

LILLY ELI & CO  
Form 10-Q  
November 05, 2007

**SECURITIES AND EXCHANGE COMMISSION**  
**Washington, D.C. 20549**  
**Form 10-Q**  
**Quarterly Report Under Section 13 or 15(d) of the**  
**Securities Exchange Act of 1934**  
**FOR THE QUARTER ENDED SEPTEMBER 30, 2007**  
**COMMISSION FILE NUMBER 001-6351**  
**ELI LILLY AND COMPANY**  
(Exact name of Registrant as specified in its charter)

INDIANA 35-0470950  
(State or other jurisdiction of (I.R.S. Employer  
incorporation or organization) Identification No.)

LILLY CORPORATE CENTER, INDIANAPOLIS, INDIANA 46285  
(Address of principal executive offices)

Registrant's telephone number, including area code (317) 276-2000

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months and (2) has been subject to such filing requirements for the past 90 days.

Yes  No

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

Large accelerated filer  Accelerated filer  Non-accelerated filer

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes  No

The number of shares of common stock outstanding as of October 20, 2007:

Class	Number of Shares Outstanding
Common	1,134,312,781

PART I. FINANCIAL INFORMATION*Item 1. Financial Statements*

## CONSOLIDATED CONDENSED STATEMENTS OF INCOME

(Unaudited)

Eli Lilly and Company and Subsidiaries

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
	(Dollars in millions except per-share data)			
Net sales	\$4,586.8	\$3,864.1	\$13,443.9	\$11,445.7
Cost of sales	1,054.6	860.4	2,976.0	2,527.5
Research and development	844.5	755.7	2,533.1	2,271.3
Marketing and administrative	1,477.8	1,198.2	4,339.3	3,579.0
Acquired in-process research and development			656.6	
Asset impairments, restructuring, and other special charges	81.3		204.3	
Other income net	(49.8)	(56.0)	(89.9)	(135.1)
	3,408.4	2,758.3	10,619.4	8,242.7
Income before income taxes	1,178.4	1,105.8	2,824.5	3,203.0
Income taxes	252.1	232.2	725.9	672.6
Net income	\$ 926.3	\$ 873.6	\$ 2,098.6	\$ 2,530.4
Earnings per share basic	\$ .85	\$ .80	\$ 1.93	\$ 2.33
Earnings per share diluted	\$ .85	\$ .80	\$ 1.93	\$ 2.33
Dividends paid per share	\$ .425	\$ .40	\$ 1.275	\$ 1.20

See Notes to Consolidated Condensed Financial Statements.

CONSOLIDATED CONDENSED BALANCE SHEETS  
Eli Lilly and Company and Subsidiaries

	September 30, 2007	December 31, 2006
	(Dollars in millions)	
	(Unaudited)	
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$ 2,495.5	\$ 3,109.3
Short-term investments	1,070.3	781.7
Accounts receivable, net of allowances of \$97.2 (2007) and \$82.5 (2006)	2,516.3	2,298.6
Other receivables	422.4	395.8
Inventories	2,498.0	2,270.3
Deferred income taxes	380.9	519.2
Prepaid expenses	1,070.3	319.5
<b>TOTAL CURRENT ASSETS</b>	<b>10,453.7</b>	<b>9,694.4</b>
<b>OTHER ASSETS</b>		
Prepaid pension	1,161.8	1,091.5
Investments	570.6	1,001.9
Goodwill and other intangibles net	2,453.6	130.0
Sundry	1,893.1	1,885.3
	6,079.1	4,108.7
<b>PROPERTY AND EQUIPMENT</b>		
Land, buildings, equipment, and construction-in-progress	14,577.2	13,716.7
Less allowances for depreciation	(6,136.5)	(5,564.4)
	8,440.7	8,152.3
	\$24,973.5	\$ 21,955.4
<b>LIABILITIES AND SHAREHOLDERS EQUITY</b>		
<b>CURRENT LIABILITIES</b>		
Short-term borrowings	\$ 442.1	\$ 219.4
Accounts payable	744.9	789.4
Employee compensation	635.5	607.7
Dividends payable		463.3
Income taxes payable	130.6	640.6
Other current liabilities	2,118.5	2,365.1
<b>TOTAL CURRENT LIABILITIES</b>	<b>4,071.6</b>	<b>5,085.5</b>
Long-term debt	4,532.2	3,494.4
Accrued retirement benefit	1,550.4	1,586.9
Long-term income taxes payable	1,079.6	
Deferred income taxes	55.8	62.2

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Other noncurrent liabilities	737.0	745.7
	7,955.0	5,889.2
SHAREHOLDERS' EQUITY		
Common stock	709.5	707.9
Additional paid-in capital	3,747.3	3,571.9
Retained earnings	12,090.1	10,926.7
Employee benefit trust	(2,635.0)	(2,635.0)
Deferred costs-ESOP	(97.0)	(100.7)
Accumulated other comprehensive loss	(767.6)	(1,388.7)
	13,047.3	11,082.1
Less cost of common stock in treasury	100.4	101.4
	12,946.9	10,980.7
	\$24,973.5	\$ 21,955.4

See Notes to Consolidated Condensed Financial Statements.

CONSOLIDATED CONDENSED STATEMENTS OF CASH FLOWS  
(Unaudited)  
Eli Lilly and Company and Subsidiaries

	Nine Months Ended September 30,	
	2007	2006
	(Dollars in millions)	
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net income	\$ 2,098.6	\$ 2,530.4
Adjustments to reconcile net income to cash flows from operating activities:		
Changes in operating assets and liabilities, net of acquisitions of ICOS Corporation, Hypnion, Inc., and Ivy Animal Health, Inc.	(628.5)	(1,318.6)
Depreciation and amortization	773.1	628.2
Stock-based compensation expense	214.5	274.3
Change in deferred taxes	(245.0)	130.5
Acquired in-process research and development, net of tax	634.7	
Asset impairments, restructuring, and other special charges, net of tax	107.4	
Other, net	(30.0)	(126.6)
<b>NET CASH PROVIDED BY OPERATING ACTIVITIES</b>	<b>2,924.8</b>	<b>2,118.2</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Net purchases of property and equipment	(715.7)	(667.8)
Net change in short-term investments	(225.2)	580.4
Purchases of noncurrent investments	(471.3)	(1,218.7)
Proceeds from sales and maturities of noncurrent investments	924.7	1,135.1
Cash paid for ICOS Corporation, Hypnion, Inc., and Ivy Animal Health, Inc., net of cash acquired	(2,667.5)	
Purchase of in-process research and development	(25.0)	
Other, net	(84.0)	124.4
<b>NET CASH USED IN INVESTING ACTIVITIES</b>	<b>(3,264.0)</b>	<b>(46.6)</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Dividends paid	(1,389.8)	(1,301.5)
Proceeds from issuance of long-term debt	2,500.0	
Repayment of long-term debt	(1,057.7)	(1,599.0)
Purchase of common stock		(122.1)
Issuances of common stock under stock plans	21.6	44.2
Net change in short-term borrowings	(432.1)	(1.8)
Other, net	3.8	6.3
<b>NET CASH USED IN FINANCING ACTIVITIES</b>	<b>(354.2)</b>	<b>(2,973.9)</b>
Effect of exchange rate changes on cash and cash equivalents	79.6	65.5

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NET DECREASE IN CASH AND CASH EQUIVALENTS	(613.8)	(836.8)
Cash and cash equivalents at January 1	3,109.3	3,006.7
CASH AND CASH EQUIVALENTS AT SEPTEMBER 30	\$ 2,495.5	\$ 2,169.9

See Notes to Consolidated Condensed Financial Statements.

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CONSOLIDATED CONDENSED STATEMENTS OF COMPREHENSIVE INCOME  
(Unaudited)  
Eli Lilly and Company and Subsidiaries

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
	(Dollars in millions)			
Net income	\$ 926.3	\$ 873.6	\$2,098.6	\$2,530.4
Other comprehensive income <sup>1</sup>	374.4	132.3	621.1	433.0
Comprehensive income	\$1,300.7	\$1,005.9	\$2,719.7	\$2,963.4

<sup>1</sup> The significant components of other comprehensive income were gains from foreign currency translation adjustments of \$304.3 million and \$495.9 million for the three months and nine months ended September 30, 2007, respectively, and \$123.4 million and \$346.7 million for the three months and nine months ended September 30, 2006, respectively.

See Notes to Consolidated Condensed Financial Statements.



## SEGMENT INFORMATION

We operate in one significant business segment — pharmaceutical products. Operations of our animal health business segment are not material and share many of the same economic and operating characteristics as our pharmaceutical products. Therefore, they are included with pharmaceutical products for purposes of segment reporting. 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. Income before income taxes for the animal health business was \$32.0 million and \$47.8 million for the quarters ended September 30, 2007 and 2006, respectively, and \$99.5 million and \$122.9 million for the nine months ended September 30, 2007 and 2006, respectively.

