to us.

Bristol-Myers Squibb Company

Pursuant to a commercial agreement with Bristol-Myers Squibb Company and E.R. Squibb (collectively, BMS), relating to Erbitux, ImClone is co-developing and co-promoting Erbitux in North America with BMS, and is co-developing and co-promoting Erbitux in Japan with BMS. The companies had jointly agreed to expand the investment in the ongoing clinical development plan for Erbitux to further explore its use in additional tumor types. Under this arrangement, Erbitux research and development and other costs, up to threshold amounts, are the sole responsibility of BMS, with costs in excess of the thresholds shared by both companies according to a predetermined ratio.

Responsibilities associated with clinical and other ongoing studies are apportioned between the parties as determined pursuant to the agreement. Collaborative reimbursements received by ImClone for supply of product for research and development, for a portion of royalty expenses, and for a portion of marketing, selling, and administrative expenses, are recorded as a reduction to the respective expense line items on the consolidated statement of operations. Royalty expense paid to third parties is included in costs of sales. We receive a distribution fee in the form of a royalty from BMS, based on a percentage of net sales in the U.S. and Canada, which is recorded in net sales.

We are responsible for the manufacture and supply of all requirements of Erbitux in bulk-form active pharmaceutical ingredient (API) for clinical and commercial use in the territory, and BMS will purchase all of its requirements of API for commercial use from us, subject to certain stipulations per the agreement. Sales of Erbitux to BMS for commercial use are reported in net sales.

Merck KGaA

A development and license agreement between ImClone and Merck KGaA (Merck) with respect to Erbitux granted Merck exclusive rights to market Erbitux outside of North America and co-exclusive rights with BMS in Japan. Merck also has rights to manufacture Erbitux for supply in its territory. We manufacture and provide a portion of Merck's requirements for API; we also receive a royalty on the sales of Erbitux outside of the U.S. and Canada, both of which are included in net sales as earned. Collaborative reimbursements received for supply of product for research and development, reimbursement of a portion of royalty expense, and marketing, selling, and administrative expenses are recorded as a reduction to the respective expense line items on the consolidated statement of operations. Royalty expense paid to third parties is included in cost of sales.

Exenatide

We are in a collaborative arrangement with Amylin Pharmaceuticals (Amylin) for the joint development, marketing, and selling of Byetta and other forms of exenatide such as exenatide once weekly. Byetta (exenatide injection) is presently approved as an adjunctive therapy to improve glycemic control in patients with type 2 diabetes who have not achieved adequate glycemic control using metformin, a sulfonylurea and/or a thiazolidinediene (U.S. only), three common oral therapies for type 2 diabetes. Lilly and Amylin are co-promoting exenatide in the U.S. Amylin is responsible for manufacturing and primarily utilizes third-party contract manufacturing organizations to supply Byetta. However, Lilly is manufacturing Byetta pen delivery devices for Amylin. Lilly is responsible for development and commercialization costs outside the U.S.

Under the terms of our collaboration with Amylin, we report as revenue our 50 percent share of gross margin on sales in the U.S., 100 percent of sales outside the U.S., and our sales of Byetta pen delivery devices to Amylin. We recorded revenues of \$396.1 million, \$330.7 million, and \$219.0 million in 2008, 2007, and 2006, respectively, for Byetta. We pay Amylin a percentage of the gross margin of exenatide sales outside of the U.S., and these costs are recorded in cost of sales. Under the 50/50 profit-sharing arrangement for the U.S., in addition to recording as revenue our 50 percent share of exenatide's gross margin, we also report 50 percent of U.S. research and development costs, and marketing and selling costs in the research and development and marketing, selling, and administrative line items, respectively, on the consolidated statements of income.

Exenatide once weekly is presently in Phase III clinical trials and has not received regulatory approval. Amylin is constructing and will operate a manufacturing facility for exenatide once weekly, and we have entered into a supply agreement in which Amylin will supply exenatide once weekly product to us for sales outside the U.S. The estimated total cost of the facility is approximately \$550 million. In 2008, we paid \$125.0 million to Amylin, which we will amortize to cost of sales over the estimated life of the supply agreement beginning with product launch. We would be required to reimburse Amylin for a portion of any future impairment of this facility, recognized in accordance with GAAP. A portion of the \$125.0 million payment we made to Amylin would be creditable against any amount we would owe as a result of impairment. We have also agreed to loan up to \$165.0 million to Amylin at an indexed rate beginning December 1, 2009, and any borrowings have to be repaid by June 30, 2014.

Cymbalta

Boehringer Ingelheim

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

Collaborative reimbursements or payments for the cost sharing of marketing, selling, and administrative expenses are recorded in the respective expense line items in the consolidated statement of operations. The commission paid to BI is recognized in marketing, selling, and administrative expenses.

Quintiles

We are in a collaborative arrangement with Quintiles Transnational Corp. (Quintiles) to market and promote Cymbalta in the U.S. Pursuant to the terms of the agreement, Quintiles shares in the costs to co-promote Cymbalta with us. In exchange, Quintiles receives a payment based upon net sales. According to the current agreement, Quintiles' obligation to promote Cymbalta expires in 2009, and we will pay a lower rate on net sales for three years post their promotion efforts. The royalties paid to Quintiles are recorded in marketing, selling, and administrative expenses.

Prasugrel

We are in a collaborative arrangement with Daiichi Sankyo Company, Limited (D-S) to develop, market, and promote prasugrel, an antiplatelet agent for the treatment of patients with acute coronary syndromes (ACS) who are being managed with an artery-opening procedure known as percutaneous coronary intervention (PCI). Prasugrel was approved for marketing by the European Commission under the tradename Efient in February 2009. We have submitted a new drug application to the FDA and are currently awaiting its decision. Within this arrangement, we have agreed to co-promote under the same trademark in certain territories (including the U.S. and five major European markets), while we have exclusive marketing rights in certain other territories. D-S has exclusive marketing rights in Japan. Pursuant to the terms of the agreement, we paid D-S an upfront license fee and agreed to pay future success milestones. Both parties share in the costs of the development and marketing in the co-promotion territories and share in the profits according to the terms specified in the agreement. D-S is responsible for supplying bulk product, but we will produce the finished product for our exclusive and co-promotion territories. Profits in the U.S. and other co-promotion territories will be shared according to the agreement. In our exclusive territories, we will pay D-S a royalty specific to those territories. Profit share payments made to D-S will be recorded as marketing, selling, and administrative expenses. All royalties paid to D-S will be recorded in cost of sales.

TPG-Axon Capital

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

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

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

Asset Impairments and Related Restructuring and Other Charges

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

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

Further, in the third quarter of 2008, as a result of our previously announced agreements with Covance Inc. (Covance), Quintiles Transnational Corp. (Quintiles), and Ingenix Pharmaceutical Services, Inc., doing business as i3 Statprobe (i3), and as part of our efforts to transform into a more flexible organization, we recognized asset impairments, restructuring, and other special charges of \$182.4 million. We sold our Greenfield, Indiana site to Covance, a global drug development services firm, and entered into a 10-year service agreement under which Covance will provide preclinical toxicology work and perform additional

clinical trials for us as well as operate the site to meet our needs and those of other pharmaceutical industry clients. In addition, we signed agreements with Quintiles for clinical trial monitoring services and with i3 for clinical data management services. Components of the third-quarter restructuring charge include non-cash charges of \$148.3 million primarily related to the loss on sale of assets sold to Covance, severance costs of \$27.8 million, and exit costs of \$6.3 million. Substantially all of these costs were paid in 2008.

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

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

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

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

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

In the fourth quarter of 2006, management approved plans to close two research and development facilities and one production facility outside the U.S. Management also made the decision to stop construction of a planned insulin manufacturing plant in the U.S. in an effort to increase productivity in research and development operations and to reduce excess manufacturing capacity. These decisions, as well as other strategic changes, resulted in non-cash charges of \$308.8 million for the write down of certain impaired assets, substantially all of which have no future use, and other charges of \$141.5 million, primarily related to

severance and contract termination payments. The impairment charges were necessary to adjust the carrying value of the assets to fair value. These restructuring activities were substantially complete at December 31, 2007.

Product Liability and Other Special Charges

As a result of our product liability exposures, the substantial majority of which were related to Zyprexa, we recorded net pretax charges of \$111.9 million and \$494.9 million in 2007 and 2006, respectively. These charges, which are net of anticipated insurance recoveries, include the costs of product liability settlements and related defense costs, reserves for product liability exposures and defense costs regarding known product liability claims, and expected future claims to the extent we could formulate a reasonable estimate of the probable number and cost of the claims. See Note 14 for further discussion.

Note 6: Financial Instruments and Investments

Financial instruments that potentially subject us to credit risk consist principally of trade receivables and interest-bearing investments. Wholesale distributors of life-sciences products and managed care organizations account for a substantial portion of trade receivables; collateral is generally not required. The risk associated with this concentration is mitigated by our ongoing credit review procedures and insurance. We place substantially all of our interest-bearing investments with major financial institutions, in U.S. government securities, or with top-rated corporate issuers. At December 31, 2008, our investments in debt securities were comprised of 41 percent corporate securities, 34 percent asset-backed securities, and 25 percent U.S. government securities. In accordance with documented corporate policies, we limit the amount of credit exposure to any one financial institution or corporate issuer. We are exposed to credit-related losses in the event of nonperformance by counterparties to financial instruments but do not expect any counterparties to fail to meet their obligations given their high credit ratings.

Fair Value of Financial Instruments

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

Description	2008				2007		
	Carrying Amount	Fair Value Measurements Using			Fair Value	Carrying Amount	Fair Value
Quoted Prices in Active Markets for Identical Assets (Level 1)		Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)				
Short-term investments							
Debt securities	\$ 429.4	\$ 212.3	\$ 217.1	\$ —	\$ 429.4	\$ 1,610.7	\$ 1,610.7
Long-term investments							
Debt securities	\$ 1,194.9	\$ 179.2	\$ 1,004.6	\$ 11.1	\$ 1,194.9	\$ 408.3	\$ 408.3
Marketable equity	221.9	221.9	—	—	221.9	70.0	70.0
Equity method and other investments	127.8				NA	98.8	NA
	<u>\$ 1,544.6</u>					<u>\$ 577.1</u>	
Long-term debt, including current portion	\$ (5,036.1)	—	\$ (5,180.1)	—	\$ (5,180.1)	\$ (4,988.6)	\$ (5,056.9)
Risk-management instruments — asset	455.0	—	455.0	—	455.0	23.6	23.6

NA — Not available

We determine fair values based on a market approach using quoted market values, significant other observable inputs for identical or comparable assets or liabilities, or discounted cash flow analyses, principally for long-term debt. The fair value of equity method and other investments is not readily available. Approximately \$1.1 billion of our investments in debt securities mature within five years.

A summary of the fair value of available-for-sale securities in an unrealized gain or loss position and the amount of unrealized gains and losses (pretax) in other comprehensive income at December 31 follows:

	2008	2007
Unrealized gross gains	\$ 69.9	\$ 43.5
Unrealized gross losses	239.0	22.0
Fair value of securities in an unrealized gain position	767.5	921.7
Fair value of securities in an unrealized loss position	1,046.1	964.6

The securities in an unrealized loss position are comprised of fixed-rate debt securities of varying maturities. The value of fixed income securities is sensitive to changes to the yield curve and other market conditions which led to the decline in value during 2008.

Approximately 90 percent of the securities in a loss position are investment-grade debt securities. The majority of these securities first moved into an unrealized loss position during 2008. At this time, there is no indication of default on interest or principal payments for asset-backed securities. We have the intent and ability to hold the securities in a loss position until the market values recover or all of the underlying cash flows have been received and we have concluded that no other-than-temporary loss exists at December 31, 2008. The fair values of all of our auction rate securities and collateralized debt obligations held at December 31, 2008 were determined using Level 3 inputs. We do not hold securities issued by structured investment vehicles at December 31, 2008.

The net adjustment to unrealized gains and losses (net of tax) on available-for-sale securities increased (decreased) other comprehensive income by \$(125.8) million, \$(5.4) million, and \$0.3 million in 2008, 2007, and 2006, respectively. Activity related to our available-for-sale investment portfolio was as follows:

	2008	2007	2006
Proceeds from sales	\$ 1,876.4	\$ 1,212.1	\$ 2,848.4
Realized gross gains on sales	45.7	21.4	63.5
Realized gross losses on sales	8.7	6.1	9.0

During the years ended December 31, 2008, 2007, and 2006, net losses related to ineffectiveness and net losses related to the portion of our risk-management hedging instruments, fair value and cash flow hedges, excluded from the assessment of effectiveness were not material.

We expect to reclassify an estimated \$10.2 million of pretax net losses on cash flow hedges of the variability in expected future interest payments on floating rate debt from accumulated other comprehensive loss to earnings during 2009.

Available-for-sale investment securities are classified as long-term investments when they are likely to be held for more than one year because of our intent to hold securities in an unrealized loss position until the market values recover or all of the underlying cash flows have been received.

Note 7: Borrowings

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

	2008	2007
4.50 to 7.13 percent notes (due 2012 — 2037)	\$ 3,987.4	\$ 3,987.4
Floating rate bonds (due 2037)	400.0	400.0
2.90 percent notes (due 2008)	—	300.0
Other, including capitalized leases	116.8	222.0
SFAS 133 fair value adjustment	531.9	79.2
	5,036.1	4,988.6
Less current portion	(420.4)	(395.1)
	\$ 4,615.7	\$ 4,593.5

In March 2007, we issued \$2.50 billion of fixed-rate notes (\$1.00 billion at 5.20 percent due in 2017; \$700.0 million at 5.50 percent due in 2027; and \$800.0 million at 5.55 percent due in 2037).

The \$400.0 million of floating rate bonds outstanding at December 31, 2008 are due in 2037 and have variable interest rates at LIBOR plus our six-month credit spread, adjusted semiannually (total of 4.10 percent at December 31, 2008). We pay interest monthly on this borrowing program. We expect to refinance the bonds in 2009 and have classified them as current at December 31, 2008.

The 6.55 percent Employee Stock Ownership Plan (ESOP) debentures are obligations of the ESOP but are shown on the consolidated balance sheet because we guarantee them. The principal and interest on the debt are funded by contributions from us and by dividends received on certain shares held by the ESOP. Because of the amortizing feature of the ESOP debt, bondholders will receive both interest and principal payments each quarter. The balance was \$81.9 million and \$90.6 million at December 31, 2008 and 2007, respectively, and is included in Other in the table above.

The aggregate amounts of maturities on long-term debt for the next five years are as follows: 2009, \$420.4 million; 2010, \$19.7 million; 2011, \$13.1 million; 2012, \$510.8 million; and 2013, \$11.1 million.

At December 31, 2008 and 2007, short-term borrowings included \$5.43 billion and \$18.6 million, respectively, of notes payable to banks and commercial paper. Commercial paper was issued in late 2008 for the acquisition of ImClone. At December 31, 2008, we have \$1.24 billion of unused committed bank credit facilities, \$1.20 billion of which backs our commercial paper program. Additionally, in November 2008, we obtained a one-year short-term revolving credit facility in the amount of \$4.00 billion as back-up, alternative financing. Compensating balances and commitment fees are not material, and there are no conditions that are probable of occurring under which the lines may be withdrawn.

We have converted approximately 50 percent of all fixed-rate debt to floating rates through the use of interest rate swaps. The weighted-average effective borrowing rates based on debt obligations and interest rates at December 31, 2008 and 2007, including the effects of interest rate swaps for hedged debt obligations, were 4.77 percent and 5.47 percent, respectively.

In 2008, 2007, and 2006, cash payments of interest on borrowings totaled \$203.1 million, \$159.2 million, and \$305.7 million, respectively, net of capitalized interest.

In accordance with the requirements of SFAS 133, the portion of our fixed-rate debt obligations that is hedged is reflected in the consolidated balance sheets as an amount equal to the sum of the debt's carrying value plus the fair value adjustment representing changes in fair value of the hedged debt attributable to movements in market interest rates subsequent to the inception of the hedge.

Note 8: Stock Plans

Stock-based compensation expense in the amount of \$255.3 million, \$282.0 million, and \$359.3 million was recognized in 2008, 2007, and 2006, respectively, as well as related tax benefits of \$88.6 million, \$96.4 million, and \$115.9 million, respectively. Our stock-based compensation expense consists primarily of performance awards (PAs), shareholder value awards (SVAs), and stock options. We recognize the stock-based compensation expense over the requisite service period of the individual grantees, which generally equals the vesting period. We provide newly issued shares and treasury stock to satisfy stock option exercises and for the issuance of PA and SVA shares. We classify tax benefits resulting from tax deductions in excess of the compensation cost recognized for exercised stock options as a financing cash flow in the consolidated statements of cash flows.

At December 31, 2008, additional stock options, PAs, SVAs, or restricted stock grants may be granted under the 2002 Lilly Stock Plan for not more than 88.0 million shares.

Performance Award Program

Performance awards (PAs) are granted to officers and management and are payable in shares of our common stock. The number of PA shares actually issued, if any, varies depending on the achievement of certain pre-established earnings-per-share targets over a one-year period. PA shares are accounted for at fair value based upon the closing stock price on the date of grant and fully vest at the end of the fiscal year of the grant. The fair values of performance awards granted in 2008, 2007, and 2006 were \$51.22, \$54.23, and \$56.18, respectively. The number of shares ultimately issued for the performance award program is dependent upon the earnings achieved during the vesting period. Pursuant to this plan, approximately 2.5 million shares, 2.3 million shares, and 1.7 million shares were issued in 2008, 2007, and 2006, respectively. Approximately 2.8 million shares are expected to be issued in 2009.

Shareholder Value Award Program

In 2007, we implemented a shareholder value award (SVA) program, which replaced our stock option program. SVAs are granted to officers and management and are payable in shares of common stock at the end of a three-year period. The number of shares actually issued varies depending on our stock price at the end of the three-year vesting period compared to pre-established target stock prices. We measure the fair value of the SVA unit on the grant date using a Monte Carlo simulation model. The Monte Carlo simulation model utilizes multiple input variables that determine the probability of satisfying the market condition stipulated in the award grant and calculates the fair value of the award. Expected volatilities utilized in the model are based on implied volatilities from traded options on our stock, historical volatility of our stock price, and other factors. Similarly, the dividend yield is based on historical experience and our estimate of future dividend yields. The risk-free interest rate is derived from the U.S. Treasury yield curve in effect at the time of grant. The weighted-average fair values of the SVA units granted during 2008 and 2007 were \$43.46 and \$49.85, respectively, determined using the following assumptions:

	2008	2007
Expected dividend yield	3.00%	2.75%
Risk-free interest rate	2.05% - 2.29%	4.81% - 5.16%
Range of volatilities	20.48% - 21.48%	22.54% - 23.90%

A summary of the SVA activity is presented below:

	Units Attributable to SVAs (In thousands)
Outstanding at January 1, 2007	—
Granted	969
Issued	—
Forfeited or expired	(47)
Outstanding at December 31, 2007	922
Granted	1,282
Issued	—
Forfeited or expired	(301)
Outstanding at December 31, 2008	1,903

The maximum number of shares that could ultimately be issued upon vesting of the SVA units outstanding at December 31, 2008, is 2.7 million. As of December 31, 2008, the total remaining unrecognized compensation cost related to nonvested SVAs amounted to \$46.7 million, which will be amortized over the weighted-average remaining requisite service period of 21.6 months.

Stock Option Program

Stock options were granted in 2006 to officers and management at exercise prices equal to the fair market value of our stock price at the date of grant. No stock options were granted in 2008 or 2007. Options fully vest three years from the grant date and have a term of 10 years. We utilized a lattice-based option valuation model for estimating the fair value of the stock options. The lattice model allows the use of a range of assumptions related to volatility, risk-free interest rate, and employee exercise behavior. Expected volatilities utilized in the lattice model are based on implied volatilities from traded options on our stock, historical volatility of our stock price, and other factors. Similarly, the dividend yield is based on historical experience and our estimate of future dividend yields. The risk-free interest rate is derived from the U.S. Treasury yield curve in effect at the time of grant. The model incorporates exercise and post-vesting forfeiture assumptions based on an analysis of historical data. The expected life of the 2006 grants is derived from the output of the lattice model. The weighted-average fair values of the individual options granted during 2006 were \$15.61, determined using the following assumptions:

	2006
Dividend yield	2.0%
Weighted-average volatility	25.0%
Range of volatilities	24.8%-27.0%
Risk-free interest rate	4.6%-4.8%
Weighted-average expected life	7 years

Stock option activity during 2008 is summarized below:

	Shares of Common Stock Attributable to Options (in thousands)	Weighted-Average Exercise Price of Options	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at January 1, 2008	81,149	\$ 69.57		
Granted	—	—		
Exercised	(145)	19.69		
Forfeited or expired	(8,979)	72.31		
Outstanding at December 31, 2008	72,025	69.35	3.6	\$ 1.9
Exercisable at December 31, 2008	68,033	70.04	3.4	1.9

A summary of the status of nonvested options as of December 31, 2008, and changes during the year then ended, is presented below:

	Shares (in thousands)	Weighted-Average Grant Date Fair Value
Nonvested at January 1, 2008	9,049	\$ 16.47
Granted	—	—
Vested	(5,045)	17.51
Forfeited	(12)	15.76
Nonvested at December 31, 2008	<u>3,992</u>	<u>15.26</u>

The intrinsic value of options exercised during 2008, 2007, and 2006 amounted to \$4.8 million, \$1.5 million, and \$40.8 million, respectively. The total grant date fair value of options vested during 2008, 2007, and 2006 amounted to \$84.1 million, \$381.8 million, and \$249.1 million, respectively. We received cash of \$2.9 million, \$15.2 million, and \$66.2 million from exercises of stock options during 2008, 2007, and 2006, respectively, and recognized related tax benefits of \$0.5 million, \$0.4 million, and \$11.3 million during those same years.

As of December 31, 2008, there was no significant remaining unrecognized compensation cost related to non-vested stock options.

Note 9: Other Assets and Other Liabilities

Our other receivables include receivables from our collaboration partners and a variety of other items. The decrease in other receivables is primarily attributable to a decrease in income tax receivable, and lower insurance recoverables.

Our sundry assets primarily include our deferred tax assets (Note 12), capitalized computer software, and the fair value of our interest rate swaps. The increase in sundry assets is primarily attributable to an increase in deferred tax assets and an increase in the fair value of our interest rate swaps.

Our other current liabilities include product litigation, tax liabilities, and a variety of other items. The increase in other current liabilities is caused primarily by an increase in product litigation liabilities, specifically, the \$1.42 billion related to the EDPA settlements discussed in Note 14, and an increase in current deferred taxes.

Our other noncurrent liabilities include deferred income from our collaboration and out-licensing arrangements, the long-term portion of our estimated product return liabilities, product litigation, and a variety of other items. The increase in other noncurrent liabilities is primarily due to an increase in deferred income attributable to our 2008 acquisitions and other business development arrangements.

Note 10: Shareholders' Equity

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

	Additional Paid-in Capital	Retained Earnings ESOP	Deferred Costs	Common Stock in Treasury Shares (in thousands) Amount	
Balance at January 1, 2006	\$ 3,323.8	\$ 9,866.7	\$ (106.3)	934	\$ 104.1
Net income		2,662.7			
Cash dividends declared per share: \$1.63		(1,763.2)			
Retirement of treasury shares	(129.1)			(2,297)	(130.6)
Purchase for treasury				2,145	122.1
Issuance of stock under employee stock plans — net	6.2			128	5.8
Stock-based compensation	359.3				
ESOP transactions	11.7		5.6		
Balance at December 31, 2006	3,571.9	10,766.2	(100.7)	910	101.4
Net income		2,953.0			
Cash dividends declared per share: \$1.75		(1,903.9)			
Retirement of treasury shares	(3.9)			(76)	(3.9)
Issuance of stock under employee stock plans — net	(55.2)			65	3.0
Stock-based compensation	282.0				
ESOP transactions	10.4		5.5		
FIN 48 implementation (Note 12)		(8.6)			
Balance at December 31, 2007	3,805.2	11,806.7	(95.2)	899	100.5
Net loss		(2,071.9)			
Cash dividends declared per share: \$1.90		(2,079.9)			
Retirement of treasury shares	(10.9)			(170)	(11.1)
Issuance of stock under employee stock plans — net	(84.9)			160	9.8
Stock-based compensation	255.3				
ESOP transactions	11.9		8.9		
Balance at December 31, 2008	\$ 3,976.6	\$ 7,654.9	\$ (86.3)	889	\$ 99.2

As of December 31, 2008, we have purchased \$2.58 billion of our announced \$3.0 billion share repurchase program. We acquired approximately 2.1 million shares in 2006 under this program. No shares were repurchased in 2008 or 2007.

We have 5 million authorized shares of preferred stock. As of December 31, 2008 and 2007, no preferred stock has been issued.

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

increases of \$2.61 billion in additional paid-in capital and \$25.0 million in common stock. Any dividend transactions between us and the trust are eliminated. Stock held by the trust is not considered outstanding in the computation of earnings per share. The assets of the trust were not used to fund any of our obligations under these employee benefit plans in 2008, 2007, or 2006. In the first quarter of 2009, we contributed an additional 10.0 million shares to the trust.

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

Note 11: Earnings (Loss) Per Share

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

	2008	2007	2006
	(Shares in thousands)		
Income (loss) available to common shareholders	\$(2,071.9)	\$2,953.0	\$2,662.7
Basic earnings (loss) per share			
Weighted-average number of common shares outstanding, including incremental shares	1,094,499	1,090,430	1,086,239
Basic earnings (loss) per share	\$(1.89)	\$2.71	\$2.45
Diluted earnings (loss) per share			
Weighted-average number of common shares outstanding	1,092,041	1,088,929	1,085,337
Stock options and other incremental shares	2,458	1,821	2,153
Weighted-average number of common shares outstanding — diluted	1,094,499	1,090,750	1,087,490
Diluted earnings (loss) per share	\$(1.89)	\$2.71	\$2.45

Note 12: Income Taxes

Following is the composition of income tax expense:

	2008	2007	2006
Current			
Federal	\$(207.6)	\$489.5	\$197.7
Foreign	623.6	412.1	390.6
State	(44.6)	27.7	(25.2)
	371.4	929.3	563.1
Deferred			
Federal	363.0	53.0	78.3
Foreign	23.7	(27.9)	113.5
State	6.2	(30.6)	0.4
	392.9	(5.5)	192.2
Income taxes	\$ 764.3	\$923.8	\$755.3

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

	2008	2007
Deferred tax assets		
Compensation and benefits	\$ 1,154.6	\$ 654.8
Tax credit carryforwards and carrybacks	755.0	361.5
Intercompany profit in inventories	585.0	810.5
Tax loss carryforwards and carrybacks	562.3	712.2
Contingencies	345.2	49.3
Asset purchases	251.5	174.6
Debt	211.6	27.7
Sale of intangibles	117.9	69.1
Product return reserves	100.8	110.0
Other	313.6	302.1
	4,397.5	3,271.8
Valuation allowances	(845.4)	(354.2)
Total deferred tax assets	3,552.1	2,917.6
Deferred tax liabilities		
Intangibles	(860.2)	(532.5)
Property and equipment	(620.7)	(662.2)
Inventories	(542.7)	(432.4)
Unremitted earnings	(467.3)	(65.3)
Prepaid employee benefits	—	(675.9)
Other	(287.8)	(133.0)
Total deferred tax liabilities	(2,778.7)	(2,501.3)
Deferred tax assets — net	\$ 773.4	\$ 416.3

At December 31, 2008, we had net operating losses and other carryforwards for international and U.S. income tax purposes of \$1.24 billion: \$84.3 million will expire within 10 years; \$1.09 billion will expire between 10 and 20 years; and \$63.1 million of the carryforwards will never expire. The primary component of the remaining portion of the deferred tax asset for tax loss carryforwards and carrybacks is related to net operating losses for state income tax purposes that are fully reserved. We also have tax credit carryforwards and carrybacks of \$755.0 million available to reduce future income taxes; \$295.1 million will be carried back; \$84.1 million of the tax credit carryforwards will expire after 5 years; and \$13.0 million of the tax credit carryforwards will never expire. The remaining portion of the tax credit carryforwards is related to federal tax credits of \$97.4 million and state tax credits of \$265.4 million, both of which are fully reserved.

Domestic and Puerto Rican companies generated the entire consolidated loss before income taxes in 2008 and contributed approximately 7 percent and 18 percent in 2007 and 2006, respectively, to consolidated income before income taxes. We have a subsidiary operating in Puerto Rico under a tax incentive grant. The current tax incentive grant will not expire prior to 2017.

At December 31, 2008, we had an aggregate of \$13.31 billion of unremitted earnings of foreign subsidiaries that have been or are intended to be permanently reinvested for continued use in foreign operations and that, if distributed, would result in additional income tax expense at approximately the U.S. statutory rate.

Cash payments (refunds) of income taxes totaled \$(52.0) million, \$1.01 billion, and \$864.0 million in 2008, 2007, and 2006, respectively.

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

	2008	2007	2006
Income tax (benefit) at the U.S. federal statutory tax rate	\$ (457.7)	\$1,356.9	\$1,196.3
Add (deduct)			
Acquisitions and non-deductible acquired in-process research and development	1,819.4	208.1	—
International operations, including Puerto Rico	(641.3)	(450.7)	(229.9)
Government investigation charges	359.3	—	—
IRS audit conclusion	(210.3)	—	—
General business credits	(58.0)	(60.3)	(47.6)
Sundry	(47.1)	(130.2)	(163.5)
Income tax expense	<u>\$ 764.3</u>	<u>\$ 923.8</u>	<u>\$ 755.3</u>

We adopted FIN 48 on January 1, 2007. FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. As a result of the implementation of FIN 48, we recognized an increase of \$8.6 million in the liability for unrecognized tax benefits, and an offsetting reduction to the January 1, 2007 balance of retained earnings. A reconciliation of the beginning and ending amount of gross unrecognized tax benefits is as follows:

	2008	2007
Beginning balance at January 1	\$1,657.4	\$1,470.8
Additions based on tax positions related to the current year	115.6	206.4
Additions for tax positions of prior years	288.8	35.6
Reductions for tax positions of prior years	(234.9)	(53.1)
Lapses of statutes of limitation	(216.2)	—
Settlements	(598.4)	(2.3)
Balance at December 31	<u>\$1,012.3</u>	<u>\$1,657.4</u>

The total amount of unrecognized tax benefits that, if recognized, would affect our effective tax rate was \$863.8 million at December 31, 2008.

We file income tax returns in the U.S. federal jurisdiction and various state, local, and non-U.S. jurisdictions. We are no longer subject to U.S. federal, state and local, or non-U.S. income tax examinations in major taxing jurisdictions for years before 2002. During the first quarter of 2008, we completed and effectively settled our Internal Revenue Service (IRS) audit of tax years 2001-2004 except for one matter for which we will seek resolution through the IRS administrative appeals process. As a result of the IRS audit conclusion, gross unrecognized tax benefits were reduced by approximately \$618 million, and the consolidated results of operations were benefited by \$210.3 million through a reduction in income tax expense. The majority of the reduction in gross unrecognized tax benefits related to intercompany pricing positions that were agreed with the IRS in a prior audit cycle for which a prepayment of tax was made in 2005. Application of the prepayment and utilization of tax carryovers resulted in a refund of approximately \$50 million. The IRS began its examination of tax years 2005-2007 during the third quarter of 2008. We do not believe it is reasonably possible that the total amount of unrecognized tax benefits will significantly increase or decrease within the next twelve months.

We recognize both accrued interest and penalties related to unrecognized tax benefits in income tax expense. During the years ended December 31, 2008, 2007, and 2006, we recognized income tax expense (benefit) of \$(118.0) million, \$66.6 million, and \$51.2 million, respectively, related to interest and penalties. At December 31, 2008 and 2007, our accruals for the payment of interest and penalties totaled \$177.6 million

and \$364.2 million, respectively. Substantially all of the expense (benefit) and accruals relate to interest. The change in the 2008 accrual reflects the impact of the effective settlement of the IRS audit discussed above.

