

LILLY ELI & CO
Form 10-Q
August 06, 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 June 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.

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 July 20, 2007:

Class	Number of Shares Outstanding
Common	1,134,282,921

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

CONSOLIDATED CONDENSED STATEMENTS OF INCOME

(Unaudited)

Eli Lilly and Company and Subsidiaries

	Three Months Ended June 30,		Six Months Ended June 30,	
	2007	2006	2007	2006
	(Dollars in millions, except per-share data)			
Net sales	\$4,631.0	\$3,866.9	\$8,857.1	\$7,581.6
Cost of sales	998.9	860.6	1,921.4	1,667.1
Research and development	854.4	774.8	1,688.6	1,515.6
Marketing and administrative	1,524.7	1,237.9	2,861.5	2,380.8
Acquired in-process research and development	328.1		656.6	
Asset impairments, restructuring, and other special charges			123.0	
Other income net	(1.8)	(46.9)	(40.1)	(79.1)
	3,704.3	2,826.4	7,211.0	5,484.4
Income before income taxes	926.7	1,040.5	1,646.1	2,097.2
Income taxes	263.1	218.5	473.8	440.4
Net income	\$ 663.6	\$ 822.0	\$1,172.3	\$1,656.8
Earnings per share basic	\$.61	\$.76	\$ 1.08	\$ 1.53
Earnings per share diluted	\$.61	\$.76	\$ 1.08	\$ 1.53
Dividends paid per share	\$.425	\$.40	\$.85	\$.80

See Notes to Consolidated Condensed Financial Statements.

CONSOLIDATED CONDENSED BALANCE SHEETS
Eli Lilly and Company and Subsidiaries

	June 30, 2007	December 31, 2006
	(Dollars in millions)	
	(Unaudited)	
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 2,220.5	\$ 3,109.3
Short-term investments	783.9	781.7
Accounts receivable, net of allowances of \$96.2 (2007) and \$82.5 (2006)	2,414.2	2,298.6
Other receivables	400.0	395.8
Inventories	2,330.0	2,270.3
Deferred income taxes	494.9	519.2
Prepaid expenses	917.8	319.5
TOTAL CURRENT ASSETS	9,561.3	9,694.4
OTHER ASSETS		
Prepaid pension	1,099.5	1,091.5
Investments	552.9	1,001.9
Goodwill and other intangibles net	2,494.3	130.0
Sundry	2,037.9	1,885.3
	6,184.6	4,108.7
PROPERTY AND EQUIPMENT		
Land, buildings, equipment, and construction-in-progress	14,296.1	13,716.7
Less allowances for depreciation	(5,986.4)	(5,564.4)
	8,309.7	8,152.3
	\$24,055.6	\$ 21,955.4
LIABILITIES AND SHAREHOLDERS EQUITY		
CURRENT LIABILITIES		
Short-term borrowings	\$ 464.2	\$ 219.4
Accounts payable	719.3	789.4
Employee compensation	488.8	607.7
Dividends payable	464.1	463.3
Income taxes payable	175.5	640.6
Other current liabilities	2,233.3	2,365.1
TOTAL CURRENT LIABILITIES	4,545.2	5,085.5
Long-term debt	4,574.0	3,494.4
Accrued retirement benefit	1,516.0	1,586.9
Long-term income taxes payable	1,039.5	
Deferred income taxes	56.9	62.2

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

Other noncurrent liabilities	764.0	745.7
	7,950.4	5,889.2
SHAREHOLDERS' EQUITY		
Common stock	709.5	707.9
Additional paid-in capital	3,663.0	3,571.9
Retained earnings	11,163.1	10,926.7
Employee benefit trust	(2,635.0)	(2,635.0)
Deferred costs-ESOP	(98.2)	(100.7)
Accumulated other comprehensive loss	(1,142.0)	(1,388.7)
	11,660.4	11,082.1
Less cost of common stock in treasury	100.4	101.4
	11,560.0	10,980.7
	\$24,055.6	\$ 21,955.4

See Notes to Consolidated Condensed Financial Statements.