## SALES BY PRODUCT CATEGORY

Worldwide sales by product category were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
	(Dollars in millions)			
Net sales to unaffiliated customers				
Neurosciences	\$1,903.6	\$1,676.1	\$ 5,682.1	\$ 4,869.4
Endocrinology	1,363.7	1,221.0	3,990.1	3,680.9
Oncology	609.4	511.8	1,776.9	1,477.6
Cardiovascular <sup>1</sup>	419.0	172.3	1,154.9	549.1
Animal health	236.6	216.2	666.4	615.5
Anti-infectives	53.4	58.5	165.2	216.0
Other pharmaceuticals	1.1	8.2	8.3	37.2
Net sales	\$4,586.8	\$3,864.1	\$13,443.9	\$11,445.7

<sup>1</sup> 2007 Cialis® sales are included in Cardiovascular and 2006 Cialis sales have been reclassified from Other pharmaceuticals to be consistent with the 2007 presentation.

## NOTES TO CONSOLIDATED CONDENSED FINANCIAL STATEMENTS

### BASIS OF PRESENTATION

We have prepared the accompanying unaudited consolidated condensed financial statements in accordance with the requirements of Form 10-Q and, therefore, they do not include all information and footnotes necessary for a fair presentation of financial position, results of operations, and cash flows in conformity with accounting principles generally accepted in the United States (GAAP). In our opinion, the financial statements reflect all adjustments (including those that are normal and recurring) that are necessary for a fair presentation of the results of operations for the periods shown. In preparing financial statements in conformity with GAAP, we must 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. The information included in this Quarterly Report on Form 10-Q should be read in conjunction with our consolidated financial statements and accompanying notes included in our Annual Report on Form 10-K for the year ended December 31, 2006.

### CONTINGENCIES

#### 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):

Dr. Reddy's Laboratories, Ltd. (Reddy), Teva Pharmaceuticals, and Zenith Goldline Pharmaceuticals, Inc., which was subsequently acquired by Teva Pharmaceuticals (together, Teva), each submitted Abbreviated New Drug Applications (ANDAs) seeking permission to market generic versions of Zyprexa® prior to the expiration of our relevant U.S. patent (expiring in 2011) and alleging that this patent was invalid or not enforceable. We filed lawsuits against these companies in the U.S. District Court for the Southern District of Indiana, seeking a ruling that the patent is valid, enforceable, and being infringed. The district court ruled in our favor on all counts on April 14, 2005, and on December 26, 2006, that ruling was upheld by the Court of Appeals for the Federal Circuit. On October 1, 2007, the United States Supreme Court denied the generic companies' petition for certiorari, bringing this litigation to a close.

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

Sicor Pharmaceuticals, Inc. (Sicor), Mayne Pharma (USA) Inc. (Mayne), and Sun Pharmaceutical Industries Inc. (Sun) each submitted ANDAs seeking permission to market generic versions of Gemzar® prior to the expiration of our relevant U.S. patents (expiring in 2010 and 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), Mayne (October 2006), and Sun (December 2006), seeking a ruling that these patents are valid and are being infringed. Each generic company moved to dismiss our lawsuit, arguing that the Indiana court lacks jurisdiction. The court denied Sicor's motion in April 2007 and Mayne's motion in August 2007. In September 2007, before the court ruled on Sun's motion to dismiss, we elected to voluntarily dismiss our lawsuit against Sun without prejudice to our right to commence another infringement action against Sun should future developments warrant. We expect to prevail in this litigation and believe that these claims are without

merit. However, it is not possible to predict or determine the outcome of this litigation, and accordingly, we can provide no assurance that we will prevail. An unfavorable outcome could have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

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), Synthon Laboratories, Inc. (Synthon), 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 Sandoz filed a declaratory judgment action in the same court. In September 2007, we amended the complaint in the New Jersey lawsuit to add Glenmark, Sun, Sandoz, Mylan, Teva, Apotex, Aurobindo, Synthon, and Zydus as defendants. We expect to prevail in this litigation and believe that these claims are without merit. However, it is not possible to predict or determine the outcome of this litigation, and accordingly, we can provide no assurance that we will prevail. An unfavorable outcome could have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

We have received challenges to Zyprexa patents in a number of countries outside the United States:

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 Apotex has appealed that ruling. In June 2007, the Canadian Federal Court held that the invalidity allegations of a second challenger, Novopharm Ltd. (Novapharm), were justified and denied our request that Novapharm be prohibited from receiving marketing approval for generic olanzapine in Canada. Novapharm began selling generic olanzapine in certain provinces of Canada in the third quarter of 2007. We have appealed that decision and sued Novopharm for patent infringement. The appeal is scheduled to be heard November 6, 2007. The patent infringement suit has been tentatively scheduled for trial in the third quarter of 2008.

In Germany, generic pharmaceutical manufacturers Egis-Gyogyszergyar and Neolabs Ltd. challenged the validity of our Zyprexa compound and method-of-use patents (expiring in 2011). In June 2007, the German Federal Patent Court held that our patent is invalid. We are appealing the decision. We anticipate generic olanzapine will be launched by competitors in the fourth quarter of this year.

We have received challenges in a number of other countries, including Spain, the UK, and several smaller European countries. In Spain, we were successful in the trial court in defeating the generic manufacturer's challenge, but the case has been appealed. We anticipate a decision in the first quarter of 2008. In the UK, a trial date has tentatively been set for July 2008.

We are vigorously contesting the various legal challenges to our Zyprexa patents on a country-by-country basis. We cannot predict or determine the outcome of this litigation. The availability of generic olanzapine in Canada and Germany will have a material adverse impact on our consolidated results of operations. The availability of generic olanzapine in additional markets could have a material adverse impact on our consolidated results of operations. 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<sup>®</sup> 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 the week of August 7, 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 filed a motion for reconsideration of the verdict, or alternatively for a new trial. If it becomes necessary, we will appeal any adverse decision. 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 a civil 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<sup>®</sup>, and Prozac Weekly<sup>™</sup>. A number of State Medicaid Fraud Control Units are coordinating with the EDPA in its investigation of any Medicaid-related claims relating to our marketing and promotion of Zyprexa. In October 2005, the EDPA advised that it is also conducting an inquiry regarding certain rebate agreements we entered into with a pharmacy benefit manager covering Axid<sup>®</sup>, Evista, Humalog<sup>®</sup>, Humulin<sup>®</sup>, Prozac, and

Zyprexa. The inquiry includes a review of Lilly's Medicaid best price reporting related to the product sales covered by the rebate agreements.

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.

In February 2007, we received a subpoena from the Office of the Attorney General of the State of Illinois, seeking production of documents and information relating to sales of Zyprexa and our marketing and promotional practices, including our communications with physicians and remuneration of physician consultants and advisors, with respect to Zyprexa.

Beginning in August 2006, we have 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 are now part of a multistate investigative effort being coordinated by an executive committee of attorneys general. We are aware that approximately 30 states are participating in this joint effort, and it is possible that additional states will join the investigation. These attorneys general are seeking a broad range of Zyprexa documents, including documents relating to sales, marketing and promotional practices, and remuneration of health care providers. In addition, we have been named as a defendant in a private suit in California State Court, which was recently removed to federal court, alleging violations of the California False Claims Act with respect to certain Zyprexa marketing and promotional practices. This suit was brought by an individual on behalf of the government, under the qui tam provision of the California False Claims Act.

We are cooperating in each of these investigations, including providing a broad range of documents and information relating to the investigations. It is possible that other Lilly 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. We cannot predict or determine the outcome of these matters or reasonably estimate the amount or range of amounts of any fines or penalties that might result from an adverse outcome. It is possible, however, that an adverse outcome could have a material adverse impact on our consolidated results of operations, liquidity, and financial position. We have implemented and continue to review and enhance a broadly based compliance program that includes comprehensive compliance-related activities designed to ensure that our marketing and promotional practices, physician communications, remuneration of health care professionals, managed care arrangements, and Medicaid best price reporting comply with applicable laws and regulations.

#### Product Liability and Related Litigation

We have been named as a defendant in a large number of Zyprexa product liability lawsuits in the United States 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 30,200 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. That settlement is being administered by special settlement masters appointed by Judge Weinstein.

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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 recorded in other current liabilities in our December 31, 2006 consolidated balance sheet; a majority of these settlements have been paid and the remainder will be paid during 2007.

The U.S. Zyprexa product liability claims not subject to these agreements include approximately 310 lawsuits in the U.S. covering approximately 1,200 plaintiffs. Trial dates have been set for February 19 and May 12, 2008, in the Eastern District of New York, for several of the U.S. plaintiffs. 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. We are prepared to continue our vigorous defense of Zyprexa in all remaining cases. We have insurance coverage for a portion of our Zyprexa product liability claims exposure. The third-party insurance carriers have raised defenses to their liability under the policies and are seeking to rescind the policies. The dispute is now the subject of litigation in the federal court in Indianapolis against certain of the carriers and in arbitration in Bermuda against other carriers. While we believe our position has merit, there can be no assurance that we will prevail. As discussed in Asset Impairments, Restructuring, and Other Special Charges, we have reached a settlement with one of the insurance carriers that is part of this litigation.