Note 13: Retirement Benefits

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

	Defined Benefit Pension Plans		Retiree Health Benefit Plans	
	2008	2007	2008	2007
Change in benefit obligation				
Benefit obligation at beginning of year	\$ 6,561.0	\$6,480.3	\$1,622.8	\$1,740.7
Service cost	260.1	287.1	62.1	70.4
Interest cost	409.8	362.4	105.7	101.4
Actuarial (gain) loss	(257.4)	(373.1)	101.6	16.4
Benefits paid	(338.4)	(311.0)	(92.2)	(81.6)
Plan amendments	(2.4)	32.7	—	(227.7)
Foreign currency exchange rate changes and other adjustments	(279.0)	82.6	(3.7)	3.2
Benefit obligation at end of year	<u>6,353.7</u>	<u>6,561.0</u>	<u>1,796.3</u>	<u>1,622.8</u>
Change in plan assets				
Fair value of plan assets at beginning of year	7,304.2	6,519.0	1,348.5	1,157.3
Actual return on plan assets	(2,187.8)	833.8	(438.6)	147.4
Employer contribution	223.7	202.9	87.9	125.4
Benefits paid	(326.1)	(301.4)	(92.2)	(81.6)
Foreign currency exchange rate changes and other adjustments	(217.9)	49.9	—	—
Fair value of plan assets at end of year	<u>4,796.1</u>	<u>7,304.2</u>	<u>905.6</u>	<u>1,348.5</u>
Funded status	(1,557.6)	743.2	(890.7)	(274.3)
Unrecognized net actuarial loss	3,474.8	1,143.3	1,409.6	820.3
Unrecognized prior service cost (benefit)	72.7	88.4	(261.6)	(297.7)
Net amount recognized	<u>\$ 1,989.9</u>	<u>\$1,974.9</u>	<u>\$ 257.3</u>	<u>\$ 248.3</u>
Amounts recognized in the consolidated balance sheet consisted of				
Prepaid pension	\$ —	\$1,670.5	\$ —	\$ —
Other current liabilities	(52.9)	(47.9)	(7.8)	(8.6)
Accrued retirement benefit	(1,504.7)	(879.4)	(882.9)	(265.7)
Accumulated other comprehensive loss before income taxes	3,547.5	1,231.7	1,148.0	522.6
Net amount recognized	<u>\$ 1,989.9</u>	<u>\$1,974.9</u>	<u>\$ 257.3</u>	<u>\$ 248.3</u>

The unrecognized net actuarial loss and unrecognized prior service cost (benefit) have not yet been recognized in net periodic pension costs and are included in accumulated other comprehensive loss at December 31, 2008.

In 2009, we expect to recognize from accumulated other comprehensive loss as components of net periodic benefit cost, \$97.5 million of unrecognized net actuarial loss and \$8.7 million of unrecognized prior service cost related to our defined benefit pension plans, and \$69.4 million of unrecognized net actuarial loss and

\$35.9 million of unrecognized prior service benefit related to our retiree health benefit plans. We do not expect any plan assets to be returned to us in 2009.

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

(Percents)	Defined Benefit Pension Plans		Retiree Health Benefit Plans	
	2008	2007	2008	2007
Weighted-average assumptions as of December 31				
Discount rate for benefit obligation	6.7	6.4	6.9	6.7
Discount rate for net benefit costs	6.4	5.7	6.7	6.0
Rate of compensation increase for benefit obligation	4.1	4.6	—	—
Rate of compensation increase for net benefit costs	4.6	4.6	—	—
Expected return on plan assets for net benefit costs	9.0	9.0	9.0	9.0

In evaluating the expected return on plan assets, we have considered our historical assumptions compared with actual results, an analysis of current market conditions, asset allocations, and the views of leading financial advisers and economists. Our plan assets in our U.S. defined benefit pension and retiree health plans comprise approximately 84 percent of our worldwide benefit plan assets. Including the investment losses due to overall market conditions in 2001, 2002, and 2008, our 20-year annualized rate of return on our U.S. defined benefit pension plans and retiree health benefit plan was approximately 8.2 percent as of December 31, 2008. Health-care-cost trend rates are assumed to increase at an annual rate of 8.5 percent in 2009, decreasing by approximately 0.6 percent per year to an ultimate rate of 5.5 percent by 2014.

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

	2009	2010	2011	2012	2013	2014-2018
Defined benefit pension plans	\$360.5	\$378.6	\$384.8	\$392.4	\$403.3	\$2,234.0
Retiree health benefit plans — gross	\$103.3	\$106.0	\$109.8	\$110.3	\$114.7	\$ 599.0
Medicare rebates	(11.6)	(7.9)	(8.7)	(10.0)	(10.6)	(69.0)
Retiree health benefit plans — net	\$ 91.7	\$ 98.1	\$101.1	\$100.3	\$104.1	\$ 530.0

The total accumulated benefit obligation for our defined benefit pension plans was \$5.64 billion and \$5.69 billion at December 31, 2008 and 2007, respectively. The projected benefit obligation and fair value of the plan assets for the defined benefit pension plans with projected benefit obligations in excess of plan assets were \$6.35 billion and \$4.80 billion, respectively, as of December 31, 2008, and \$1.04 billion and \$160.9 million, respectively, as of December 31, 2007. The accumulated benefit obligation and fair value of the plan assets for the defined benefit pension plans with accumulated benefit obligations in excess of plan assets were \$4.98 billion and \$4.06 billion, respectively, as of December 31, 2008, and \$825.8 million and \$46.9 million, respectively, as of December 31, 2007.

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

	2008	Defined Benefit Pension Plans 2007	2006	2008	Retiree Health Benefit Plans 2007	2006
Components of net periodic benefit cost						
Service cost	\$ 260.1	\$ 287.1	\$ 280.0	\$ 62.1	\$ 70.4	\$ 72.2
Interest cost	409.8	362.4	343.5	105.7	101.4	97.9
Expected return on plan assets	(603.0)	(548.2)	(494.8)	(118.4)	(102.1)	(89.9)
Amortization of prior service cost (benefit)	8.2	7.7	8.3	(36.0)	(15.7)	(15.6)
Recognized actuarial loss	76.6	130.0	149.6	62.7	95.0	107.9
Net periodic benefit cost	\$ 151.7	\$ 239.0	\$ 286.6	\$ 76.1	\$ 149.0	\$172.5

If the health-care-cost trend rates were to be increased by one percentage point each future year, the December 31, 2008, accumulated postretirement benefit obligation would increase by \$247.8 million (13.9 percent) and the aggregate of the service cost and interest cost components of the 2008 annual expense would increase by \$26.9 million (16.0 percent). A one-percentage-point decrease in these rates would decrease the December 31, 2008, accumulated postretirement benefit obligation by \$192.0 million (10.8 percent) and the aggregate of the 2008 service cost and interest cost by \$20.7 million (12.3 percent).

The following represents the amounts recognized in other comprehensive income (loss) in 2008:

	Defined Benefit Pension Plans	Retiree Health Benefit Plans
Actuarial loss arising during period	\$ 2,533.4	\$ 658.6
Plan amendments during period	(2.4)	—
Amortization of prior service cost (benefit) included in net income	(8.2)	36.0
Amortization of net actuarial loss included in net income	(76.6)	(62.7)
Foreign currency exchange rate changes	(130.4)	(6.5)
Total other comprehensive loss during period	\$ 2,315.8	\$ 625.4

We have defined contribution savings plans that cover our eligible employees worldwide. The purpose of these defined contribution plans is generally to provide additional financial security during retirement by providing employees with an incentive to save. Our contributions to the plan are based on employee contributions and the level of our match. Expenses under the plans totaled \$114.1 million, \$112.3 million, and \$106.5 million, for the years 2008, 2007, and 2006, respectively.

We provide certain other postemployment benefits primarily related to disability benefits and accrue for the related cost over the service lives of employees. Expenses associated with these benefit plans in 2008, 2007, and 2006 were not significant.

Our U.S. defined benefit pension and retiree health benefit plan investment allocation strategy currently comprises approximately 88 percent to 92 percent growth investments and 8 percent to 12 percent fixed-income investments. Within the growth investment allocation, the plan asset strategy encompasses equity and equity-like instruments that are expected to represent approximately 75 percent of our plan asset portfolio of both public and private market investments. The largest component of these equity and equity-like instruments is public equity securities that are well diversified and invested in U.S. and international small-to-large companies. The remaining portion of the growth investment allocation includes alternative investments.

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

(Percents)	Percentage of Pension Plan Assets		Percentage of Retiree Health Plan Assets	
	2008	2007	2008	2007
Asset Category				
Equity securities and equity-like instruments	70	75	74	78
Debt securities	12	10	14	11
Real estate	1	1	—	—
Other	17	14	12	11
Total	100	100	100	100

In 2009, we expect to contribute approximately \$55 million to our defined benefit pension plans to satisfy minimum funding requirements for the year. In addition, we expect to contribute approximately \$15 million of additional discretionary funding in 2009 to our defined benefit plans. We do not expect to make any contributions to our post-retirement health benefit plans during 2009.

Note 14: Contingencies

We are a party to various legal actions, government investigations, and environmental proceedings. The most significant of these are described below. While it is not possible to determine the outcome of these matters, we believe that, except as specifically noted below, the resolution of all such matters will not have a material adverse effect on our consolidated financial position or liquidity, but could possibly be material to our consolidated results of operations in any one accounting period.

Patent Litigation

We are engaged in the following patent litigation matters brought pursuant to procedures set out in the Hatch-Waxman Act (the Drug Price Competition and Patent Term Restoration Act of 1984):

- *Cymbalta*: Sixteen generic drug manufacturers have submitted Abbreviated New Drug Applications (ANDAs) seeking permission to market generic versions of Cymbalta prior to the expiration of our relevant U.S. patents (the earliest of which expires in 2013). Of these challengers, all allege non-infringement of the patent claims directed to the commercial formulation, and eight allege invalidity of the patent claims directed to the active ingredient duloxetine. Of the eight challengers to the compound patent claims, one further alleges invalidity of the claims directed to the use of Cymbalta for treating fibromyalgia, and one alleges the patent having claims directed to the active ingredient is unenforceable. Lawsuits have been filed in U.S. District Court for the Southern District of Indiana against Activis Elizabeth LLC; Aurobindo Pharma Ltd.; Cobalt Laboratories, Inc.; Impax Laboratories, Inc.; Lupin Limited; Sandoz Inc.; Sun Pharma Global, Inc.; and Wockhardt Limited, seeking rulings that the patents are valid, infringed, and enforceable. Answers to the complaints are pending.
- *Gemzar*: Sicor Pharmaceuticals, Inc. (Sicor), Mayne Pharma (USA) Inc. (Mayne), and Sun Pharmaceutical Industries Inc. (Sun) each submitted an ANDA seeking permission to market generic versions of Gemzar prior to the expiration of our relevant U.S. patents (compound patent expiring in 2010 and method-of-use patent expiring in 2013), and alleging that these patents are invalid. We filed lawsuits in the U.S. District Court for the Southern District of Indiana against Sicor (February 2006) and Mayne (October 2006 and January 2008), seeking rulings that these patents are valid and are being infringed. The suit against Sicor has been scheduled for trial in July 2009. Sicor’s ANDAs have been approved by the FDA; however, Sicor must provide 90 days notice prior to marketing generic Gemzar to allow time for us to seek a preliminary injunction. Both suits against Mayne have been administratively closed, and the parties have agreed to be bound by the results of the Sicor suit. In November 2007, Sun filed a declaratory judgment action in the United States District Court for the Eastern District of Michigan, seeking rulings that our method-of-use and

compound patents are invalid or unenforceable, or would not be infringed by the sale of Sun's generic product. This trial is scheduled for December 2009.

- *Alimta*: Teva Parenteral Medicines, Inc. (Teva) and APP Pharmaceuticals, LLC (APP) each submitted ANDAs seeking approval to market generic versions of Alimta prior to the expiration of the relevant U.S. patent (licensed from the Trustees of Princeton University and expiring in 2016), and alleging the patent is invalid. We, along with Princeton, filed lawsuits in the U.S. District Court for the District of Delaware against Teva and APP, seeking rulings that the compound patent is valid and infringed. Trial is scheduled for November 8, 2010.
- *Evista*: Barr Laboratories, Inc. (Barr) submitted an ANDA in 2002 seeking permission to market a generic version of Evista prior to the expiration of our relevant U.S. patents (expiring in 2012-2017) and alleging that these patents are invalid, not enforceable, or not infringed. In November 2002, we filed a lawsuit against Barr in the U.S. District Court for the Southern District of Indiana, seeking a ruling that these patents are valid, enforceable, and being infringed by Barr. Teva Pharmaceuticals USA, Inc. (Teva) has also submitted an ANDA seeking permission to market a generic version of Evista. In June 2006, we filed a similar lawsuit against Teva in the U.S. District Court for the Southern District of Indiana. The lawsuit against Teva is currently scheduled for trial beginning March 9, 2009, while no trial date has been set in the lawsuit against Barr. In April 2008, the FDA granted Teva tentative approval of its ANDA, but Teva's ability to market a generic product is subject to a statutory stay, which has been extended to expire on March 9, 2009. If the stay expires and the company cannot obtain preliminary relief from the court, Teva can launch its generic product, regardless of the status of the current litigation, but subject to our right to recover damages, should we prevail at trial.

We believe each of these Hatch-Waxman challenges is without merit and expect to prevail in this litigation. However, it is not possible to determine the outcome of this litigation, and accordingly, we can provide no assurance that we will prevail. An unfavorable outcome in any of these cases could have a material adverse impact on our future consolidated results of operations, liquidity, and financial position.

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

- In Canada, several generic pharmaceutical manufacturers have challenged the validity of our Zyprexa compound and method-of-use patent (expiring in 2011). In April 2007, the Canadian Federal Court ruled against the first challenger, Apotex Inc. (Apotex), and that ruling was affirmed on appeal in February 2008. In June 2007, the Canadian Federal Court held that an invalidity allegation of a second challenger, Novopharm Ltd. (Novopharm), was justified and denied our request that Novopharm be prohibited from receiving marketing approval for generic olanzapine in Canada. Novopharm began selling generic olanzapine in Canada in the third quarter of 2007. We sued Novopharm for patent infringement, and the trial began in November 2008. We expect the trial to run through the first quarter of 2009, with a decision in the second half of 2009. In November 2007, Apotex filed an action seeking a declaration of the invalidity of our Zyprexa compound and method-of-use patents, and no trial date has been set. We have brought similar actions against Pharmascience (August 2007), Sandoz (July 2007), Nu-Pharm (June 2008), Genpharm (June 2008) and Cobalt (January 2009); none of these suits has been scheduled for trial. Pharmascience has agreed to be bound by the outcome of the Novopharm suit, and, pending the outcome of the lawsuit, we have agreed not to take any further steps to prevent the company from coming to market with generic olanzapine tablets, subject to a contingent damages obligation should we be successful against Novopharm.
- In Germany, generic pharmaceutical manufacturers Egis-Gyogyszergyar and Neolab Ltd. challenged the validity of our Zyprexa compound and method-of-use patent (expiring in 2011). In June 2007, the German Federal Patent Court held that our patent is invalid. Generic olanzapine was launched by competitors in Germany in the fourth quarter of 2007. We appealed the decision to the German Federal Supreme Court and following a hearing in December 2008, the Supreme Court reversed the Federal Patent Court and found the patent to be valid. Following the decision of the Supreme Court, the generic companies either agreed to withdraw from the market or were subject to preliminary injunction. We are pursuing these companies for damages arising from infringement.

- We have received challenges in a number of other countries, including Spain, the United Kingdom (U.K.), France, and several smaller European countries. In Spain, we have been successful at both the trial and appellate court levels in defeating the generic manufacturers' challenges, but further legal challenge is now pending before the Commercial Court in Madrid. In the U.K., the generic pharmaceutical manufacturer Dr. Reddy's Laboratories (UK) Limited has challenged the validity of our Zyprexa compound and method-of-use patent (expiring in 2011). In October 2008, the Patents Court in the High Court, London ruled that our patent was valid. Dr. Reddy's appealed this decision, and a hearing date for the appeal has not been set.

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

Xigris and Evista: In June 2002, Ariad Pharmaceuticals, Inc., the Massachusetts Institute of Technology, the Whitehead Institute for Biomedical Research, and the President and Fellows of Harvard College in the U.S. District Court for the District of Massachusetts sued us, alleging that sales of two of our products, Xigris and Evista, were inducing the infringement of a patent related to the discovery of a natural cell signaling phenomenon in the human body, and seeking royalties on past and future sales of these products. On May 4, 2006, a jury in Boston issued an initial decision in the case that Xigris and Evista sales infringe the patent. The jury awarded the plaintiffs approximately \$65 million in damages, calculated by applying a 2.3 percent royalty to all U.S. sales of Xigris and Evista from the date of issuance of the patent through the date of trial. In addition, a separate bench trial with the U.S. District Court of Massachusetts was held in August 2006, on our contention that the patent is unenforceable and impermissibly covers natural processes. In June 2005, the United States Patent and Trademark Office (USPTO) commenced a reexamination of the patent, and in August 2007 took the position that the Ariad claims at issue are unpatentable, a position that Ariad continues to contest. In September 2007, the Court entered a final judgment indicating that Ariad's claims are patentable, valid, and enforceable, and finding damages in the amount of \$65 million plus a 2.3 percent royalty on net U.S. sales of Xigris and Evista since the time of the jury decision. However, the Court deferred the requirement to pay any damages until after all rights to appeal have been exhausted. We have appealed this judgment. The Court of Appeals for the Federal Circuit heard oral arguments on the appeal on February 6, 2009. We believe that these allegations are without legal merit, that we will ultimately prevail on these issues, and therefore that the likelihood of any monetary damages is remote.

Government Investigations and Related Litigation

In March 2004, the Office of the U.S. Attorney for the Eastern District of Pennsylvania (EDPA) advised us that it had commenced an investigation related to our U.S. marketing and promotional practices, including our communications with physicians and remuneration of physician consultants and advisors, with respect to Zyprexa, Prozac, and Prozac Weekly. In addition, the State Medicaid Fraud Control Units of more than 30 states coordinated with the EDPA in its investigation of any Medicaid-related claims relating to our marketing and promotion of Zyprexa. In January 2009, we announced that we reached resolution of this matter. As part of the resolution, we pled guilty to one misdemeanor violation of the Food, Drug, and Cosmetic Act and agreed to pay \$615.0 million. The misdemeanor plea is for the off-label promotion of Zyprexa in elderly populations as treatment for dementia, including Alzheimer's dementia, between September 1999 and March 2001. We have also entered into a settlement agreement resolving the federal civil claims, under which we will pay approximately \$438.0 million, although we do not admit to the allegations. We have also agreed to settle the civil investigations brought by the State Medicaid Fraud Control Units of the states that have coordinated with the EDPA in its investigation, and will make available a maximum of approximately \$362.0 million for payment to those states that agree to settle. The charge we recorded for this matter in the third quarter of \$1.42 billion will be sufficient to cover these payments. Also, as part of the settlement, we have entered into a corporate integrity agreement with the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS). This agreement will require us to maintain our compliance program and to undertake a set of defined corporate integrity obligations for five years. The agreement also provides for an independent third-party review organization to assess and report on the company's systems, processes, policies, procedures and practices.

In June 2005, we received a subpoena from the Office of the Attorney General, Medicaid Fraud Control Unit, of the State of Florida, seeking production of documents relating to sales of Zyprexa and our marketing and promotional practices with respect to Zyprexa. In September 2006, we received a subpoena from the California Attorney General's Office seeking production of documents related to our efforts to obtain and maintain Zyprexa's status on California's formulary, marketing and promotional practices with respect to Zyprexa, and remuneration of health care providers. We expect these matters to be resolved if Florida and California participate in the state component of the EDPA resolution.

Beginning in August 2006, we received civil investigative demands or subpoenas from the attorneys general of a number of states under various state consumer protection laws. Most of these requests became part of a multi-state investigative effort coordinated by an executive committee of attorneys general. In October 2008, we reached a settlement with 32 states and the District of Columbia. While there is no finding that we have violated any provision of the state laws under which the investigations were conducted, we paid \$62.0 million and agreed to undertake certain commitments regarding Zyprexa for a period of six years, through consent decrees filed in the settling states. The 32 states participating in the settlement are: Alabama, Arizona, California, Delaware, Florida, Hawaii, Illinois, Indiana, Iowa, Kansas, Maine, Maryland, Massachusetts, Michigan, Missouri, Nebraska, Nevada, New Jersey, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Dakota, Tennessee, Texas, Vermont, Washington, and Wisconsin.

Product Liability and Related Litigation

We have been named as a defendant in a large number of Zyprexa product liability lawsuits in the U.S. and have been notified of many other claims of individuals who have not filed suit. The lawsuits and unfiled claims (together the "claims") allege a variety of injuries from the use of Zyprexa, with the majority alleging that the product caused or contributed to diabetes or high blood-glucose levels. The claims seek substantial compensatory and punitive damages and typically accuse us of inadequately testing for and warning about side effects of Zyprexa. Many of the claims also allege that we improperly promoted the drug. Almost all of the federal lawsuits are part of a Multi-District Litigation (MDL) proceeding before The Honorable Jack Weinstein in the Federal District Court for the Eastern District of New York (MDL No. 1596).

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

- In June 2005, we reached an agreement in principle (and in September 2005 a final agreement) to settle more than 8,000 claims for \$690.0 million plus \$10.0 million to cover administration of the settlement.
- In January 2007, we reached agreements with a number of plaintiffs' attorneys to settle more than 18,000 claims for approximately \$500 million.

The 2005 settlement totaling \$700.0 million was paid during 2005. The January 2007 settlements were paid during 2007.

We are prepared to continue our vigorous defense of Zyprexa in all remaining claims. The U.S. Zyprexa product liability claims not subject to these agreements include approximately 105 lawsuits in the U.S. covering approximately 120 plaintiffs, of which about 80 cases covering about 90 plaintiffs are part of the MDL. No trials have been scheduled related to these claims.

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

Since the beginning of 2005, we have recorded aggregate net pretax charges of \$1.61 billion for Zyprexa product liability matters. The net charges, which take into account our actual insurance recoveries, covered the following:

- The cost of the Zyprexa product liability settlements to date; and
- Reserves for product liability exposures and defense costs regarding the known Zyprexa product liability claims and expected future claims to the extent we could formulate a reasonable estimate of the probable number and cost of the claims.

In December 2004, we were served with two lawsuits brought in state court in Louisiana on behalf of the Louisiana Department of Health and Hospitals, alleging that Zyprexa caused or contributed to diabetes or high blood-glucose levels, and that we improperly promoted the drug. These cases have been removed to federal court and are now part of the MDL proceedings in the Eastern District of New York (EDNY). In these actions, the Department of Health and Hospitals seeks to recover the costs it paid for Zyprexa through Medicaid and other drug-benefit programs, as well as the costs the department alleges it has incurred and will incur to treat Zyprexa-related illnesses. We have been served with similar lawsuits filed by the states of Alaska, Arkansas, Connecticut, Idaho, Minnesota, Mississippi, Montana, New Mexico, Pennsylvania, South Carolina, Utah, and West Virginia in the courts of the respective states. The Connecticut, Louisiana, Minnesota, Mississippi, Montana, New Mexico, and West Virginia cases are part of the MDL proceedings in the EDNY. The Alaska case was settled in March 2008 for a payment of \$15.0 million, plus terms designed to ensure, subject to certain limitations and conditions, that Alaska is treated as favorably as certain other states that may settle with us in the future over similar claims. The following cases have been set for trial in 2009: Connecticut in the EDNY in June, Pennsylvania in November, and South Carolina in August, in their respective states.

In 2005, two lawsuits were filed in the EDNY purporting to be nationwide class actions on behalf of all consumers and third-party payors, excluding governmental entities, which have made or will make payments for their members or insured patients being prescribed Zyprexa. These actions have now been consolidated into a single lawsuit, which is brought under certain state consumer protection statutes, the federal civil RICO statute, and common law theories, seeking a refund of the cost of Zyprexa, treble damages, punitive damages, and attorneys' fees. Two additional lawsuits were filed in the EDNY in 2006 on similar grounds. In September 2008, Judge Weinstein certified a class consisting of third-party payors, excluding governmental entities and individual consumers. We appealed the certification order, and Judge Weinstein's order denying our motion for summary judgment, in September 2008. In 2007, The Pennsylvania Employees Trust Fund brought claims in state court in Pennsylvania as insurer of Pennsylvania state employees, who were prescribed Zyprexa on similar grounds as described in the New York cases. As with the product liability suits, these lawsuits allege that we inadequately tested for and warned about side effects of Zyprexa and improperly promoted the drug. The Pennsylvania case is set for trial in October 2009.

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

In addition, we have been named as a defendant in numerous other product liability lawsuits involving primarily diethylstilbestrol (DES) and thimerosal. The majority of these claims are covered by insurance, subject to deductibles and coverage limits.

Because of the nature of pharmaceutical products, it is possible that we could become subject to large numbers of product liability and related claims for other products in the future. In the past few years, we have experienced difficulties in obtaining product liability insurance due to a very restrictive insurance market. Therefore, for substantially all of our currently marketed products, we have been and expect that we will continue to be completely self-insured for future product liability losses. In addition, there is no assurance that we will be able to fully collect from our insurance carriers in the future.

Environmental Matters

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

Note 15: Other Comprehensive Income (Loss)

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

	Foreign Currency Translation Gains (Losses)	Unrealized Gains (Losses) on Securities	Defined Benefit Pension and Retiree Health Benefit Plans	Effective Portion of Cash Flow Hedges	Accumulated Other Comprehensive Income (Loss)
Beginning balance at January 1, 2008	\$ 1,317.0	\$ 14.6	\$ (1,151.6)	\$ (166.8)	\$ 13.2
Other comprehensive income (loss)	(766.1)	(125.8)	(1,924.8)	16.7	(2,800.0)
Balance at December 31, 2008	\$ 550.9	\$ (111.2)	\$ (3,076.4)	\$ (150.1)	\$ (2,786.8)

The amounts above are net of income taxes. The income taxes associated with the unrecognized net actuarial losses and prior service costs on our defined benefit pension and retiree health benefit plans (Note 13) were a benefit of \$1.02 billion for 2008. The income taxes related to the other components of comprehensive income were not significant, as income taxes were not provided for foreign currency translation.

The unrealized gains (losses) on securities is net of reclassification adjustments of \$1.7 million, \$5.8 million, and \$16.9 million, net of tax, in 2008, 2007, and 2006, respectively, for net realized gains on sales of securities included in net income. The effective portion of cash flow hedges is net of reclassification adjustments of \$9.6 million, \$8.8 million, and \$2.3 million, net of tax, in 2008, 2007, and 2006, respectively, for realized losses on foreign currency options and \$7.9 million, \$11.6 million, and \$17.1 million, net of tax, in 2008, 2007, and 2006, respectively, for interest expense on interest rate swaps designated as cash flow hedges.

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

Management's Reports

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

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

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

The consolidated financial statements have been audited by Ernst & Young LLP, an independent registered public accounting firm. Their responsibility is to examine our consolidated financial statements in accordance with generally accepted auditing standards of the Public Company Accounting Oversight Board (United States). Ernst & Young's opinion with respect to the fairness of the presentation of the statements (see opinion on page 66) is included in our annual report. Ernst & Young reports directly to the audit committee of the board of directors.

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

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

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

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

We conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under this framework, we concluded that our internal control over financial reporting was effective as of December 31, 2008. However, because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

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

John C. Lechleiter, Ph.D.
*Chairman, President, and
Chief Executive Officer*

Derica W. Rice
*Senior Vice President and
Chief Financial Officer*

February 16, 2009

Report of Independent Registered Public Accounting Firm

Board of Directors and Shareholders Eli Lilly and Company

We have audited the accompanying consolidated balance sheets of Eli Lilly and Company and subsidiaries as of December 31, 2008 and 2007, and the related consolidated statements of operations, cash flows, and comprehensive income (loss) (pages 43 through 48 and pages 52 through 84) for each of the three years in the period ended December 31, 2008. These financial statements are the responsibility of the company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Eli Lilly and Company and subsidiaries at December 31, 2008 and 2007, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2008, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Eli Lilly and Company and subsidiaries' internal control over financial reporting as of December 31, 2008, based on criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 16, 2009 expressed an unqualified opinion thereon.

As discussed in Note 12 to the financial statements, in 2007 Eli Lilly and Company and subsidiaries adopted a new accounting pronouncement for income taxes.

/s/ Ernst & Young LLP

Indianapolis, Indiana
February 16, 2009

Report of Independent Registered Public Accounting Firm

Board of Directors and Shareholders Eli Lilly and Company

We have audited Eli Lilly and Company and subsidiaries' internal control over financial reporting as of December 31, 2008, based on criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Eli Lilly and Company and subsidiaries' management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

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

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

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

In our opinion, Eli Lilly and Company and subsidiaries maintained, in all material respects, effective internal control over financial reporting as of December 31, 2008, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the 2008 consolidated financial statements of Eli Lilly and Company and subsidiaries and our report dated February 16, 2009, expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Indianapolis, Indiana
February 16, 2009

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

None.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

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

Our management, with the participation of John C. Lechleiter, Ph.D., chairman, president, and chief executive officer, and Derica W. Rice, senior vice president and chief financial officer, evaluated our disclosure controls and procedures as of December 31, 2008, and concluded that they are effective.

Internal Control over Financial Reporting

Dr. Lechleiter and Mr. Rice provided a report on behalf of management on our internal control over financial reporting, in which management concluded that the company's internal control over financial reporting is effective at December 31, 2008. In addition, Ernst & Young LLP, the company's independent registered public accounting firm, provided an attestation report on the company's internal control over financial reporting. You can find the full text of management's report and Ernst & Young's attestation report in Part II, Item 8, and both reports are incorporated by reference in this Item.

Changes in Internal Controls

During the fourth quarter of 2008, there were no changes in our internal control over financial reporting that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

Not applicable.

Part III

Item 10. Directors, Executive Officers and Corporate Governance

Directors and Executive Officers

Information relating to our Board of Directors is found in our Proxy Statement to be dated on or about March 9, 2009 (the "Proxy Statement") under "Board of Directors" at pages 73-76, and is incorporated in this report by reference.

Information relating to our executive officers is found at Part I, Item 1 of this Form 10-K under "Executive Officers of the Company."

Code of Ethics

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

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

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

Corporate Governance

In our proxy statements, we describe the procedures by which shareholders can recommend nominees to our board of directors. There have been no changes in those procedures since they were last published in our proxy statement of March 10, 2008.

The board has appointed an audit committee consisting entirely of independent directors in accordance with applicable SEC and New York Stock Exchange rules for audit committees. The members of the committee are Mr. J. Michael Cook (chairman), Michael L. Eskew, Dr. Martin S. Feldstein, Douglas R. Oberhelman, and Ms. Kathi P. Seifert. The board has determined that Messrs. Cook and Eskew are audit committee financial experts as defined in the SEC rules.

Item 11. Executive Compensation

Information on director compensation, executive compensation, and compensation committee matters can be found in the Proxy Statement under "Directors' Compensation" at pages 83-85, "Executive Compensation" at pages 89-110, and "Compensation Committee Interlocks and Insider Participation" at page 89. That information is incorporated in this report by reference.

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

Security Ownership of Certain Beneficial Owners and Management

Information relating to ownership of the Company's common stock by management and by persons known by the Company to be the beneficial owners of more than five percent of the outstanding shares of common stock is found in the Proxy Statement under "Ownership of Company Stock," at pages 111-112. That information is incorporated in this report by reference.

Securities Authorized for Issuance Under Equity Compensation Plans

Information on securities authorized for issuance under our equity compensation plans can be found in the Proxy Statement under "Item 4 – Reapproval of Material Terms of Performance Goals for the Eli Lilly and Company Bonus Plan" at page 116. That information is incorporated in this report by reference.

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

Related Person Transactions

Information relating to a now-terminated time-share arrangement between the company and Mr. Sidney Taurel, retired chairman and chief executive officer, relating to his personal use of the corporate aircraft can be found in the Proxy Statement under “Related Person Transaction” at pages 110, and information relating to the board’s policies and procedures for approval of related person transactions can be found in the Proxy Statement under “Highlights of the Company’s Corporate Governance Guidelines – Review and Approval of Transactions with Related Persons” at pages 80-81. That information is incorporated in this report by reference.

Director Independence

Information relating to director independence can be found in the Proxy Statement under “Composition of the Board – Independence Determinations” at pages 77-78, and is incorporated in this report by reference.

Item 14. Principal Accountant Fees and Services

Information related to the fees and services of our principal independent accountants, Ernst & Young LLP, can be found in the Proxy Statement under “Services Performed by the Independent Auditor” and “Independent Auditor Fees” at pages 87-88. That information is incorporated in this report by reference.