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

	Six Months Ended June 30,	
	2007	2006
	(Dollars in millions)	
CASH FLOWS FROM OPERATING ACTIVITIES		
Net income	\$ 1,172.3	\$ 1,656.8
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.	(551.5)	(1,357.3)
Depreciation and amortization	507.6	414.0
Stock-based compensation expense	135.2	191.3
Change in deferred taxes	(426.7)	120.7
Acquired in-process research and development, net of tax	634.7	
Asset impairments, restructuring, and other special charges, net of tax	37.4	
Other, net	(28.7)	(83.3)
NET CASH PROVIDED BY OPERATING ACTIVITIES	1,480.3	942.2
CASH FLOWS FROM INVESTING ACTIVITIES		
Net purchases of property and equipment	(485.6)	(392.1)
Net change in short-term investments	63.7	103.9
Purchases of noncurrent investments	(358.2)	(1,003.2)
Proceeds from sales and maturities of noncurrent investments	811.4	906.2
Cash paid for ICOS Corporation, Hypnion, Inc., and Ivy Animal Health, Inc., net of cash acquired	(2,579.9)	
Purchase of in-process research and development	(25.0)	
Other, net	(34.7)	126.9
NET CASH USED IN INVESTING ACTIVITIES	(2,608.3)	(258.3)
CASH FLOWS FROM FINANCING ACTIVITIES		
Dividends paid	(926.5)	(864.6)
Proceeds from issuance of long-term debt	2,500.0	
Repayment of long-term debt	(1,002.2)	(100.1)
Purchase of common stock		(122.1)
Issuances of common stock under stock plans	20.2	13.9
Net change in short-term borrowings	(372.9)	4.9
Other, net	.4	.2
NET CASH PROVIDED BY (USED IN) FINANCING ACTIVITIES	219.0	(1,067.8)
Effect of exchange rate changes on cash and cash equivalents	20.2	46.9

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

NET DECREASE IN CASH AND CASH EQUIVALENTS	(888.8)	(337.0)
Cash and cash equivalents at January 1	3,109.3	3,006.7
CASH AND CASH EQUIVALENTS AT JUNE 30	\$ 2,220.5	\$ 2,669.7

See Notes to Consolidated Condensed Financial Statements.

4

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2007	2006	2007	2006
	(Dollars in millions)			
Net income	\$663.6	\$822.0	\$1,172.3	\$1,656.8
Other comprehensive income ¹	215.1	170.5	246.8	300.7
Comprehensive income	\$878.7	\$992.5	\$1,419.1	\$1,957.5

¹ The significant components of other comprehensive income were gains of \$118.1 million and \$191.6 million from foreign currency translation adjustments for the three months and six months ended June 30, 2007, respectively, compared with gains from foreign currency translation adjustments of \$172.5 million and \$223.3 million for the three months and six months ended June 30, 2006, respectively. Gains from cash

flow hedges
were
\$11.5 million
and
\$78.3 million
for the three
months and six
months ended
June 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 for the second quarter of 2007 and 2006 was \$29.3 million and \$40.9 million, respectively, and \$67.5 million and \$75.1 million for the six months ended June 30, 2007 and 2006, respectively.

SALES BY PRODUCT CATEGORY

Worldwide sales by product category for the three months and six months ended June 30, 2007 and 2006 were as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2007	2006	2007	2006
	(Dollars in millions)			
Net sales to unaffiliated customers				
Neurosciences	\$1,981.1	\$1,686.2	\$3,778.6	\$3,193.3
Endocrinology	1,360.6	1,231.2	2,626.4	2,459.8
Oncology	602.7	496.7	1,167.4	965.8
Cardiovascular ¹	414.7	178.6	735.9	378.1
Animal health	214.7	201.0	429.8	399.3
Anti-infectives	53.7	69.6	111.8	157.5
Other pharmaceuticals	3.5	3.6	7.2	27.8
Net sales	\$4,631.0	\$3,866.9	\$8,857.1	\$7,581.6

¹ 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. Reddy's and Teva's combined petition for rehearing at the Federal Circuit was denied. Reddy and Teva are seeking review of the Federal Circuit's decision by the U.S. Supreme Court. We are confident that Reddy's and Teva's claims are without merit and we expect to prevail. An unfavorable outcome would have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

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 lawsuit against Teva in the U.S. District Court for the Southern District of Indiana, seeking a ruling that our relevant U.S. patents are valid, enforceable, and being infringed by Teva. 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. On April 17, 2007, the court denied Sicor's motion. The two remaining motions to dismiss have

not been decided. We expect to prevail in litigation involving our Gemzar patents and believe that claims made by these generic companies that our patents are not valid 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.