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.

In the second quarter of 2005, we recorded a net pretax charge of \$1.07 billion for product liability matters. The charge took into account our estimated recoveries from our insurance coverage related to these matters. The charge covered the following:

The cost of the June 2005 Zyprexa settlements; and

Reserves for product liability exposures and defense costs regarding the then-known and expected product liability claims to the extent we could formulate a reasonable estimate of the probable number and cost of the claims. A substantial majority of those exposures and costs were related to then-known and expected Zyprexa claims.

As a result of the January 2007 settlements discussed above, we incurred a pre-tax charge of \$494.9 million in the fourth quarter of 2006. The charge covered the following:

The cost of the January 2007 Zyprexa settlements; and

Reserves for product liability exposures and defense costs regarding the then-known and expected Zyprexa product liability 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. 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, Mississippi, Montana, New Mexico, Pennsylvania, South Carolina, Utah, and West Virginia in the courts of the respective states. The Mississippi, Montana, New Mexico, and West Virginia cases have been removed to federal court and are now part of the MDL proceedings in the Eastern District of New York.

In 2005, two lawsuits were filed in the Eastern District of New York 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 Eastern District of New York in 2006 on similar grounds. 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.

We cannot predict 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.

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 largely self-insured for future product liability losses. In addition, as noted above, there is no assurance that we will be able to fully collect from our insurance carriers on past claims.

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

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.

While it is not possible to predict or determine the outcome of the patent, product liability, or other legal actions brought against us or the ultimate cost of environmental matters, we believe that, except as noted above, the resolution of all such matters will not have a material adverse effect on our consolidated financial position or liquidity, but could possibly be material to the consolidated results of operations in any one accounting period.

#### EARNINGS PER SHARE

Unless otherwise noted in the footnotes, all per-share amounts are presented on a diluted basis, that is, based on the weighted-average number of outstanding common shares plus the effect of all potentially dilutive common shares (primarily unexercised stock options).

#### STOCK-BASED COMPENSATION

The fair value of stock-based compensation is required to be recognized in net income. In 2007, our stock-based compensation expense consists primarily of performance awards (PAs), shareholder value awards (SVAs), and stock options. In 2006, our stock-based compensation expense consisted primarily of PAs and stock options. We recognized pretax stock-based compensation cost in the amount of \$79.3 million and \$83.0 million in the third quarter of 2007 and 2006, respectively. In the nine months of 2007 and 2006, we recognized stock-based compensation expense of \$214.5 million and \$274.3 million, respectively.

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 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.

In 2007 we implemented an SVA program that 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 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.

As of September 30, 2007, the total remaining unrecognized compensation cost associated with our equity programs is \$138.9 million and the weighted-average remaining requisite service period is 15 months.

## RETIREMENT BENEFITS

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

	Defined Benefit Pension Plans			
	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2007	2006	2007	2006
	(Dollars in millions)			
Components of net periodic benefit cost				
Service cost	\$ 62.9	\$ 67.8	\$ 194.9	\$ 206.1
Interest cost	86.5	81.8	258.9	244.0
Expected return on plan assets	(134.6)	(121.2)	(403.1)	(361.5)
Amortization of prior service cost	1.4	1.4	4.0	4.3
Recognized actuarial loss	30.9	31.8	93.1	94.9
Net periodic benefit cost	\$ 47.1	\$ 61.6	\$ 147.8	\$ 187.8

	Retiree Health Benefit Plans			
	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2007	2006	2007	2006
	(Dollars in millions)			
Components of net periodic benefit cost				
Service cost	\$ 17.6	\$ 18.0	\$ 54.3	\$ 53.9
Interest cost	25.3	24.4	76.0	73.3
Expected return on plan assets	(25.3)	(22.5)	(77.0)	(67.4)
Amortization of prior service cost	(3.9)	(3.9)	(11.7)	(11.6)
Recognized actuarial loss	23.8	27.0	70.9	80.9
Net periodic benefit cost	\$ 37.5	\$ 43.0	\$ 112.5	\$ 129.1

In 2007, we expect to contribute approximately \$80 million to our defined benefit pension plans to satisfy minimum funding requirements for the year. In addition, we expect to contribute approximately \$85 million of additional discretionary funding to our defined benefit plans and approximately \$50 million of discretionary funding to our post retirement health benefit plans. As of September 30, 2007, approximately \$160 million of the total \$215 million expected 2007 contributions has been contributed.

## OTHER INCOME NET

Other income net, was comprised of the following:

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2007	2006	2007	2006
	(Dollars in millions)			
Interest expense	\$ 55.8	\$ 62.7	\$ 167.9	\$ 193.5
Interest income	(49.6)	(67.5)	(157.0)	(195.6)
Joint venture income		(23.8)	(11.0)	(66.1)
Other	(56.0)	(27.4)	(89.8)	(66.9)

\$ (49.8)      \$ (56.0)      \$ (89.9)      \$ (135.1)

The joint venture (income) loss represents our share of the Lilly ICOS LLC joint venture results of operations, net of income taxes, prior to the acquisition of ICOS Corporation on January 29, 2007.

**SHAREHOLDERS EQUITY**

As of September 30, 2007, we have purchased \$2.58 billion of our previously announced \$3.0 billion share repurchase program. During the third quarter of 2007, we did not acquire any shares pursuant to this program, nor do we expect any share repurchases under this program for the remainder of 2007.

#### IMPLEMENTATION OF NEW FINANCIAL ACCOUNTING PRONOUNCEMENTS

We adopted the provisions of Financial Accounting Standards Board (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. 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. We also reclassified \$921.4 million of income taxes payable from current to non-current liabilities. The total amount of gross unrecognized tax benefits at January 1, 2007 was \$1.34 billion and the total amount of unrecognized tax benefits that, if recognized, would affect our effective tax rate was \$1.27 billion at January 1, 2007.

We file income tax returns in the United States (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 2001.

We are currently under audit by the Internal Revenue Service ( IRS ) for tax years 2001-2004. Management believes it is reasonably possible that this audit could conclude within the next 12 months, which could cause a significant change in the total amount of unrecognized tax benefits. However, the ultimate resolution of the 2001-2004 IRS audit is dependent upon a number of factors, including the potential for formal administrative and legal proceedings. As a result, it is not possible to estimate the full range of the reasonably possible changes in unrecognized tax benefits that could occur in total within the next 12 months, nor is it possible to estimate reliably the total future cash flows related to these unrecognized tax benefits.

We recognize both accrued interest and penalties related to unrecognized tax benefits in income tax expense. At January 1, 2007, our accruals for the payment of interest and penalties totaled approximately \$171.8 million, substantially all of which relates to interest.

In June 2007, the FASB ratified the consensus reached by the Emerging Issues Task Force on 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. 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 as 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 effective for us beginning January 1, 2008, and is to be applied prospectively for contracts entered into on or after the effective date. While we have not yet completed our analysis, we do not anticipate the implementation of this Issue to be material to our consolidated financial position or results of operations.

In February 2007, the FASB issued Statement of Financial Accounting Standards (SFAS) No. 159, The Fair Value Option for Financial Assets and Financial Liabilities. This Statement permits entities to choose to measure many financial instruments and certain other items at fair value. The objective is to improve financial reporting by providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. This Statement is effective for us beginning January 1, 2008, if adopted. We do not anticipate the implementation of this Statement would be material to our consolidated financial position or results of operations.

In September 2006, the FASB issued SFAS No. 157, Fair Value Measurements. SFAS 157 defines fair value, establishes a framework for measuring fair value in GAAP, and expands disclosures about fair value measurements. This Statement is effective for us beginning January 1, 2008, and applies to interim periods. We do not anticipate the implementation of this Statement will be material to our consolidated financial position or results of operations.

#### ACQUISITIONS

##### ICOS Corporation Acquisition

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 sales of Cialis for the treatment of erectile dysfunction. The acquisition brings the full value of Cialis to us and enables us to realize operational efficiencies in the further development, marketing, and selling of this product. Under the terms of the agreement, each outstanding share of ICOS common stock was redeemed for \$34 in cash for an aggregate purchase price of approximately \$2.3 billion,

which was financed through borrowings.

The acquisition has been accounted for as a business combination under the purchase method of accounting. Under the purchase method of accounting, the assets acquired and liabilities assumed from ICOS are recorded at their respective fair values as of the acquisition date in our consolidated financial statements. The excess of the purchase price over the fair value of the acquired net assets has been recorded as goodwill in the amount of \$628.4 million. No portion of this goodwill is expected to be deductible for tax purposes. ICOS results of operations are included in our consolidated financial statements from the date of acquisition.