Item 15. Exhibits and Financial Statement Schedules

(a)1. Financial Statements

The following consolidated financial statements of the Company and its subsidiaries are found at Part II, Item 8:

- Consolidated Statements of Operations – Years Ended December 31, 2008, 2007, and 2006
- Consolidated Balance Sheets – December 31, 2008 and 2007
- Consolidated Statements of Cash Flows – Years Ended December 31, 2008, 2007, and 2006
- Consolidated Statements of Comprehensive Income (Loss) – Years Ended December 31, 2008, 2007, and 2006
- Segment Information
- Notes to Consolidated Financial Statements

(a)2. Financial Statement Schedules

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

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

(a)3. Exhibits

- 2 Agreement and Plan of Merger dated October 6, 2008, among Eli Lilly and Company, Alaska Acquisition Corporation and ImClone Systems Incorporated
- 3.1 Amended Articles of Incorporation
- 3.2 By-laws, as amended
- 4.1 Form of Indenture with respect to Debt Securities dated as of February 1, 1991, between Eli Lilly and Company and Citibank, N.A., as Trustee

- 4.2 Agreement dated September 13, 2007 appointing Deutsche Bank Trust Company Americas as Successor Trustee under the Indenture listed above
- 4.3 Form of Standard Multiple-Series Indenture Provisions dated, and filed with the Securities and Exchange Commission on, February 1, 1991
- 4.4 Form of Indenture dated March 10, 1998, among The Lilly Savings Plan Master Trust Fund C, as issuer; Eli Lilly and Company, as guarantor; and The Chase Manhattan Bank, as Trustee, relating to ESOP Amortizing Debentures due 2017¹
- 4.5 Form of Fiscal Agency Agreement dated May 30, 2001, between Eli Lilly and Company and Citibank, N.A., Fiscal Agent, relating to Resetable Floating Rate Debt Security due 2037¹
- 4.6 Form of Resetable Floating Rate Debt Security due 2037¹
- 10.1 1998 Lilly Stock Plan, as amended²
- 10.2 2002 Lilly Stock Plan, as amended²
- 10.3 Form of Performance Award under 2002 Lilly Stock Plan²
- 10.4 Form of two-year Performance Award under 2002 Lilly Stock Plan²
- 10.5 Form of Shareholder Value Award under 2002 Lilly Stock Plan²
- 10.6 The Lilly Deferred Compensation Plan, as amended²
- 10.7 The Lilly Directors' Deferral Plan, as amended²
- 10.8 The Eli Lilly and Company Bonus Plan, as amended²
- 10.9 2007 Change in Control Severance Pay Plan for Select Employees, as amended effective January 1, 2009²
- 10.10 2007 Change in Control Severance Pay Plan for Select Employees, as amended effective October 20, 2010²
- 10.11 Letter agreement between the company and Charles E. Golden concerning retirement benefits²
- 10.12 Letter agreement between the company and Steven M. Paul, M.D. concerning retirement benefits²
- 10.13 Arrangement regarding retirement benefits for Robert A. Armitage²
- 10.14 Time Sharing Agreement between the company and Sidney Taurel for use of corporate aircraft
- 10.15 Guilty Plea Agreement in *The United States District Court for the Eastern District of Pennsylvania, United States of America v. Eli Lilly and Company*
- 10.16 Settlement Agreement among the company and the United States of America, acting through the United States Department of Justice, Civil Division, and the United States Attorney's Office of the Eastern District of Pennsylvania, the Office of the Inspector General of the Department of Health and Human Services, TRICARE Management Activity, and the United States Office of Personnel Management, and certain individual relators
- 10.17 Corporate Integrity Agreement between the company and the Office of Inspector General of the Department of Health and Human Services
- 12 Statement re: Computation of Ratio of Earnings (Loss) to Fixed Charges
- 21 List of Subsidiaries
- 23 Consent of Independent Registered Public Accounting Firm
- 31.1 Rule 13a-14(a) Certification of John C. Lechleiter, Ph.D., Chairman of the Board, President and Chief Executive Officer
- 31.2 Rule 13a-14(a) Certification of Derica W. Rice, Senior Vice President and Chief Financial Officer
- 32 Section 1350 Certification

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

² Indicates management contract or compensatory plan.

Signatures

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

Eli Lilly and Company

By /s/ John C. Lechleiter

John C. Lechleiter, Ph.D., Chairman of the Board, President and
Chief Executive Officer

February 27, 2009

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below on February 27, 2009 by the following persons on behalf of the Registrant and in the capacities indicated.

Signature	Title
<u>/s/ John C. Lechleiter</u> JOHN C. LECHLEITER, Ph.D.	Chairman of the Board, Chief Executive Officer, and a Director (principal executive officer)
<u>/s/ Derica W. Rice</u> DERICA W. RICE	Senior Vice President and Chief Financial Officer (principal financial officer)
<u>/s/ Arnold C. Hanish</u> ARNOLD C. HANISH	Vice President and Chief Accounting Officer (principal accounting officer)
<u>/s/ Sir Winfried Bischoff</u> SIR WINFRIED BISCHOFF	Director
<u>/s/ J. Michael Cook</u> J. MICHAEL COOK	Director
<u>/s/ Michael L. Eskew</u> MICHAEL L. ESKEW	Director
<u>/s/ Martin S. Feldstein</u> MARTIN S. FELDSTEIN, Ph.D.	Director
<u>/s/ J. Erik Fyrwald</u> J. ERIK FYRWALD	Director
<u>/s/ Karen N. Horn</u> KAREN N. HORN, Ph.D.	Director
<u>/s/ Alfred G. Gilman</u> ALFRED G. GILMAN, M.D., Ph.D.	Director

Signature

Title

/s/ Ellen R. Marram Director
ELLEN R. MARRAM

/s/ Douglas R. Oberhelman Director
DOUGLAS R. OBERHELMAN

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

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

Trademarks Used In This Report

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

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

Axid® is a trademark of Reliant Pharmaceuticals, LLC

Byetta® is a trademark of Amylin Pharmaceuticals, Inc.

Index to Exhibits

The following documents are filed as part of this report:

Exhibit		Location
2	Agreement and Plan of Merger, dated as of October 6, 2008, among Eli Lilly and Company, Alaska Acquisition Corporation and ImClone Systems Incorporated	Incorporated by reference from Exhibit 2.1 to the Company's Report on Form 8-K filed October 10, 2008
3.1	Amended Articles of Incorporation	Incorporated by reference from Exhibit 3.1 to the Company's Report on Form 10-Q for the quarter ended March 31, 2008
3.2	By-laws, as amended	Incorporated by reference from Exhibit 3.2 to the Company's Report on Form 10-Q for the quarter ended March 31, 2008
4.1	Form of Indenture with respect to Debt Securities dated as of February 1, 1991, between Eli Lilly and Company and Citibank, N.A., as Trustee	Incorporated by reference from Exhibit 4.1 to the Company's Registration Statement on Form S-3, Amendment No. 1, Registration No. 333-106478
4.2	Agreement dated September 13, 2007 appointing Deutsche Bank Trust Company Americas as Successor Trustee under the Indenture listed above	Attached
4.3	Form of Standard Multiple-Series Indenture Provisions dated, and filed with the Securities and Exchange Commission on February 1, 1991	Incorporated by reference from Exhibit 4.2 to the Company's Registration Statement on Form S-3, Amendment No. 1, Registration No. 333-106478
4.4	Form of Indenture dated March 10, 1998, among The Lilly Savings Plan Master Trust Fund C, as issuer; Eli Lilly and Company, as guarantor; and The Chase Manhattan Bank, as Trustee, relating to ESOP Amortizing Debentures due 2017	*
4.5	Form of Fiscal Agency Agreement dated May 30, 2001, between Eli Lilly and Company and Citibank, N.A., Fiscal Agent, relating to Resettable Floating Rate Debt Security due 2037	*
4.6	Form of Resettable Floating Rate Debt Security due 2037	*
10.1	1998 Lilly Stock Plan, as amended	Incorporated by reference from Exhibit 10.1 to the Company's Report on Form 10-K for the year ended December 31, 2006
10.2	2002 Lilly Stock Plan, as amended	Incorporated by reference from Exhibit 10.1 to the Company's Report on Form 10-Q for the quarter ended September 30, 2008
10.3	Form of Performance Award under 2002 Lilly Stock Plan	Incorporated by reference from Exhibit 10 to the Company's Report on Form 10-Q for the quarter ended September 30, 2004
10.4	Form of two-year Performance Award under 2002 Lilly Stock Plan	Incorporated by reference from Exhibit 10.1 to the Company's Report on Form 8-K filed December 11, 2008
10.5	Form of Shareholder Value Award under 2002 Lilly Stock Plan	Incorporated by reference from Exhibit 10.1 to the Company's Report on Form 10-Q for the quarter ended March 31, 2007

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

Exhibit		Location
10.6	The Lilly Deferred Compensation Plan, as amended	Incorporated by reference from Exhibit 10.3 to the Company's Report on Form 10-Q for the quarter ended September 30, 2008
10.7	The Lilly Directors' Deferral Plan, as amended	Incorporated by reference from Exhibit 10.2 to the Company's Report on Form 10-Q for the quarter ended September 30, 2008
10.8	The Eli Lilly and Company Bonus Plan, as amended	Attached
10.9	2007 Change in Control Severance Pay Plan for Select Employees, as amended effective January 1, 2009	Incorporated by reference from Exhibit 10.4 to the Company's Report on Form 10-Q for the quarter ended September 30, 2008
10.10	2007 Change in Control Severance Pay Plan for Select Employees, as amended effective October 20, 2010	Incorporated by reference from Exhibit 10.5 to the Company's Report on Form 10-Q for the quarter ended September 30, 2008
10.11	Letter agreement between the Company and Charles E. Golden concerning retirement benefits	Incorporated by reference from Exhibit 10.13 to the Company's Report on Form 10-K for the year ended December 31, 2004
10.12	Letter agreement between the Company and Steven M. Paul, M.D. concerning retirement benefits	Incorporated by reference from Exhibit 10.14 to the Company's Report on Form 10-K for the year ended December 31, 2004
10.13	Arrangement regarding retirement benefits for Robert A. Armitage	Incorporated by reference from Exhibit 10.15 to the Company's Report on Form 10-K for the year ended December 31, 2004
10.14	Time Sharing Agreement between the Company and Sidney Taurel for use of corporate aircraft	Incorporated by reference from Exhibit 10.16 to the Company's Report on Form 10-K for the year ended December 31, 2004
10.15	Guilty Plea Agreement in <i>The United States District Court for the Eastern District of Pennsylvania, United States of America v. Eli Lilly and Company</i>	Attached
10.16	Settlement Agreement among the company and the United States of America, acting through the U. S. Department of Justice, Civil Division, and the U. S. Attorney's Office of the Eastern District of Pennsylvania, the Office of the Inspector General of the Department of Health and Human Services, TRICARE Management Activity, and the U. S. Office of Personnel Management, and certain individual relators	Attached
10.17	Corporate Integrity Agreement between the company and the Office of Inspector General of the Department of Health and Human Services	Attached
12	Statement re: Computation of Ratio of Earnings (Loss) to Fixed Charges	Attached
21	List of Subsidiaries	Attached
23	Consent of Registered Independent Public Accounting Firm	Attached
31.1	Rule 13a-14(a) Certification of John C. Lechleiter, Ph.D., Chairman of the Board and Chief Executive Officer	Attached
31.2	Rule 13a-14(a) Certification of Derica W. Rice, Senior Vice President and Chief Financial Officer	Attached
32	Section 1350 Certification	Attached

TRIPARTITE AGREEMENT**UNSECURED DEBT**

Eli Lilly and Company, Issuer

Citibank, N.A., Previous Trustee

INSTRUMENT OF RESIGNATION, APPOINTMENT AND ACCEPTANCE (the "Agreement") entered into as of the 13th day of September, 2007, among Eli Lilly and Company, an Indiana corporation (the "Issuer"), Citibank, N.A., a national banking association duly organized and existing under the laws of the United States of America ("Citibank"), and Deutsche Bank Trust Company Americas, a New York banking corporation ("DBTCA").

WITNESSETH

WHEREAS, the Issuer and Citibank entered into a certain Indenture dated as of February 1, 1991, as amended and supplemented (the "Indenture") with respect to the issuance from time to time of the following debt securities (collectively, the "Securities"):

ISSUE DESCRIPTION	PRINCIPAL OUTSTANDING	CUSIP No.
2.90% Notes Due 2008	\$ 300,000,000	532457AW8
6% Notes Due 2012	\$ 500,000,000	532457AU2
6.57% Notes due 2016	\$ 200,000,000	532457AN8
5.20% Notes due 2017	\$1,000,000,000	532457BB3
4.50% Notes Due 2018	\$ 200,000,000	532457AX6
7.125% Notes Due 2025	\$ 301,370,000	532457AM0
5.50% Notes Due 2027	\$ 700,000,000	532457AZ1
6.77% Notes Due 2036	\$ 286,000,000	532457AP3
5.55% Notes Due 2037	\$ 800,000,000	532457BA5

WHEREAS, Citibank has been acting as Trustee under the Indenture; and

WHEREAS, Section 7.08 of the Indenture provides that Citibank may resign at any time and be discharged of the trust created by the Indenture by giving written notice thereof to the Issuer

and to the Holders of Securities in the manner provided in Section 1.04 of the Indenture, and upon the appointment of and acceptance of such appointment by a successor trustee; and

WHEREAS, Citibank, pursuant to the provisions of Section 7.08 of the Indenture has given such written notice to the Issuer on the 31st day of July, 2007 and pursuant to the provisions of Section 1.04 of the Indenture has given such written notice to the Holders of Securities, a copy of which is attached hereto as Exhibit A, which resignation shall create a vacancy in the office of the Trustee; and

WHEREAS, Section 7.08 of the Indenture further provides that the Issuer shall promptly appoint a successor Trustee to fill a vacancy in the office of Trustee under the Indenture; and

WHEREAS, the Issuer wishes to appoint DBTCA as successor Trustee under the Indenture; and

WHEREAS, DBTCA is willing to accept such appointment as successor Trustee on the terms and conditions set forth herein and under the Indenture; and

WHEREAS, DBTCA is eligible to act as successor Trustee under the Indenture;

NOW, 'THEREFORE, pursuant to the provisions of the Indenture and in consideration of the covenants herein contained, it is agreed among the Issuer, Citibank and DBTCA as follows:

1. The Issuer hereby accepts the resignation of Citibank as Trustee and, pursuant to the authority vested in it by Section 7.08 of the Indenture and by resolution of its Board of Directors dated April 16, 2007 a copy of which is attached as Exhibit C, hereby appoints DBTCA as successor Trustee under the Indenture, with all the estate, properties, rights, powers, trusts, duties and obligations heretofore vested in Citibank as Trustee under the Indenture and designates the office of DBTCA presently located at 60 Wall Street, 27th Floor, New York, New York 10005, Attention: Trust and Securities Services, as the office or agency of the Issuer in New York, New York where the Securities may be presented for payment, conversion, registration of transfer and exchange. Such office shall also constitute the "Corporate Trust Office" as such term is used in the Indenture. Citibank's resignation as Trustee and DBTCA's appointment and acceptance as successor Trustee, shall be effective as of the opening of business on the date first above written upon the execution and delivery hereof by each of the parties hereto.
 2. The Issuer represents and warrants that:
 - (a) it is validly organized and existing under the laws of the jurisdiction of its incorporation;
 - (b) the Securities were validly and lawfully issued;
 - (c) to its knowledge, it has performed or fulfilled each covenant, agreement and condition on its part to be performed or fulfilled under the Indenture;
 - (d) it has no knowledge of the existence of any default, or Event of Default (as defined in the Indenture), or any event which upon notice or passage of time or both would become an Event of Default, under the Indenture;
 - (e) it has not appointed any paying agents under the Indenture other than Citibank;
-

- (f) it will continue to perform the obligations undertaken by it under the Indenture; and
- (g) promptly after the execution and delivery of this Instrument, it will mail or cause to be mailed to each securityholder a Notice of Appointment of Successor Trustee, of which is attached hereto as Exhibit B.

3. Citibank represents and warrants to DBTCA that:

- (a) it has made, or promptly will make available to DBTCA originals of all documents relating to the trust created by the Indenture and all information in the possession of its corporate trust department relating to the administration and status thereof and will furnish to DBTCA any of such documents or information DBTCA may select;
- (b) to the best of the knowledge of the officers of Citibank assigned to its corporate trust department, no default, or Event of Default (as defined in the Indenture), or any event which upon notice or lapse of time or both would become and Event of Default under the Indenture, exists;
- (c) it has lawfully and fully discharged its duties as Trustee under the Indenture; and;
- (d) no covenant or condition contained in the Indenture has been waived by Citibank or by the securityholders of the percentage in aggregate principal amount of the Securities required by the Indenture to effect any such waiver.

Citibank agrees to investigate from time to time as DBTCA may reasonably request, at the expense of the Issuer, the completeness or accuracy of any information in the Security Register which relates to any transaction occurring prior to the appointment of DBTCA as registrar for the securities.

4. DBTCA represents that it is eligible to act as Trustee under the provisions of the Indenture.

5. DBTCA hereby accepts its appointment as successor Trustee under the Indenture and accepts the trust created thereby, and assumes all rights, powers, duties and obligations of the Trustee under the Indenture. DBTCA will perform said trust and will exercise said rights, powers, duties, and obligations upon the terms and conditions set forth in the Indenture; *provided, however*, that it is understood and agreed by the parties hereto that DBTCA does not assume responsibility for or any liability in connection with any negligence or other misconduct on the part of Citibank or its agents in connection with Citibank's performance of the respective trusts, duties and obligations under the Indenture and it is further understood and agreed by the parties that the provisions of Section 7.05 of the Indenture shall survive, for the benefit of Citibank, Citibank's resignation hereunder.

6. DBTCA hereby accepts the designation of its Corporate Trust Office as the office or agency of the Issuer in New York, New York where the Securities may be presented for payment, and registration of transfer.

7. Pursuant to the written request of DBTCA and the Issuer hereby made, Citibank, upon payment of its outstanding charges, receipt of which is hereby acknowledged, confirms, assigns, transfers and sets over to DBTCA, as successor Trustee under the Indenture, upon the trust expressed in the Indenture, any and all moneys and all the rights, powers, duties and obligations which Citibank now holds under and by virtue of the Indenture.

8. The Issuer, for the purpose of more fully and certainly vesting in and confirming to DBTCA, as successor Trustee under the Indenture, said trusts, rights, powers, duties and obligations, at the request of DBTCA, hereby joins in the execution hereof.
 9. The Issuer, and Citibank hereby agree, upon the request of DBTCA, to execute, acknowledge and deliver such further instruments of conveyance and assurance and to do such other things as may be required for more fully and certainly vesting and confirming in DBTCA all of the properties, rights, powers, duties and obligations of Citibank as Trustee under the Indenture.
 10. Terms not otherwise defined in this Agreement shall have the definitions given thereto in the Indenture.
 11. The effect and meaning of this Agreement and the rights of all parties hereunder shall be governed by, and construed in accordance with, the laws of the State of New York.
 12. This Agreement may be simultaneously executed in any number of counterparts. Each such counterpart so executed shall be deemed to be an original, but all together shall constitute but one and the same instrument.
 13. The Issuer acknowledges that in accordance with Section 326 of the USA Patriot Act the successor Trustee, like all financial institutions is required to obtain, verify, and record information that identifies each person or legal entity that establishes a relationship or opens an account with Deutsche Bank Trust Company Americas. The Issuer; agrees that it will provide the successor Trustee with such information as it may request in order for the successor Trustee to satisfy the requirements of the USA Patriot Act.
-

IN WITNESS WHEREOF, Eli Lilly and Company has caused this instrument to be executed by one of its duly authorized officers; Citibank, N.A. has caused this instrument to be executed by one of its duly authorized officers; and Deutsche Bank Trust Company Americas has caused this instrument to be executed by one of its duly authorized officers, all as of the date first written above.

ELI LILLY AND COMPANY

By: /s/ Thomas W. Grein
Name: Thomas W. Grein
Title: Vice President and Treasurer

CITIBANK, N.A.

By: /s/ Wafaa Orfy
Name: Wafaa Orfy
Title: Vice President

DEUTSCHE BANK TRUST COMPANY AMERICAS

By: /s/ Richard L. Buckwalter
Name: Richard L. Buckwalter
Title: Director

By: /s/ Carol Ng
Name: Carol Ng
Title: Vice President

The Eli Lilly and Company Bonus Plan
(as amended January 1, 2009)

SECTION 1. PURPOSE

The purpose of The Eli Lilly and Company Bonus Plan is to encourage and promote eligible employees to create and deliver innovative pharmaceutical-based health care solutions that enable people to live longer, healthier and more active lives, to outgrow our competitors through a constant stream of pharmaceutical innovation, and to materially increase shareholder value. The Plan is designed to accomplish the following key objectives:

- a. motivate superior employee performance through the implementation of a performance-based bonus system for all eligible management employees, United States employees (including those in Puerto Rico) and other employees as may be designated from time to time;
- b. encourage eligible employees to take greater ownership of the company and provide "Answers that Matter" daily by creating a direct relationship between key company measurements and individual bonus payouts; and
- c. enable the Company to attract and retain employees that will be instrumental in driving sustained growth and performance of Eli Lilly and Company by providing a competitive bonus program that rewards outstanding performance consistent with the Company's mission, values and increased shareholder value.

The Plan is intended to satisfy the requirements for providing "performance-based" compensation under Section 162(m) of the Internal Revenue Code.

SECTION 2. DEFINITIONS

The following words and phrases as used in this Plan will have the following meanings unless a different meaning is clearly required by the context. Masculine pronouns will refer both to males and to females:

- 2.1 Applicable Year means the calendar year immediately preceding the year in which payment of the Company Bonus is payable pursuant to Section 6. For example, the Applicable Year for 2010 payout is January 1, 2009 through December 31, 2009.
- 2.2 Bonus Target means the percentage of Participant Earnings for each Participant as described in Section 5.6(a) below.
- 2.3 Committee means (i) with respect to the Executive Officers of Lilly, the Compensation Committee, the members of which will be selected by the Board of Directors of Lilly, from among its members; and (ii) with respect to all other Eligible Employees, the Compensation Committee of the Board of Directors or its designee. Each member of the Compensation Committee will, to the extent deemed necessary or appropriate by the

Board of Directors, satisfy the requirements of an “outside director” within the meaning of Section 162(m) of the Internal Revenue Code.

- 2.4 Company means Eli Lilly and Company and its subsidiaries.
- 2.5 Company Bonus means the amount of bonus compensation payable to a Participant as described in Section 5 below. Notwithstanding the foregoing, however, the Committee may determine, in its sole discretion, to reduce the amount of a Participant’s Company Bonus if such Participant becomes eligible to participate in such other bonus program of the Company as may be specifically designated by the Committee. Such reduction may be by a stated percentage up to and including 100% of the Company Bonus.
- 2.6 Company Performance Bonus Multiple means the amount as calculated in Sections 5.3 and 5.4 below.
- 2.7 Disabled means a Participant who (i) has become eligible for a payment under The Lilly Extended Disability Plan, assuming eligibility to participate in that plan, or (ii) for those employees ineligible to participate in The Lilly Extended Disability Plan, has become otherwise “disabled” under the applicable disability benefit plan or program for the Participant, or, in the event that there is no such disability benefit plan or program, has become disabled under applicable local law.
- 2.8 Earnings Per Share (EPS) means the diluted earnings per share of the Company as reported in the Company’s “Consolidated Statements of Income” in accordance with generally accepted accounting principles and Section 3.4 below.
- 2.9 Earnings Per Share Growth (EPS Growth) means the percentage increase in EPS in the Applicable Year compared to the prior year.
- 2.10 Effective Date means January 1, 2004, as amended from time to time.
- 2.11 Eligible Employee means:
- a. with respect to employees of Lilly, Lilly USA, LLC. or Lilly’s Puerto Rican subsidiaries, a person (1) who is employed as an employee by the Company on a scheduled basis of twenty (20) or more hours per week and is scheduled to work at least five (5) months per year; and (2) who is receiving compensation, including temporary illness pay under Lilly’s Illness Pay Program or similar short-term disability program, from the Company for services rendered as an employee. Notwithstanding anything herein to the contrary, the term “Eligible Employee” will not include:
- (1) a person who has reached Retirement with the Company;
 - (2) a person who is Disabled;
 - (3) a person who is a “leased employee” within the meaning of Section 414(n) of the Internal Revenue Code of 1986, as amended, or whose basic

compensation for services on behalf of the Company is not paid directly by the Company;

- (4) a person who is classified as a “Fixed Duration Employee”, as that term is used by Lilly;
- (5) a person who is classified as a special status employee because his employment status is temporary, seasonal, or otherwise inconsistent with regular employment status;
- (6) a person who is eligible to participate in the Eli Lilly and Company Premier Rewards Plan, a bonus or incentive plan for eligible employees of Elanco Animal Health or such other Company bonus or incentive program as may be specifically designated by the Committee or its designee; or
- (7) a person who submits to the Committee in writing a request that he not be considered eligible for participation in the Plan or is a member of the Board of Directors of Lilly unless he or she is also an Eligible Employee.
- (8) any other category of employees designated by the Committee in its discretion with respect to any Applicable Year.

- b. with respect to those employees who are employed by the Company, but not by Lilly, Lilly USA, LLC., or a Puerto Rican subsidiary, an employee of the Company designated by the Committee as a Participant in the Plan with respect to any Applicable 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, levels, subsidiaries or other appropriate classification will be Participants.
- c. Notwithstanding anything herein to the contrary, the term Eligible Employee will not include any person who is not so recorded on the payroll records of the Company, including any such person who is subsequently reclassified by a court of law or regulatory body as a common law employee of the Company. Consistent with the foregoing, and for purposes of clarification only, the term employee or Eligible Employee does not include any individual who performs services for the Company as an independent contractor or under any other non-employee classification.

2.12 Lilly means Eli Lilly and Company.

2.13 Lilly Executive Officer or Section 162(m) Participant means a Participant who has been designated by the Board of Directors of Lilly as an executive officer pursuant to Rule 3b-7 under the Securities Exchange Act of 1934, as amended. For purposes of this Plan, a Lilly Executive Officer will be considered a Section 162(m) Participant whether or not he is a “covered employee” under Section 162(m).

2.14 Participant means an Eligible Employee who is participating in the Plan.

2.15 Participant Earnings means (A) those amounts described below that are earned during the portion of the Applicable Year during which the employee is a Participant in the Plan:

- (i) regular compensation (including applicable deferred compensation amounts), overtime, shift premiums and other forms of additional compensation determined by and paid currently pursuant to an established formula or procedure;
- (ii) salary reduction contributions to The Lilly Employee 401(k) Plan or elective contributions under any similar tax-qualified plan that is intended to meet the requirements of Section 401(k) of the Internal Revenue Code or similar Company savings program;
- (iii) elective contributions to any cafeteria plan that is intended to meet the requirements of Section 125 of the Internal Revenue Code or other pre-tax contributions to a similar Company benefit plan;
- (iv) payments made under the terms of Lilly's Illness Pay Program or other similar Company or government-required leave program during an Applicable Year to a Participant who is on approved leave of absence and is receiving one hundred percent (100%) of his base pay; and
- (v) other legally-mandated or otherwise required pre-tax deductions from a Participant's base salary.

(B) The term "Participant Earnings" does not include:

- (i) compensation paid in lieu of earned vacation;
- (ii) amounts contributed to the Retirement Plan or any other qualified plan, except as provided in clause (A)(ii), above;
- (iii) payments made under the terms of Lilly's Illness Pay Program or other similar Company or government-required leave program during an Applicable Year to a Participant who is on approved leave of absence and is receiving less than the full amount of his base pay;
- (iv) amounts paid under this Plan or other bonus or incentive program of the Company;
- (v) payments made under The Lilly Severance Pay Plan or any other severance-type benefit (whether company-sponsored or mandated by law) arising out of or relating to a Participant's termination of employment;
- (vi) payments based upon the discretion of the Company;
- (vii) in the case of a person employed by a Lilly subsidiary, foreign service, cost of living, or other allowances that would not be paid were the person employed by Lilly;
- (viii) amounts paid as commissions, sales bonuses, or Market Premiums (as defined under the Retirement Plan); or
- (ix) earnings with respect to the exercise of stock options or vesting of restricted stock.

- 2.16 Performance Benchmarks mean the amounts as calculated in Section 5.3 below. The Performance Benchmarks will be established after considering expected pharmaceutical peer group performance and based on performance measures as described in Section 5.2.
- 2.17 Plan means The Eli Lilly and Company Bonus Plan as set forth herein and as hereafter modified or amended from time to time. The Plan is an incentive compensation program and is not subject to the Employee Retirement Income Security Act of 1974, as amended (“ERISA”), pursuant to Department of Labor Regulation Section 2510.3.
- 2.18 Plant Closing means the closing of a plant site or other Company location that directly results in termination of employment.
- 2.19 Reduction in Workforce means the elimination of a work group, functional or business unit or other broadly applicable reduction in job positions that directly results in termination of employment.
- 2.20 Retirement means the cessation of employment upon the attainment of age fifty-five with ten years of service (55 and 10), age sixty-five with five years of service (65 and 5) or at least eighty (80) points, as determined by the provisions of the Retirement Plan as amended from time to time, assuming eligibility to participate in that plan. For persons who are not participants in the Retirement Plan, Retirement means the cessation of employment as a retired employee under the applicable retirement benefit plan or program as provided by the Company or applicable law.
- 2.21 Retirement Plan means The Lilly Retirement Plan.
- 2.22 Sales means, for any Applicable Year, the consolidated net sales of the Company as set forth in the “Consolidated Statements of Income” as reported by the Company in accordance with generally accepted accounting principles and Section 3.4 below.
- 2.23 Sales Growth means the percentage increase in Sales in the Applicable Year compared to the prior year.
- 2.24 Section 162(m) means Section 162(m) of the Internal Revenue Code of 1986, as amended.
- 2.25 Service means the aggregate time of employment of an Eligible Employee by the Company.

SECTION 3. ADMINISTRATION

- 3.1 Committee. The Plan will be administered by the Compensation Committee of the Board of Directors of Eli Lilly and Company or, if the name of the Compensation Committee is changed, the Plan will be administered by such successor committee. For all Eligible Employees other than Lilly Executive Officers, the Compensation Committee may delegate all or a portion of its responsibilities within its sole discretion by resolution. Any reference in this Plan to the Committee or its authority will be deemed to include such designees (other than with respect to Lilly Executive Officers or a member of the Board of Directors or for purposes of Section 9).

- 3.2 **Powers of the Committee.** The Committee will have the right 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. The Committee will have authority to adopt, amend and rescind rules consistent with the Plan, to make exceptions in particular cases to the rules of eligibility for participation in the Plan (except with respect to Lilly Executive Officers), and to delegate authority for approval of participation of any Eligible Employee except for Lilly Executive Officers or a member of the Board of Directors. The Committee will take all necessary action to establish annual Performance Benchmarks and approve the timing of payments, as necessary.
- 3.3 **Certification of Results.** Before any amount is paid under the Plan, the Committee will certify in writing the calculation of EPS, EPS Growth, Sales and Sales Growth (or other applicable performance measures) for the Applicable Year and the satisfaction of all other material terms of the calculation of the Company Performance Bonus Multiple and Company Bonus.
- 3.4 **Adjustments for Significant Events.** Not later than 90 days after the beginning of an Applicable Year, the Committee may specify with respect to Company Bonuses for the Applicable Year that the performance measures described in Section 5.2 will be determined before the effects of acquisitions, divestitures, restructurings or special charges or gains, 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 Lilly Executive Officers.
- 3.5 **Finality of Committee Determinations.** Any determination by the Committee of Sales, Sales Growth, EPS, EPS Growth, any other performance measure, Performance Benchmarks and the level and entitlement to Company Bonus, and any interpretation, rule, or decision adopted by the Committee under the Plan or in carrying out or administering the Plan, will be final and binding for all purposes and upon all interested persons, their heirs, and personal representatives. The Committee may rely conclusively on determinations made by Lilly and its auditors to determine Sales, Sales Growth, EPS, EPS Growth and related information for administration of the Plan, whether such information is determined by the Company, auditors or a third-party vendor engaged specifically to provide such information to the Company. This subsection is not intended to limit the Committee's power, to the extent it deems proper in its discretion, to take any action permitted under the Plan.

SECTION 4. PARTICIPATION IN THE PLAN

- 4.1 **General Rule.** Only Eligible Employees may participate in and receive payments under the Plan.
- 4.2 **Commencement of Participation.** An Eligible Employee will become a Participant in the Plan as follows: (i) in the case of Eligible Employees under Section 2.11(a), on the date

on which the individual completes at least one hour of employment as an Eligible Employee within the United States or Puerto Rico, and (ii) in the case of Eligible Employees under Section 2.11(b), on the date as of which the Committee has designated the individual to become a Participant in the Plan.

- 4.3 Termination of Participation. An Eligible Employee will cease to be a Participant upon termination of employment with the Company for any reason, or at the time he otherwise ceases to be an Eligible Employee under the Plan.