During 2005, two generic pharmaceutical manufacturers, Apotex Inc. (Apotex) and Novopharm Ltd. (Novopharm) (a wholly-owned subsidiary of Teva), challenged the validity of our Zyprexa compound and method-of-use patent (expiring in 2011) in Canada. The generic companies allege that our patent is invalid. In April 2007, the Canadian Federal Court ruled against Apotex, and Apotex has appealed the ruling. No hearing date has been set, but a hearing could be held as early as the fourth quarter of 2007. In June 2007, the Canadian Federal Court held that Novopharm's allegations of invalidity were justified and denied our request that Novopharm be prohibited from receiving marketing approval for generic olanzapine in Canada. We have appealed the decision and sued Novopharm for patent infringement. We anticipate the appeal hearing in the fourth quarter of 2007, if at all. The patent infringement suit has been tentatively scheduled for trial in July 2008. In May 2004, Egis-Gyogyszergyar (Egis), and in May 2006, Neolabs Ltd. (Neolabs), both generic pharmaceutical manufacturers, challenged the validity of our Zyprexa compound and method-of-use patents (expiring in 2011) in Germany. The Egis and Neolabs suits were joined and heard together. In June, the German Federal Patent Court held that our patent is invalid. We are appealing the decision. We have received challenges to Zyprexa patents in a number of other countries as well, including the UK (where a trial is scheduled for July 2008), Spain, and several other European countries. 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 for sale in one or more of these countries could have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

In June 2002, Ariad Pharmaceuticals, Inc., the Massachusetts Institute of Technology, the Whitehead Institute for Biomedical Research, and the President and Fellows of Harvard College in the U.S. District Court for the District of Massachusetts sued us, alleging that sales of two of our products, Xigris and Evista, were inducing the infringement of a patent related to the discovery of a natural cell signaling phenomenon in the human body, and seeking royalties on past and future sales of these products. On May 4, 2006, a jury in Boston issued an initial decision in the case that Xigris and Evista sales infringe the patent. The jury awarded the plaintiffs approximately \$65 million in damages, calculated by applying a 2.3 percent royalty to all U.S. sales of Xigris and Evista from the date of issuance of the patent through the date of trial. In addition, a separate bench trial with the U.S. District Court of Massachusetts was held the week of August 7, 2006, on our contention that the patent is unenforceable and impermissibly covers natural processes. In a statement issued July 6, 2007, the court indicated that Ariad's claims are patentable, valid, and enforceable. In June 2005, the United States Patent and Trademark Office (USPTO) commenced a reexamination of the patent, and has taken the position that the Ariad claims at issue are unpatentable, subject to Ariad's right to appeal. We are seeking to delay entry of a final judgment in the bench trial pending a final resolution of the reexamination. If it becomes necessary, we will appeal any adverse decision. Should we lose, it is likely that the damages would include a royalty on relevant future U.S. sales of Evista and Xigris; however, 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

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 U.S. Attorney's Office 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.

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

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.

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.

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 350 lawsuits covering approximately 540 claims in the U.S. A tentative trial date has been set for October 15, 2007, in the Eastern District of New York, for five of the U.S. claims. In addition, we have been served with a lawsuit seeking class certification in which the members of the purported class are seeking refunds and medical monitoring. 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.

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 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 \$62.5 million and \$91.1 million in the second quarter of 2007 and 2006, respectively. In the first half of 2007 and 2006, we recognized stock-based compensation expense of \$135.2 million and \$191.3 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 June 30, 2007, the total remaining unrecognized compensation cost associated with our equity programs is \$193.3 million and the weighted-average remaining requisite service period is 16 months.