We have preliminarily determined the following estimated fair values for the assets purchased and liabilities assumed as of the date of acquisition. The determination of estimated fair value requires management to make significant estimates and assumptions. Although we do not anticipate any significant adjustments, to the extent that our estimates used in the purchase accounting allocation need to be adjusted, we will do so upon making that determination but not later than one year from the date of acquisition.

	Estimated Fair Value at January 29, 2007 (Dollars in millions)
Cash and short-term investments	\$ 197.7
Developed product technology (Cialis) <sup>1</sup>	1,659.9
Acquired in-process research and development	303.5
Tax benefit of net operating losses	404.1
Goodwill	628.4
Other assets and liabilities net	(19.5)
Deferred taxes	(581.0)
Long-term debt assumed	(275.6)
 Total estimated purchase price	 \$ 2,317.5

<sup>1</sup> The intangible asset will be amortized over Cialis remaining expected patent lives in each country, which range from 2015 to 2017.

The acquired in-process research and development (IPR&D) represents compounds currently under development that have not yet achieved regulatory approval for marketing. New indications for and formulations of the Cialis compound currently in clinical testing represent approximately 48 percent of the estimated fair value of the IPR&D. The remaining value of IPR&D represents several other products in development, with no one asset comprising a significant portion of this value. In accordance with FIN 4, Applicability of FASB Statement No. 2 to Business Combinations Accounted for by the Purchase Method, these IPR&D intangible assets totaling \$303.5 million have been written off by a charge to income immediately subsequent to the acquisition because the compounds do not have any alternative future use. This charge is not deductible for tax purposes. The ongoing activity with respect to each of these compounds under development is not material to our research and development expenses.

There are several methods that can be used to determine the estimated fair value of the acquired IPR&D. We utilized the income method, which applies a probability weighting to the estimated future net cash flows that are derived from projected sales revenues and estimated costs. These projections are based on factors such as relevant market size, patent protection, historical pricing of similar products, and expected industry trends. The estimated future net cash flows are then discounted to the present value using an appropriate discount rate. This analysis is performed for each project independently. The discount rate we used in valuing the acquired IPR&D projects was 20 percent.

Other Acquisitions

In October 2007, we entered into an agreement with Glenmark Pharmaceuticals Limited India whereby we acquired the rights to a portfolio of transient receptor potential vanilloid sub-family 1 (TRPV1) antagonist molecules, including a clinical phase compound. The compound is currently 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. Our charge for acquired IPR&D was \$45.0 million, is deductible for tax purposes, and will be included as expense in the fourth quarter of 2007.

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. Our charge for acquired IPR&D was \$44.0 million, is deductible for tax purposes, and will be included as expense in the fourth quarter of 2007.

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 ongoing activities with respect to these companies' products in development are not material to our research and development expenses. The results of operations are included in our consolidated financial statements from the respective dates of acquisition.



The acquisition of Hypnion provides 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 a charge of \$291.1 million, representing the estimated fair value of the acquired compound, to acquired IPR&D in the second quarter of 2007 because the development-stage compound acquired did not have any alternative future use. This charge 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 product lines that complement those of our animal health business. This acquisition has been accounted for as a business combination under the purchase method of accounting. While the allocation of the purchase price has not been finalized, we anticipate that \$88.7 million will be allocated to other identifiable intangible assets, primarily related to marketed products, \$37.0 million will be allocated to acquired IPR&D, and \$25.0 million will be recorded as goodwill. The IPR&D represents products in development that are not yet approved for marketing and have no alternative future use. Accordingly, the \$37.0 million allocated to acquired IPR&D was expensed immediately subsequent to the acquisition. The other identifiable intangible assets will be amortized over their estimated remaining useful lives of 10 to 20 years. Goodwill resulting from this acquisition has been fully allocated to the animal health business segment. The amount allocated to each of the intangible assets acquired, including goodwill, is expected to be deductible for tax purposes.

During the first quarter of 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. Our charge for acquired IPR&D related to this arrangement was \$25.0 million, is included as expense in the first quarter of 2007, and is deductible for tax purposes.

#### ASSET IMPAIRMENTS, RESTRUCTURING, AND OTHER SPECIAL CHARGES

During the third quarter of 2007, following a settlement with one of our insurance carriers over Zyprexa product liability claims, we reduced our expected product liability insurance recoveries. This resulted in a charge of \$81.3 million (pretax).

During the first quarter of 2007, in connection with previously announced strategic decisions, we recorded asset impairment, restructuring, and other special charges of \$123.0 million. These charges primarily relate to a voluntary severance program at one of our U.S. plants and other costs related to this action as well as the decision to stop construction of a planned insulin manufacturing plant in the U.S. Also included are charges related to our previous decision to close two research and development facilities and one production facility outside the U.S. The component of this charge related to the non-cash asset impairment was \$68.5 million (pretax) and was necessary to adjust the carrying value of the assets to fair value. We expect to complete these restructuring activities by December 31, 2007.

*Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations*

#### OPERATING RESULTS

##### Executive Overview

##### I. Financial Results

Our worldwide sales increased 19 percent to \$4.59 billion and 17 percent to \$13.44 billion for the third quarter and first nine months of 2007, respectively, as compared with the same periods of 2006. Net income was \$926.3 million, or \$.85 per share, for the third quarter of 2007 compared with \$873.6 million, or \$.80 per share, for the third quarter of 2006, representing an increase of 6 percent in both net income and earnings per share. While sales increased 19 percent in the third quarter of 2007, our earnings growth of 6 percent was impacted by cost of products sold increasing at a rate higher than sales, as well as the special charge noted below. Net income was \$2.10 billion, or \$1.93 per share, for the first nine months of 2007 compared with \$2.53 billion, or \$2.33 per share, for the first nine months of 2006, representing a decrease of 17 percent in both net income and earnings per share. The decrease in earnings in the nine-month period was driven primarily by the items discussed below. Net income comparisons between the periods are affected by the following significant items, which occurred in 2007 and are reflected in our

financial results:

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. This resulted in a charge of \$81.3 million (pretax), which decreased earnings per share by \$.06 in the third quarter.

We incurred in-process research and development (IPR&D) charges associated with the acquisition of Hypnion of \$291.1 million (no tax benefit) and the acquisition of Ivy of \$37.0 million (pretax), which decreased earnings per share by \$.29 in the second quarter.

We incurred IPR&D charges associated with the acquisition of ICOS of \$303.5 million (no tax benefit) and the licensing arrangement with OSI Pharmaceuticals of \$25.0 million (pretax), which decreased earnings per share by \$.29 in the first quarter.

We recognized asset impairments, restructuring, and other special charges associated with previously announced strategic decisions affecting manufacturing and research facilities of \$123.0 million (pretax), which decreased earnings per share by \$.08 in the first quarter.

## II. Business Development and Recent Product and Late-Stage Pipeline Developments

### *Significant Items Since July 1, 2007:*

In November, with our collaboration partner Daiichi Sankyo Company, Limited, we announced that in the pivotal Phase III head-to-head TRITON TIMI-38 clinical trial our investigational antiplatelet agent prasugrel produced a highly significant 19 percent reduction in relative risk in the composite primary endpoint of cardiovascular death, non-fatal heart attack, and non-fatal stroke when compared with clopidogrel (Plavix®) in the treatment of patients across the full spectrum of acute coronary syndrome undergoing percutaneous coronary intervention. In a key secondary endpoint analysis, patients on prasugrel experienced a 52 percent reduction in a relative risk compared with clopidogrel in recurrence of stent-related thrombosis (clots). Prasugrel-treated patients experienced a statistically significant increase in major bleeding from causes other than coronary artery bypass grafting compared to clopidogrel-treated patients (2.4 percent vs. 1.8 percent, respectively), including higher rates of life-threatening bleeding (1.4 percent vs. 0.9 percent, respectively). In both treatment arms, the study identified three distinct patient subpopulations with a higher risk of major bleeding: patients 75 years of age or older, patients weighing less than 132 pounds, and patients with a history of transient ischemic attack (a mild stroke) or stroke. We and Daiichi Sankyo are in the process of finalizing the regulatory submission documents and are still hoping to complete our submission to the U.S. FDA by year end.

In October, with our collaboration partners, Amylin Pharmaceuticals, Inc. and Alkermes, Inc., we announced positive results from a 30-week comparator study of once-weekly exenatide long-acting release (LAR) injection and Byetta (exenatide) injection taken twice daily in patients with type 2 diabetes. Once-weekly exenatide showed statistically superior glucose control compared to Byetta. After 30 weeks of treatment, both once-weekly exenatide and Byetta treatment resulted in average weight loss of approximately 8 pounds. The side-effect profile of once-weekly exenatide was similar to that of Byetta.

In October, we entered into an agreement with Glenmark Pharmaceuticals Limited India whereby we acquired the rights to a portfolio of transient receptor potential vanilloid sub-family 1 (TRPV1) antagonist molecules, including a clinical phase compound. The compound is currently in early clinical phase development as a potential next-generation treatment for various pain conditions, including osteoarthritic pain. Under the terms of the agreement, we incurred a charge to earnings for acquired IPR&D of \$45.0 million (pretax) which will be included as expense in the fourth quarter of 2007.