SECTION 5. DEFINITION AND COMPUTATION OF COMPANY BONUS

- 5.1 Computation for Eligible Employees. Company Bonus amounts will depend significantly on Company performance as well as Participants' individual performance for certain Eligible Employees. As more specifically described below, a Participant's Company Bonus is calculated by multiplying the Participant's Bonus Target by his Participant Earnings and the Company Performance Bonus Multiple. For eligible management and Lilly employees and those Participants designated by the Committee, individual performance will also impact the Company Bonus calculation, as described in Section 5.6(c) below. Company Bonuses are paid out to eligible Participants in the manner provided below.
- 5.2 Establishment of Performance Measures. Not later than 90 days after the beginning of each Applicable Year, the Committee will, in its sole discretion, determine appropriate performance measures for use in calculating Company Bonus amounts. These performance measures may include Sales Growth, EPS Growth, growth in net income, return on assets, return on equity, total shareholder return, EVA, MVA or any of the foregoing before the effect of acquisitions, divestitures, accounting changes, restructurings and special charges or gains (determined according to objective criteria established by the Committee not later than ninety (90) days after the beginning of the Applicable Year). Unless otherwise specified in a written resolution adopted by the Committee for the Applicable Year, the Committee will use EPS Growth and Sales Growth, in each case before the effect of acquisitions, divestitures, accounting changes, restructurings and special charges or gains (determined as described above) as performance measures.
- 5.3 Establishment of Performance Benchmarks. Not later than 90 days after the beginning of each Applicable Year, the Committee will establish Performance Benchmarks for the Company based on the performance measures described in Section 5.2 above. Unless otherwise specified in a written resolution adopted by the Committee for the Applicable Year, the Performance Benchmarks will correspond with EPS Growth and Sales Growth amounts for the Applicable Year, established after considering expected pharmaceutical peer group performance. The Performance Benchmarks will correspond to EPS Growth and Sales Growth multiples equal to 1.0. The Committee will also adopt a formula that will determine the extent to which the performance measure multiples will vary as the Company's actual results vary from the Performance Benchmarks.
- 5.4 Company Performance Bonus Multiple. Unless otherwise specified in a written resolution adopted by the Committee not later than 90 days after the beginning of the

Applicable Year, the Company Performance Bonus Multiple is equal to the product of the EPS Growth multiple and 0.75 plus the product of the Sales Growth multiple and 0.25 (i.e., Company Performance Bonus Multiple = (EPS Growth multiple * 0.75) + (Sales Growth multiple * 0.25)).

5.5 Company Performance Bonus Multiple Threshold and Ceiling: Notwithstanding Sections 5.3 and 5.4, the Company Performance Bonus Multiple will not be less than 0.25 or greater than 2.0 in an Applicable Year. If the calculations described in Sections 5.3 and 5.4 above result in a number that is less than 0.25, the Company Performance Bonus Multiple will equal 0.25 for the Applicable Year. If the calculations described in Sections 5.3 and 5.4 above result in a multiple greater than 2.0, the Company Performance Bonus Multiple will equal 2.0 for the Applicable Year. Notwithstanding the foregoing, the Committee may reduce the Company Performance Bonus Multiple (including but not limited to a reduction to below 0.25) for some or all Eligible Employees, in its discretion.

5.6 Participant Company Bonus.

a. Bonus Target. Not later than 90 days after the beginning of the Applicable Year, the Bonus Target for each Participant, whether such Participant is designated on an individual basis or by specified job categories, classifications, levels, subsidiaries or other appropriate classification, will be determined by the Committee on a basis that takes into consideration a Participant's pay grade level and job responsibilities. The Bonus Target for each Participant for the Applicable Year will be expressed as a percentage of Participant Earnings as of December 31 of the Applicable Year. No later than early in the Applicable Year, each Participant will receive information regarding the Participant's Bonus Target. In the event that a Participant's pay grade level changes during the Applicable Year (e.g., because of promotion, demotion or otherwise), the Participant's Bonus Target will be prorated based on the Bonus Target applicable to each pay grade level (with related job responsibilities) and the percentage of time that the Participant is employed at each pay grade level during the Applicable Year.

b. Company Bonus Calculation. Except as described in Section 5.6(c) below, a Participant's Company Bonus will equal the product of the Company Performance Bonus Multiple and the Participant's Bonus Target and the Participant's Earnings.

c. Adjustment for Performance Multiplier, if Applicable.

Notwithstanding anything herein to the contrary, all eligible management employees (except Lilly Executive Officers), United States employees and other employees as may be designated from time to time by the Committee are subject to individual performance multipliers. For all such Participants subject to an individual performance multiplier, the amount calculated in Section 5.6(b) above will be adjusted based on the Participant's performance rating at the end of the Applicable Year as described below. Not later than 90 days after the beginning of the Applicable Year, the Committee will determine applicable performance multipliers for the applicable performance rating system in effect for the Participant. For each such Participant, the performance rating will be determined by the Participant's supervision.

In the event that a Participant does not receive a year-end performance rating, but is otherwise eligible for a Company Bonus, the amount calculated in Section 5.6(b) will be multiplied by 1.0 so that the Participant's actual Company Bonus will be the amount calculated in Section 5.6(b) above.

- 5.7 Conditions on Company Bonus. Payment of any Company Bonus is neither guaranteed nor automatic. A Participant's Company Bonus is not considered to be any form of compensation, wages, or benefits, unless and until paid.
- 5.8 Required Employment. Except as provided below in this Section 5.8 or as otherwise designated by the Committee, if a Participant is not employed by the Company on the last day of the Applicable Year, or is otherwise not an Eligible Employee on that date, the Participant is not entitled to any Company Bonus payment under this Plan for that Applicable Year.
- a. Leaves of Absence. A Participant who, on the last day of the Applicable Year, is on approved leave of absence under the Family and Medical Leave Act of 1993, military leave under the Uniformed Services Employment and Reemployment Rights Act, or such other approved leave of absence will be considered to be an Eligible Employee on that date for purposes of this Plan.
 - a. Transfer. An employee who is a Participant in this Plan for a portion of the Applicable Year and then transfers to a position within the Company in which he is ineligible to participate in this Plan, but who remains employed by the Company on the last day of the Applicable Year, will be treated as satisfying the last-day-of-Applicable Year requirement for purposes of this Plan. In that event, his Company Bonus will be based on his Participant Earnings for the portion of the Applicable Year in which the employee was a Participant in the Plan.
 - b. Retirement, Disability or Death. Except as described below, a Participant who was an Eligible Employee for some portion of the Applicable Year and then takes Retirement, becomes and remains Disabled through the end of the Applicable Year, or dies during the Applicable Year will be considered to satisfy the last-day-of-Applicable-Year requirement described in this Section 5.8 for purposes of this Plan. Notwithstanding the foregoing, an Eligible Employee in the United States who has not received a year-end performance rating and (1) is on employment probation (or its equivalent outside the United States) for unsatisfactory performance and takes Retirement in lieu of a termination of employment; or (2) takes Retirement in lieu of termination of employment because of an immediately terminable offense (e.g. absence of three days without notice, insubordination, violation of substance abuse policy, possession of firearms, misconduct) will not be considered to satisfy the last day of Applicable Year requirement.
 - c. Reallocation, Medical Reassignment, Plant Closing or Reduction in Workforce. A Participant who was an Eligible Employee for some portion of the Applicable Year and whose employment is terminated as a result of his

failure to locate a position following his reallocation or medical reassignment in the United States, or a Plant Closing or Reduction in Workforce will be considered to satisfy the last-day-of-Applicable Year requirement described in this Section 5.8 for purposes of this Plan. The Committee or its designee's determination regarding whether a Participant's termination is a direct result of either a Plant Closing or a Reduction in Workforce will be final and binding.

- d. **Notice of Resignation.** In addition, a Participant who submits a notice of resignation from employment with the Company prior to the end of the Applicable Year and whose effective date of resignation is two (2) weeks or less from the date of notice of resignation will be considered employed by the Company for purposes of this Plan until the end of his specified notice period.
- 5.9 **New Participants.** If an Eligible Employee began participation in the Plan during an Applicable Year and is eligible for a Company Bonus, his Company Bonus will be based on Participant Earnings earned after the employee became a Participant. An Eligible Employee who became assigned to a position eligible for a Company Bonus at any time other than the first of the month will become a Participant the first of the following month.
- 5.10 **Section 162(m) Requirements, Bonus Maximum.** In the case of Lilly Executive Officers, all determinations necessary for computing a Company Bonus for the Applicable Year, including establishment of all components of EPS, EPS Growth, Sales, Sales Growth, Company Performance Bonus Multiple and Bonus Target percentages, shall be made by the Committee not later than 90 days after the commencement of the Applicable Year. As and to the extent required by Section 162(m), the terms of a Company Bonus for a Lilly Executive Officer must state, in terms of an objective formula or standard, the method of computing the amount of compensation payable to the Lilly Executive Officer, 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 Company Bonus that may be payable to a Lilly Executive Officer in respect of any Applicable Year will be \$7 million.

SECTION 6. TIME OF PAYMENT

- 6.1 **General Rule.** Payment under the Plan will be made in the year following the Applicable Year on or prior to March 15 of such year.
- 6.2 **Terminated Employee.** Except as provided in Section 5.8 above, in the event an Eligible Employee's employment with the Company ends for any reason prior to the last day of the Applicable Year, he will not receive any Company Bonus for the Applicable Year.
- 6.3 **Deceased Eligible Employee.** In the event an Eligible Employee dies before payment under the Plan is made, the Committee may, in its sole discretion, authorize the Company to pay to his personal representative or beneficiary an amount not to exceed the amount established by the Committee to reflect the payment accrued at the date of death. Any

such payment would be paid consistent with the timing requirements described in subsection 6.1 above.

SECTION 7. ADMINISTRATIVE GUIDELINES

- 7.1 Establishment and Amendment by the Committee. The Committee may establish objective and nondiscriminatory written guidelines for administering those provisions of the Plan that expressly provide for the determination of eligibility, Company Bonus or benefits on the basis of rules established by the Committee. The Committee may, from time to time, amend or supplement the administrative guidelines established in accordance with this subsection 7.1. The administrative guidelines established or amended in accordance with this subsection 7.1 will not be effective to the extent that they materially increase the Plan's liability, or to the extent that they are inconsistent with, or purport to amend, any provision of the Plan set forth in a document other than such administrative guidelines.
- 7.2 Amendment by Board of Directors. Any administrative guidelines established by the Committee pursuant to subsection 7.1 may be amended or revoked by the Board of Directors, either prospectively or retroactively, in accordance with the general amendment procedures set forth in section 9 below.

SECTION 8. MISCELLANEOUS

- 8.1 No Vested Right. No employee, participant, beneficiary, or other individual will have a vested right to a Company Bonus or any part thereof until payment is made to him under Section 6.
- 8.2 No Employment Rights. No provision of the Plan or any action taken by the Company, the Board of Directors of the Company, or the Committee will give any person any right to be retained in the employ of the Company. The right and power of the Company to dismiss or discharge any Participant for any reason or no reason, with or without notice, is specifically reserved.
- 8.3 No Adjustments. After the certification of the calculation of EPS, EPS Growth, Sales, Sales Growth and any other material terms of the calculation of the Company Performance Bonus Multiple and Company Bonus for the Applicable Year as described in Section 3.3 above, no adjustments will be made to reflect any subsequent change in accounting, the effect of federal, state, or municipal taxes later assessed or determined, or otherwise. Notwithstanding the foregoing, the Company reserves the right to and, in appropriate cases, will, seek restitution of any Company Bonus awarded to a Lilly Executive Officer if:
- a. The amount of the Company Bonus was calculated based upon the achievement of certain financial results that were subsequently the subject of a restatement of all or a portion of the Company's financial statements;

- b. The Lilly Executive Officer engaged in intentional misconduct that caused or partially caused the need for such a restatement; and
- c. The amount of the Company Bonus that would have been awarded to the Lilly Executive Officer had the financial results been properly reported would have been lower than the amount actually awarded.

This subsection is not intended to limit the Company's power to take such action as it deems necessary to remedy the misconduct, prevent its recurrence and, if appropriate, based on all relevant facts and circumstances, punish the wrongdoer in a manner it deems appropriate.

- 8.4 Other Representations. Nothing contained in this Plan, and no action taken pursuant to its provisions, will create or be construed to create a trust of any kind, or a fiduciary relationship between the Company and any employee, participant, beneficiary, legal representative, or any other person. Although Participants generally have no right to any payment from this Plan, to the extent that any Participant acquires a right to receive payments from the Company under the Plan, such right will be no greater than the right of an unsecured general creditor of the Company. All payments to be made hereunder will be paid from the general funds of the Company and no special or separate fund will be established, and no segregation of assets will be made, to assure payment of such amount.
- 8.5 Tax Withholding. The Company will make such provisions and take such steps as it may deem necessary or appropriate for the withholding of all federal, state, local, and other taxes required by law to be withheld with respect to Company Bonus payments under the Plan, including, but not limited to, deducting the amount required to be withheld from the amount of cash otherwise payable under the Plan, or from salary or any other amount then or thereafter payable to an employee, Participant, beneficiary, or legal representative.
- 8.6 Currency. The Company Bonus will be based on the currency in which the highest portion of base pay is regularly paid. The Committee will determine the appropriate foreign exchange conversion methodology in its discretion.
- 8.7 Effect of Plan on other Company plans. Nothing contained in this Plan is intended to amend, modify, terminate, or rescind other benefit or compensation plans established or maintained by the Company. Whether and to what extent a Participant's Company Bonus is taken into account under any other plan will be determined solely in accordance with the terms of such plan.
- 8.8 Construction. This Plan and all the rights thereunder will be governed by, and construed in accordance with, the laws of the state of Indiana, without reference to the principles of conflicts of law thereof.
- 8.9 Notice. Any notice to be given to the Company or Committee pursuant to the provisions of the Plan will be in writing and directed to Secretary, Eli Lilly and Company, Lilly Corporate Center, Indianapolis, IN 46285.

SECTION 9. AMENDMENT, SUSPENSION, OR TERMINATION

The Board of Directors of the Company will have the right to amend, modify, suspend, revoke, or terminate the Plan, in whole or in part, at any time and without notice, by written resolution of the Board of Directors. The Committee also will have the right to amend the Plan, except that the Committee may not amend this Section 9. 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 by the Company's stockholders of the Plan or any amendments to the Plan or any aspect of the Plan or Plan amendments. Any such approval shall be obtained in a separate vote of stockholders, with approval by a majority of the votes cast on the issue, including abstentions to the extent abstentions are counted as voting under applicable state law and the Articles of Incorporation and By-laws of the Company. To the extent deemed necessary or advisable by the Board of Directors to comply with Section 162(m), the material terms of the performance measures used in calculating Company Bonus amounts will be disclosed to and reapproved by the stockholders of the Company no later than the Company's 2014 annual meeting.

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

UNITED STATES OF AMERICA

:

v.

:

CRIMINAL NO.

ELI LILLY AND COMPANY

:

GUILTY PLEA AGREEMENT

Under Federal Rule of Criminal Procedure 11(c)(1)(C), the government, the defendant, Eli Lilly and Company (hereinafter "Eli Lilly"), and Eli Lilly's counsel enter into the following guilty plea agreement. Any reference to the United States or the government in this agreement shall mean the Office of the United States Attorney for the Eastern District of Pennsylvania and the Office of Consumer Litigation of the Department of Justice.

1. Eli Lilly agrees to plead guilty to Count One of an Information, waiving prosecution by indictment, charging it with the introduction into interstate commerce of drugs that were misbranded, a misdemeanor, in violation of 21 U.S.C. §§ 331(a), 333(a)(1) and 352(f)(1), and not to contest forfeiture as set forth in the notice of forfeiture seeking forfeiture of \$100,000,000 in substitute assets, in lieu of the drugs which were promoted illegally and are no longer available, all arising from Eli Lilly's illegal promotion of its drug Zyprexa in the United States between September 1999 and March 31, 2001. Eli Lilly further acknowledges its waiver of rights, as set forth in Exhibit A to this agreement.

2. The parties agree that this plea agreement is made pursuant to Fed.R.Crim.P. 11(c)(1)(C) and that the following specific sentence is the appropriate disposition

of this case. Taking into consideration the factors set forth in 18 U.S.C. §§ 3553(a) and 3572, the agreed upon sentence is as follows:

A. Eli Lilly agrees to pay the special assessment in the amount of \$125 on the date of sentencing.

B. Eli Lilly agrees to pay \$615,000,000 to resolve this Information, of which \$515,000,000 will be applied as a criminal fine, and \$100,000,000 will be applied as substitute assets to satisfy the forfeiture obligation described in paragraph 2(C) below. Eli Lilly will pay these amounts within 10 business days of the date of sentencing. Eli Lilly and the government agree that this fine and forfeiture represent a fair and just resolution of all issues associated with loss, fine and forfeiture calculations.

C. Eli Lilly agrees that as a result of its acts or omissions, the forfeitable property, that is the drugs which were promoted off-label, are no longer available for forfeiture as the drugs cannot be located or have been transferred, sold or deposited with a third party, or otherwise disposed of, within the meaning of federal law. As a result, Eli Lilly agrees to the entry and satisfaction of a judgment and preliminary order of forfeiture on the date of the guilty plea, forfeiting to the United States the sum of \$100,000,000 as substitute assets for the pertinent drugs. Eli Lilly agrees that, within 10 business days of the date of sentencing, Eli Lilly will make payment to the United States, by means of a wire transfer to the United States Marshal Service or check payable to same, in the amount of \$100,000,000, this amount representing substitute assets of the offense for which it is pleading guilty, subject to forfeiture in full satisfaction of the judgment and preliminary order of forfeiture.

D. In light of the anticipated Corporate Integrity Agreement, Eli Lilly will not be placed on probation.

3. Eli Lilly and the United States intend to execute a separate civil settlement agreement. Eli Lilly waives any and all defenses and objections in this matter or in that civil proceeding which might be available under the Double Jeopardy and Excessive Fines clauses of the Eighth Amendment. The parties agree that, in light of the separate civil settlement agreement, and to avoid unduly complicating and prolonging the sentencing process, the appropriate disposition of this case does not include a restitution order.

4. Eli Lilly waives any claim under the Hyde Amendment, 18 U.S.C. § 3006A (Statutory Note), for attorney's fees and other litigation expenses arising out of the investigation or prosecution of this matter.

5. Eli Lilly understands, agrees and has had explained to it by counsel that the Court may impose the following statutory maximum sentence: a fine of \$200,000, or twice the gross gain or gross loss, whichever is greater; a special assessment of \$125; restitution as ordered by the Court; and a five-year term of Court supervision; in addition, forfeiture may be ordered. Eli Lilly further understands that the terms and conditions of any Court supervision may be changed, and extended, by the Court if Eli Lilly violates any of the terms and conditions of that supervision.

6. With respect to Eli Lilly's conduct:

A. The parties stipulate to the following facts and basis for the plea, criminal fine and forfeiture:

- (1) Eli Lilly marketed Zyprexa, which was a drug within the meaning of 21 U.S.C. § 321(g)(1).
- (2) Shipments of a drug in interstate commerce must be accompanied by labeling bearing adequate directions for use for each of the drug's intended uses.
- (3) In September 1996, Zyprexa was approved by FDA for the short term management of the manifestations of psychotic disorders. In March 2000, FDA approved the addition of the subheading "schizophrenia" to the short term management of the manifestations of psychotic disorders. Also in March 2000, FDA approved Zyprexa for the short-term treatment of acute manic episodes associated with Bipolar I Disorder. In November 2000, FDA approved new labeling for Zyprexa for the short term treatment of schizophrenia in place of the management of the manifestations of psychotic disorders. Also in November 2000, FDA approved Zyprexa for maintaining treatment response in schizophrenic patients who had been stable for approximately eight weeks and were then followed for a period of up to eight months.
- (4) Between September 1999 and March 31, 2001, Eli Lilly promoted Zyprexa in elderly populations as treatment for

dementia, including Alzheimer's dementia. Zyprexa is not approved by the FDA for treatment of dementia or Alzheimer's dementia. Eli Lilly's promotion of Zyprexa for these additional intended uses violated 21 U.S.C. § 352(f)(1), because Zyprexa's labeling did not bear adequate directions for each of the drug's intended uses.

B. The United States contends that, as a matter of relevant conduct, the conduct which forms the basis for this plea agreement, as set forth in subsection (A) above, continued past March 31, 2001. Eli Lilly does not admit that this conduct extended past March 31, 2001.

7. Eli Lilly and the United States retain the right to withdraw from this guilty plea agreement, and this plea agreement will be null and void, if the civil settlement agreement and Corporate Integrity Agreement are not executed prior to the filing of the Information.

8. Except as provided herein, the United States agrees that, other than the charges in the Information in this case, it will not bring any other criminal charges against Eli Lilly, its present and former parents, affiliates, divisions, and subsidiaries; their predecessors, successors and assigns for conduct which (A) falls within the scope of the criminal investigation in the Eastern District of Pennsylvania relating to Eli Lilly's drug Zyprexa; or (B) was known to the United States Attorney's Office for the Eastern District of Pennsylvania or the Office of Consumer Litigation of the Department of Justice as of the date of the execution of this plea agreement, and which concerned the sale, promotion, or marketing of Zyprexa in the United

States. The non-prosecution provisions of this paragraph are binding on the Office of the United States Attorney for the Eastern District of Pennsylvania, the Office of Consumer Litigation of the Department of Justice, and the United States Attorney's Offices for each of the other 93 judicial districts of the United States. The non-prosecution provisions are also binding on the Criminal Division of the United States Department of Justice, except that the investigation of Eli Lilly and its affiliates, divisions, and subsidiaries, being conducted by the Fraud Section of the Criminal Division regarding possible violations of the Foreign Corrupt Practices Act and related offenses in connection with the sales and marketing of Eli Lilly's products to foreign customers is specifically excluded from the non-prosecution provisions and release provided by this paragraph and agreement. Attached as Exhibit B is a copy of the letter to Acting United States Attorney Laurie Magid from the Assistant Attorney General, Criminal Division, Department of Justice, authorizing this agreement.

9. Eli Lilly understands that this guilty plea agreement does not bind any other government agency, or any component of the Department of Justice except as specified in paragraph 8 of this guilty plea agreement. Further, Eli Lilly understands that the United States takes no position as to the proper tax treatment of any of the payments made by Eli Lilly pursuant to this plea agreement, the civil settlement agreement, or the Corporate Integrity Agreement referenced in this plea agreement.

10. Eli Lilly agrees to waive the statute of limitations, and any other time-related defense, to the charge to which it is agreeing to plead guilty under this plea agreement, provided that the guilty plea is accepted by the Court.

11. Eli Lilly understands and agrees that, should it withdraw its plea or if Eli Lilly's guilty plea is not accepted by the Court for whatever reason, Eli Lilly may thereafter be prosecuted for any criminal violation of which the United States has knowledge arising out of this investigation, notwithstanding the expiration of any applicable statute of limitations between the time period when Eli Lilly signed this plea agreement and either Eli Lilly's withdrawal of its plea or the Court's rejection of its plea. In that event, Eli Lilly agrees that it will not raise the expiration of any statute of limitations as a defense to any such prosecution, except to the extent that the statute of limitations would have been a defense pursuant to the terms of a Tolling Agreement between the parties effective October 7, 2008, all subsequent extensions of the Tolling Agreement, and this paragraph.

12. In exchange for the undertakings made by the government in entering this plea agreement, Eli Lilly voluntarily and expressly waives all rights to appeal or collaterally attack the defendant's conviction, sentence, or any other matter relating to this prosecution, whether such a right to appeal or collateral attack arises under 18 U.S.C. § 3742, 28 U.S.C. § 1291, 28 U.S.C. § 2255, or any other provision of law. This waiver is not intended to bar the assertion of constitutional claims that the relevant case law holds cannot be waived.

13. Eli Lilly also waives all rights, whether asserted directly or by a representative, to request or receive from any department or agency of the United States any records pertaining to the investigation or prosecution of this case, including without limitation any records that may be sought under the Freedom of Information Act, 5 U.S.C. § 552, or the Privacy Act, 5 U.S.C. § 552a.

14. Eli Lilly is satisfied with the legal representation provided by its lawyers; Eli Lilly and its lawyers have fully discussed this guilty plea agreement; and Eli Lilly is agreeing to plead guilty because Eli Lilly admits that it is guilty of the misdemeanor described in paragraph 1.

15. Eli Lilly will acknowledge acceptance of this guilty plea agreement by the signature of its counsel and of an authorized corporate officer. Eli Lilly shall provide to the government for attachment as Exhibit C to this plea agreement a notarized resolution by Eli Lilly's Board of Directors authorizing the corporation to enter a plea of guilty, and authorizing a corporate officer to execute this agreement.

16. If acceptable to the Court, the parties agree to waive the presentence investigation and report pursuant to Rule 32(c)(1) of the Federal Rules of Criminal Procedure, and ask that Eli Lilly be sentenced at the time the guilty plea is entered.

17. It is agreed that the parties' guilty plea agreement contains no additional promises, agreements or understandings other than those set forth in this written guilty plea agreement, and that no additional promises, agreements or understandings will be entered into unless in writing and signed by all parties.

SIGNATURES FOR THE UNITED STATES

GREGORY G. KATSAS
Assistant Attorney General
Civil Division
United States Department of Justice

/s/ Eugene M. Thirolf
EUGENE M. THIROLF
Director, Office of Consumer Litigation
United States Department of Justice

/s/ Jeffrey I. Steger
JEFFREY I. STEGER
Trial Attorney
Office of Consumer Litigation
United States Department of Justice

/s/ Ross S. Goldstein
ROSS S. GOLDSTEIN
Trial Attorney
Office of Consumer Litigation
United States Department of Justice

/s/ Laurie Magid
LAURIE MAGID
Acting United States Attorney

/s/ Linda Dale Hoffa
LINDA DALE HOFFA
Chief, Criminal Division
Assistant United States Attorney

/s/ Catherine Votaw
CATHERINE VOTAW
Assistant United States Attorney

/s/ Marilyn S. May
MARILYN S. MAY
Assistant United States Attorney

/s/ Denise S. Wolf
DENISE S. WOLF
Assistant United States Attorney

DATE: 1-14-09

SIGNATURE FOR ELI LILLY

DATE: 14 Jan. 2009

/s/ Robert A. Armitage
ROBERT A. ARMITAGE
Senior Vice President and General Counsel
Eli Lilly and Company

SIGNATURES OF ELI LILLY'S ATTORNEYS

DATE: 1/14/09

/s/ Nina M. Gussack
NINA M. GUSSACK
Pepper Hamilton LLP
Counsel for Defendant

DATE: 1/14/09

/s/ Thomas M. Gallagher
THOMAS M. GALLAGHER
Pepper Hamilton LLP
Counsel for Defendant

DATE: 1/14/09

/s/ Paul E. Kalb
PAUL E. KALB
Sidley Austin LLP
Counsel for Defendant

DATE: 1/14/09

/s/ Bradford A. Berenson
BRADFORD A. BERENSON
Sidley Austin LLP
Counsel for Defendant

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA

:

v.

:

CRIMINAL NO.

ELI LILLY AND COMPANY

:

ACKNOWLEDGMENT OF RIGHTS

Eli Lilly and Company ("Eli Lilly"), through its properly authorized officer, hereby acknowledges that it has certain rights that it will be giving up by pleading guilty.

1. Eli Lilly understands that it does not have to plead guilty.
 2. Eli Lilly may plead not guilty and insist upon a trial.
 3. At that trial, Eli Lilly understands:
 - a. that Eli Lilly would have the right to be tried by a jury that would be selected from the Eastern District of Pennsylvania and that along with its attorney, Eli Lilly would have the right to participate in the selection of that jury;
 - b. that the jury could only convict Eli Lilly if all twelve jurors agreed that they were convinced of Eli Lilly's guilt beyond a reasonable doubt;
 - c. that the government would have the burden of proving Eli Lilly's guilt beyond a reasonable doubt and that Eli Lilly would not have to prove anything;
 - d. that Eli Lilly would be presumed innocent unless and until such time as the jury was convinced beyond a reasonable doubt that the government had proven that Eli Lilly was guilty;
 - e. that Eli Lilly would have the right to be represented by a lawyer at this trial and at any appeal following the trial, and that if Eli Lilly could not afford to hire a lawyer, the court would appoint one for Eli Lilly free of charge;
 - f. that through Eli Lilly's lawyer Eli Lilly would have the right to confront and cross-examine the witnesses against Eli Lilly;
-

- g. that Eli Lilly could call witnesses to testify in its defense if Eli Lilly wanted to, and Eli Lilly could subpoena witnesses for this purpose if Eli Lilly wanted to; and
 - h. that Eli Lilly would not have to call witnesses to testify or otherwise present any defense if Eli Lilly did not want to, and that if Eli Lilly did not present any evidence, the jury could not hold that against Eli Lilly.
4. Eli Lilly understands that if Eli Lilly pleaded guilty, there will be no trial and Eli Lilly would be giving up all of the rights listed above, as well as any other rights associated with the trial process arising under statute, common-law, or judicial precedent.
 5. Eli Lilly understands that if Eli Lilly decides to enter a plea of guilty, the judge will ask Eli Lilly representatives questions under oath, and that if any of those representatives lie on behalf of Eli Lilly in answering those questions, those persons could be prosecuted for the crime of perjury, that is, for lying under oath.
 6. Eli Lilly understands that if Eli Lilly pleads guilty, Eli Lilly has waived its right to appeal, except as set forth in appellate waiver provisions of the plea agreement.
 7. Understanding that Eli Lilly has all these rights and that by pleading guilty Eli Lilly is giving them up, Eli Lilly still wishes to plead guilty.

/s/ Robert A. Armitage

ROBERT A. ARMITAGE
Senior Vice President and General Counsel
Eli Lilly and Company

/s/ Paul E. Kalb

PAUL E. KALB
Sidley Austin LLP
Counsel for Defendant

Exhibit B



Acting Assistant Attorney General

U.S. Department of Justice

Criminal Division

Washington, D.C. 20530

JAN 9 2009

The Honorable Laurie Magid
Acting United States Attorney
Eastern District of Pennsylvania
Philadelphia, Pennsylvania 19106

Attention: Catherine Votaw
Assistant United States Attorney

Re: Global Non-prosecution Agreement for Eli Lilly and Company.

Dear Ms. Magid:

This is in response to your request for authorization to enter into a global case disposition agreement with the business entity known as Eli Lilly and Company.

I hereby approve the terms of the Plea Agreement, including Paragraph 8, in which the United States Attorney's Offices and the Criminal Division of the Department of Justice agree not to initiate further criminal prosecutions as set out therein.

You are authorized to make this approval a matter of record in this proceeding.

Sincerely,

Matthew W. Friedrich
Acting Assistant Attorney General

/s/ John C. Keeney

John C. Keeney
Deputy Assistant Attorney General
Criminal Division

SETTLEMENT AGREEMENT**I. PARTIES**

This Settlement Agreement (“Agreement”) is entered into among the United States of America, acting through the United States Department of Justice, Civil Division, and the United States Attorney’s Office for the Eastern District of Pennsylvania, the Office of Inspector General (“OIG-HHS”) of the Department of Health and Human Services (“HHS”), TRICARE Management Activity (“TMA”) and the United States Office of Personnel Management (“OPM”) (collectively the “United States”); the Relators as identified in Paragraphs B through E of the Preamble to this Agreement (“Relators”); and Eli Lilly and Company (“Eli Lilly”). Collectively, all of the above will be referred to as “the Parties.”

II. PREAMBLE

As a preamble to this Agreement, the Parties agree to the following:

A. At all relevant times, Eli Lilly, an Indiana corporation headquartered in Indianapolis, Indiana, distributed, marketed and sold pharmaceutical products in the United States, including a drug sold under the trade name of Zyprexa.

The qui tam actions identified in Paragraphs (B) through (E) will be referred to collectively as the “Civil Actions.”

B. Robert Rudolph (“Rudolph”), Hector Rosado (“Rosado”), and Robert Evan Daywitt (“Daywitt”) filed a qui tam action in the United States District Court for the Eastern

District of Pennsylvania captioned United States of America ex rel. Robert Rudolph, et al., v. Eli Lilly and Company, Civil Action No. 03-943. On August 13, 2003, Rudolph, Rosado and Daywitt filed a first amended complaint, adding relators Bradley Lutz (“Lutz”) and James Wetta (“Wetta”). A second amended complaint was filed on September 27, 2007, adding relator William Lofing (“Lofing”).

C. Joseph Faltaous (“Faltaous”) filed a qui tam action in the United States District Court for the Eastern District of New York captioned United States of America ex rel. Joseph Faltaous v. Eli Lilly and Company, Civil Action No. 05-1471. That action was transferred to the Eastern District of Pennsylvania as Civil Action No. 06-2909.

D. Steven Woodward (“Woodward”) filed a qui tam action in the United States District Court for the Eastern District of Pennsylvania captioned United States ex rel. Steven Woodward v. Dr. George B. Jerusalem, Tesse Jerusalem, Bay Psychiatric Services, and Eli Lilly, Civil Action No. 06-5526.

E. Jaydeen Vicente (“Vicente”) filed a qui tam action in the United States District Court for the Eastern District of Pennsylvania captioned United States of America ex rel. Javdeen Vicente v. Eli Lilly and Company, Civil Action No. 07-1791.