RETIREMENT BENEFITS

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

	Defined Benefit Pension Plans			
	Three Months Ended June 30,		Six Months Ended June 30,	
	2007	2006	2007	2006
	(Dollars in millions)			
Components of net periodic benefit cost				
Service cost	\$ 66.4	\$ 68.8	\$ 132.0	\$ 138.1
Interest cost	86.4	81.5	172.3	162.2
Expected return on plan assets	(134.2)	(120.8)	(268.4)	(240.2)
Amortization of prior service cost	1.3	1.5	2.6	2.9
Recognized actuarial loss	30.9	32.8	62.2	63.1
Net periodic benefit cost	\$ 50.8	\$ 63.8	\$ 100.7	\$ 126.1

	Retiree Health Benefit Plans			
	Three Months Ended June 30,		Six Months Ended June 30,	
	2007	2006	2007	2006
	(Dollars in millions)			
Components of net periodic benefit cost				
Service cost	\$ 17.6	\$ 16.3	\$ 36.7	\$ 36.0
Interest cost	25.4	24.4	50.7	48.8
Expected return on plan assets	(25.3)	(23.0)	(51.6)	(45.0)
Amortization of prior service cost	(3.9)	(3.9)	(7.8)	(7.7)
Recognized actuarial loss	23.7	28.8	47.0	53.9

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

Net periodic benefit cost	\$ 37.5	\$ 42.6	\$ 75.0	\$ 86.0
---------------------------	---------	---------	---------	---------

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 in 2007 to our defined benefit plans. We also expect to contribute approximately \$55 million of discretionary funding to our postretirement health benefit plans during 2007. As of June 30, 2007, approximately \$90 million of the total \$220 million expected 2007 contributions has been contributed.

OTHER INCOME NET

Other income net, was comprised of the following:

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2007	2006	2007	2006
	(Dollars in millions)			
Interest expense	\$ 59.1	\$ 65.8	\$ 112.1	\$ 130.8
Interest income	(50.4)	(68.4)	(107.4)	(128.1)
Joint venture income		(22.5)	(11.0)	(42.3)
Other	(10.5)	(21.8)	(33.8)	(39.5)
	\$ (1.8)	\$ (46.9)	\$ (40.1)	\$ (79.1)

The joint venture income 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 June 30, 2007, we have purchased \$2.58 billion of our previously announced \$3.0 billion share repurchase program. During the second 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 examination by the Internal Revenue Service for tax years 2001-2004, and 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 range of the reasonably possible changes in uncertain tax positions that could occur within the next 12 months. In addition, it is not possible to reliably estimate future cash flows related to FIN 48 liabilities.

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 September 2006, the FASB issued Statement of Financial Accounting Standards (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.

In February 2007, the FASB issued 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 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.

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) ¹	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

¹ 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

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 \$444.1 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 \$24.1 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. The purchase price of Ivy has a contingency based upon the final determination of net working capital at closing. Any resulting purchase price adjustment will be reflected in the final allocation to goodwill.

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 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

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

Sales increased 20 percent and 17 percent for the second quarter and first half of 2007, respectively. The second-quarter and first-half 2007 earnings per share decreased 20 percent and 29 percent, respectively, compared with the same periods of 2006. The second-quarter and first-half 2007 net income decreased 19 percent and 29 percent, respectively, compared with the same periods of 2006. 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 in-process research and development 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 in-process research and development 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

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.

In June, the European Commission approved Cialis for once-a-day use to treat erectile dysfunction.

In early July, the European Commission granted approval to expand the Forsteo[®] label to include the treatment of osteoporosis in men who are at increased risk of fracture. The label has also been expanded to include a statement that in postmenopausal women, a significant reduction in the incidence of non-vertebral fractures but not hip fractures has been demonstrated.

In early July, the United Kingdom's National Institute for Clinical Excellence (NICE) reversed its previous ruling on Alimta[®] reimbursement within the UK's National Health Service. NICE is now recommending Alimta for patients with advanced mesothelioma who are able to carry out daily tasks but for whom surgery is not appropriate.

In the second quarter, we submitted new drug applications to the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for approval of olanzapine (Zyprexa) long-acting injection.

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.

In June, 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.

In July, the Oncologic Drugs Advisory Committee of the FDA voted to recommend approval of Evista for a new use to reduce invasive breast cancer risk in two populations: postmenopausal women with osteoporosis and postmenopausal women at high risk for breast cancer. Advisory committee recommendations to the FDA are non-binding. We expect FDA action prior to year end.

III. Legal, Regulatory, and Other Matters

In December 2006, the U.S. Court of Appeals for the Federal Circuit affirmed a district court ruling upholding the validity of our Zyprexa patent. We are very confident we will maintain our U.S. patent protection on Zyprexa until 2011.

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 350 lawsuits covering approximately 540 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.

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.

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.