In October, we entered into a global strategic alliance with MacroGenics, Inc. 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. Teplizumab is currently being studied in the PROTÉGÉ trial, a global pivotal Phase II/III clinical trial for individuals with recent-onset type 1 diabetes. Under the terms of the agreement, we incurred a charge to earnings for acquired IPR&D of \$44.0 million (pretax) which will be included as expense

in the fourth quarter of 2007.

We submitted a supplemental new drug application to the U.S. Food and Drug Administration (FDA) for Cymbalta® for the management of fibromyalgia.

In September, the FDA approved Evista for a new use to reduce the risk of invasive breast cancer in two populations: postmenopausal women with osteoporosis and postmenopausal women at high risk for invasive breast cancer.

We submitted an application with the European Medicines Agency for centralized review of Alimta®, in combination with cisplatin, for the first-line treatment of advanced non-small cell lung cancer.

*Significant Items Prior to July 1, 2007:*

On January 29, 2007 we completed the acquisition of ICOS Corporation at a cost of approximately \$2.3 billion. The acquisition brings the full value of Cialis to us and enables us to realize operational efficiencies in the further development, marketing, and selling of this product.

In January, we licensed from OSI Pharmaceuticals its glucokinase activator (GKA) program for the treatment of type 2 diabetes, including the lead compound PSN010. Lilly received an exclusive license to develop and market any compounds derived from the GKA program.

On April 3, 2007, we completed the acquisition of Hypnion, Inc., a privately held neuroscience drug discovery company focused on sleep disorders. The deal expands our presence in the area of sleep disorder research and provides ownership of HY10275, a novel Phase II insomnia compound with a dual mechanism of action aimed at promoting better sleep onset and sleep maintenance.

On June 29, 2007, we completed the acquisition of Ivy Animal Health, Inc., a privately held applied research and pharmaceutical product development company focused on the animal health industry. The acquisition provides us with product lines that complement those of our animal health business.

III. Legal, Regulatory, and Other Matters

In October 2007, the United States Supreme Court denied the petitions for certiorari that were filed by Teva Pharmaceuticals and Dr. Reddy's Laboratories, bringing to an end the two companies' challenges to the validity of Lilly's U.S. Zyprexa patent.

In October 2007, as a part of ongoing discussions with the FDA, we updated the Zyprexa (olanzapine) and Symbyax® (olanzapine and fluoxetine HCl) U.S. product labels. Specifically, the changes include new warnings for weight gain and hyperlipidemia (elevation

of triglycerides and cholesterol) and updated information in the warning for hyperglycemia (elevated blood sugar). The label also states that while relative risk estimates are inconsistent, the association between atypical antipsychotics and increases in glucose levels appears to fall on a continuum and olanzapine appears to have a greater association than some other atypical antipsychotics.

In October 2007, we announced an upcoming update to the Byetta U.S. label. The precautions section of the label is being updated with information about acute pancreatitis, including additional guidance regarding the symptoms that may be suggestive of acute pancreatitis and subsequent patient management.

In June 2007, we received notice of two court rulings by the Canadian Federal Court and the German Patent Court that permit the entry of generic olanzapine by competitors into the Canadian and German markets. Generic olanzapine is available for sale in certain provinces in Canada. We expect generic olanzapine to become available for sale by competitors in Germany during the fourth quarter of 2007.

In July 2007, the Centers for Medicare and Medicaid Services released a final rule seeking to implement sections of the Deficit Reduction Act of 2005. This rule relates to the Medicaid Program and seeks to cover the calculation and use of Average Manufacturer Price and Best Price for pharmaceuticals. We do not anticipate that implementation of the final rule will be material to our financial position or results of operations.

We have reached agreements with claimants' attorneys involved in U.S. Zyprexa product liability litigation to settle a total of approximately 30,200 claims against us relating to the medication. Approximately 1,200 claims remain. As a result of our product liability exposures, the substantial majority of which were related to Zyprexa, we recorded net pretax charges of \$1.07 billion in the second quarter of 2005 and \$494.9 million in the fourth quarter of 2006.

We have received requests for information about Zyprexa from the offices of Representative Henry Waxman, Chair of the House Committee on Oversight and Government Reform, and Senator Charles Grassley, ranking member of the Senate Finance Committee, and we are cooperating with their requests.

In the United States, implementation of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), which provides a prescription drug benefit under the Medicare program, took effect January 1, 2006. Various measures have been discussed and/or passed in both the U.S. House of Representatives and U.S. Senate that would legalize the importation of prescription drugs and either allow or require the Secretary of Health and Human Services to negotiate drug prices directly with pharmaceutical manufacturers. We expect pricing pressures at the federal and state levels to continue.

In March 2004, we were notified by the U.S. Attorney's office for the Eastern District of Pennsylvania that it had commenced a civil investigation relating to our U.S. marketing and promotional practices.

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.

#### Sales

Third-quarter and first-nine-months 2007 sales growth of 19 percent and 17 percent, respectively, was driven primarily by increased volume of several products launched this decade, most notably Cymbalta, and by the inclusion of Cialis since our January 29, 2007 acquisition of ICOS. Sales in the U.S. increased by \$370.4 million, or 18 percent, and \$1.05 billion, or 17 percent, for the third quarter and first nine months of 2007, respectively, compared with the same periods of 2006. Sales outside the U.S. increased \$352.2 million, or 20 percent, and \$946.1 million, or 18 percent, for the third quarter and first nine months of 2007, respectively. For the third quarter, worldwide sales volume increased 14 percent, exchange rates increased sales 3 percent, and selling prices increased sales 2 percentage points. For the first nine months of 2007, worldwide sales volume increased 12 percent, while exchange rates and selling prices contributed 3 percent and 2 percent to sales growth, respectively.

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The following tables summarize our net sales activity:

Product	Three Months Ended September 30, 2007			Three Months Ended September 30, 2006	Percent Change From 2006
	U.S. <sup>1</sup>	Outside U.S.	Total	Total	
	(Dollars in millions)				
Zyprexa	\$ 540.6	\$ 625.5	\$1,166.1	\$1,084.7	8
Cymbalta	444.3	68.9	513.2	348.6	47
Gemzar	166.5	227.9	394.4	354.6	11
Humalog	216.1	146.4	362.5	322.2	12
Cialis <sup>2</sup>	116.6	194.8	311.4	55.0	NM
Evista	169.5	93.7	263.2	257.9	2
Humulin	90.8	152.5	243.3	230.0	6
Animal health products	112.4	124.2	236.6	216.2	9
Alimta	110.8	104.2	215.0	157.2	37
Forteo <sup>®</sup>	124.8	55.7	180.5	149.1	21
Strattera	103.6	26.9	130.5	126.4	3
Humatrope <sup>®</sup>	51.5	54.1	105.6	101.6	4
Other pharmaceutical products	229.6	234.9	464.5	460.6	1
Total net sales	\$2,477.1	\$2,109.7	\$4,586.8	\$3,864.1	19

Product	Nine Months Ended September 30, 2007			Nine Months Ended September 30, 2006	Percent Change From 2006
	U.S. <sup>1</sup>	Outside U.S.	Total	Total	
	(Dollars in millions)				
Zyprexa	\$1,627.4	\$1,859.7	\$ 3,487.1	\$ 3,207.1	9
Cymbalta	1,288.3	186.3	1,474.6	892.3	65
Gemzar	495.0	671.9	1,166.9	1,036.9	13
Humalog	639.4	421.0	1,060.4	947.3	12
Evista	518.5	286.5	805.0	775.0	4
Cialis <sup>2</sup>	290.8	506.8	797.6	161.2	NM
Humulin	263.7	448.2	711.9	668.3	7
Animal health products	301.3	365.2	666.5	615.5	8
Alimta	322.2	287.8	610.0	440.4	39
Forteo	355.7	155.4	511.1	422.2	21
Strattera	338.4	74.2	412.6	422.7	(2)
Humatrope	161.8	164.8	326.6	306.2	7
Other pharmaceutical products	689.3	724.3	1,413.6	1,550.6	(9)

Total net sales	\$7,291.8	\$6,152.1	\$13,443.9	\$11,445.7	17
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NM Not meaningful

<sup>1</sup>U.S. sales include sales in Puerto Rico.

<sup>2</sup>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 taxes, is reported in other income net in our consolidated condensed income statement. Subsequent to the acquisition, all Cialis product sales are included in our net sales in our consolidated condensed income statement.





### Product Highlights

U.S. sales of Zyprexa, a treatment for schizophrenia, bipolar mania, and bipolar maintenance, increased 4 percent and 5 percent in the third quarter and first nine months of 2007, respectively, compared with the same periods of 2006, due to higher prices, offset in part by declining demand. Sales outside the U.S. increased 11 percent and 13 percent in the third quarter of 2007 and first nine months of 2007, respectively, driven by the favorable impact of foreign exchange rates and increased demand.