F. Eli Lilly has entered into a plea agreement with the United States Attorney for the Eastern District of Pennsylvania and the Office of Consumer Litigation of the Department of Justice and has agreed to plead guilty, pursuant to Fed.R.Crim.P. 11 to specific conduct described in a plea agreement to be filed in United States v. Eli Lilly and Company (the “Federal Criminal Action”).

G. Eli Lilly will be entering into separate settlement agreements, described in

Paragraph III.1(b) below (hereinafter referred to as the “Medicaid State Settlement Agreements”) with certain states and the District of Columbia in settlement of the Covered Conduct. States with which Eli Lilly executes a Medicaid State Settlement Agreement in the form to which Eli Lilly and the National Association of Medicaid Fraud Control Units (“NAMFCU”) have agreed, or in a form otherwise agreed to by Eli Lilly and an individual State, shall be defined as “Medicaid Participating States.”

H. The United States and the Medicaid Participating States allege that Eli Lilly caused claims for payment for Zyprexa to be submitted to the Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v (“the Medicaid Program”).

I. The United States further alleges that Eli Lilly caused claims for payment for Zyprexa to be submitted to the TRICARE program, 10 U.S.C. §§ 1071-1109; the Federal Employees Health Benefits Program (“FEHBP”), 5 U.S.C. §§ 8901-8914; and caused purchases of Zyprexa by the Department of Veterans Affairs (“DVA”), the Bureau of Prisons (“BOP”), the Department of Defense, the Department of Labor, and the Public Health Service Entities.

J. The United States contends that it has certain civil claims against Eli Lilly, as specified in Paragraph III.2 below, for engaging in the following conduct concerning the marketing, promotion and sale of Zyprexa between September 1999 and December 31, 2005 (hereinafter referred to as the “Covered Conduct”):

Eli Lilly knowingly promoted the sale and use of Zyprexa to psychiatrists, other physicians (including primary care physicians), and other health care professionals (collectively, "Health Care Professionals") for certain uses for which the Food and Drug Administration had not approved (i.e. "unapproved uses"); Eli Lilly implemented a marketing strategy to promote Zyprexa to Health Care Professionals, who treated patients of all ages, for unapproved uses; Eli Lilly also promoted Zyprexa to Health Care Professionals treating patients in long term care facilities for unapproved uses; Eli Lilly encouraged Health Care Professionals to prescribe Zyprexa in higher amounts than the recommended dose; the promotion of Zyprexa for these unapproved uses violated the Food Drug and Cosmetic Act, 21 U.S.C. § 331 (a) and 21 U.S.C. § 352(f); Eli Lilly, in connection with its marketing and promotional efforts for Zyprexa, provided remuneration and other things of value to Health Care Professionals; and these unapproved uses were not medically accepted indications for which the United States and State Medicaid programs provided coverage.

As a result of the foregoing alleged conduct, the United States contends that Eli Lilly knowingly caused false and/or fraudulent claims to be submitted to the United States and the Medicaid programs and caused TRICARE, the FEHBP, the Department of Veterans Affairs, the Bureau of Prisons, the Department of Defense, the Department of Labor, and Public Health Service Entities to purchase Zyprexa for these unapproved uses.

K. The United States also contends that it has certain administrative claims against Eli Lilly as specified in Paragraphs III.4-6 below, for engaging in the Covered Conduct.

L. This Agreement is made in compromise of disputed claims. This Agreement is neither an admission of facts or liability by Eli Lilly nor a concession by the United States that its

claims are not well-founded. With the exception of the specific conduct for which Eli Lilly is pleading guilty as described in the plea agreement filed in connection with the Federal Criminal action, Eli Lilly expressly denies the allegations of the United States and the Relators as set forth herein and in the Civil Actions and denies that it has engaged in any wrongful conduct in connection with the Covered Conduct. Neither this agreement, its execution, nor the performance of any obligation under it, including any payment, nor the fact of settlement, is intended to be, or shall be understood as, an admission of liability or wrongdoing, or other expression reflecting upon the merits of the dispute by Eli Lilly.

M. To avoid the delay, expense, inconvenience, and uncertainty of protracted litigation of these claims, the Parties mutually desire to reach a full and final settlement as set forth below.

III. TERMS AND CONDITIONS

1. Subject to the terms and procedures set forth below, Eli Lilly agrees to pay to the United States the sum of Four Hundred Thirty Eight Million, One Hundred Seventy One Thousand, Five Hundred Forty Three Dollars and Fifty Eight Cents (\$438,171,543.58) plus accrued interest in an amount of 3% per annum from October 20, 2008 and continuing until and including the day of payment (the "Federal Settlement Amount"), and — pursuant to the terms of Paragraph III.1.b — agrees to pay to all of the States and the District of Columbia (which shall be defined, for purposes of this Agreement, as a State) Three Hundred Sixty One Million, Eight Hundred Twenty Eight Thousand, Four Hundred Fifty Six Dollars and Forty Two Cents (\$361,828,456.42) plus accrued interest in the amount described in sub-paragraph III.1.b(ii)

below, of which One Million, Four Hundred Thirty Three Thousand, Six Hundred Forty Two Dollars and Ninety Six Cents (\$1,433,642.96) has already been paid to the State of Alaska pursuant to a separate settlement agreement. The amount of Three Hundred Sixty Million, Three Hundred Ninety Four Thousand, Eight Hundred Thirteen Dollars and Forty Six Cents (\$360,394,813.46) shall be defined as the "Medicaid State Settlement Amount".

(a) The Federal Settlement Amount shall be paid by electronic funds transfer pursuant to written instructions to be provided by the United States. Eli Lilly agrees to make this electronic funds transfer no later than ten (10) business days after the date on which the Court accepts Eli Lilly's guilty plea in connection with the Federal Criminal Action and imposes the agreed-upon sentence.

(b) Eli Lilly shall pay the States according to the following terms:

(i) No later than ten (10) business days following the date on which the Court accepts Eli Lilly's guilty plea in connection with the Federal Criminal Action and imposes the agreed-upon sentence (the "Account Establishment Date"), Eli Lilly shall deposit the Medicaid State Settlement Amount plus accrued interest in the amount of 3% per annum earned on that amount from October 20, 2008 to the Account Establishment Date into one or more interest-bearing money market or bank accounts that are held in the name of Eli Lilly but segregated from other Eli Lilly accounts (the "State Settlement Accounts").

(ii) From the State Settlement Accounts, Eli Lilly shall pay (through the mechanism described below involving the New York State Attorney General's National Global Settlement Account (the "NY State Account")) to each State (with the exception of Alaska, with which Eli Lilly has reached a separate agreement including this matter) that

becomes a Medicaid Participating State (as that term is defined above) within the time limits established in subparagraph III.1.b(iv) below, that State's share of the Medicaid State Settlement Amount (as set forth in a communication from NAMFCU to Eli Lilly counsel on January 13, 2009) (the "Individual State Share") plus accrued interest on that Individual State Share in the amount of 3% per annum from October 20, 2008 to the Account Establishment Date plus that State's pro rata share of interest accrued in the State Settlement Accounts from the day following the Account Establishment Date until the date that payment is made to the NY State Account. Eli Lilly shall execute a Medicaid State Settlement Agreement with any State that executes such an agreement; provided, however, that Eli Lilly reserves the right not to execute a Medicaid State Settlement Agreement with any State that is engaged in litigation with Eli Lilly in a matter relating to Zyprexa. Eli Lilly shall pay the aggregate amount that it owes to the States that become Medicaid Participating States within 60 days following the Account Establishment Date to the NY State Account, pursuant to written wire instructions provided by NAMFCU, on the 70th day following the Account Establishment Date or within two (2) business days following receipt by Eli Lilly of the written wire instructions, whichever is later.

(iii) Eli Lilly may, at its sole discretion, waive any rights that it has reserved in sub-paragraph III.1.b(ii) with respect to the payment of any of the Individual State Shares.

(iv) Except as otherwise provided in this sub-paragraph, absent Lilly's consent, no State may become a Medicaid Participating State if it has not executed a Medicaid State Settlement Agreement within 60 days following the Account Establishment Date. (A Medicaid Participating State shall be deemed to have become a Medicaid Participating State on

the date on which it executed a Medicaid State Settlement Agreement.) If, on the 60th day following the Account Establishment Date, Eli Lilly is obligated pursuant to the terms of sub-paragraph III.1.b(ii) to pay to the NY State Account an aggregate amount less than the Medicaid State Settlement Amount, Eli Lilly shall be entitled to retain any such difference, commingle it with any other corporate funds, and use it for any purpose, and no State shall be entitled to any portion of that difference pursuant to the terms of this Agreement. In the event that there are twenty five (25) or more Medicaid Participating States by the 60th day following the Account Establishment Date, the deadline for becoming a Medicaid Participating State shall be extended by 30 days, and Eli Lilly's rights pursuant to this sub-paragraph III.1.b(iv) shall accrue on the 90th day following the Account Establishment Date. In the event that the immediately foregoing clause is triggered, Eli Lilly shall pay the aggregate amount that it owes to the States that become Medicaid Participating States in the period from 61-90 days following the Account Establishment Date to the NY State Account, pursuant to written wire instructions provided by NAMFCU, on the 100th day following the Account Establishment Date or within two (2) business days following receipt by Eli Lilly of the written wire instructions, whichever is later.

(c) Subject to the terms of this paragraph, Eli Lilly shall mail checks to affected Public Health Service entities the aggregate sum of Seven Hundred Fifty One Thousand, Five Hundred and Forty Three Dollars and Eighty Eight Cents (\$751,543.88, plus interest accrued thereon at a rate of 3% per annum from October 20, 2008, continuing until and including the day before checks are mailed pursuant to this paragraph (the "Public Health Settlement Amount"). Within 60 days of the date on which the Court accepts Eli Lilly's guilty plea in connection with the Federal Criminal Action and imposes the agreed-upon sentence, Eli

Lilly shall distribute to each affected Public Health Service entity a check in the amount of its proportionate share of the Public Health Settlement Amount along with a cover letter referencing this Agreement and providing that, by cashing the check, the entity is releasing Eli Lilly and its predecessors and current and former parents, affiliates, divisions, subsidiaries, successors, transferees, heirs, and assigns, and their current and former directors, officers and employees, individually and collectively, from liability for the Covered Conduct.

(d) Contingent upon the United States receiving the Federal Settlement Amount from Eli Lilly, the United States agrees to pay, as soon as feasible after receipt, to Relator Rudolph \$78,870,877.84 plus the pro rata share of the actual accrued interest paid to the United States by Eli Lilly on the amount set forth in Paragraph III.1.a above ("Relator's Share").

(e) Relators have entered into a separate agreement concerning the allocation of the Relators' Share among themselves.

2. Subject to the exceptions in Paragraph 7 below (concerning excluded claims), in consideration of the obligations of Eli Lilly in this Agreement, conditioned upon Eli Lilly's full payment of the Federal Settlement Amount, and subject to Paragraph 16 below (concerning bankruptcy proceedings commenced within 91 days of the Effective Date of this Agreement or any payment made under this Agreement), the United States (on behalf of itself, its officers, agents, agencies, and departments) agrees to release Eli Lilly, its predecessors, current and former parents, affiliates, divisions, subsidiaries, successors, transferees, heirs, and assigns, and their current and former directors, officers and employees, individually and collectively, from any civil or administrative monetary claim the United States has or may have for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Program Fraud Civil

Remedies Act, 31 U.S.C. §§ 3801-12; any statutory provision creating a cause of action for civil damages or civil penalties for which the Civil Division of the Department of Justice has actual and present authority to assert and compromise pursuant to 28 C.F.R. Part O, Subpart I, Section 0.45(D) (1999) or the common law theories of payment by mistake, unjust enrichment, fraud, disgorgement of illegal profits, and, if applicable, breach of contract.

Subject to the exceptions in Paragraph 7 below (concerning excluded claims), in consideration of the obligations of Eli Lilly in this Agreement, conditioned upon Eli Lilly's full payment of the Federal Settlement Amount and compliance with sub-paragraphs III.1.b(i), (ii), and (iv) of this Agreement, subject to Paragraph 16 below (concerning bankruptcy proceedings commenced within 91 days of the Effective Date of this Agreement or any payment made under this Agreement), the United States (on behalf of itself, its officers, agents, agencies, and departments) agrees to release Eli Lilly, its predecessors and current and former parents, affiliates, divisions, subsidiaries, successors, transferees, heirs, and assigns, and their current and former directors, officers and employees, individually and collectively, from any claim the United States has or may have for the Covered Conduct under the Civil Monetary Penalties Law, 42 U.S.C. §1320a-7a.

3. In consideration of the obligations of Eli Lilly in this Agreement, conditioned upon Eli Lilly's full payment of the Federal Settlement Amount and compliance with sub-paragraphs III.1.b(i), (ii), and (iv) of this Agreement, Relators Faltaous, Woodward, Vicente, Rudolph, Rosado, Daywitt, Bradley Lutz, Wetta, and Lofing, for themselves and for their heirs, successors, transferees, attorneys, agents, and assigns, agree to dismiss with prejudice any currently pending claims against Eli Lilly and release Eli Lilly, its predecessors and current and

former parents, affiliates, divisions, subsidiaries, successors, transferees, heirs, and assigns, and their current and former directors, officers, employees, agents, servants, representatives, attorneys, consultants, successors, heirs, executors, administrators, and assigns, individually and collectively, from all liability, claims, demands, actions or causes of action whatsoever, known or unknown, fixed or contingent, in law or in equity, in contract or in tort, under any federal or state statute or regulation or that they otherwise would have standing to bring, except that they expressly reserve any claims arising under the *qui tam* provisions of the False Claims Act of any State with which Eli Lilly does not execute a Medicaid State Settlement Agreement pursuant to the terms of this Agreement.

4. In consideration of the obligations of Eli Lilly set forth in this Agreement and the Corporate Integrity Agreement (“CIA”) entered into between OIG-HHS and Eli Lilly, conditioned on Eli Lilly’s payment in full of the Federal Settlement Amount and compliance with sub-paragraphs III.1.b(i), (ii), and (iv) of this Agreement, and subject to Paragraph 16 below (concerning bankruptcy proceedings commenced within 91 days of the Effective Date of this Agreement or any payment under this Agreement), the OIG-HHS agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from the Medicare, Medicaid, and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against Eli Lilly and Lilly USA, LLC under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks or other prohibited activities) for the Covered Conduct, except as reserved in Paragraph 7 (concerning excluded claims), below, and as reserved in this Section.

In consideration of the obligations of Eli Lilly set forth in this Agreement and the CIA entered into between OIG-HHS and Eli Lilly, conditioned on Eli Lilly's payment in full of the Federal Settlement Amount and compliance with sub-paragraphs III.1.b(i), (ii), and (iv) of this Agreement, and subject to Paragraph 16 below (concerning bankruptcy proceedings commenced within 91 days of the Effective Date of this Agreement or any payment made under this Agreement), the OIG-HHS agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against Eli Lilly under 42 U.S.C. § 1320a-7(b)(1) (permissive exclusion for conviction relating to fraud) based on the Federal Criminal Action referenced in Paragraph F, except as reserved in paragraph 7 (concerning excluded claims) below, and as reserved in this Section.

The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude Eli Lilly from the Medicare, Medicaid, or other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct or the Federal Criminal Action. Nothing in this Section precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 7, below.

5. In consideration of the obligations of Eli Lilly set forth in this Agreement, conditioned upon Eli Lilly's full payment of the Federal Settlement Amount and compliance with sub-paragraphs III.1.b(i), (ii), and (iv) of this Agreement, and subject to Paragraph 16, below (concerning bankruptcy proceedings commenced within 91 days of the Effective Date of this Agreement or any payment under this Agreement), TMA agrees to release and refrain from

instituting, directing, or maintaining any administrative action seeking exclusion from the TRICARE Program against Eli Lilly, its predecessors and current and former parents, affiliates, divisions, subsidiaries, successors, transferees, heirs, and assigns, and their current and former directors, officers and employees, individually and collectively, under 32 C.F.R. § 199.9 for the Covered Conduct, except as reserved in Paragraph 7 (concerning excluded claims) below, and as reserved in this Paragraph. TMA expressly reserves its authority to exclude Eli Lilly under 32 C.F.R. § 199.9(f)(1)(i)(A), (f)(1)(i)(B), and (f)(1)(iii), based upon the Covered Conduct. Nothing in this Paragraph precludes TMA or the TRICARE Program from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 7, below.

6. In consideration of the obligations of Eli Lilly set forth in this Agreement and conditioned upon Eli Lilly's full payment of the Federal Settlement Amount and compliance with sub-paragraphs III.1.b(i), (ii), and (iv) of this Agreement, and subject to Paragraph 16 below (concerning bankruptcy proceedings commenced within 91 days of the Effective Date of this Agreement or any payment under this Agreement), OPM agrees to release and refrain from instituting, directing, or maintaining any administrative action against Eli Lilly, its predecessors and current and former parents, affiliates, divisions, subsidiaries, successors, transferees, heirs, and assigns, and their current and former directors, officers and employees, individually and collectively, under 5 U.S.C. § 8902a(b) or 5 C.F.R. Part 919 for the Covered Conduct, except as reserved in Paragraph 7 (concerning excluded claims) below, and except if required by 5 U.S.C. § 8902a(b). Nothing in this Paragraph precludes OPM from taking action against entities or

persons, or for conduct and practices, for which claims have been reserved in Paragraph 7, below.

7. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including Eli Lilly and Relators) are the following claims of the United States:

(a) Any criminal, civil, or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code);

(b) Any criminal liability except as set forth in the Plea Agreement resolving the Federal Criminal Action;

(c) Except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion from Federal health care programs;

(d) Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;

(e) Any liability based upon such obligations as are created by this Agreement;

(f) Any liability for express or implied warranty claims or other claims for defective or deficient products and services, including quality of goods and services;

(g) Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct; and

(h) Any liability for failure to deliver items or services due.

8. Relators, their heirs, successors, attorneys, agents, and assigns agree not to object to this Agreement and agree and confirm that this Agreement is fair, adequate, and reasonable

under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B). Conditioned upon Relator Rudolph's receipt of the Relators' Share, Relators, for themselves individually, and for their heirs, successors, agents, and assigns, fully and finally release, waive, and forever discharge the United States, its officers, agents, and employees from any claims arising from or relating to 31 U.S.C. § 3730; from any claims arising from the filing of the Civil Actions identified in Paragraphs II (B) through II (E); from any other claims for a share of the Settlement Amount; and in full settlement of any claims Relators may have under this Agreement. This Agreement does not resolve or in any manner affect any claims the United States has or may have against the Relators arising under Title 26, U.S. Code (Internal Revenue Code), or any claims arising under this Agreement.

9. Eli Lilly waives and shall not assert any defenses it may have to criminal prosecution or administrative action relating to the Covered Conduct based in whole or in part on a contention that, under the Double Jeopardy Clause of the Fifth Amendment of the Constitution, or the Excessive Fines Clause of the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action. Nothing in this paragraph or any other provision of this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

10. Eli Lilly fully and finally releases, waives and discharges the United States, its agencies, employees, servants, and agents from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that Eli Lilly has asserted, could have asserted, or may assert in the future against the United States, its agencies, employees, servants,

and agents, related to or arising from the Covered Conduct and the United States' investigation and prosecution of the Covered Conduct and the Civil Actions identified in Paragraphs II (B) through (E).

11. Neither the Federal Settlement Amount nor the Medicaid State Settlement Amount shall be decreased as a result of the denial of claims for payment now being withheld from payment by any State or Federal payer, related to the Covered Conduct; and Eli Lilly shall not resubmit to any State or Federal payer any previously denied claims, which denials were based on the Covered Conduct, and shall not appeal or cause the appeal of any such denials of claims.

12. Eli Lilly agrees to the following:

(a) Unallowable Costs Defined. All costs (as defined in the Federal Acquisition Regulation ("FAR"), 48 C.F.R. § 31.205-47 and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395hhh and 1396-1396v, and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Eli Lilly, its predecessors, parents, divisions, subsidiaries, or affiliates, and its present or former officers, directors, employees, and agents in connection with the following shall be "unallowable costs" on Government contracts: (1) the matters covered by this Agreement; (2) the United States' audit and civil and criminal investigation relating to matters covered by this Agreement; (3) Eli Lilly's investigation, defense, and any corrective actions undertaken in response to the United States' civil and criminal investigations in connection with the matters covered by this Agreement (including attorneys' fees); (4) the negotiation and performance of this Agreement and the Medicaid State Settlement Agreements and any agreement(s) with Relators concerning

fees and costs; (5) the payments made to the United States or any State pursuant to this Agreement or the Medicaid State Settlement Agreements and any payments that Eli Lilly may make to any qui tam plaintiffs; and (6) the negotiation of and obligations undertaken pursuant to the CIA to: (a) retain an independent review organization to perform annual reviews as described in Section III of the CIA; and (b) prepare and submit reports to OIG-HHS. However, nothing in this Paragraph affects the status of costs that are not allowable based on any other authority applicable to Eli Lilly. (All costs described or set forth in this Paragraph are hereafter, "Unallowable Costs").

(b) Future Treatment of Unallowable Costs. If applicable, these Unallowable Costs shall be separately estimated and accounted for by Eli Lilly and Eli Lilly shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by Eli Lilly, its predecessors, parents, divisions, subsidiaries, or affiliates to any government program.

(c) Treatment of Unallowable Costs Previously Submitted for Payment. If applicable, Eli Lilly further agrees that, within 90 days of the Effective Date of this Agreement, it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid, DVA, BOP, and FEHBP fiscal agents, any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid Program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Eli Lilly, its predecessors, parents, divisions, subsidiaries, or affiliates and shall request, and agree, that such

cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the Unallowable Costs. Eli Lilly agrees that the United States, at a minimum, shall be entitled to recoup from Eli Lilly any overpayment, plus applicable interest and penalties, as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment. Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or of the affected agencies. The United States reserves its rights to disagree with any calculations submitted by Eli Lilly, its predecessors, parents, divisions, subsidiaries or affiliates on the effect of inclusion of Unallowable Costs on Eli Lilly's or its predecessors', parents', divisions', subsidiaries' or affiliates' cost reports, cost statements, or information reports.

(d) Nothing in this Agreement shall constitute a waiver of the rights of the United States to examine or re-examine Eli Lilly's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

13. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraph 14 (Waiver for Beneficiaries paragraph), below.

14. Eli Lilly shall not seek payment for any of the claims for reimbursement covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

15. Eli Lilly warrants that it has reviewed its financial situation and that it is currently solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I), and shall remain

solvent following payment of the Federal Settlement Amount and compliance with sub-paragraphs III.1.b(i), (ii), and (iv) of this Agreement. Further, the Parties expressly warrant that, in evaluating whether to execute this Agreement, they (a) have intended that the mutual promises, covenants, and obligations set forth herein constitute a contemporaneous exchange for new value given to Eli Lilly, within the meaning of 11 U.S.C. § 547(c)(1); and (b) have concluded that these mutual promises, covenants and obligations do, in fact, constitute such a contemporaneous exchange. Further, the Parties warrant that the mutual promises, covenants, and obligations set forth herein are intended to and do, in fact, represent a reasonably equivalent exchange of value that is not intended to hinder, delay, or defraud any entity that Eli Lilly was or became indebted to on or after the date of this transfer, within the meaning of 11 U.S.C. § 548(a) (1).

16. If within 91 days of the Effective Date of this Agreement or of any payment made under this Agreement, Eli Lilly commences, or a third party commences, any case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors (a) seeking to have any order for relief of Eli Lilly's debts, or seeking to adjudicate Eli Lilly as bankrupt or insolvent; or (b) seeking appointment of a receiver, trustee, custodian, or other similar official for Eli Lilly or for all or any substantial part of Eli Lilly's assets, Eli Lilly agrees as follows, to the extent consistent with applicable law:

(a) Eli Lilly's obligations under this Agreement may not be avoided pursuant to 11 U.S.C. § 547, and Eli Lilly shall not argue or otherwise take the position in any such case, proceeding, or action that: (i) Eli Lilly's obligations under this Agreement may be avoided under 11 U.S.C. § 547; (ii) Eli Lilly was insolvent at the time this Agreement was entered into, or

became insolvent as a result of the payment made to the United States; or (iii) the mutual promises, covenants, and obligations set forth in this Agreement do not constitute a contemporaneous exchange for new value given to Eli Lilly.

(b) In the event that Eli Lilly's obligations hereunder are avoided for any reason, including, but not limited to, the exercise of a trustee's avoidance powers under the Bankruptcy Code, the United States, at its sole option, may rescind the releases in this Agreement, and bring any civil and/or administrative claim, action, or proceeding against Eli Lilly for the claims that would otherwise be covered by the releases provided in this Agreement. If the United States chooses to do so, Eli Lilly agrees that, for purposes only of any case, action, or proceeding referenced in the first clause of this Paragraph, (i) any such claims, actions or proceedings brought by the United States (including any proceedings to exclude Eli Lilly from participation in Medicare, Medicaid, or other federal health care programs) are not subject to an "automatic stay" pursuant to 11 U.S.C. Section 362(a) as a result of the action, case or proceeding described in the first clause of this Paragraph, and that Eli Lilly will not argue or otherwise contend that the United States' claims, actions or proceedings are subject to an automatic stay; (ii) that Eli Lilly will not plead, argue or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any such civil or administrative claims, actions, or proceedings which are brought by the United States within 30 calendar days of written notification to Eli Lilly that the releases herein have been rescinded pursuant to this Paragraph, except to the extent such defenses were available before February 21, 2003; and (iii) the United States and the Medicaid Participating States have valid claims against Eli Lilly in the aggregate amount of at least \$800,000,000 plus applicable multipliers and

penalties, and they may pursue their claims, inter alia, in the case, action or proceeding referenced in the first clause of this Paragraph, as well as in any other case, action, or proceeding; and

(c) Eli Lilly acknowledges that its agreements in this Paragraph are provided in exchange for valuable consideration provided in this Agreement.

17. The United States shall file a Notice of Partial Intervention as to all Federal Counts in the Civil Actions that pertain to the Covered Conduct, along with an executed copy of this Agreement. Within five business days after payment of the Federal Settlement Amount and Eli Lilly's compliance with subparagraph III.1.b(i) of this Agreement, the United States and the Relators shall file Stipulations of Dismissal With Prejudice as to all Federal Counts in the Civil Actions that pertain to the Covered Conduct pursuant to the terms of this Agreement.

18. Except as expressly provided to the contrary in this Agreement, each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

19. Eli Lilly represents that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

20. Relators represent that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

21. This Agreement is governed by the laws of the United States. The Parties agree that the exclusive jurisdiction and venue for any dispute arising between and among the Parties under this Agreement shall be the United States District Court for the Eastern District of

Pennsylvania, except that disputes arising under the CIA shall be resolved exclusively through the dispute resolution provisions set forth in the CIA.

22. For purposes of construction, this Agreement shall be deemed to have been drafted by all parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

23. This Agreement constitutes the complete agreement between the Parties with respect to the issues covered by this Agreement. This Agreement may not be amended except by written consent of the Parties.

24. The individuals signing this Agreement on behalf of Eli Lilly represent and warrant that they are authorized by Eli Lilly to execute this Agreement. The individual(s) signing this Agreement on behalf of Relators represent and warrant that they are authorized by that Relator to execute this Agreement. The United States signatories represent that they are signing this Agreement in their official capacities and that they are authorized to execute this Agreement.

25. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

26. This Agreement is binding on Eli Lilly's successors, transferees, heirs, and assigns.

27. This Agreement is binding on Relators' successors, transferees, heirs, attorneys, agents, and assigns.

28. All Parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

29. This Agreement is effective on the date of signature of the last signatory to the Agreement (the "Effective Date"). Facsimiles of signatures shall constitute acceptable binding signatures for purposes of this Agreement.

30. Notwithstanding any other provision of this Agreement, if the guilty plea referenced in Paragraph II.F is not accepted by the Court or the Court does not impose the agreed upon sentence for whatever reason, this Agreement shall be null and void at the option of either the United States or Eli Lilly. If either the United States or Eli Lilly exercises this option, which option shall be exercised by notifying all Parties, through counsel, in writing within 5 business days of the Court's decision, the Parties will not object and this Agreement will be rescinded. If the Agreement is rescinded, Eli Lilly waives any affirmative defenses based in whole or in part on the running of the statute of limitations during the period from the Effective Date of this Agreement through 30 days after the effective date of the rescission.

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UNITED STATES OF AMERICA

By: /s/ Laurie Magid
LAURIE MAGID
Acting United States Attorney
United States Attorney's Office
Eastern District of Pennsylvania

Dated: 1/14/09

By: /s/ Virginia Gibson
VIRGINIA GIBSON
Chief, Civil Division
United States Attorney's Office
Eastern District of Pennsylvania

Dated: 1/14/09

By: /s/ Margaret L. Hutchinson
MARGARET L. HUTCHINSON
Deputy Chief, Civil Division
United States Attorney's Office
Eastern District of Pennsylvania

Dated: 1/14/09

By: /s/ Joseph Trautwein
JOSEPH TRAUTWEIN
Assistant U.S. Attorney
United States Attorney's Office
Eastern District of Pennsylvania

Dated: 1/14/09

By: /s/ Patricia Hanower
PATRICIA HANOWER
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

Dated: January 14, 2009

By: /s/ Gregory E. Demske

Dated: 1/14/09

GREGORY E. DEMSKE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services

By: /s/ Laurel C. Gillespe

LAUREL C. GILLESPE
Deputy General Counsel
TRICARE Management Activity
United States Department of Defense On behalf of the TRICARE program

Dated: 12 Jan 2009

Eli Lilly Settlement Agreement

By: /s/ Lorraine E. Dettman
LORRAINE E. DETTMAN
Assistant Director
for Insurance Services Programs
United States Office of Personnel Management

Dated: 1/12/09

By: /s/ J. David Cope
J. DAVID COPE
Assistant Inspector General for Legal Affairs
United States Office of Personnel Management

Dated: 1/13/09

On behalf of the Federal Employees Health Benefits Program

ELI LILLY AND COMPANY

By: /s/ Robert A. Armitage
ROBERT A. ARMITAGE
Senior Vice President and General Counsel
Eli Lilly and Company

Dated: 14 Jan 2009

By: /s/ Paul E. Kalb
PAUL E. KALB, M.D.
Sidley Austin LLP
Counsel for Eli Lilly and Company

Dated: 1/14/09

By: /s/ Bradford A. Berenson
BRADFORD A. BERENSON
Sidley Austin LLP
Counsel for Eli Lilly and Company

Dated: 1/14/09

By: /s/ Nina M. Gussack
NINA M. GUSSACK
Pepper Hamilton LLP
Counsel for Eli Lilly and Company

Dated: 1/14/09

By: /s/ Thomas M. Gallagher
THOMAS M. GALLAGHER
Pepper Hamilton LLP
Counsel for Eli Lilly and Company

Dated: 1/14/09

RELATORS

By: /s/ Robert Rudolph
ROBERT RUDOLPH

Dated: 1/14/09

By: /s/ Hector Rosado
HECTOR ROSADO

Dated: 1/14/09

By: /s/ Robert Evan Daywitt
ROBERT EVAN DAYWITT

Dated: 1/14/09

By: /s/ Bradley Lutz
BRADLEY LUTZ

Dated: 1/14/09

By: /s/ James Wetta
JAMES WETTA

Dated: 1/14/09

By: /s/ William Lofing
WILLIAM LOFING

Dated: 1/14/09

By: /s/ Michael M. Mustokoff
MICHAEL M. MUSTOKOFF
Duane Morris, LLP

Dated: 1/14/09

By: /s/ Stephen A. Sheller
STEPHEN A. SELLER

Dated: 1/14/09

By: /s/ Gary M. Farmer
GARY M. FARMER, JR.
Rothstein Rosenfeldt Adler

Dated: 1/14/09

(Attorneys for Robert Rudolph, Hector Rosado, Robert Evan Daywitt, Bradley Lutz, James Wetta and William Lofing)

By: /s/ Joseph Faltaous
JOSEPH FALTAOUS

Dated: 1-14-09

By: /s/ Joel Androphy
JOEL ANDROPHY
SARAH M. FRAZIER
Berg & Androphy

Dated: 1-14-09

(Attorneys for Joseph Faltaous)

By: /s/ Steven Woodward
STEVEN WOODWARD

Dated: 1/13/09

By: /s/ Brian P. Kenney
BRIAN P. KENNEY
Kenney Egan McCafferty & Young

Dated: 1/14/09

(Attorneys for Steven Woodward)

By: /s/ Jaydeen Vicente
JAYDEEN VICENTE

Dated: 01/13/09

By: /s/ Brian P. Kenney
BRIAN P. KENNEY
Kenney Egan McCafferty & Young

Dated: 1/14/09

By: /s/ Mark Burton
MARK BURTON
Hersh & Hersh

Dated: 1/14/09

(Attorneys for Jaydeen Vicente)

CORPORATE INTEGRITY AGREEMENT

BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
ELI LILLY AND COMPANY

I. PREAMBLE

Eli Lilly and Company (Lilly) hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements) and with the statutes, regulations, and written directives of the Food and Drug Administration (FDA requirements). Contemporaneously with this CIA, Lilly is entering into a Settlement Agreement with the United States. Lilly will also enter into settlement agreements with various States (State Settlement Agreement and Release) and Lilly's agreement to this CIA is a condition precedent to those agreements.