On July 6, 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. While we have not yet completed our analysis of the rule in its current form (as there is an additional period for further comment), we do not anticipate that implementation of the final rule will be material to our financial position or results of operations.

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 pressure at the federal level to continue. In addition, although the successful implementation of the MMA may have relieved some state budget pressures, it is unlikely to result in reduced pricing pressures at the state level.

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

Second-quarter and first-half 2007 sales growth of 20 percent and 17 percent, respectively, was driven primarily by increased volume, by 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 \$406.1 million, or 19 percent, and \$681.8 million, or 16 percent, for the second quarter and first half of 2007, respectively, compared with the same periods of 2006. Sales outside the U.S. increased \$358.0 million, or 20 percent, and \$593.7 million, or 17 percent, for the second quarter and first half of 2007, respectively. For the second quarter, worldwide sales volume increased 14 percent, while selling prices and exchange rates each contributed 3 percentage points of sales growth. For the first six months of 2007, worldwide sales volume increased 10 percent, selling prices increased sales 4 percent, and exchange rates increased sales by 3 percent.

The following tables summarize our net sales activity for the three- and six-month periods ended June 30, 2007 and 2006:

Product	Three Months Ended			Three Months Ended	Percent Change from 2006
	U.S. ¹	Outside U.S.	Total	June 30, 2006	
	(Dollars in millions)				
Zyprexa	\$ 563.5	\$ 649.5	\$1,213.0	\$1,115.0	9
Cymbalta	457.6	61.9	519.5	310.4	67
Gemzar	165.8	229.8	395.6	343.5	15
Humalog	213.1	145.3	358.4	320.5	12
Cialis ²	110.2	182.9	293.1	50.5	NM
Evista	176.9	101.1	278.0	275.5	1
Humulin	87.7	155.1	242.8	219.8	10
Animal health products	96.1	118.6	214.7	201.0	7
Alimta	107.4	99.7	207.1	153.0	35
Forteo	123.6	53.6	177.2	146.1	21
Strattera®	117.2	25.1	142.3	144.1	(1)
Humatrope	54.2	58.9	113.1	108.0	5

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

Other pharmaceutical products	230.5	245.7	476.2	479.5	(1)
Total net sales	\$2,503.8	\$2,127.2	\$4,631.0	\$3,866.9	20

16

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

Product	Six Months Ended			Six Months	Percent Change from 2006
	June 30, 2007			Ended June 30, 2006	
	U.S. ¹	Outside U.S.	Total	Total	
	(Dollars in millions)				
Zyprexa	\$1,086.8	\$1,234.2	\$2,321.0	\$2,122.4	9
Cymbalta	843.9	117.4	961.3	543.7	77
Gemzar	328.5	444.0	772.5	682.3	13
Humalog	423.4	274.5	697.9	625.0	12
Evista	349.0	192.8	541.8	517.0	5
Cialis ²	174.2	311.9	486.1	106.2	NM
Humulin	172.9	295.7	468.6	438.3	7
Animal health products	188.8	241.0	429.8	399.3	8
Alimta	211.4	183.5	394.9	283.2	39
Forteo	230.9	99.7	330.6	273.1	21
Strattera	234.9	47.3	282.2	296.4	(5)
Humatrope	110.3	110.7	221.0	204.6	8
Other pharmaceutical products	459.9	489.5	949.4	1,090.1	(13)
Total net sales	\$4,814.9	\$4,042.2	\$8,857.1	\$7,581.6	17

NM Not Meaningful

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

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

In the second quarter and first half of 2007, U.S. sales of Zyprexa, a treatment for schizophrenia, bipolar mania, and bipolar maintenance, increased 4 percent and 5 percent, respectively, compared with the same periods of 2006 due to higher prices, offset partially by lower demand. Zyprexa sales in international markets increased 14 percent during both periods, driven by volume increases and the favorable impact of foreign exchange rates. We now expect modest growth in worldwide Zyprexa sales for 2007.

Results from our primary diabetes care products are as follows:

U.S. sales of Humalog, our insulin analog, increased 8 percent and 10 percent for the second quarter and first half of 2007, respectively, driven by increased volume and prices. Humalog sales outside the U.S. increased 17 percent and 14 percent, for the second quarter and first half of 2007, respectively, driven by increased volume and the favorable impact of exchange rates, offset in part, by decreased prices in the first half of 2007.