Results from our primary diabetes care products are as follows:

U.S. sales of Humalog, our insulin analog, increased 9 percent during the third quarter and first nine months of 2007, due to increased prices and higher demand. Humalog sales outside the U.S. increased 19 percent and 16 percent during the third quarter and first nine months of 2007, respectively, due to increased demand, as well as a favorable impact of foreign exchange rates, offset in part by declining prices.

U.S. sales of Humulin, a biosynthetic human insulin, decreased 6 percent and remained flat for the third quarter and first nine months of 2007, respectively, driven primarily by lower demand, offset in part by higher prices. Humulin sales outside the U.S. increased 14 percent and 11 percent during the third quarter and first nine months of 2007, respectively, driven primarily by increased volume and the favorable impact of foreign exchange rates, offset in part by declining prices.

Sales of Byetta<sup>®</sup>, the first in a new class of medicines known as incretin mimetics for type 2 diabetes that we market with Amylin Pharmaceuticals (Amylin), were \$164.8 million and \$466.6 million during the third quarter and first nine months of 2007, respectively. 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, which increased 40 percent to \$87.1 million and 59 percent to \$238.6 million during the third quarter and first nine months of 2007, respectively, compared with the same periods in 2006.

U.S. revenues of Actos<sup>®</sup>, an oral agent for the treatment of type 2 diabetes, were \$40.8 million and \$122.3 million during the third quarter and first nine months of 2007, respectively, as compared to \$34.7 million and \$237.0 million, respectively, for the same periods in 2006. Actos is manufactured by Takeda Chemical Industries, Ltd. Our U.S. marketing rights with respect to Actos expired in September 2006; however, we will continue receiving royalties from Takeda Pharmaceuticals North America at a declining rate through September 2009. We continue to market the product in many countries outside the U.S. Sales outside the U.S. increased 35 percent, to \$57.1 million, and 27 percent, to \$155.1 million, during the same periods, due to increased demand, as well as a favorable impact of foreign exchange rates, offset in part by lower prices.

U.S. sales of Cymbalta, a treatment of major depressive disorder, diabetic peripheral neuropathic pain, and generalized anxiety disorder, increased 45 percent and 65 percent for the third quarter of 2007 and first nine months of 2007, respectively, as compared with the same period last year, due primarily to increased demand. Cymbalta sales outside the U.S. increased 64 percent and 69 percent for the third quarter and first nine months of 2007, respectively, driven primarily by higher demand, and to a lesser extent the impact of foreign exchange rates and higher prices. Cymbalta continues to gain market share in the U.S. and internationally.

U.S. sales of Gemzar, a product approved to fight various cancers, increased 9 percent for both the third quarter and first nine months of 2007, as compared to the same periods in 2006, due to higher prices and increased demand. Gemzar sales outside the U.S. increased 13 percent and 15 percent for the third quarter and first nine months of 2007, respectively, due primarily to increased demand and a favorable impact of foreign exchange rates.

Total worldwide sales of Cialis, a treatment for erectile dysfunction, were \$311.4 million and \$870.3 million during the third quarter and first nine months of 2007, respectively. This includes \$72.7 million of sales in the Lilly ICOS joint-venture territories for the period prior to the acquisition of ICOS. Worldwide sales grew 27 percent in the third quarter of 2007 and 24 percent in the first nine months of 2007, compared with the same periods in 2006. U.S. sales increased 22 percent and 19 percent, during the third quarter and first nine months of 2007, respectively, due to

increased demand and prices. Sales outside the U.S. increased 30 percent and 27 percent during the third quarter and first nine months of 2007, respectively, due to increased demand, a favorable impact of foreign exchange rates, and increased prices. Prior to the ICOS acquisition, Cialis sales in our territories were reported in revenue, while in the joint venture territories our 50 percent share of revenues, net of expenses and taxes, was reported in other income net. U.S. 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, increased 4 percent and 6 percent for the third quarter and first nine months of 2007, respectively, as compared to the same periods in 2006, due primarily to higher prices. Evista sales outside the U.S. decreased 1 percent for the third quarter and nine month periods of 2007, due primarily to lower prices, offset in part by a favorable impact of foreign exchange rates.

U.S. sales of Alimta, a treatment for malignant pleural mesothelioma and second-line treatment of non-small cell lung cancer, increased 23 percent and 26 percent for the third quarter and first nine months of 2007, respectively, as compared to the same periods in 2006, due primarily to increased demand. Alimta sales outside the U.S. increased 55 percent and 56 percent during the third quarter and first nine months of 2007, respectively, due primarily to increased demand as well as a favorable impact of foreign exchange rates.

U.S. sales of Forteo, a treatment for severe osteoporosis, increased 20 percent and 22 percent in the U.S. in the third quarter and first nine months of 2007, respectively, as compared to the same periods in 2006, due primarily to higher net effective selling prices. Sales outside the U.S. increased 24 percent and 20 percent for the third quarter and first nine months of 2007, respectively, due primarily to higher demand as well as a favorable impact in foreign exchange rates.

U.S. sales of Strattera, a treatment of attention-deficit hyperactivity disorder in children, adolescents, and adults, decreased 8 percent and 9 percent during the third quarter and first nine months of 2007, respectively, as compared with the same periods in 2006, due to a decline in demand in both periods, offset in part by increased prices in the first nine months of 2007. Strattera sales outside the U.S. increased 91 percent and 51 percent for the third quarter and first nine months of 2007, respectively, due primarily to higher demand.

#### Gross Margin, Costs, and Expenses

For the third quarter of 2007, gross margins as a percent of net sales decreased by 0.7 percentage points, to 77.0 percent. This decrease was primarily due to planned third-quarter 2007 maintenance shutdowns of certain manufacturing facilities, the expense resulting from the amortization of the intangible assets acquired in the ICOS acquisition, and the impact of foreign exchange rates, offset in part by manufacturing expenses growing at a slower rate than sales. For the first nine months of 2007, gross margins as a percentage of net sales remained flat at 77.9 percent.

Overall, marketing and administrative expenses rose 23 percent, to \$1.48 billion, and 21 percent, to \$4.34 billion for the third quarter and first nine months of 2007, respectively. This increase was largely due to the impact of the ICOS acquisition, increased marketing and selling expenses in support of key products (primarily Cymbalta and the diabetes care products) and, for the first nine months of 2007, an increase in litigation-related costs. Research and development expenses were \$844.5 million and \$2.53 billion for the third quarter and first nine months of 2007, respectively.

Compared with the third quarter and first nine months of 2006, research and development expenses increased 12 percent. In addition to the acquisition of ICOS, this increase was due to increases in incentive compensation, discovery research, and late-stage clinical trial costs. Research and development expenses for the first nine months of 2007 also increased compared with the same period in 2006 due to costs associated with the consequences of the FDA's decision on Arxxant<sup>TM</sup> and the withdrawal of the Arxxant application in Europe.

In the third quarter of 2007, we incurred a special charge of \$81.3 million related to a reduction in our expected product liability insurance recoveries. With the acquisitions of Hypnion and Ivy in the second quarter of 2007, and the acquisition of ICOS and the product acquisition from OSI in the first quarter of 2007, total in-process research and development charges for the first nine months of 2007 were \$656.6 million.

Other income net decreased by \$6.2 million, to \$49.8 million, and by \$45.2 million, to \$89.9 million for the third quarter and first nine months of 2007, respectively. Other income net consists of interest expense, interest income, the after-tax operating results of the Lilly ICOS joint venture prior to the ICOS acquisition, and all other miscellaneous income and expense items.

Interest expense for the third quarter and nine-month period in 2007 decreased \$6.9 million, to \$55.8 million, and \$25.6 million to \$167.9 million, respectively, due to lower average debt balances in 2007 as compared with the same periods of 2006.

Interest income decreased \$17.9 million, to \$49.6 million and \$38.6 million to \$157.0 million for the third quarter and first nine months of 2007, respectively, due to lower cash balances in 2007 as compared with the same periods of 2006.

The Lilly ICOS joint venture income for the third quarter and first nine months of 2007 decreased by \$23.8 million and \$55.1 million, respectively, as a result of the acquisition. Subsequent to the acquisition of ICOS, all sales and expenses associated with Cialis are included in their respective lines on Lilly's income statement.

Net other miscellaneous income and expense items increased \$28.6 million to \$56.0 million and \$22.9 million to \$89.8 million for third-quarter 2007 and first nine months of 2007, respectively, as compared with the same periods in 2006. The increases are primarily a result of higher business development income resulting from out-licensing of legacy and development-stage products, offset by lower gains on sales of equity instruments. We incurred tax expense of \$252.1 million and \$725.9 million, for the third quarter and first nine months of 2007, respectively. The effective tax rate was 21.4 percent and 25.7 percent, up from 21.0 percent for the comparable periods in 2006, primarily because the in-process research and development charges associated with the acquisitions of ICOS and Hynion were not deductible.