Prior to the Effective Date of this CIA (as defined below), Lilly established a voluntary compliance program applicable to all Lilly employees (Compliance Program). Lilly's Compliance Program includes a Chief Compliance Officer who reports directly to the Board of Directors and the CEO, and a Compliance Committee. The Compliance Program also includes a Code of Conduct (known as "The Red Book") applicable to all employees that is regularly reviewed and disseminated, written policies and procedures, educational and training initiatives, a Disclosure Program that allows for the confidential disclosure and investigation of potential compliance violations and appropriate disciplinary procedures, and regular monitoring and internal auditing procedures.

Lilly shall continue its Compliance Program throughout the term of this CIA and shall do so in accordance with the terms set forth below. Lilly may modify its Compliance Program as appropriate, but, at a minimum, Lilly shall ensure that during the term of this CIA, it shall comply with the obligations set forth herein.

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Eli Lilly Company

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by Lilly under this CIA shall be five years from the effective date of this CIA, unless otherwise specified. The effective date shall be the date by which Lilly is obligated to pay the Federal Settlement Amount as set forth in the Settlement Agreement between Eli Lilly and the United States (Effective Date). Each one-year period, beginning with the one-year period following the first day of the first calendar month following the Effective Date, shall be referred to as a "Reporting Period."

B. Sections VII, IX, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) Lilly's final Annual Report; or (2) any additional materials submitted by Lilly pursuant to OIG's request, whichever is later.

C. The scope of this CIA shall be governed by the following definitions:

1. "Covered Persons" includes:
 - a. all owners who are natural persons and: (i) have an ownership interest of 5% or more of the outstanding shares; or (ii) are involved in the business operations of Lilly or Lilly USA, LLC (Lilly USA);
 - b. all officers and directors of Lilly and Lilly USA, and all employees of Lilly and Lilly USA based in the United States except as carved out below in this Section II.C.1; and
 - c. all contractors, subcontractors, agents, and other persons who perform Promotional and Product Services Related Functions (as defined below in Section II.C.4) on behalf of Lilly or Lilly USA.

Notwithstanding the above, the term "Covered Persons" does not include: (i) officers or employees of Elanco; (ii) part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become "Covered Persons" at the point when they work more than 160 hours during the calendar year.

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2. “Relevant Covered Persons” includes all Covered Persons whose job responsibilities relate to Promotional and Product Services Related Functions. This group includes, but is not limited to, Covered Persons from the following groups or divisions who perform, supervise, or have responsibilities relating to, or in support of, the Promotional and Product Services Related Functions of Lilly or Lilly USA: Financial, Quality, Information Technology, Legal, Lilly Research Laboratories, Global Marketing and Sales Organization, Regulatory, Corporate Affairs, and Human Resources.
3. “Government Reimbursed Products” refers to all Lilly human pharmaceutical products that are reimbursed by Federal health care programs. This term includes all products promoted or sold by Lilly or Lilly USA in the United States.
4. The term “Promotional and Product Services Related Functions” includes: (a) the selling, detailing, marketing, advertising, promoting, or branding of Government Reimbursed Products; and (b) the preparation or dissemination of materials or information about, or the provision of services relating to, Government Reimbursed Products that are distributed in the United States.
5. The term “Third Party Educational Activity” shall mean any continuing medical education (CME), disease awareness, or other scientific, educational, or professional program, meeting, or event sponsored by Lilly, including but not limited to, sponsorship of symposia at medical conferences.
6. The term “Third Party Personnel” shall mean personnel of the entities with whom Lilly or Lilly USA have or may in the future enter into agreements to co-promote a Government Reimbursed Product in the United States or engage in joint promotional activities in the United States relating to such a product. Lilly has represented that: (1) the Third Party Personnel are employed by entities independent of Lilly or Lilly USA; (2) Lilly or Lilly USA does not control Third Party Personnel; and (3) it would be commercially impracticable to compel the compliance of Third Party Personnel with the requirements set forth in this CIA. Lilly agrees to promote compliance by Third Party

Personnel with Federal health care program and FDA requirements by complying with the provisions set forth below in Sections III.B.2, V.A.7, and V.B.4 related to Third Party Personnel who meet the definition of Covered Persons. Provided that Lilly complies with the requirements of Sections III.B.2, V.A.7, and V.B.4, Lilly shall not be required to fulfill the other CIA obligations that would otherwise apply to Third Party Personnel who meet the definition of Covered Persons.

III. CORPORATE INTEGRITY OBLIGATIONS

Lilly shall establish and maintain a Compliance Program throughout the term of this CIA that includes the following elements:

A. Compliance Responsibilities of Certain Lilly Employees and the Board of Directors.

1. *Chief Compliance Officer.* Prior to the Effective Date, Lilly appointed a Chief Compliance Officer, and Lilly shall maintain a Chief Compliance Officer during the term of the CIA. The Chief Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements and FDA requirements. The Chief Compliance Officer shall be a member of senior management of Lilly, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors or a Committee of the Board of Directors of Lilly, and shall be authorized to report on such matters to the Board of Directors or such Committee at any time. The Chief Compliance Officer shall not be, or be subordinate to, the General Counsel or Chief Financial Officer. The Chief Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by Lilly as well as for any reporting obligations created under this CIA.

Lilly shall report to OIG, in writing, any changes in the identity or position description of the Chief Compliance Officer, or any actions or changes that would affect the Chief Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

2. *Compliance Committee.* Prior to the Effective Date, Lilly established a Compliance Committee, and Lilly shall maintain a Compliance Committee during the term of this CIA. The Compliance Committee shall, at a minimum, include the Chief

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Eli Lilly Company

Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as Legal, Human Resources, Lilly Research Laboratories, Corporate Affairs, Global Marketing and Sales, Regulatory, Account Based Markets-Lilly USA, Marketing and Operations — Lilly USA, and Health Care Professional Markets — Lilly USA). The Chief Compliance Officer shall chair the Compliance Committee and the Compliance Committee shall support the Chief Compliance Officer in fulfilling his/her responsibilities under the CIA (e.g., shall assist in the analysis of the organization's risk areas and shall oversee monitoring of internal and external audits and investigations).

Lilly shall report to OIG, in writing, any changes in the composition of the Compliance Committee, or any actions or changes that would affect the Compliance Committee's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

3. *Board of Directors Compliance Obligations.* A Committee of the Board of Directors (Committee) shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA. The Committee shall, at a minimum, be responsible for the following:

a. The Committee shall meet at least quarterly to review and oversee Lilly's Compliance Program, including but not limited to evaluating its effectiveness and receiving updates about the activities of the Chief Compliance Officer and other compliance personnel.

b. The Committee shall consist of at least three members, all of whom shall be independent directors. The Chief Compliance Officer is required to make at least four reports a year to the Committee or more often, if requested by the Committee or the Chief Compliance Officer.

c. The Committee shall arrange for the performance of a review on the effectiveness of Lilly's Compliance Program (Compliance Program Review) for each Reporting Period of the CIA and shall review the results of the Compliance Program Review as part of the review and assessment of Lilly's Compliance Program. A copy of the Compliance Program Review Report shall be provided to OIG in each Annual Report submitted by Lilly.

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d. For each Reporting Period of the CIA, the Committee shall adopt a resolution, signed by each individual member of the Committee, summarizing its review and oversight of Lilly's compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA.

At minimum, the resolution shall include the following language:

"The **[insert name of Committee]** Committee of the Board of Directors has made a reasonable inquiry into the operations of Lilly's Compliance Program, including but not limited to evaluating its effectiveness and receiving updates about the activities of its Chief Compliance Officer and other compliance personnel. The Board also has arranged for the performance of, and reviewed the result of, the Compliance Program Review. Based on its inquiry, the Committee has concluded that, to the best of its knowledge, Lilly has implemented an effective Compliance Program to meet Federal health care program requirements, FDA requirements, and the obligations of the CIA."

If the Committee is unable to provide such a conclusion in the resolution, the Committee shall include in the resolution a written explanation of the reasons why it is unable to provide the conclusion and the steps it is taking to assure implementation by Lilly of an effective Compliance Program at Lilly.

Lilly shall report to OIG, in writing, any changes in the composition of the Committee, or any actions or changes that would affect the Committee's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

The Board of Directors may by resolution reserve to itself the powers and responsibilities assigned to the Committee under this CIA. In that event, all references in this CIA to the Committee shall be deemed to be references to the Board of Directors.

4. *Management Accountability and Certifications:* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain Lilly employees ("Certifying Employees") are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify, in writing or electronically, that the applicable Lilly component is compliant with Federal health care program requirements, FDA requirements, and the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following individuals from Lilly: President and Chief Executive Officer; and Executive Vice President, Global Marketing and Sales.

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They also shall include, at minimum, the following individuals from Lilly USA: President, U.S. Operations; Senior Vice President, Account-Based Markets; Senior Vice President, Health Care Professional Markets; Vice President, Chief Marketing and Operations Officer; and all national and executive sales directors, brand leaders, and business unit leaders in the HCP Markets, executive directors and directors in Account-Based Markets, and executive directors and directors in Marketing and Operations.

For each Reporting Period, each Certifying Employee shall sign a certification that states:

“I have been trained on and understand the compliance requirements and responsibilities as they relate to [department or functional area], an area under my supervision. My job responsibilities include ensuring compliance with regard to the _____ [insert name of the department or functional area.] To the best of my knowledge, except as otherwise described herein, the _____ [insert name of department or functional area] of Lilly is in compliance with all applicable Federal health care program requirements, FDA requirements, and the obligations of the CIA.”

B. Written Standards.

1. *Code of Conduct.* Prior to the Effective Date, Lilly developed, implemented, and distributed a written Code of Conduct (known as “The Red Book”) to all Covered Persons. Lilly currently requires all newly employed Covered Persons to certify in writing or electronically, that they have received, read, understood, and shall abide by Lilly’s Code of Conduct. Lilly shall continue to make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all Covered Persons.

The Code of Conduct sets forth and shall continue to set forth, at a minimum, the following:

- a. Lilly’s commitment to full compliance with all Federal health care program and FDA requirements, including its commitment to market, sell, promote, research, develop, provide information about, and advertise its products in accordance with Federal health program requirements and FDA requirements;

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Eli Lilly Company

- b. Lilly's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program and FDA requirements and with Lilly's own Policies and Procedures as implemented pursuant to Section III.B (including the requirements of this CIA);
- c. the requirement that all of Lilly's Covered Persons shall be expected to report to the Chief Compliance Officer, or other appropriate individual designated by Lilly, suspected violations of any Federal health care program and FDA requirements or of Lilly's own Policies and Procedures;
- d. the possible consequences to both Lilly and Covered Persons of failure to comply with Federal health care program and FDA requirements and with Lilly's own Policies and Procedures and the failure to report such noncompliance; and
- e. the right of all individuals to use the Disclosure Program described in Section III.E, and Lilly's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

To the extent not already accomplished, within 120 days after the Effective Date, the Code of Conduct shall be distributed to each Covered Person and each Covered Person shall certify, in writing or electronically, that he or she has received, read, understood, and shall abide by Lilly's Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later.

Lilly shall periodically review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such review. Any revised Code of Conduct shall be distributed within 30 days after any revisions are finalized by the Compliance Office. Each Covered Person shall certify, in writing or electronically, that he or she has received, read, understood, and shall abide by the revised Code of Conduct within 30 days after the distribution of the revised Code of Conduct.

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2. *Third Party Personnel.* Within 90 days after the Effective Date, and annually thereafter by the anniversary of the Effective Date, Lilly shall send a letter to each entity employing Third Party Personnel. The letter shall outline Lilly's obligations under the CIA and its commitment to full compliance with all Federal health care program and FDA requirements. The letter shall include a description of Lilly's Compliance Program. Lilly shall attach a copy of its Code of Conduct to the letter and shall request the entity employing Third Party Personnel to either: (a) make a copy of Lilly's Code of Conduct and a description of Lilly's Compliance Program available to its Third Party Personnel; or (b) represent to Lilly that it has and enforces a substantially comparable code of conduct and compliance program for its Third Party Personnel.

3. *Policies and Procedures.* Prior to the Effective Date, Lilly implemented written Policies and Procedures regarding the operation of the Compliance Program and Lilly's compliance with Federal health care program and FDA requirements (Policies and Procedures). To the extent not already accomplished, within 90 days after the Effective Date, Lilly shall ensure that the Policies and Procedures address or shall continue to address:

- a. the subjects relating to the Code of Conduct identified in Section III.B.1;
- b. appropriate ways to conduct Promotional and Product Services Related Functions in compliance with all applicable Federal healthcare program requirements, including, but not limited to the Federal anti-kickback statute (codified at 42 U.S.C. § 1320a-7b), and the False Claims Act (codified at 31 U.S.C. §§ 3729-3733);
- c. appropriate ways to conduct Promotional and Product Services Related Functions in compliance with all applicable FDA requirements;
- d. the materials and information that may be distributed by Lilly sales representatives and account executives about Lilly's Government Reimbursed Products and the manner in which Lilly sales representatives and account executives respond to requests for information about non-FDA approved (or "off-label") uses of Lilly's Government Reimbursed Products;

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- e. the materials and information that may be distributed by the Lilly Answers Center (TLAC) and the mechanisms through, and manner in which, TLAC receives and responds to requests for information submitted by sales representatives and account executives about non-FDA approved (“off-label”) uses of Lilly’s Government Reimbursed Products; the form and content of information disseminated by Lilly in response to such requests; and the internal review process for the information disseminated.

The Policies and Procedures shall include a requirement that TLAC develop database(s) to track requests for information about Lilly’s products that are submitted by Lilly’s sales representatives and account executives, or by members of the public, to TLAC. This database shall be referred to as the “TLAC Database.” The TLAC Database shall include the following items of information for each unique inquiry (Inquiry) received for information about Lilly’s products: 1) date of Inquiry; 2) form of Inquiry (e.g., fax, phone, etc.); 3) name of the requesting health care professional (HCP) or health care institution (HCI) in accordance with applicable privacy laws; 4) nature and topic of request (including exact language of the Inquiry if made in writing); 5) nature/form of the response from Lilly (including a record of the materials provided to the HCP or HCI in response to the request); and 6) the name of the Lilly representative who called on or interacted with the HCP or HCI, if known;

- f. systems, processes, policies, and procedures relating to the manner and circumstances under which Medical Liaisons and Outcomes Liaisons participate in meetings or events with HCPs or HCIs (either alone or with sales representatives or account executives) and the role of the Medical Liaisons and Outcomes Liaisons at such meetings or events, as well as how they handle responses to unsolicited requests about off-label indications of Lilly’s Government Reimbursed Products;
- g. systems, processes, policies, and procedures relating to the development, implementation, and review of call plans using

Lilly's Territory to Physician (TTP) business rules for field sales representatives who promote Government Reimbursed Products. For each Government Reimbursed Product, the Policies and Procedures shall require that Lilly review the call plans for the product and the bases upon, and circumstances under, which HCPs and HCIs belonging to specified medical specialties or types of clinical practice are included in, or excluded from, the call plans. The Policies and Procedures shall also require that Lilly modify the call plans as necessary to ensure that Lilly is promoting its Government Reimbursed Products in a manner that complies with all applicable Federal health care program and FDA requirements. The call plan reviews shall occur at least annually and shall also occur each time when the FDA approves a new or additional indication for a Government Reimbursed Product;

- h. systems, processes, policies, and procedures relating to the development, implementation, and review of plans for the distribution of samples of Lilly's Government Reimbursed Products (Sample Distribution Plans). This shall include a review of the bases upon, and circumstances under, which HCPs and HCIs belonging to specified medical specialties or types of clinical practice may receive samples from Lilly (including, separately, from Lilly sales representatives or account executives and/or directly from Lilly's medical services department). The Policies and Procedures shall also require that Lilly modify the Sample Distribution Plans as necessary to ensure that Lilly is promoting its products in a manner that complies with all applicable Federal health care program and FDA requirements;
- i. consultant or other fee-for-service arrangements entered into with HCPs or HCIs (including, but not limited to speaker programs, speaker training programs, presentations, consultant task force meetings, advisory boards, and ad hoc advisory activities, and any other financial engagement or arrangement with an HCP or HCI,) and all events and expenses relating to such engagements or arrangements. These Policies and Procedures shall be designed to ensure that the arrangements and related events are

used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements. The Policies shall include requirements about the content and circumstances of such arrangements and events;

- j. programs to educate field representatives, including but not limited to presentations by HCPs at sales meetings and experience-based learning activities. These Policies and Procedures shall be designed to ensure that the programs are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements. The Policies shall include requirements about the content and circumstances of such arrangements and events;
- k. sponsorship or funding of grants (including educational grants) or charitable contributions. These Policies and Procedures shall be designed to ensure that Lilly's funding and/or sponsorship complies with all applicable Federal health care program and FDA requirements;
- l. funding of, or participation in, any Third Party Educational Activity as defined in Section II.C.5 above. These Policies and Procedures shall be designed to ensure that Lilly's funding and/or sponsorship of such programs satisfies all applicable Federal health care program and FDA requirements.

The Policies and Procedures shall require that: 1) Lilly disclose its financial support of the Third Party Educational Activity and, to the extent feasible consistent with subsection 5 below, any financial relationships with faculty, speakers, or organizers at such Activity; 2) as a condition of funding, the third party shall agree to disclose Lilly's financial support of the Third Party Educational Activity and any financial relationships that Lilly might have with faculty, speakers, or organizers at such Activity; 3) any faculty, speakers, or organizers at the Third Party Educational Activity disclose any financial relationship with Lilly; 4) the Third Party Educational Activity have an educational focus; 5) the content, organization, and operation of the Third

Party Educational Activity be independent of Lilly control; 6) Lilly support only Third Party Educational Activity that is non-promotional in tone/nature; and 7) Lilly support of a Third Party Educational Activity shall be contingent on the provider's commitment to provide information at the Educational Activity that is fair, balanced, accurate and not misleading;

- m. review of all promotional and written materials and information intended to be disseminated outside Lilly by appropriate qualified personnel (such as regulatory, medical, and/or legal personnel) in a manner designed to ensure that legal, regulatory, and medical concerns are properly addressed during Lilly's review and approval process and are elevated when appropriate. The Policies and Procedures shall be designed to ensure that such materials and information, when finally approved, comply with all applicable Federal health care program and FDA requirements;
- n. sponsorship or funding of research or related activities. These Policies and Procedures shall be designed to ensure that Lilly's funding and/or sponsorship complies with all applicable Federal health care program and FDA requirements;
- o. compensation (including salaries and bonuses) for Relevant Covered Persons. These Policies and Procedures shall be designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in improper promotion, sales, and marketing of Lilly's products; and
- p. disciplinary policies and procedures for violations of Lilly's Policies and Procedures, including policies relating to Federal health care program and FDA requirements.

To the extent not already accomplished, within 120 days after the Effective Date, the relevant portions of the Policies and Procedures shall be made available to all Covered Persons whose job functions relate to those Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

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At least annually (and more frequently, if appropriate), Lilly shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be made available to all Covered Persons whose job functions relate to those Policies and Procedures.

C. Training and Education.

Lilly represents that it provides training to its employees on a regular basis concerning a variety of topics. The training covered by this CIA need not be separate and distinct from the regular training provided by Lilly, but instead may be integrated fully into such regular training so long as the training covers the areas specified below.

1. *General Training.* Within 120 days after the Effective Date, Lilly shall provide at least two hours of General Training to each Covered Person. This training, at a minimum, shall explain Lilly's:

- a. CIA requirements; and
- b. Lilly's Compliance Program (including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues).

To the extent that Lilly provided General Training to Covered Persons during the 180 days immediately prior to the Effective Date that satisfied the requirements set forth in Section III.C.1.b above, the OIG shall credit that training for purposes of satisfying Lilly's General Training obligations of this Section III.C.1 for the first Reporting Period. Lilly may satisfy its remaining General Training obligations for the Covered Persons who received the training described in the preceding sentence by notifying them within 90 days after the Effective Date in writing or in electronic format of the fact that Lilly entered a CIA and providing an explanation of Lilly's requirements and obligations under the CIA.

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Covered Person shall receive at least one hour of General Training in each subsequent Reporting Period.

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2. *Specific Training.* Within 120 days after the Effective Date, each Relevant Covered Person shall receive at least three hours of Specific Training applicable to their specific job functions in addition to the General Training required above.

This Specific Training shall include a discussion of:

- a. all applicable Federal health care program requirements relating to Promotional and Product Services Related Functions;
- b. all applicable FDA requirements relating to Promotional and Product Services Related Functions;
- c. all Lilly Policies and Procedures and other requirements applicable to Promotional and Product Services Related Functions;
- d. the personal obligation of each individual involved in Promotional and Product Services Related Functions to comply with all applicable Federal health care program and FDA requirements and all other applicable legal requirements;
- e. the legal sanctions for violations of the applicable Federal health care program and FDA requirements; and
- f. examples of proper and improper practices related to Promotional and Product Services Related Functions.

To the extent that Lilly provided Specific Training to Relevant Covered Persons during the 180 days immediately prior to the Effective Date that satisfied the requirements set forth in this Section III.C.2 above, the OIG shall credit that training for purposes of satisfying Lilly's Specific Training obligations of this Section III.C.2 for the first Reporting Period.

New Relevant Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or within 120 days after the Effective Date, whichever is later. A Lilly employee who has completed the Specific Training shall review or supervise (as applicable) a new Relevant Covered

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Person's work, to the extent that the work relates to Promotional and Product Services Related Functions, until such time as the new Relevant Covered Person completes his or her Specific Training.

After receiving the initial Specific Training described in this Section, each Relevant Covered Person shall receive at least three hours of Specific Training in each subsequent Reporting Period.

3. *Certification.* Each individual who is required to complete training shall certify, in writing or electronically, if applicable, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Chief Compliance Officer (or designee) shall retain the certifications, along with all course materials. These shall be made available to OIG, upon request.

4. *Qualifications of Trainer.* Persons providing the training shall be knowledgeable about the subject area of the training, including applicable Federal health care program and FDA requirements. The training and education required under this Section III.C may be provided by supervisory employees, knowledgeable staff, Lilly trainers, and/or outside consultant trainers selected by Lilly, or may be satisfied by relevant continuing education programs provided they cover the topics outlined above in Section III.C.2.

5. *Update of Training.* Lilly shall review the training annually, and, where appropriate, update the training to reflect changes in Federal health care program requirements, FDA requirements, any issues discovered during any internal audits or any IRO Review, and any other relevant information.

6. *Computer-based Training.* Lilly may provide the training required under this CIA through appropriate computer-based training approaches. If Lilly chooses to provide computer-based training, it shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the Covered Persons receiving such training. In addition, if Lilly chooses to provide computer-based General or Specific Training, all applicable requirements to provide a number of "hours" of training in this Section III.C may be met with respect to computer-based training by providing the required number of "normative" hours as that term is used in the computer-based training industry.

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D. Review Procedures.

1. *General Description.*

a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, Lilly shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter “Independent Review Organization” or “IRO”), to perform reviews to assist Lilly in assessing and evaluating its Promotional and Product Services Related Functions. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.

Each IRO engaged by Lilly shall have expertise in applicable Federal health care program and FDA requirements as may be appropriate to the Review for which the IRO is retained. Each IRO shall assess, along with Lilly, whether it can perform the engagement in a professionally independent and objective fashion, as appropriate to the nature of the review, taking into account any other business relationships or other engagements that may exist.

The IRO(s) shall conduct reviews that assess Lilly’s systems, processes, policies, procedures, and practices relating to Promotional and Product Services Related Functions (Promotional and Product Services Reviews).

b. *Frequency and Brief Description of Reviews.* As set forth more fully in Appendix B, the Promotional and Product Services Review shall consist of two components — a Systems Review and a Transactions Review. The Systems Review shall assess Lilly’s systems, processes, policies, and procedures relating to Promotional and Product Services Related Functions. If there are no material changes in Lilly’s systems, processes, policies, and procedures relating to Promotional and Product Services Related Functions, the Promotional and Product Services Systems Review shall be performed for the periods covering the first and fourth Reporting Periods. If Lilly materially changes its systems, processes, policies, and procedures relating to Promotional and Product Services Related Functions, the IRO shall perform a Systems Review for the

Reporting Period in which such changes were made in addition to conducting the Systems Review for the first and fourth Reporting Periods.

The Promotional and Product Services Transactions Review shall be performed annually and shall cover each of the five Reporting Periods. The IRO(s) shall perform all components of each annual Transaction Review. As set forth more fully in Appendix B, the Transactions Review shall include several components, including a review relating to inquiries included in Lilly's TLAC Database, a review of Lilly's Call Plan Assessments, a review of Sampling Events, and a review of records relating to a sample of the Payments that are reported by Lilly pursuant to Section III.M below. In addition, each Transactions Review shall also include a review of up to three additional areas or practices of Lilly identified by the OIG in its discretion (hereafter "Additional Items".)

For purposes of identifying the Additional Items to be included in the Transactions Review for a particular Reporting Period, the OIG will consult with Lilly and may consider internal audit work conducted by Lilly and/or the Lilly Compliance Monitoring Program, Lilly's Government Reimbursed Product portfolio, the nature and scope of Lilly's promotional practices and arrangements with HCPs and HCIs, and other information known to it.

As set forth more fully in Section III.E of Appendix B, Lilly may propose to the OIG that its internal audit(s) be partially substituted for one or more of the Additional Items that would otherwise be reviewed by the IRO as part of the Transactions Review. The OIG retains sole discretion over whether, and in what manner, to allow Lilly's internal audit work to be substituted for a portion of the Additional Items review conducted by the IRO.

The OIG shall notify Lilly of the nature and scope of the IRO review for each of the Additional Items not later than 120 days prior to the end of each Reporting Period. Prior to undertaking the review of the Additional Items, the IRO and/or Lilly shall submit an audit work

plan to the OIG for approval and the IRO shall conduct the review of the Additional Items based on a work plan approved by the OIG.

c. *Retention of Records.* The IRO and Lilly shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Lilly) related to the reviews.

2. *IRO Review Reports.* The IRO(s) shall prepare a report (or reports) based upon each Review performed. The information and content to be included in the report is described in Appendix B, which is incorporated by reference.

3. *Validation Review.* In the event OIG has reason to believe that: (a) any IRO Review fails to conform to the requirements of this CIA; or (b) the IRO's findings or Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the applicable IRO Review complied with the requirements of the CIA and/or the findings or Review results are inaccurate (Validation Review). Lilly shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents. Any Validation Review of Reports submitted as part of Lilly's final Annual Report shall be initiated no later than one year after Lilly's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Lilly of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, Lilly may request a meeting with OIG to: (a) discuss the results of any Review submissions or findings; (b) present any additional information to clarify the results of the applicable Review or to correct the inaccuracy of the Review; and/or (c) propose alternatives to the proposed Validation Review. Lilly agrees to provide any additional information as may be requested by OIG under this Section III.D.3 in an expedited manner. OIG will attempt in good faith to resolve any Review issues with Lilly prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

4. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to Lilly a certification or sworn affidavit that it has evaluated its professional independence and objectivity, as appropriate to the nature of the engagement, with regard

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to the applicable Review and that it has concluded that it is, in fact, independent and objective.

E. Disclosure Program.

Lilly represents that it has a disclosure program designed to facilitate communications relating to compliance with Federal health care program and FDA requirements and Lilly's policies (the "Disclosure Program"). During the term of the CIA, Lilly shall maintain a Disclosure Program that includes a mechanism (a toll-free compliance telephone line and/ or on-line electronic reporting) to enable individuals to disclose, to the Chief Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Lilly's policies, conduct, practices, or procedures with respect to a Federal health care program or FDA requirement believed by the individual to be a potential violation of criminal, civil, or administrative law. Lilly shall continue to appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a nonretaliation policy, and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Disclosures made by individuals residing outside the United States shall be in accordance with applicable laws, including the European Union Data Protection Directive. Upon receipt of a disclosure, the Chief Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Chief Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, Lilly shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

The Chief Compliance Officer (or designee) shall maintain a disclosure log, which shall include a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. The disclosure log shall be made available to OIG upon request.

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F. Ineligible Persons.

1. *Definitions.* For purposes of this CIA:

- a. an "Ineligible Person" shall include an individual or entity who:
 - i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or
 - ii. has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.
- b. "Exclusion Lists" include:
 - i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://www.oig.hhs.gov>); and
 - ii. the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://www.epls.gov>).
- c. "Screened Persons" shall include all Covered Persons.

2. *Screening Requirements.* Lilly shall ensure that all Screened Persons are not Ineligible Persons, by implementing the following screening requirements.

- a. Lilly shall screen all Screened Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require such Screened Persons to disclose whether they are Ineligible Persons.

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b. Lilly shall screen all Screened Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.

c. Lilly shall implement a policy requiring all Screened Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

Nothing in this Section affects the responsibility of (or liability for) Lilly to (if applicable) refrain from billing Federal health care programs for items or services furnished, ordered, or prescribed by an Ineligible Person. Lilly understands that items or services furnished by excluded persons are not payable by Federal health care programs and that Lilly may be liable for overpayments (if applicable) and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Lilly meets the requirements of Section III.F.

3. *Removal Requirement.* If Lilly has actual notice that a Screened Person has become an Ineligible Person, Lilly shall remove such Screened Person from responsibility for, or involvement with, Lilly's business operations related to the Federal health care programs and shall remove such Screened Person from any position for which the Screened Person's compensation or the items or services furnished, ordered, or prescribed by the Screened Person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the Screened Person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If Lilly has actual notice that a Screened Person is charged with a criminal offense that falls within the ambit of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Screened Person's employment or contract term, Lilly shall take all appropriate actions to ensure that the responsibilities of that Screened Person have not and shall not adversely affect the accuracy of any claims submitted to any Federal health care program.

G. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery by senior management at U.S. corporate headquarters of Lilly or Lilly USA, Lilly shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Lilly conducted or brought by a governmental entity or its agents involving an allegation that Lilly has committed a crime or has engaged in

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fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Lilly shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceedings, if any.

H. Reporting.

1. *Reportable Events*.

a. *Definition of Reportable Event*. For purposes of this CIA, a “Reportable Event” means anything that involves:

- i. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program and/or applicable to any FDA requirements relating to the promotion of Lilly Government Reimbursed Products for which penalties or exclusion may be authorized; or
- ii. the filing of a bankruptcy petition by Lilly.

A Reportable Event may be the result of an isolated event or a series of occurrences.

b. *Reporting of Reportable Events*. If Lilly or Lilly USA determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Lilly shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists. The report to OIG shall include the following information:

- i. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program and/or FDA authorities implicated;
- ii. a description of Lilly’s actions taken to correct the Reportable Event; and

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- iii. any further steps Lilly plans to take to address the Reportable Event and prevent it from recurring.
- iv. If the Reportable Event involves the filing of a bankruptcy petition, the report to the OIG shall include documentation of the filing and a description of any Federal health care program authorities and/or FDA authorities implicated.
- v. Lilly shall not be required to report as a Reportable Event any matter previously disclosed under Section III.G.

I. Notification of Communications with FDA.

Within 30 days after the date of any written report, correspondence, or communication between Lilly and the FDA that materially discusses Lilly's or a Covered Person's actual or potential unlawful or improper promotion of Lilly's products (including any improper dissemination of information about off-label indications), Lilly shall provide a copy of the report, correspondence, or communication to the OIG. Lilly shall also provide written notice to the OIG within 30 days after the resolution of any such disclosed off-label matter, and shall provide the OIG with a description of the findings and/or results of the matter, if any.

J. Review of Records Reflecting the Content of Detailing Sessions.

For each Reporting Period, Lilly shall obtain non-Lilly records (*e.g.*, Verbatims, message recall studies, or similar records) generated by an independent entity (Survey Entity) reflecting the purported content and subject matter of detailing interactions between Lilly sales representatives and HCPs for up to three Covered Products (as defined below). In order to satisfy its obligations under this Section III.J, Lilly may propose that it obtain an alternative type of survey record. The OIG will consider Lilly's proposal, and after considering Lilly's proposal shall, in its discretion, identify the type of survey records to be obtained.

For each Covered Product, Lilly shall contract with the Survey Entity to conduct inquiries into the content and subject matter of the detailing interactions. The OIG shall select and notify the Survey Entity of a one week period within every other quarter of the Reporting Period for which the surveys shall be conducted beginning in the second full

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quarter after the Effective Date. For each Covered Product, Lilly shall obtain records reflecting the purported content and subject matter of detailing sessions during the identified week in all regions across the United States.