U.S. sales of Humulin, a biosynthetic human insulin, increased by 10 percent and 3 percent, for the second quarter and first half of 2007, respectively, driven by higher prices in the U.S. and offset in part, by decreased demand. Humulin sales outside the U.S. increased 11 percent and 9 percent for the second quarter and first half of 2007, respectively, due to increased demand and the favorable impact of exchange rates,

offset in part, by decreased prices.

Sales of Byetta[®], the first in a new class of medicines known as incretin mimetics for type 2 diabetes that we market with Amylin Pharmaceuticals (Amylin), were \$152.1 million and \$298.6 million during the second quarter and first half of 2007, respectively. We report as revenue our 50 percent share of Byetta's gross margins and our sales of Byetta pen delivery devices to our partner, Amylin, which totaled \$80.0 million and \$151.5 million during the second quarter and first half of 2007, respectively, compared with \$52.1 million and \$88.0 million for the same periods in 2006.

U.S. revenues of Actos, an oral agent for the treatment of type 2 diabetes, were \$40.8 million and \$81.5 million during the second quarter and first half of 2007, respectively, as compared to \$50.9 million and \$202.3 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 26 percent, to \$52.5 million, and 23 percent, to \$98.0

million, during the same periods, due primarily to increased volume in addition to a favorable impact of foreign exchange rates.

U.S. sales of Cymbalta, a treatment of major depressive disorder, diabetic peripheral neuropathic pain, and generalized anxiety disorder, increased 70 percent and 77 percent during the second quarter and first half of 2007, respectively, due to increased demand. We continue to see share-of-market growth in the U.S. Sales outside the U.S. increased 53 percent and 73 percent compared to the same periods in 2006.

U.S. sales of Gemzar, a product approved to fight various cancers, increased 11 percent and 10 percent during the second quarter and first half of 2007, respectively, due to higher prices and demand. Gemzar sales outside the U.S. increased 19 percent and 16 percent during the second quarter and first half of 2007, respectively, as a result of increased demand and the favorable impact of foreign exchange rates.

Total worldwide sales of Cialis, a treatment for erectile dysfunction, were \$293.1 million and \$558.8 million during the second quarter and first half 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 26 percent in the second quarter of 2007 and 23 percent in the first half of 2007, compared with the same periods in 2006, reflecting increased global demand. U.S. sales increased 17 percent during the second quarter and first half of 2007 due to increased prices and volume. Sales outside the U.S. increased 32 percent and 26 percent during the second quarter and first half of 2007, respectively, due to increased volume, increased prices, and the favorable impact of foreign exchange rates. Prior to the ICOS acquisition, Cialis sales in our territories were reported in revenue, while our 50 percent share of the joint-venture territory sales, 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, increased 1 percent and 8 percent during the second quarter and first half of 2007, respectively, driven by higher prices, partially offset by lower demand. Evista sales outside the U.S. increased 1 percent and remained flat for the same periods, driven by higher demand and the favorable impact of foreign exchange rates, offset by decreased prices.

U.S. sales of Alimta, a treatment for malignant pleural mesothelioma and second-line treatment of non-small cell lung cancer, increased 22 percent and 28 percent during the second quarter and first half of 2007, respectively, due to increased demand and higher prices. Alimta sales outside the U.S. increased 53 percent and 56 percent for the same periods, due primarily to increased demand and the favorable impact of foreign exchange rates.

U.S. sales of Forteo, a treatment for severe osteoporosis, increased 22 percent and 23 percent during the second quarter and first half of 2007, respectively. U.S. sales benefited from access to medical coverage through the Medicare Part D program and decreased utilization of our U.S. patient assistance program. Forteo sales outside the U.S. grew 19 percent and 17 percent for the same periods due primarily to increased demand and the favorable impact of foreign exchange rates.

U.S. sales of Strattera, a treatment of attention-deficit hyperactivity disorder in children, adolescents, and adults, decreased 7 percent and 10 percent during the second quarter and first half of 2007, respectively, compared with the same periods in 2006. The sales decrease was primarily due to a decline in demand. Strattera sales outside the U.S. increased 38 percent and 35 percent during the second quarter and first half of 2007, respectively, primarily due to higher demand.