## FINANCIAL CONDITION

As of September 30, 2007, cash, cash equivalents, and short-term investments totaled \$3.57 billion compared with \$3.89 billion at December 31, 2006. Cash flows from operations of \$2.92 billion during the first nine months of 2007 and net proceeds from the issuance of long-term debt of \$1.44 billion were more than offset by the net cash paid for corporate acquisitions of \$2.67 billion, dividends paid of \$1.39 billion, and net purchases of property and equipment of \$715.7 million.

Total debt at September 30, 2007, was \$4.97 billion, an increase of \$1.26 billion from December 31, 2006. In the first nine months of 2007, we issued approximately \$2.5 billion of debt to finance our acquisition of ICOS, including the acquisition of ICOS stock and refinancing of ICOS debt, and repaid \$1.06 billion of long-term debt. Our current debt ratings from Standard & Poor's and Moody's remain at AA and Aa3, respectively.

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 product liability litigation, dividends, and taxes in 2007. We believe that amounts available through our existing commercial paper program should be adequate to fund maturities of short-term borrowings, if necessary. We currently have \$1.20 billion of unused committed bank credit facilities, which backs our commercial paper program. Various risks and uncertainties, including those discussed in the Financial Expectations for 2007 section, may affect our operating results and cash generated from operations.

## LEGAL AND REGULATORY MATTERS

### 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):

Dr. Reddy's Laboratories, Ltd. (Reddy), Teva Pharmaceuticals, and Zenith Goldline Pharmaceuticals, Inc., which was subsequently acquired by Teva Pharmaceuticals (together, Teva), each submitted Abbreviated New Drug Applications (ANDAs) seeking permission to market generic versions of Zyprexa prior to the expiration of our relevant U.S. patent (expiring in 2011) and alleging that this patent was invalid or not enforceable. We filed lawsuits against these companies in the U.S. District Court for the Southern District of Indiana, seeking a ruling that the patent is valid, enforceable, and being infringed. The district court ruled in our favor on all counts on April 14, 2005, and on December 26, 2006, that ruling was upheld by the Court of Appeals for the Federal Circuit. On October 1, 2007, the United States Supreme Court denied the generic companies' petition for certiorari, bringing this litigation to a close.

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

Sicor Pharmaceuticals, Inc. (Sicor), Mayne Pharma (USA) Inc. (Mayne), and Sun Pharmaceutical Industries Inc. (Sun) each submitted ANDAs seeking permission to market generic versions of Gemzar prior to the expiration of our relevant U.S. patents (expiring in 2010

and 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), Mayne (October 2006), and Sun (December 2006), seeking a ruling that these patents are valid and are being infringed. Each generic company moved to dismiss our lawsuit, arguing that the Indiana court lacks jurisdiction. The court denied Sicor's motion in April 2007 and Mayne's motion in August 2007. In September 2007, before the court ruled on Sun's motion to dismiss, we elected to voluntarily dismiss our lawsuit against Sun without prejudice to our right to commence another infringement action against Sun should future developments warrant. We expect to prevail in this litigation and believe that these claims are without merit. However, it is not possible to predict or determine the outcome of this litigation, and accordingly, we can provide no assurance that we will prevail. An unfavorable outcome could have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

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), Synthon Laboratories, Inc. (Synthon), 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 Sandoz filed a declaratory judgment action in the same court. In September 2007, we amended the complaint in the New Jersey lawsuit to add Glenmark, Sun, Sandoz, Mylan, Teva, Apotex, Aurobindo, Synthon, and Zydus as defendants. We expect to prevail in this litigation and believe that these claims are without merit. However, it is not possible to predict or determine the outcome of this litigation, and accordingly, we can provide no assurance that we will prevail. An unfavorable outcome could have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

We have received challenges to Zyprexa patents in a number of countries outside the United States:

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 Apotex has appealed that ruling. In June 2007, the Canadian Federal Court held that the invalidity allegations of a second challenger, Novopharm Ltd. (Novopharm), were justified and denied our request that Novopharm be prohibited from receiving marketing approval for generic olanzapine in Canada. Novopharm began selling generic olanzapine in certain provinces of Canada in the third quarter of 2007. We have appealed that decision and sued Novopharm for patent infringement. The appeal is scheduled to be heard November 6, 2007. The patent infringement suit has been tentatively scheduled for trial in the third quarter of 2008.

In Germany, generic pharmaceutical manufacturers Egis-Gyogyszergyar and Neolabs Ltd. challenged the validity of our Zyprexa compound and method-of-use patents (expiring in 2011). In June 2007, the German Federal Patent Court held that our patent is invalid. We are appealing the decision. We anticipate generic olanzapine will be launched by competitors in the fourth quarter of this year.

We have received challenges in a number of other countries, including Spain, the UK, and several smaller European countries. In Spain, we were successful in the trial court in defeating the generic manufacturer's challenge, but the case has been appealed. We anticipate a decision in the first quarter of 2008. In the UK, a trial date has tentatively been set for July 2008.

We are vigorously contesting the various legal challenges to our Zyprexa patents on a country-by-country basis. We cannot predict or determine the outcome of this litigation. The availability of generic olanzapine in Canada and Germany will have a material adverse impact on our consolidated results of operations. The availability of generic olanzapine in additional markets could have a material adverse impact on our consolidated results of operations. 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<sup>®</sup> 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 the week of August 7, 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 filed a motion for reconsideration of the verdict, or alternatively for a new trial. If it becomes necessary, we will appeal any adverse decision. 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 a civil 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. A number of State



Medicaid Fraud Control Units are coordinating with the EDPA in its investigation of any Medicaid-related claims relating to our marketing and promotion of Zyprexa. In October 2005, the EDPA advised that it is also 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 Lilly's Medicaid best price reporting related to the product sales covered by the rebate agreements.

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.

In February 2007, we received a subpoena from the Office of the Attorney General of the State of Illinois, seeking production of documents and information relating to sales of Zyprexa and our marketing and promotional practices, including our communications with physicians and remuneration of physician consultants and advisors, with respect to Zyprexa.

Beginning in August 2006, we have 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 are now part of a multistate investigative effort being coordinated by an executive committee of attorneys general. We are aware that approximately 30 states are participating in this joint effort, and it is possible that additional states will join the investigation. These attorneys general are seeking a broad range of Zyprexa documents, including documents relating to sales, marketing and promotional practices, and remuneration of health care providers. In addition, we have been named as a defendant in a private suit in California State Court, which was recently removed to federal court, alleging violations of the California False Claims Act with respect to certain Zyprexa marketing and promotional practices. This suit was brought by an individual on behalf of the government, under the qui tam provision of the California False Claims Act.

We are cooperating in each of these investigations, including providing a broad range of documents and information relating to the investigations. It is possible that other Lilly 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. We cannot predict or determine the outcome of these matters or reasonably estimate the amount or range of amounts of any fines or penalties that might result from an adverse outcome. It is possible, however, that an adverse outcome could have a material adverse impact on our consolidated results of operations, liquidity, and financial position. We have implemented and continue to review and enhance a broadly based compliance program that includes comprehensive compliance-related activities designed to ensure that our marketing and promotional practices, physician communications, remuneration of health care professionals, managed care arrangements, and Medicaid best price reporting comply with applicable laws and regulations.

#### Product Liability and Related Litigation

We have been named as a defendant in a large number of Zyprexa product liability lawsuits in the United States 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 30,200 claimants, including a large number of previously filed lawsuits and other asserted claims. The two primary settlements were as follows:

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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. That settlement is being administered by special settlement masters appointed by Judge Weinstein.

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 recorded in other current liabilities in our December 31, 2006 consolidated balance sheet; a majority of these settlements have been paid and the remainder will be paid during 2007.

The U.S. Zyprexa product liability claims not subject to these agreements include approximately 310 lawsuits in the U.S. covering approximately 1,200 plaintiffs. Trial dates have been set for February 19 and May 12, 2008, in the Eastern District of New York, for several of the U.S. plaintiffs. 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. We are prepared to continue our vigorous defense of Zyprexa in all remaining cases. We have insurance coverage for a portion of our Zyprexa product liability claims exposure. The third-party insurance carriers have raised defenses to their liability under the policies and are seeking to rescind the policies. The dispute is now the subject of litigation in the federal court in Indianapolis against certain of the carriers and in arbitration in Bermuda against other carriers. While we believe our position has merit, there can be no assurance that we will prevail. As discussed in Asset Impairments, Restructuring, and Other Special Charges, we have reached a settlement with one of the insurance carriers that is part of this litigation.

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.

In the second quarter of 2005, we recorded a net pretax charge of \$1.07 billion for product liability matters. The charge took into account our estimated recoveries from our insurance coverage related to these matters. The charge covered the following:

- The cost of the June 2005 Zyprexa settlements; and

- Reserves for product liability exposures and defense costs regarding the then-known and expected product liability claims to the extent we could formulate a reasonable estimate of the probable number and cost of the claims. A substantial majority of those exposures and costs were related to then-known and expected Zyprexa claims.