Prior to the start of the second Reporting Period and every Reporting Period thereafter, based on the information provided and other information known to it, and after consultation with Lilly, the OIG shall select up to three Government Reimbursed Products to be the basis for the review outlined in this Section III.J and shall notify Lilly of its selection. These identified products shall be known as the "Covered Products." The parties have already identified the Covered Products for the first Reporting Period.

Lilly shall review the records obtained from the Survey Entity and shall identify any instances in which the records appear to indicate that Covered Persons may have discussed and/or disseminated information about off-label uses of the Covered Products. Lilly shall make findings based on its review (Off-Label Findings) and shall take any responsive action it deems necessary. If necessary for purposes of its review, Lilly shall endeavor to gather additional factual information about the circumstances relating to any Off-Label Findings. As part of each Annual Report, Lilly shall provide the OIG with copies of the underlying records of the detailing interactions, a copy of Lilly's Off-Label Findings, and a description of the action(s), if any, Lilly took in response to the Off-Label Findings.

K. Field Force Monitoring and Review Efforts

To the extent not already accomplished, within 120 days after the Effective Date, Lilly shall establish a Field Force Monitoring Program (FFMP) to evaluate and monitor field sales force representatives' interactions with HCPs. The FFMP shall be a formalized process designed to directly observe the appropriateness of field sales force representative's interactions with HCPs and to identify potential off-label promotional activities.

Under this program, Lilly compliance personnel or appropriately trained Lilly employees who are not currently working in the marketing or the field sales organization shall conduct direct field observations (Observations) of field sales force representatives to assess whether the messages delivered and materials distributed to HCPs are consistent with Lilly's Policies and Procedures. These Observations shall be full day ride-alongs with field sales representatives, and each Observation shall consist of directly observing all meetings between a sales representative and HCPs during the workday. The

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Observations shall be scheduled throughout the year, randomly selected by Lilly compliance personnel, include each therapeutic area and actively promoted product, and be conducted across the United States. At the completion of each Observation, Lilly compliance personnel or the designee shall prepare a report which includes:

- 1) the identity of the sales representative;
- 2) the identity of the Lilly compliance professional or other Lilly employee;
- 3) the date and duration of the Observation;
- 4) the product(s) promoted during the Observation;
- 5) an overall assessment of compliance with Lilly policy; and
- 6) the identification of any potential off-label promotional activity by the field sales representative.

Lilly compliance personnel shall conduct at least 50 full-day Observations during each Reporting Period. The number of inspections conducted for each therapeutic area and product shall be proportional in number to the size of each therapeutic area and product, and shall be conducted across the United States.

In the event that a compliance issue, including but not limited to a potential off-label promotion or noncompliance with Lilly's compliance program or policies and procedures, is identified during any Observation, Lilly shall investigate the incident consistent with established Policies and Procedures for the handling of investigations. As part of the formal investigation procedures, findings shall be made and all necessary and appropriate responsive action (including disciplinary action) and corrective action shall be taken. The Compliance Officer shall disclose Reportable Events pursuant to Section III.H above, if applicable. Any compliance issues identified during an Observation and any corrective action shall be recorded in the files of the compliance department.

Lilly shall include a summary of the FFMP and the results of the FFMP as part of each Annual Report. As part of each Annual Report, Lilly also shall provide the OIG with copies of the Observation report for any instances in which it was determined that improper promotion occurred and a description of the action(s) that Lilly took as a result of such determinations. Lilly shall make the Observation reports for all other Observations available to the OIG upon request.

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L. Notice to Health Care Providers and Entities

Within 90 days after the Effective Date, Lilly shall send, by first class mail, postage prepaid and return receipt requested, a notice containing the language set forth below to all HCPs and HCIs that Lilly currently details. This notice shall be dated and shall be signed by Lilly's Chief Executive Officer. The body of the letter shall state the following:

As you may be aware, Eli Lilly and Company (Lilly) recently entered into a global civil, criminal, and administrative settlement with the United States and individual states in connection of its promotion of its drug Zyprexa.

This letter provides you with additional information about the settlement, explains Lilly's commitments going forward, and provides you with access to information about those commitments. In general terms, the Government alleged that Lilly unlawfully promoted the drug Zyprexa for certain uses not approved by the Food & Drug Administration (FDA). To resolve these matters, Lilly pled guilty to a misdemeanor criminal violation of the Federal Food Drug and Cosmetic Act and agreed to pay more than \$1 billion to the Federal Government and state Medicaid programs. More information about this settlement may be found at the following: **[Lilly shall include a link to the USAO, OCL, and Eli Lilly websites in the letter.]**

As part of the federal settlement, Lilly also entered into a five-year corporate integrity agreement with the Office of Inspector General of the U.S. Department of Health and Human Services. The corporate integrity agreement is available at <http://oig.hhs.gov/fraud/cia/index.html>. Under this agreement, Lilly agreed to undertake certain obligations designed to promote compliance with Federal healthcare program and FDA requirements. We also agreed to notify healthcare providers about the settlement and inform them that they can report any questionable practices by Lilly's representatives to Lilly's Compliance Department or the FDA.

Please call or email Lilly at **1-800-TBD** or **[Lilly shall insert website address in the letter.]** if you have questions about the settlement referenced above or to report any instances in which you believe that a Lilly representative inappropriately promoted a product or engaged in other questionable conduct. Alternatively, you may report any such instances to the FDA's Division of Drug Marketing, Advertising, and Communications at 301-796-1200. You should direct medical questions or concerns about the products to The Lilly Answer Center at 1-800-Lilly-Rx.

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We appreciate your time and attention. We are dedicated to ensuring that we bring you the scientific and medical information you need to make well-informed decisions about whether Lilly products are right for your patients.

The Chief Compliance Officer (or a designee) shall maintain a log of all calls and messages received in response to the notice. The log shall include a record and summary of each call and message received (whether anonymous or not), the status of the call or message, and any corrective action taken in response to the call or message. The disclosure log shall be made available to OIG upon request. As part of the Implementation Report and each Annual Report, Lilly shall provide to the OIG a summary of the calls and messages received.

M. Reporting of Physician Payments

1. Phase I Reporting

On or before August 1, 2009, Lilly shall post in a prominent position on its website an easily accessible and readily searchable listing of all U.S.-based physicians and Related Entities (as defined below in Section III.M.4) who or which received Phase I Payments (as defined below in Section III.M.4) directly or indirectly from Lilly or Lilly USA during the first three months of 2009 and the aggregate value of such Payments.

After the initial posting, 30 days after the end of each subsequent calendar quarter, Lilly shall also post on its website a listing of updated information about all Phase I Payments provided during the applicable calendar year during the preceding quarter(s). On or before May 1, 2010, Lilly shall also post on its website a report of the cumulative value of Phase I Payments provided to each physician and/or Related Entity during the preceding calendar year. The quarterly and annual reports shall be easily accessible and readily searchable.

Each listing made pursuant to this Section III.M.1 or Sections III.M.2 or 3 below, shall include a complete list of all individual physicians and Related Entities to whom or to which Lilly or Lilly USA directly or indirectly made the Phase I, II, or III Payments (as applicable) in the preceding calendar quarter or year (as applicable). Each listing shall be arranged alphabetically according to the physicians' last name or the name of the Related

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Entity. The Payment amounts in the lists shall be reported in \$10,000 increments (e.g., \$0 - \$10,000; \$10,001- \$20,000; etc.) For each physician, the applicable listing shall include the following information: i) physician's full name; ii) name of Related Entity (if applicable); iii) city and state that the physician or the Related Entity has provided to Lilly for contact purposes; and (iv) the aggregate value of the payment(s) in the preceding quarter(s) or year (as applicable). If payments for multiple physicians have been made to one Related Entity, the aggregate value of all payments to the Related Entity will be the reported amount.

2. Phase II Reporting

On or before August 1, 2010, Lilly shall post in a prominent position on its website an easily accessible and readily searchable listing of all U.S.-based physicians and Related Entities (as defined below in Section III.M.4) who provided or which received Phase II Payments (as defined below in Section III.M.4) directly or indirectly from Lilly or Lilly USA during the first three months of 2010 and the aggregate value of such Payments.

After the initial posting, 30 days after the end of each subsequent calendar quarter, Lilly shall also post on its website a listing of updated information about all Phase II Payments provided during the applicable calendar year during the preceding quarter(s). On or before May 1, 2011, Lilly shall also post on its website a report of the cumulative value of Phase II Payments provided to each physician and/or Related Entity during the preceding calendar year. The quarterly and annual reports shall be easily accessible and readily searchable.

3. Phase III Reporting

On or before August 1, 2011, Lilly shall post in a prominent position on its website an easily accessible and readily searchable listing of all U.S.-based physicians and Related Entities (as defined below in Section III.M.4) who or which received Phase III Payments (as defined below in Section III.M.4) directly or indirectly from Lilly or Lilly USA during the first three months of 2011 and the aggregate value of such Payments.

After the initial posting, 30 days after the end of each subsequent calendar quarter, Lilly shall also post on its website a listing of updated information about all Phase III Payments provided during the applicable calendar year during the preceding quarter(s). On or before May 1, 2012, Lilly shall also post on its website a report of the cumulative

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value of Phase III Payments provided to each physician and/or Related Entity during the preceding calendar year. Thereafter, on or before May 1 of each subsequent year, Lilly shall post a report of the cumulative value of Payments provided to each physician and/or Related Entity during the preceding calendar year. The quarterly and annual reports shall be easily accessible and readily searchable.

4. Definitions and Miscellaneous Provisions

Lilly shall continue to make each annual listing and the most recent quarterly listing of Phase I, Phase II, and Phase III Reporting available on its website at least throughout the term of this CIA. Lilly shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and records related to all applicable Payments and to the annual and quarterly listings of Payments. Nothing in this Section III.M affects the responsibility of Lilly to comply with (or liability for noncompliance with) all applicable Federal health care program requirements and state laws as they relate to all applicable Payments made to physicians or Related Entities.

If the proposed Physician Payments Sunshine Act of 2008 or similar legislation is enacted, the OIG shall determine whether the purposes of this Section III.M are reasonably satisfied by Lilly's compliance with such legislation. In such case, and in its sole discretion, the OIG may agree to modify or terminate provisions of Section III.M as appropriate.

For purposes of this Section III.M, the term "Phase I Payments" is defined as all honoraria payments made in connection with physicians serving as speakers, participating in speaker training, or serving as consultants (including participating in advisory boards, providing training to Lilly employees, or providing ad hoc advising.)

For purposes of this Section III.M, the term "Phase II Payments" is defined as all payments (including, for example, honoraria payments, other payments, and reimbursement for lodging, travel and other expenses) made in connection with physicians serving as speakers, participating in speaker training, or serving as consultants (including participating in advisory boards, providing training to Lilly employees, or providing ad hoc advising).

For purposes of this Section III.M, the term "Phase III Payments" is defined to include all payments or transfers of value (whether in cash or in kind) made to physicians. The term also includes all payments or transfers of value made to Related Entities on

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behalf of, at the request of, for the benefit or use of, or under the name of a physician for whom Lilly would otherwise report a Payment if made directly to the physician. Phase III Payments includes all Phase I and Phase II Payments. Phase III Payments include, for example, payments or compensation for services rendered; grants; fees; and payments relating to research or education. The term Phase III Payments also includes payment or reimbursement for food, entertainment, gifts, trips or travel, product(s)/item(s) provided for less than fair market value, or other economic benefit paid or transferred. Phase III Payments do not include: i) samples of drug products that meet the definition set forth in 21 C.F.R. § 203.3(i), or ii) discounts, rebates, or other pricing terms.

For purposes of this Section III.M, the term “Related Entity” is defined to be any entity by or in which any physician receiving Phase I, II, or III Payments is employed, has tenure, or has an ownership interest.

IV. CHANGES TO BUSINESS UNITS OR LOCATIONS

A. Change or Closure of Unit or Location. In the event that, after the Effective Date, Lilly or Lilly USA changes locations or closes a business unit or location related to Promotional and Product Services Related Functions, Lilly shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change or closure of the location.

B. Purchase or Establishment of New Unit or Location. In the event that, after the Effective Date, Lilly or Lilly USA purchases or establishes a new business unit or location related to Promotional and Product Services Related Functions, Lilly shall notify OIG no later than the date that the purchase or establishment is publicly disclosed by Lilly. This notification shall include the address of the new business unit or location, phone number, fax number, Federal health care program provider or supplier number (if applicable), and the name and address of the contractor that issued each number (if applicable). Each new business unit or location and all Covered Persons at each new business unit or location shall be subject to the applicable requirements of this CIA.

C. Sale of Unit or Location. In the event that, after the Effective Date, Lilly or Lilly USA proposes to sell any or all of its business units or locations related to the Promotional and Product Services-Related Functions that are subject to this CIA, Lilly shall notify OIG of the proposed sale no later than the date the sale is publicly disclosed by Lilly. This notification shall include a description of the business unit or location to be sold, a brief description of the terms of the sale, and the name and contact information of

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the prospective purchaser. This CIA shall be binding on the purchaser of such business unit or location, unless otherwise determined and agreed to in writing by the OIG.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. **Implementation Report**. Within 150 days after the Effective Date, Lilly shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A.1, and a summary of other noncompliance job responsibilities the Compliance Officer may have;
2. the names and positions of the members of the Compliance Committee required by Section III.A.2;
3. the names of the members of the Committee of the Board referenced in Section III.A.3;
4. the names and positions of the Certifying Employees required by Section III.A.4;
5. a copy of Lilly's Code of Conduct required by Section III.B.1;
6. the number of Covered Persons required to complete the Code of Conduct certification required by Section III.B.1, the percentage of Covered Persons who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);
7. (a) a copy of the letter (including all attachments) required by Sections II.C.6 and III.B.2 sent to each party employing Third Party Personnel; (b) a list of all such existing agreements; and (c) a description of the entities' response to Lilly's letter;
8. to the extent not already provided to the OIG, a copy of all Policies and Procedures required by Section III.B.3;

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9. the following information regarding each type of training required by Section III.C:

- a. a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and
- b. the number of Covered Persons required to be trained, percentage of Covered Persons actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request;

10. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; and (c) a summary and description of any and all current and prior engagements and agreements between Lilly and the IRO;

11. a certification from the IRO regarding its professional independence and objectivity with respect to Lilly;

12. a description of the Disclosure Program required by Section III.E;

13. a description of the process by which Lilly fulfills the requirements of Section III.F regarding Ineligible Persons;

14. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F; the actions taken in response to the screening and removal obligations set forth in Section III.F;

15. a certification by the Chief Compliance Officer that the notice required by Section III.L was mailed to each HCP and HCI, the number of HCPs and HCIs that received a copy of the notice, a sample copy of the notice required by Section III.L, and a summary of the calls or messages received in response to the notice;

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16. a certification from the Chief Compliance Officer that, if required under Section III.M and to the best of his/her knowledge, information regarding Payments has been posted on Lilly's website as required by Section III.M;

17. a list of all of Lilly's U.S. locations (including locations and mailing addresses) at which it performs Promotional and Product Services Related Functions; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Federal health care program provider or supplier number(s) (if applicable), and the name and address of each Federal health care program contractor to which Lilly currently submits claims (if applicable);

18. a description of Lilly's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and

19. the certifications required by Section V.C.

B. Annual Reports. Lilly shall submit to OIG annually a report with respect to the status of, and findings regarding, Lilly's compliance activities for each of the five Reporting Periods (Annual Report).

Each Annual Report shall include, at a minimum:

1. an explanation of any change in the identity, position description, or other noncompliance job responsibilities of the Chief Compliance Officer and any change in the membership of the Compliance Committee, the compliance Committee of the Board of Directors, or the group of Certifying Employees described in Sections III.A.2-4, and a copy of the Compliance Program Review Report described in Section III.A.3;

2. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B and the reasons for such changes (e.g., change in applicable requirements);

3. the number of Covered Persons required to complete the Code of Conduct certification required by Section III.B.1, the percentage of Covered Persons who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);

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4. (a) a copy of the letter (including all attachments) required by Sections II.C.6 and III.B.2 sent to each entity employing Third Party Personnel; (b) a list of all such existing agreements; and (c) a description of the entities' response to Lilly's letter;
5. the following information regarding each type of training required by Section III.C:
 - a. a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and
 - b. the number of Covered Persons required to be trained, percentage of Covered Persons actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request.

6. a complete copy of all reports prepared pursuant to Section III.D, along with a copy of the IRO's engagement letter (if applicable);
7. Lilly's response and corrective action plan(s) related to any issues raised by the reports prepared pursuant to Section III.D;
8. a summary and description of any and all current and prior engagements and agreements between Lilly and the IRO, if different from what was submitted as part of the Implementation Report;
9. a certification from the IRO regarding its professional independence and objectivity with respect to Lilly;
10. a summary of the disclosures in the disclosure log required by Section III.E that relate to Federal health care programs;
11. any changes to the process by which Lilly fulfills the requirements of Section III.F regarding Ineligible Persons;
12. the name, title, and responsibilities of any person who is determined to

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be an Ineligible Person under Section III.F; the actions taken by Lilly in response to the screening and removal obligations set forth in Section III.F;

13. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.G. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

14. a summary of Reportable Events (as defined in Section III.H) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;

15. a summary describing any written communication with the FDA required to have been reported pursuant to Section III.I. This summary shall include a description of the matter and the status of the matter;

16. all information required by Section III.J;

17. all information required by Section III.K;

18. a summary of the calls and messages received in response to the notice required by Section III.L and the disposition of those calls and messages

19. a description of all changes to the most recently provided list of Lilly's locations (including addresses) as required by Section V.A.17; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Federal health care program provider or supplier number(s) (if applicable), and the name and address of each Federal health care program contractor to which Lilly currently submits claims (if applicable); and

20. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

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C. Certifications. The following certifications shall be included in the Implementation Report and Annual Reports:

1. Certifying Employees: In each Annual Report, Lilly shall include the certifications of Certifying Employees as required by Section III.A.4;

2. Chief Compliance Officer: In the Implementation Report and Annual Reports, Lilly shall include the following individual certification by the Chief Compliance Officer:

a. he or she has reviewed the Report and has made reasonable inquiry regarding its content and believes that the information in the Report is accurate and truthful;

b. to the best of his or her knowledge, except as otherwise described in the applicable report, Lilly is in compliance with the Federal health care program and FDA requirements and the obligations of the CIA;

c. to the best of his or her knowledge, Lilly has complied with its obligations under the Settlement Agreement: (a) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (b) not to charge to or otherwise seek payment from federal or state payors for unallowable costs (as defined in the Settlement Agreement); and (c) to identify and adjust any past charges or claims for unallowable costs;

d. Lilly's: 1) Policies and Procedures as referenced in Section III.B.3 above; 2) templates for standardized contracts and other similar documents; and 3) the training materials used for purposes of Section III.C all have been reviewed by competent legal counsel and/or legal personnel working at their direction and have been found to be in compliance with all applicable Federal health care program and FDA requirements. In addition, Lilly's promotional materials containing claims or information about Government Reimbursed Products and other materials and information intended to be disseminated outside Lilly have been reviewed by competent regulatory, medical, and/or legal personnel in accordance with applicable Policies and Procedures to ensure that legal, medical, and regulatory concerns are properly addressed and are elevated when appropriate, and that the materials and information when finally approved are in compliance with all applicable Federal health care program and FDA requirements. If the

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applicable legal requirements have not changed, after the initial review of the documents listed above, only material changes to the documents must be reviewed by competent regulatory, medical, and/or legal personnel. The certification shall include a description of the document(s) reviewed and approximately when the review was completed. The documentation supporting this certification shall be available to OIG, upon request; and

e. Lilly's call plans for Government Reimbursed Products were reviewed at least once during the Reporting Period (consistent with Section III.B.3.g) and, for each product the call plans were found to be consistent with Lilly's policy objectives as referenced above in Section III.B.3.g.

D. Designation of Information. Lilly shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. Lilly shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG: Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, S.W.
Washington, DC 20201
Telephone: 202.619.2078
Facsimile: 202.205.0604

Lilly: Chief Compliance Officer
Eli Lilly and Company
Lilly Corporate Center, DC 1114
Indianapolis, IN 46285
Telephone: 317.276.9937
Facsimile: 317.655.1921

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Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt. Upon request by OIG, Lilly may be required to provide OIG with an electronic copy of each notification or report required by this CIA in searchable portable document format (pdf), either instead of or in addition to, a paper copy.

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of Lilly's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Lilly's locations for the purpose of verifying and evaluating: (a) Lilly's compliance with the terms of this CIA; and (b) Lilly's compliance with the requirements of the Federal health care programs in which it participates and with all applicable FDA requirements. The documentation described above shall be made available by Lilly to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of Lilly's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Lilly shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Lilly's employees may elect to be interviewed with or without a representative of Lilly present.

VIII. DOCUMENT AND RECORD RETENTION

Lilly shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this CIA, for six years (or longer if otherwise required by law) from the Effective Date.

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IX. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify Lilly prior to any release by OIG of information submitted by Lilly pursuant to its obligations under this CIA and identified upon submission by Lilly as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Lilly shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. BREACH AND DEFAULT PROVISIONS

Lilly is expected to fully and timely comply with all of its CIA obligations. The breach and default remedies available to the OIG under this Section X do not preempt or limit any actions that individual States may take against Lilly under applicable legal authorities or under any applicable settlement agreement or consent decree between the State and Lilly.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Lilly and OIG hereby agree that failure to comply with certain obligations as set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Lilly fails to establish, implement, or accomplish any of the following obligations as described in Section III:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. the resolution from the Committee of the Board;
- d. a written Code of Conduct;
- e. written Policies and Procedures;
- f. the training of Covered Persons and Relevant Covered Persons;
- g. a Disclosure Program;

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- h. Ineligible Persons screening and removal requirements;
- i. notification of Government investigations or legal proceedings;
- j. notification of written communications with FDA as required by Section III.I;
- k. a review of records reflecting the content of detailing sessions;
- l. a program for FFMP;
- l. notification to HCPs and HCIs as required by Section III.L;
- m. posting of any Payments as required by Section III.M.

2. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Lilly fails to engage an IRO, as required in Section III.D and Appendices A-B.

3. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Lilly fails to submit the Implementation Report or the Annual Reports to OIG in accordance with the requirements of Section V by the deadlines for submission.

4. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Lilly fails to submit the annual IRO Review Report(s) in accordance with the requirements of Section III.D and Appendices A-B.

5. A Stipulated Penalty of \$1,500 for each day Lilly fails to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date Lilly fails to grant access.)

6. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of Lilly as part of its Implementation Report, Annual Report, additional documentation to a report (as requested by the OIG), or otherwise required by this CIA.

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7. A Stipulated Penalty of \$1,000 for each day Lilly fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Lilly, stating the specific grounds for its determination that Lilly has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Lilly shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Lilly receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-6 of this Section.

B. Timely Written Requests for Extensions. Lilly may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after Lilly fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after Lilly receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

1. *Demand Letter*. Upon a finding that Lilly has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify Lilly of: (a) Lilly's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. *Response to Demand Letter*. Within 10 days after the receipt of the Demand Letter, Lilly shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event Lilly elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Lilly cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one

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of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.D.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by electronic funds transfer to an account specified by OIG in the Demand Letter.

4. *Independence from Material Breach Determination.* Except as set forth in Section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Lilly has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA.

1. *Definition of Material Breach.* A material breach of this CIA means:

- a. a failure by Lilly to report a Reportable Event and take corrective action, as required in Section III.H;
- b. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;
- c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C;
- d. a failure to engage and use an IRO in accordance with Section III.D; or
- e. a failure of the Committee of the Board to issue a resolution in accordance with Section III.A.3.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Lilly constitutes an independent basis for Lilly's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Lilly has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Lilly of: (a) Lilly's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred

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to as the “Notice of Material Breach and Intent to Exclude”).

3. *Opportunity to Cure.* Lilly shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG’s satisfaction that:

- a. Lilly is in compliance with the obligations of the CIA cited by OIG as being the basis for the material breach;
- b. the alleged material breach has been cured; or
- c. the alleged material breach cannot be cured within the 30-day period, but that: (i) Lilly has begun to take action to cure the material breach; (ii) Lilly is pursuing such action with due diligence; and (iii) Lilly has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, Lilly fails to satisfy the requirements of Section X.D.3, OIG may exclude Lilly from participation in the Federal health care programs. OIG shall notify Lilly in writing of its determination to exclude Lilly (this letter shall be referred to hereinafter as the “Exclusion Letter”). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of Lilly’s receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, Lilly may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. *Review Rights.* Upon OIG’s delivery to Lilly of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, Lilly shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG’s determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS

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Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether Lilly was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Lilly shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders Lilly to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Lilly requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be:

- a. whether Lilly was in material breach of this CIA;
- b. whether such breach was continuing on the date of the Exclusion Letter; and
- c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) Lilly had begun to take action to cure the material breach within that period; (ii) Lilly has pursued and is pursuing such action with due diligence; and (iii) Lilly provided to OIG within that period a reasonable timetable for curing the material breach and Lilly has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Lilly, only after a DAB

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decision in favor of OIG. Lilly's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Lilly upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Lilly may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. Lilly shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Lilly, Lilly shall be reinstated effective on the date of the original exclusion.

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA.

XI. EFFECTIVE AND BINDING AGREEMENT

Lilly and OIG agree as follows:

A. This CIA shall be binding on the successors, assigns, and transferees of Lilly;

B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;

C. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA;

D. The undersigned Lilly signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA; and

E. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same CIA. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this CIA.

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ON BEHALF OF ELI LILLY AND COMPANY

/s/ Robert A. Armitage	14 January 2009
Robert A. Armitage	Date
Senior Vice President and General Counsel	

/s/ Anne Nobles	1/14/09
Anne Nobles	Date
Lilly Chief Compliance Officer	

/s/ Paul Kalb	1/14/09
Paul Kalb	Date
Kristin Koehler	
Counsel for Eli Lilly and Company	
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**ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES**

/s/ Gregory E. Demske

1/14/09

Gregory E. Demske

DATE

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U. S. Department of Health and Human Services

Corporate Integrity Agreement

Eli Lilly Company

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

This Appendix contains the requirements relating to the Independent Review Organization (IRO) required by Section III.D of the CIA.

A. IRO Engagement

Lilly shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify Lilly if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Lilly may continue to engage the IRO.

If Lilly engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, Lilly shall submit the information identified in Section V.A.8 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify Lilly if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Lilly may continue to engage the IRO.

B. IRO Qualifications.

The IRO shall:

1. assign individuals to conduct the Promotional and Product Services Review who have expertise in all applicable Federal health care program and FDA requirements relating to Promotional and Product Services Related Functions. The assigned individuals shall also be knowledgeable about the general requirements of the Federal health care program(s) under which Lilly products are reimbursed;

2. assign individuals to design and select the samples for the Transaction Reviews who are knowledgeable about the appropriate statistical sampling techniques; and

3. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

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C. IRO Responsibilities.

The IRO shall:

1. perform each Promotional and Product Services Review in accordance with the specific requirements of the CIA;
2. follow all applicable Federal health care program and FDA requirements in making assessments in each Promotional and Product Services Review;
3. if in doubt of the application of a particular Federal health care program or FDA requirement, policy, or regulation, request clarification from the appropriate authority (e.g., CMS or FDA);
4. respond to all OIG inquiries in a prompt, objective, and factual manner; and
5. prepare timely, clear, well-written reports that include all the information required by Appendix B to the CIA.

D. IRO Independence and Objectivity.

The IRO must perform the Promotional and Product Services Review in a professionally independent and objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist between the IRO and Lilly.

E. IRO Removal/Termination.

1. *Lilly Termination of IRO.* If Lilly terminates its IRO during the course of the engagement, Lilly must submit a notice explaining its reasons to OIG no later than 30 days after termination. Lilly must engage a new IRO in accordance with Paragraph A of this Appendix.

2. *OIG Removal of IRO.* In the event OIG has reason to believe that the IRO does not possess the qualifications described in Paragraph B, is not independent and/or objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG may, at its sole discretion, require Lilly to engage a new IRO in accordance with Paragraph A of this Appendix.

Prior to requiring Lilly to engage a new IRO, OIG shall notify Lilly of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, Lilly may request a meeting with OIG to discuss any aspect of the IRO's qualifications, independence or performance of its responsibilities and to present additional information regarding these matters. Lilly shall provide any additional information as may be requested by OIG under this Paragraph in an expedited manner. OIG will attempt in good faith to resolve any differences regarding the IRO with Lilly prior to requiring Lilly to terminate the IRO. However, the final determination as to whether or not to require Lilly to engage a new IRO shall be made at the sole discretion of OIG.

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Promotional and Product Services Review

I. Promotional and Product Services Review, General Description

As specified more fully below, Lilly shall retain an Independent Review Organization (IRO) to perform reviews to assist Lilly in assessing and evaluating its systems, processes, policies, procedures, and practices related to Lilly's Promotional and Product Services Related Functions (Promotional and Product Services Review). The Promotional and Product Services Review shall consist of two components - a systems review (the "Promotional and Product Services Systems Review" or "Systems Review"), and a transactions review (the "Promotional and Product Services Transactions Review" or "Transactions Review") as described more fully below. Lilly may engage, at its discretion, a single IRO to perform both components of the Promotional and Product Services Review provided that the entity has the necessary expertise and capabilities to perform both.

If there are no material changes in Lilly's systems, processes, policies, and procedures relating to Promotional and Product Services Related Functions, the IRO shall perform the Promotional and Product Services Systems Review for the first and fourth Reporting Periods. If Lilly materially changes its systems, processes, policies, and procedures relating to Promotional and Product Services Related Functions, the IRO shall perform a Promotional and Product Services Systems Review for the Reporting Period(s) in which such changes were made in addition to conducting the Review for the first and fourth Reporting Periods. The additional Systems Review(s) shall consist of: 1) an identification of the material changes; 2) an assessment of whether other systems, processes, policies, and procedures previously reported did not materially change; and 3) a review of the systems, processes, policies, and procedures that materially changed. The IRO shall conduct the Promotional and Product Services Transactions Review for each Reporting Period of the CIA.

II. Promotional and Product Services Systems Review

A. Description of Reviewed Policies and Procedures

The Promotional and Product Services Systems Review shall be a review of Lilly's systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) relating to certain Promotional and Product Services Related Functions. Where practical, Lilly personnel may compile documentation, schedule and organize interviews, and undertake other efforts to assist the IRO in performing the Systems Review. The IRO is not

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required to undertake a de novo review of the information gathered or activities undertaken by Lilly pursuant to the preceding sentence.

Specifically, the IRO shall review Lilly's systems, processes, policies, and procedures associated with the following (hereafter "Reviewed Policies and Procedures"):

1) Lilly's systems, policies, processes, and procedures applicable to the manner in which Lilly sales representatives and account executives handle and submit requests or inquiries to The Lilly Answers Center ("TLAC") relating to information about the uses of Lilly's Government Reimbursed Products (including non-FDA-approved (*i.e.*, off-label) uses) and the dissemination of materials relating to off-label uses of Lilly's Government Reimbursed Products. This review includes:

- a) the manner in which Lilly sales representatives and account executives handle and submit requests for information about off-label uses of Lilly's Government Reimbursed Products to TLAC;
- b) the manner in which TLAC personnel, handle and respond to requests submitted by sales representatives and account executives for information about off-label uses of Lilly's Government Reimbursed Products (including tracking the requests and using pre-approved materials for purposes of responding to the request);
- c) the form and content of information and materials related to Lilly's Government Reimbursed Products disseminated to physicians, pharmacists, or other health care professionals (collectively "HCPs") or health care institutions (HCIs) by Lilly;
- d) Lilly's systems, processes, and procedures (including the TLAC Database) used to track requests for information submitted by sales representatives and account executives to TLAC about off-label uses of Lilly's Government Reimbursed Products and responses to those requests;
- e) the manner in which Lilly collects and supports information reported in any systems used to track and respond to requests for product information, including the TLAC Database;

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- f) the processes and procedures by which TLAC and Lilly's Compliance Office or their designee monitor and identify situations in which it appears that improper off-label promotion may have occurred; and
 - g) Lilly's processes and procedures for investigating, documenting, resolving, and taking appropriate disciplinary action for potential situations involving off-label promotion;
- 2) Lilly's policies and procedures applicable to the manner and circumstances under which its Medical Liaisons and Outcomes Liaisons participate in meetings or events with HCPs or HCIs (either alone or with sales representatives or account executives) and the role of the Medical Liaisons and Outcomes Liaisons at such meetings or events, including use of the Eli Lilly Contact Information Management (ELCIM) system to document requests and/or the use of LillyMedical.com to respond to requests for medical information;
 - 3) Lilly's systems, policies, processes, and procedures relating to Lilly's internal review and approval of information and materials related to Lilly's Government Reimbursed Products disseminated to HCPs or HCIs by Lilly;
 - 4) Lilly's systems, policies, processes and procedures relating to incentive compensation for Covered Persons who are sales representatives, with regard to whether the systems, policies, processes, and procedures are designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in the improper promotion, sales, and marketing of Lilly's Government Reimbursed Products. This shall include a review of the bases upon which compensation is determined and the extent to which compensation is based on product performance;
 - 5) Lilly's systems, processes, policies, and procedures relating to the development and review of call plans for Lilly's Government Reimbursed Products. This shall include a review of the bases upon which HCPs and HCIs belonging to specified medical specialties are included in, or excluded from, the call plans based on expected utilization of Lilly Government Reimbursed Products for FDA-approved uses or non-FDA-approved uses; and
 - 6) Lilly's systems, processes, policies, and procedures relating to the development, implementation, and review of Sample Distribution

Plans. This shall include a review of the bases upon, and circumstances under, which HCPs and HCIs belonging to specified medical specialties or types of clinical practice may receive samples from Lilly (including, separately, from Lilly sales representatives and Lilly's medical services department).

B. Promotional and Product Services Systems Review Report

The IRO shall prepare a report based upon each Systems Review. For each of the Reviewed Policies and Procedures identified in Section II.A above, the report shall include the following items:

- 1) a description of the documentation (including policies) reviewed and any personnel interviewed;
- 2) a detailed description of Lilly's systems, policies, processes, and procedures relating to the items identified in Sections II.A.1-6 above, including a general description of Lilly's control and accountability systems (e.g., documentation and approval requirements, and tracking mechanisms) and written policies regarding the Reviewed Policies and Procedures;
- 3) a description of the manner in which the control and accountability systems and the written policies relating to the items identified in Sections II.A.1-6 above are made known or disseminated within Lilly;
- 4) a detailed description of any system(s) used to track and respond to requests for information submitted by sales representatives and account executives about Lilly's Government Reimbursed Products (including the TLAC Database);
- 5) a detailed description of Lilly's incentive compensation system for Covered Persons who are sales representatives, including a description of the bases upon which compensation is determined and the extent to which compensation is based on product performance. To the extent that Lilly may establish compensation differently for individual products, the IRO shall report separately on each such type of compensation arrangement;
- 6) findings and supporting rationale regarding any weaknesses in Lilly's systems, processes, policies, and procedures relating to the Reviewed Policies and Procedures, if any; and

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7) recommendations to improve any of the systems, policies, processes, or procedures relating to the Reviewed Policies and Procedures, if any.

III. Promotional and Product Services Transaction Review

As described more fully below in Sections III.A-E, the Promotional and Product Services Transactions Review shall include: (1) a review of a sample of Inquiries reflected in the TLAC Database; (2) a review of Lilly's call plans and Lilly's call plan review process; (3) a review of Sampling Events as defined below in Section III.C; (4) a review of records relating to a sample of the Payments that are reported by Lilly pursuant to Section III.M of the CIA; and (5) a review of up to three additional items identified by the OIG in accordance with Section III.D.1.b of the CIA (hereafter "Additional Items".) The IRO shall report on all aspects of its reviews in the Promotional and Product Services Transactions Review Reports.

A. Review of Inquiries and TLAC Database

1) Description of TLAC Database

As set forth in Section III.B.3.e of the CIA, Lilly shall establish a database (hereafter, "TLAC database") to track information relating to requests for information submitted by Lilly sales representatives and account executives to TLAC about its products (hereafter "Inquiries"). Specifically, Lilly shall document and record all Inquiries submitted based on requests from HCPs or HCIs regarding Lilly's Government Reimbursed Products in the TLAC database. Lilly shall record in the TLAC Database the following information for each Inquiry received: 1) date of Inquiry; 2) form of Inquiry (e.g., fax, phone, medical information request form); 3) name of requesting HCP or HCI, in accordance with applicable privacy laws; 4) nature and topic of request (including exact language of the Inquiry if made in writing); 5) nature/form of the response from Lilly (including a record of any materials provided in response to the request); and 6) the name of the Lilly representative who called upon or interacted with the HCP or HCI, if known.

2) Internal Review of TLAC Database

On a semi-annual basis, the Lilly's Compliance Office or designee shall review the TLAC Database and related information, as

appropriate, and shall generate a report summarizing the items of information outlined in Section III.A.1 above for each Inquiry received during the preceding two quarters (“TLAC Database Report”). Lilly’s Compliance Office or designee shall review the TLAC Database Reports to assess whether the information contained in the report suggests that improper off-label promotion may have occurred in connection with any Inquiry(ies). If the Lilly’s Compliance Office or designee, in consultation with other appropriate Lilly personnel, suspects that improper off-label promotion may have occurred in connection with any Inquiry, the Lilly’s Compliance Office or designee shall undertake a follow-up review of the Inquiry (hereafter “Off-Label Review”), make specific findings based on the Off-Label Review, and take all appropriate corrective action (including disciplinary action of the Covered Person and reporting of the conduct, including disclosing Reportable Events pursuant to Section III.H of the CIA, if applicable).

3) IRO Review of Inquiries Reflected in the TLAC Database

The IRO shall select and review a random sample of 60 Inquiries from among the Inquiries reflected in the TLAC Database for each Reporting Period. Forty-five of the Inquiries reviewed by the IRO shall be Inquiries for which Lilly conducted an Off-Label Review, and the other 15 shall be Inquiries for which Lilly did not conduct an Off-Label Review. If Lilly conducted an Off-Label Review on fewer than 45 Inquiries, additional Inquiries may be selected for which an Off-Label Review was not conducted to reach a total of 60 Inquiries. For each Inquiry reviewed, the IRO shall determine:

- a) Whether each item of information listed above in Section III.A.1 is reflected in the TLAC Database for each reviewed Inquiry; and
- b) For each Inquiry for which Lilly’s Compliance Office or designee conducted an Off-Label Review, the basis for suspecting that improper off-label promotion may have occurred; the steps undertaken as part of the Off-Label Review; the findings of the Lilly’s Compliance Office or designee as a result of the Off-Label Review; and any follow-up actions taken by Lilly based on the Off-Label Review findings.

B. IRO Review of Lilly’s Call Plans and Call Plan Review Process

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The IRO shall conduct a review and assessment of Lilly's review of its call plans for Government Reimbursed Products as set forth in Section III.B.3.g of the CIA. Lilly shall provide the IRO with: i) a list of products promoted by Lilly during the Reporting Period; ii) information about the FDA-approved uses for each Lilly product; and iii) the call plans for each product. Lilly shall also provide the IRO with information about the reviews of call plans that Lilly conducted during the Reporting Period and any modifications to the call plans made as a result of Lilly's reviews.

For each call plan, the IRO shall select a sample of 50 of the HCPs and HCIs included on the call plan. For each call plan, the IRO shall compare the sampled HCPs and HCIs against the criteria (e.g., medical specialty or practice area) used by Lilly in conducting its review and/or modification of the call plan in order to determine whether Lilly followed its criteria and Policies and Procedures in reviewing and modifying the call plan.

The IRO shall note any instances in which it appears that the sampled HCPs and HCIs on a particular call plan are inconsistent with Lilly's criteria relating to the call plan and/or Lilly's Policies and Procedures. The IRO shall also note any instances in which it appears that Lilly failed to follow its criteria or Policies and Procedures.

C. IRO Review of the Distribution of Samples of Lilly's Government Reimbursed Products

The IRO shall conduct a review and assessment of the distribution of samples of Lilly's Government Reimbursed Products to HCPs and HCIs. Lilly shall provide the IRO with: i) a list of products for which Lilly distributed samples during the Reporting Period; ii) information about the FDA-approved uses for each Lilly product; and iii) information about Lilly's policies and procedures relating to the distribution of samples of each type of product, including Lilly's Sample Distribution Plan showing which type samples may be distributed by sales representatives to HCPs and HCIs of particular medical specialties or types of clinical practices. Lilly shall also provide the IRO with information about: (1) the reviews of Sample Distribution Plans that Lilly conducted during the Reporting Period; and (2) any modifications to the distribution plans made or corrective actions that may be taken as a result of Lilly's reviews, including investigating, documenting, resolving, and taking disciplinary action.

For each product for which Lilly distributed samples during the Reporting Period, the IRO shall randomly select a sample of 50 separate instances in which Lilly provided samples of the product to HCPs or HCIs either through sales

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representation distribution or direct shipment. Each such instance shall be known as a “Sampling Event.”

For each Sampling Event, the IRO shall review all documents and information relating to the distribution of the sample to the HCP or HCI, including the sample card, direct shipment request form and/or the electronic call record. The reviewed materials shall include information about the following: 1) the quantity, dosage, and form of the Lilly product provided to the HCP or HCI; 2) the identity and type of medical specialty or clinical practice of the HCP or HCI; 3) which individual Lilly sales representative accepted the sample request form or provided the sample to the HCP or HCI; 4) the manner and mechanism through which the sample was requested (e.g., sample card or direct shipment request form); and 5) the manner and mechanism through which the request was fulfilled (e.g., sales representative distribution or direct shipment.)

For each Sampling Event, the IRO shall evaluate whether the sample was provided to an HCP or HCI whose medical specialty or clinical practice is consistent with the uses of the product approved by the FDA and whether the sample was distributed by a Lilly representative in a manner consistent with Lilly’s sample distribution policy for the product(s) provided during the Sampling Event. To the extent that a sample was provided to an HCP or HCI by a Lilly representative other than a sales representative, the IRO shall contact the HCP or HCI by letter. The letter shall request that the HCP or HCI: 1) verify that he/she/it received the quantity and type of samples identified by the IRO as the Sampling Event; 2) verify that he/she/it requested the samples provided during the Sampling Event; 3) explain or confirm its type of medical specialty or clinical practice; and 4) identify the basis for requesting the sample (e.g., conversations with a Lilly sales representative, conversation with a representative of Lilly’s medical services department, independent research or knowledge of the HCP or HCI, etc.)

For each Sampling Event, the IRO shall compare the medical specialty and type of clinical practice of the HCPs and HCIs that received the sample with uses of the product approved by the FDA. The IRO shall note any instances in which it appears that the medical specialty or clinical practice of the HCPs or HCIs that received a sample during a Sampling Event were not consistent with the uses of the product approved by the FDA. For each such situation, the IRO shall note the process followed by Lilly in determining that it was appropriate to provide a sample to such HCP or HCI and the basis for such determination. For each Sampling Event, the IRO shall also note any instances in which it appears that Lilly failed to follow its Sample Distribution Plan and sample policies and procedures for the product(s) provided during the Sampling Event and, if so, whether Lilly already had taken corrective action, including investigating, documenting, resolving, and taking disciplinary action, if appropriate.

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D. IRO Review of Physician Payment Listings

1) Information Contained in Physician Payment Listings

As set forth in Section III.M of the CIA, Lilly shall post quarterly and annual listings of physicians and Related Entities who received Phase I, II, or III Payments, as defined in the CIA, directly or indirectly from Lilly. For purposes of the IRO review as set forth in this Section III.C, each annual listing shall be referred to as the “Physician Payment Listing” or “Listing.” For each physician and Related Entity, each Physician Payment Listing shall include the following information: i) physician’s full name; ii) name of Related Entity (if applicable); iii) city and state that the physician or the Related Entity has provided to Lilly for contact purposes; and (iv) the aggregate value of the payment(s) in the preceding quarter(s) or year (as applicable). If payments for multiple physicians have been made to one Related Entity, the aggregate value of all payments to the Related Entity will be the reported amount.

For purposes of this IRO review, the term “Control Documents” shall include all documents or electronic records associated with each Payment reflected in the Physician Payments Listing for the sampled physician and/or Related Entity. For example, the term “Control Documents” includes, but is not limited to, documents relating to the nature, purpose, and amount of all Payments reflected in the Listing; contracts relating to the Payment(s) reflected in the Listing; documents relating to the occurrence of Payment(s) reflected in the Listing; documents reflecting any work product generated in connection with the Payment(s); documents submitted by sales representatives or headquarters personnel to request approval for the Payment(s); and business rationale or justification forms relating to the Payment(s).

2) Selection of Sample for Review

For each Reporting Period, the OIG shall have the discretion to identify up to 50 physicians or Related Entities from the applicable Physician Payment Listing that will be subject to the IRO review described below. If the OIG elects to exercise this discretion, it shall notify the IRO of the physicians and/or Related Entities subject to the IRO review. If the OIG elects not to exercise its discretion as described above, the IRO shall randomly select 50 physicians and/or Related Entities to be included in the review. For each selected physician and/or Related Entity, the IRO shall review the entry in the Physician Payment Listing and the Control Documents relating to Payments reflected in Listing identified by the IRO as necessary and sufficient to validate the Payment information in the Listing.

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3) IRO Review of Control Documents for Selected Physicians and/or Related Entities

For each physician and/or Related Entity selected as part of the sample, the IRO shall review the Control Documents identified by the IRO as necessary and sufficient to validate each Payment reflected in the Listing to evaluate the following:

- a) Whether Control Documents are available relating to each Payment reflected in the Listing for the sampled physician and/or Related Entity;
- b) Whether the Control Documents were completed and archived in accordance with the requirements set forth in Lilly's policies;
- c) Whether the aggregate value of the Payment(s) as reflected in the Listing for the sampled physician or Related Entity is consistent with the value of the Payments(s) reflected in the Control Documents; and
- d) Whether the Control Documents reflect that Lilly's policies were followed in connection with Payment(s) reflected in the Listing (e.g., all required written approvals for the activity were obtained in accordance with Lilly's policies.)

4) Identification of Material Errors and Additional Review

A Material Error is defined as any of the following:

- a) A situation in which all required Control Documents relating to Payments reflected in the Listing for the sampled physician and/or Related Entity do not exist and:
 - i. no corrective action was initiated prior to the selection of the sampled physicians and/or Related Entities; or
 - ii. the IRO cannot confirm that Lilly otherwise followed its policies and procedures relating to the entry in the Listing for the sampled physician or Related Entity, including its policies and procedures relating to any Payment(s) reflected in the Listing; or

b) Information or data is omitted from key fields in the Control Documents that prevents the IRO from assessing compliance with Lilly's policies and procedures, and the IRO cannot obtain this information or data from reviewing other Control Documents.

If a Control Document does not exist, but Lilly has initiated corrective action prior to the selection of the sampled physicians and/or Related Entities, or if a Control Document does not exist but the IRO can determine that Lilly otherwise followed its policies and procedures with regard to each entry in the Listing for a sampled physician or Related Entity, the IRO shall consider such a situation to be an exception (rather than a Material Error) and the IRO shall report the situation as such. The IRO shall note as exceptions any Control Documents for which non-material information or data is omitted.

If the IRO identifies any Material Errors, the IRO shall conduct such Additional Review of the underlying Payment associated with the erroneous Control Documents as may be necessary to determine the root cause of the Material Errors. For example, the IRO may need to review additional documentation and/or conduct interviews with appropriate personnel to identify the root cause of the Material Error(s) discovered.

E. IRO Review of Additional Items

As set forth in Section III.D.1.b of the CIA, for each Reporting Period, the OIG at its discretion may identify up to three additional items for the IRO to review (hereafter "Additional Items".) No later than 120 days prior to the end of the applicable Reporting Period, the OIG shall notify Lilly of the nature and scope of the IRO review to be conducted for each of the Additional Items. Prior to undertaking the review of the Additional Items, the IRO and/or Lilly shall submit an audit work plan to the OIG for approval and the IRO shall conduct the review of the Additional Items based on a work plan approved by the OIG. The IRO shall include information about its review of each Additional Item in the Transactions Review Report (including a description of the review conducted for each Additional Item; the IRO's findings based on its review for each Additional Item; and the IRO's recommendations for any changes in Lilly's systems, processes, policies, and procedures based on its review of each Additional Item.)

Lilly may propose to the OIG that its internal audit(s) and/or reviews conducted as part of the Lilly Compliance Monitoring Program be partially substituted for one or more of the Additional Items that would otherwise be reviewed by the IRO for the applicable Reporting Period. The Lilly Compliance

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Monitoring Plan is a monitoring plan developed by Lilly's Compliance Office that includes the following types of events: Advisory Board Meetings, Consultant Task Force Activities, Speaker Trainings, Speaker Programs, Exhibits, Internal Meetings, Field Sales Meetings, Sales Representative Ride-Alongs, Medical or Outcome Liaison Ride-Alongs, Good Business Practice Reviews, Grant Committee Meetings, and Activities Funded by Lilly Grant Office. The OIG retains sole discretion over whether, and in what manner, to allow Lilly's internal audit work to be substituted for a portion of the Additional Items review conducted by the IRO.

In making its decision, the OIG agrees to consider, among other factors, the nature and scope of Lilly's planned internal audit work and/or reviews conducted under the Compliance Monitoring Program, the results of the Transactions Review(s) during prior Reporting Period(s), and Lilly's demonstrated audit capabilities to perform the proposed audit work internally. If the OIG denies Lilly's request to permit its internal audit work to be substituted for a portion of the IRO's review of Additional Items in a given Reporting Period, Lilly shall engage the IRO to perform the Review as outlined in this Section III.

If the OIG agrees to permit certain of Lilly's internal audit work for a given Reporting Period to be substituted for a portion of Additional Items review, such internal work would be subject to verification by the IRO (Verification Review). In such an instance, the OIG would provide additional details about the scope of the Verification Review to be conducted by the IRO. However, for purposes of any Verification Review, the IRO shall review of at least 20% of the sampling units reviewed by Lilly in its internal audits.

F. Promotional and Product Services Transactions Review Report

For each Reporting Period, the IRO shall prepare a report based on its Promotional and Product Services Transactions Review. The report shall include the following:

- 1) General Elements to Be Included in Report
 - a) Review Objectives: A clear statement of the objectives intended to be achieved by each part of the review;
 - b) Review Protocol: A detailed narrative description of the procedures performed and a description of the sampling unit and universe utilized in performing the procedures for each sample reviewed; and

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c) Sources of Data: A full description of documentation and other information, if applicable, relied upon by the IRO in performing the Promotional and Product Services Transactions Review.

2) Results to be Included in Report

The following results shall be included in each Promotional and Product Services Review Report:

(Relating to the Review of Inquiries)

- a) in connection with the review of Inquiries, a description of each type of sample unit reviewed, including the number of each type of sample units reviewed (e.g., the number of Inquiries) and an identification of the types of documents and information reviewed for the Inquiries;
- b) for each Inquiry sample unit, the IRO shall summarize the information about the Inquiry contained in the TLAC Database;
- c) for each Inquiry sample unit, findings and supporting rationale as to whether: (i) each item of information listed in Section III.A.1 is reflected in the TLAC Database; and (ii) for each Inquiry for which an Off-Label Review was conducted, the basis for suspecting that improper off-label promotion may have occurred; the steps undertaken as part of the Off-Label Review; the findings of Lilly's Compliance Office as a result of the Off-Label Review; and any follow-up actions taken by Lilly as a result of Lilly's Compliance Office findings;
- d) the findings and supporting rationale regarding any weaknesses in Lilly's systems, processes, policies, procedures, and practices relating to the Inquiries, and the TLAC Database, if any;
- e) recommendations for improvement in Lilly's systems, processes, policies, procedures, and practices relating to the Inquiries and the TLAC Database, if any;

(Relating to the Call Plan Reviews)

- f) a list of the Government Reimbursed Products promoted by Lilly during the Reporting Period and a summary of the FDA-approved uses for such products;
- g) for each Lilly Government Reimbursed Product: i) a description of the criteria used by Lilly in developing or reviewing the call plans and for including or excluding specified types of HCPs or HCIs from the call plans; ii) a description of the review conducted by Lilly of the call plans and an indication of whether Lilly reviewed the call plans as required by Section III.B.3.g of the CIA; iii) a description of all instances for each call plan in which it appears that the HCPs and HCIs included on the call plan are inconsistent with Lilly's criteria relating to the call plan and/or Lilly's Policies and Procedures; and iv) a description of all instances in which it appears that Lilly failed to follow its criteria or Policies and Procedures relating to call plans or the review of the call plans;
- h) the findings and supporting rationale regarding any weaknesses in Lilly's systems, processes, policies, procedures, and practices relating to Lilly's call plans or the review of the call plans, if any;
- i) recommendations, if any, for changes in Lilly's systems, processes, policies, procedures, and practices that would correct or address any weaknesses or deficiencies uncovered during the Transactions Review with respect to call plans or the review of the call plans;

(Relating to the Sampling Event Reviews)

- j) for each Lilly product distributed during the Reporting Period: i) a description of Sample Distribution Plan (including whether sales representatives may provide samples of the product and, if so, to HCPs or HCIs of which medical specialty or type of clinical practice a sales representative may provide samples); ii) a detailed description of any instances from the reviews by the IRO in which it appears that the medical specialty or clinical practice of the HCPs or HCIs that received a sample during a Sampling Event were not consistent with the uses of the product approved by the

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FDA. This description shall include a description of the process followed by Lilly in determining that it was appropriate to provide a sample to such HCP or HCI and the basis for such determination; and iii) a detailed description of any instances in which it appears that Lilly failed to follow its Sample Distribution Plan for the product(s) provided during the Sampling Event;

- k) the findings and supporting rationale regarding any weaknesses in Lilly's systems, processes, policies, procedures, and practices relating to Lilly's distribution of samples of Lilly's Government Reimbursed Products, if any;
- l) recommendations, if any, for changes in Lilly's systems, processes, policies, procedures, and practices that would correct or address any weaknesses or deficiencies uncovered during the Transactions Review with respect to the distribution of samples;

(Relating to the Physician Payment Listing Reviews)

- m) a description of the entries in the Physician Payment Listing for each physician or Related Entity sampled and a description of Control Documents reviewed in connection with each selected physician or Related Entity;
- n) for each sampled physician or Related Entity, findings and supporting rationale as to whether: (i) all required Control Documents exist; (ii) each Control Document was completed in accordance with all of the requirements set forth in the applicable Lilly policy; (iii) the aggregate value of the Payment(s) as reflected in the Listing for the sampled physician or entity is consistent with the value of the Payment(s) reflected in the Control Documents; (iv) each Control Document reflects that Lilly's policies were followed in connection with the underlying activity reflected in the document (e.g., all required approvals were obtained); and (v) any corrective action or disciplinary action was undertaken in those instances in which Lilly policies were not followed;
- o) for each sampled physician or Related Entity unit reviewed, an identification and description of all exceptions discovered. The report shall also describe those instances in which

corrective action was initiated prior to the selection of the sampled physicians or Related Entities, including a description of the circumstances requiring corrective action and the nature of the corrective action;

- p) if any Material Errors are discovered in any sample unit reviewed, a description of the error, the Additional Review procedures performed and a statement of findings as to the root cause(s) of the Material Error;

(Relating to the Review of Additional Items)

- q) for each Additional Item reviewed, a description of the review conducted;
- r) for each Additional Item reviewed, the IRO's findings based on its review;
- s) for each Additional Item reviewed, the findings and supporting rationale regarding any weaknesses in Lilly's systems, processes, policies, procedures, and practices relating to the Additional Item, if any; and
- t) for each Additional Item reviewed, recommendations, if any, for changes in Lilly's systems, processes, policies, and procedures that would correct or address any weaknesses or deficiencies uncovered during the review.

Appendix B
Eli Lilly, Inc. CIA

EXHIBIT 12. STATEMENT RE: COMPUTATION OF RATIO OF EARNINGS (LOSS) TO FIXED CHARGES

ELI LILLY AND COMPANY AND SUBSIDIARIES
(Dollars in millions)

	Years Ended December 31,				
	2008	2007	2006	2005	2004
Consolidated pretax income (loss) before cumulative effect of a change in accounting principle	(\$1,307.6)	\$3,876.8	\$3,418.0	\$2,717.5	\$2,941.9
Interest ¹	276.5	322.5	344.8	245.7	162.9
Less interest capitalized during the period	(48.2)	(94.2)	(106.7)	(140.5)	(111.3)
Earnings (loss)	(\$1,079.3)	\$4,105.1	\$3,656.1	\$2,822.7	\$2,993.5
Fixed charges	\$ 276.5	\$ 322.5	\$ 344.8	\$ 245.7	\$ 162.9
Ratio of earnings (loss) to fixed charges	N/M ₂	12.7	10.6	11.5	18.4

N/M — Not Meaningful

- 1 Interest is based upon interest expense reported as such in the consolidated income statement and does not include any interest related to unrecognized tax benefits, which is included in income tax expense.
- 2 For such ratio, earnings were \$1,307.6 million less than fixed charges. The loss for the year ended December 31, 2008 included special charges related to the EDPA settlement of \$1,477.0 million and acquired in-process research and development expense of \$4,685.4 million associated with the ImClone acquisition, as described in greater detail in the notes to the accompanying consolidated financial statements.

Exhibit 21 — List of Subsidiaries & Affiliates

**The following are the subsidiaries and affiliated corporations of the Company at December 31, 2008
Certain subsidiaries have been omitted as they are not significant in the aggregate.**

	<u>State or Jurisdiction of Incorporation or Organization</u>
ELI LILLY AND COMPANY	Indiana
Eli Lilly International Corporation	Indiana
Lilly HK Finance I Limited	Hong Kong
Lilly HK Finance II Limited	Hong Kong
Eli Lilly Funding Partnership	Hong Kong
Eli Lilly Funding II Partnership	Hong Kong
Eli Lilly Holdings Ltd.	United Kingdom
Eli Lilly Group Limited	United Kingdom
Eli Lilly Group Pension Trustees Limited	United Kingdom
Eli Lilly and Company Limited	United Kingdom
Eli Lilly and Company (Ireland) Trustees Limited	Ireland
Lilly Pharma Holding GmbH	Germany
Lilly Deutschland GmbH	Germany
Lilly Pharma Fertigung & Distribution GmbH	Germany
Lilly Pharma Produktion GmbH & Co. KG	Germany
Lilly Forschung GmbH	Germany
Eli Lilly Ges.m.b.H.	Austria
Lilly GmbH	Germany
Eli Lilly and Company (Ireland) Limited	Ireland
ELCO Insurance Company Limited	Bermuda
Lilly Ilac Ticaret Limited Sirketi	Turkey
Eli Lilly Interamerica, Inc.	Indiana
Eli Lilly do Brasil Limitada	Brazil
Elanco Quimica Limitada	Brazil
Darilor Sociedad Anonima	Uruguay
Beirmirco Sociedad Anonima	Uruguay
Eli Lilly Interamerica Inc., y Compania Limitada	Chile
ELCO International Sales Corporation	U.S. Virgin Islands
ICOS Corporation	Washington
Lilly ICOS LLC	Delaware

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

ELI LILLY AND COMPANY (continued)

Eli Lilly de Mexico, S.A. de C.V.	Mexico
Lilly Singapore Centre for Drug Discovery Pte. Ltd.	Singapore
Hypnion, Inc.	Delaware
Ivy Animal Health, Inc.	Delaware
ELCO Management, Inc.	Delaware
E L Management LLC	Delaware / Canada
Eli Lilly Canada Inc.	Canada
Lilly Holdings, LLC	Delaware
Lilly Holdings GmbH	Austria
Eli Lilly S.A.	Switzerland
ImClone LLC	Delaware
ImClone Systems Corporation	Delaware
EndoClone Incorporated	Delaware
ImClone Systems Germany GmbH	Germany
ImClone GmbH	Switzerland
Eli Lilly Export S.A.	Switzerland
Eli Lilly (Suisse) S.A.	Switzerland
Eli Lilly Vostok S.A., Geneva	Switzerland
Eli Lilly Trading S.A.	Switzerland
Lilly Cayman Holdings	Cayman Islands
Eli Lilly International Trading (Shanghai) Co. Ltd.	China
GEMS Services S.A.	Belgium
Eli Lilly Suzhou Pharmaceutical Co. Ltd.	China
Eli Lilly Nederland B.V.	Netherlands
Lilly France S.A.S.	France
Eli Lilly Benelux, S.A.	Belgium
Eli Lilly Italia S.p.A.	Italy
Dista-Produtos Quimicos & Farmaceuticos, LDA	Portugal
Lilly-Portugal, Produtos Farmaceuticos, Lda.	Portugal
Vital Pharma Productos Farmaceuticos	Portugal
Greenfield-Produtos Farmaceuticos, Lda.	Portugal
Elanco-Valquimica, S.A.	Spain
Dista, S.A.	Spain
Spaly Bioquimica, S.A.	Spain
Irisfarma S.A.	Spain
Lilly S.A.	Spain
Eli Lilly Nigeria Ltd.	Nigeria
Eli Lilly CR s.r.o.	Czech Republic
Eli Lilly Egypt, S.A.E.	Egypt
ELCO for Trade and Marketing, S.A.E.	Egypt
Pharmaserve-Lilly S.A.C.I.	Greece
Pharmabrand, S.A.I.C.	Greece
PRAXICO Ltd.	Hungary
Lilly Hungaria KFT	Hungary

ELI LILLY AND COMPANY (continued)	
ELCO Management, Inc. (continued)	
Lilly Holdings, LLC (continued)	
Lilly Holdings GmbH (continued)	
Eli Lilly S.A. (continued)	
Eli Lilly Nederland B.V. (continued)	
Eli Lilly (Philippines), Incorporated	Philippines
Eli Lilly and Company (India) Pvt. Ltd.	India
Eli Lilly Israel Ltd.	Israel
Eli Lilly Japan K.K.	Japan
Lilly Korea Ltd.	Korea
Elanco Animal Health, Korea, Ltd.	Korea
Eli Lilly (Malaysia) Sdn. Bhd.	Malaysia
Eli Lilly Pakistan (Pvt.) Ltd.	Pakistan
Eli Lilly Polska Sp.z.o.o. (Ltd.)	Poland
Eli Lilly (Singapore) Pte. Ltd.	Singapore
Lilly-NUS Centre for Clinical Pharmacology	Singapore
Eli Lilly (S.A.) (Proprietary) Limited	South Africa
Eli Lilly y Compania de Venezuela, S.A.	Venezuela
Dista Products & Compania de Venezuela, S.A.	Venezuela
Eli Lilly Regional Operations GmbH	Austria
Andean Technical Operations Center	Peru
Eli Lilly Asian Operations, Limited	Hong Kong
Dista Ilac Ticaret Ltd. Sti.	Turkey
Eli Lilly Slovakia s.r.o.	Slovakia
Eli Lilly Romania SRL	Romania
UAB Eli Lilly Lietuva	Lithuania
Eli Lilly Hrvatska d.o.o.	Croatia
Lilly Pharma Ltd.	Russia
PT. Eli Lilly Indonesia	Indonesia
Eli Lilly European Clinical Trial Services S.A.	Belgium
Eli Lilly farmacevtska druzba, d.o.o.	Slovenia
Elanco Trustees Limited	Ireland
Kinsale Financial Services, Ltd.	Ireland
ELGO Insurance Company Limited	Bermuda
Eli Lilly Services, Inc.	British Virgin Islands
Eli Lilly (B.V.I.) Holding Company Unlimited	British Virgin Islands
Eli Lilly Danmark A/S	Denmark
OY Eli Lilly Finland AB	Finland
Eli Lilly Norge A.S.	Norway
Eli Lilly Sweden AB	Sweden

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements (Form S-3 Nos. 33-58466, 333-35248, 333-106478; and Form S-8 Nos. 33-37341, 33-50783, 33-56141, 333-02021, 333-62015, 333-66113, 333-90397, 333-70308, 333-104057) of Eli Lilly and Company and subsidiaries and in the related Prospectuses of our reports dated February 16, 2009, with respect to (1) the consolidated financial statements of Eli Lilly and Company and subsidiaries and (2) the effectiveness of internal control over financial reporting of Eli Lilly and Company and subsidiaries, included in this Annual Report (Form 10-K) for the year ended December 31, 2008.

/s/ Ernst & Young LLP

Indianapolis, Indiana
February 26, 2009

CERTIFICATIONS

I, John C. Lechleiter, Ph.D., chairman of the board and chief executive officer, certify that:

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

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

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

Date: February 27, 2009

By: /s/ John C. Lechleiter

John C. Lechleiter, Ph.D.
Chairman of the Board and
Chief Executive Officer

CERTIFICATIONS

I, Derica W. Rice, senior vice president and chief financial officer, certify that:

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

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

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

Date: February 27, 2009

By: /s/ Derica W. Rice

Derica W. Rice
Senior Vice President
and Chief Financial Officer

EXHIBIT 32 Section 1350 Certification

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

The Annual Report on Form 10-K for the year ended December 31, 2008 (the "Form 10-K") of the Company fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 and information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date February 27, 2009

/s/ John C. Lechleiter

John C. Lechleiter, Ph.D.
Chairman of the Board, President and
Chief Executive Officer

Date February 27, 2009

/s/ Derica W. Rice

Derica W. Rice
Senior Vice President and
Chief Financial Officer