As a result of the January 2007 settlements discussed above, we incurred a pre-tax charge of \$494.9 million in the fourth quarter of 2006. The charge covered the following:

- The cost of the January 2007 Zyprexa settlements; and

- Reserves for product liability exposures and defense costs regarding the then-known and expected Zyprexa product liability 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. 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, Mississippi, Montana, New Mexico, Pennsylvania, South Carolina, Utah, and West Virginia in the courts of the respective states. The Mississippi, Montana, New Mexico, and West Virginia cases have been removed to federal court and are now part of the MDL proceedings in the Eastern District of New York.

In 2005, two lawsuits were filed in the Eastern District of New York 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 Eastern District of New York in 2006 on similar grounds. 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.

We cannot predict 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.

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 largely self-insured for future product liability losses. In addition, as noted above, there is no assurance that we will be able to fully collect from our insurance carriers on past claims.

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

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.

While it is not possible to predict or determine the outcome of the patent, product liability, or other legal actions brought against us or the ultimate cost of environmental matters, we believe that, except as noted above, the resolution of all such matters will not have a material adverse effect on our consolidated financial position or liquidity, but could possibly be material to the consolidated results of operations in any one accounting period.

#### FINANCIAL EXPECTATIONS FOR 2007

We have updated our earnings guidance for the full year of 2007, and now expect earnings per share to be in the range of \$2.74 to \$2.79, representing growth of 12 to 14 percent as compared with full-year 2006 results. We expect fourth-quarter earnings per share of \$.81 to \$.86. The earnings per share guidance includes an anticipated increase in the effective tax rate for the fourth quarter, the acquired in-process research and development charges related to the MacroGenics and Glenmark in-licensing agreements, the impact of the potential launch of generic olanzapine by competitors in Germany, normally scheduled manufacturing shutdowns, and additional investments in research and development and sales and marketing to drive future growth. We have reconfirmed our full-year 2007 sales guidance, and continue to expect sales to grow in the mid-teens and gross margin as a percent of net sales to improve slightly compared with 2006. In addition, we continue to expect operating expenses (the aggregate of research and development and marketing and administrative expenses) percentage growth to be in the mid-teens, driven primarily by the inclusion of all Cialis operating expenses subsequent to the acquisition, as well as increased investment in research and development and ongoing expenditures for marketing and selling efforts in support of Cymbalta and the diabetes care products. We have raised our guidance on other income net, and now expect other income net to be approximately \$100 million. We expect a continuation of strong cash flow trends in 2007, with capital expenditures of approximately \$1.1 billion.

We caution investors that any forward-looking statements or projections made by us, including those above, are based on management's belief at the time they are made. However, they are subject to risks and uncertainties. Actual results could differ materially and will depend on, among other things, the continuing growth of our currently marketed products; developments with competitive products; the timing and scope of regulatory approvals and the success of our new product launches; asset impairments and restructuring charges; acquisitions and business development transactions; foreign exchange rates; wholesaler inventory changes; other regulatory developments, litigation, and government investigations; and the impact of governmental actions regarding pricing, importation, and reimbursement for pharmaceuticals or the protection of intellectual property rights. Other factors that may affect our operations and prospects are discussed in Item 1A of our 2006 Form 10-K, Risk Factors. We undertake no duty to update these forward-looking statements.

#### AVAILABLE INFORMATION ON OUR WEBSITE

## Edgar Filing: LILLY ELI & CO - Form 10-Q

We make available through our company website, 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 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 website link to our SEC filings is <http://investor.lilly.com/edgar.cfm>.

*Item 4. Controls and Procedures*

(a) *Evaluation of 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-Q) is recorded, processed, summarized, and reported on a timely basis.

Our management, with the participation of Sidney Taurel, chairman and chief executive officer, and Derica W. Rice, senior vice president and chief financial officer, evaluated our disclosure controls and procedures as of September 30, 2007, and concluded that they are effective.

(b) *Changes in Internal Controls.* During the third quarter of 2007, 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.

**PART II. OTHER INFORMATION**

*Item 1. Legal Proceedings*

See Part I, Item 2, Management's Discussion and Analysis, Legal, Regulatory, and Other Matters, for information on various legal proceedings, including but not limited to:

The patent litigation involving Zyprexa, Evista, Gemzar, and Strattera

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 healthcare payors

The legal proceedings we have filed against several of our product liability insurance carriers with respect to our coverage for the Zyprexa product liability claims

That information is incorporated into this Item by reference.

*Other Patent Litigation*

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. Lilly intends to vigorously defend this litigation. The trial has been scheduled for January 2008. We believe these claims are without legal merit and expect to prevail in this litigation; however, it is not possible to predict or determine the outcome. An unfavorable outcome could have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

*Other Product Liability Litigation*

We refer to Part I, Item 3, of our Form 10-K annual report for 2006 for the discussion of product liability litigation involving diethylstilbestrol (DES) and vaccines containing the preservative thimerosal. In the DES litigation, we have been named as a defendant in approximately 55 suits involving approximately 100 claimants including one lawsuit filed in the Eastern District of New York purporting to be a nationwide class action on behalf of women who allegedly either have developed, or are at an extremely high risk of developing, breast cancer as a result of their in utero exposure to DES. In the thimerosal litigation, we have been named as a defendant in approximately 350 suits, with approximately 930 claimants.

*Shareholder Litigation*

Two putative class action lawsuits filed in the United States District Court for the Eastern District of New York against us and various current and former directors, officers and employees (*Smith et al. v. Eli Lilly and Company et al.*, filed March 28, 2007, and *Valentine v. Eli Lilly and Company et al.*, filed April 5, 2007) have been consolidated under the caption *In re Eli Lilly and Company Securities Litigation*. In August 2007, the lead plaintiffs filed a

consolidated amended complaint, seeking certification of a putative class of purchasers of our stock from August 1, 2002, through December 22, 2006. The complaint alleges that the defendants made false and misleading statements regarding Zyprexa in violation of the Securities Exchange Act of 1934, and seeks unspecified compensatory damages and the costs of suit, including attorneys' fees. In October 2007, defendants filed a motion to dismiss the consolidated amended complaint. We believe these claims are without merit and intend to defend against them vigorously. In April 2007, the company received demands from two 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 with respect to the allegedly



improper marketing of Evista, Prozac, and Zyprexa. We received a similar demand in September related only to Zyprexa. In accordance with procedures established under the Indiana Business Corporation Law (Ind. Code §23-1-32), the board has appointed a committee to consider the demands and determine what action, if any, the company should take in response.

*Other Matters*

Between 2003 and 2005, various counties 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 counties overpaid their portion of the cost of pharmaceuticals. The suits seek monetary and other relief, including civil penalties and treble damages. A similar suit was filed against us and many other manufacturers by the state of Mississippi. The suits have been transferred to the U.S. District Court for the District of Massachusetts for pretrial proceedings and are in the earliest stages. In October 2007, the State of Iowa reportedly filed a similar suit against Lilly and 78 other pharmaceutical companies. Lilly has not yet been served with that complaint.

While it is not possible to predict or determine the outcome of the patent, product liability, or other legal actions brought against us or the ultimate cost of environmental matters, we believe that, except as noted above, the resolution of all such matters will not have a material adverse effect on our consolidated financial position or liquidity but could possibly be material to the consolidated results of operations in any one accounting period.

*Item 2. Unregistered Sales of Equity Securities and Use of Proceeds*

The following table summarizes the activity related to repurchases of our equity securities during the three-month period ended September 30, 2007:

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) (in thousands)	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs (d) (in millions)
July 2007		\$		\$ 419.2
August 2007	1	55.44		419.2
September 2007				419.2
Total	1			

The amounts presented in columns (a) and (b) above represent purchases of common stock related to employee stock option exercises. The amounts presented in columns (c) and (d) in the above table represent activity related to our \$3.0 billion share repurchase program announced in March 2000. As of September 30, 2007, we have purchased \$2.58 billion related to this program. During the third quarter of 2007, no shares were repurchased pursuant to this program and we do not expect to purchase any shares under this program during the remainder of 2007.

*Item 6. Exhibits*

The following documents are filed as exhibits to this Report:

EXHIBIT 11. Statement re: Computation of Earnings per Share

- EXHIBIT 12. Statement re: Computation of Ratio of Earnings to Fixed Charges
- EXHIBIT 31.1 Rule 13a-14(a) Certification of Sidney Taurel, Chairman of the Board and Chief Executive Officer
- EXHIBIT 31.2 Rule 13a-14(a) Certification of Derica W. Rice, Senior Vice President and Chief Financial Officer
- EXHIBIT 32. Section 1350 Certification

SIGNATURES

Pursuant to the requirements 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

(Registrant)

Date November 1, 2007

/s/James B. Lootens

James B. Lootens  
Secretary and Deputy General Counsel

Date November 1, 2007

/s/Arnold C. Hanish

Arnold C. Hanish  
Executive Director, Finance, and  
Chief Accounting Officer

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