Gross Margin, Costs, and Expenses

For the second quarter of 2007, gross margins as a percent of net sales increased by 0.7 percentage points, to 78.4 percent. For the first half of 2007, gross margins as a percentage of net sales increased by 0.3 percentage points, to 78.3 percent. This increase was primarily due to manufacturing expenses growing at a slower rate than sales and higher product prices, offset in part by the expense resulting from the amortization of the intangible assets acquired in the ICOS acquisition and the impact of foreign exchange rates.

Overall, marketing and administrative expenses rose 23 percent, to \$1.52 billion, and 20 percent, to \$2.86 billion for the second quarter and first half 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 half of 2007, an increase in litigation-related costs. Research and development expenses were \$854.4 million and \$1.69 billion for the second quarter and first half of 2007, respectively. Compared with the second quarter and first half of 2006, research and development expenses increased 10 percent and

11 percent, respectively. In addition to the acquisition of ICOS, this increase was due to increases in discovery research and late-stage clinical trial costs. Research and development expenses for the first half 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 and the withdrawal of the Arxxant application in Europe.

In the second quarter of 2007, we incurred in-process research and development charges totaling \$328.1 million related to the acquisitions of Hypnion and Ivy. With 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 half of 2007 were \$656.6 million.

Other income net decreased by \$45.1 million, to \$1.8 million, and by \$39.0 million, to \$40.1 million for the second quarter and first half 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 second quarter and first half of 2007 decreased \$6.7 million and \$18.7 million, respectively, to \$59.1 million and \$112.1 million, respectively, due to lower debt balances in 2007 as compared with the same periods of 2006.

Interest income for the second quarter and first half of 2007 decreased by \$18.0 million and \$20.7 million, respectively, to \$50.4 million and \$107.4 million, respectively, due to lower cash balances in 2007 as compared with the same periods of 2006.

The Lilly ICOS joint venture income for the second quarter and first half of 2007 decreased by \$22.5 million and \$31.3 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 items for the second quarter and first half of 2007 decreased \$11.3 million, to \$10.5 million, and \$5.7 million, to \$33.8 million, respectively, primarily as a result of lower gains on sales of equity instruments, partially offset by increased income from business development transactions.

We incurred income tax expense of \$263.1 million and \$473.8 million, respectively, for the second quarter and first half of 2007. The effective tax rate was 28.4 percent and 28.8 percent, up from 21 percent for the comparable periods in 2006, primarily because the in-process research and development charges associated with the acquisitions of ICOS and Hypnion were not deductible.

FINANCIAL CONDITION

As of June 30, 2007, cash, cash equivalents, and short-term investments totaled \$3.00 billion compared with \$3.89 billion at December 31, 2006. Cash flows from operations of \$1.48 billion during the first six months of 2007 and net proceeds from the issuance of long-term debt of \$1.50 billion were more than offset by the net cash paid for corporate acquisitions of \$2.58 billion, dividends paid of \$926.5 million, and net purchases of property and equipment of \$485.6 million.

Total debt at June 30, 2007, was \$5.04 billion, an increase of \$1.32 billion from December 31, 2006. In the first six 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 \$1.00 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. Reddy's and Teva's combined petition for rehearing at the Federal Circuit was denied. Reddy and Teva are seeking review of the Federal Circuit's decision by the U.S. Supreme Court. We are confident that Reddy's and Teva's claims are without merit and

we expect to prevail. An unfavorable outcome would have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

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 lawsuit against Teva in the U.S. District Court for the Southern District of Indiana, seeking a ruling that our relevant U.S. patents are valid, enforceable, and being infringed by Teva. 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. On April 17, 2007, the court denied Sicor's motion. The two remaining motions to dismiss have not been decided. We expect to prevail in litigation involving our Gemzar patents and believe that claims made by these generic companies that our patents are not valid 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.

During 2005, two generic pharmaceutical manufacturers, Apotex Inc. (Apotex) and Novopharm Ltd. (Novopharm) (a wholly-owned subsidiary of Teva), challenged the validity of our Zyprexa compound and method-of-use patent (expiring in 2011) in Canada. The generic companies allege that our patent is invalid. In April 2007, the Canadian Federal Court ruled against Apotex, and Apotex has appealed the ruling. No hearing date has been set, but a hearing could be held as early as the fourth quarter of 2007. In June 2007, the Canadian Federal Court held that Novopharm's allegations of invalidity were justified and denied our request that Novopharm be prohibited from receiving marketing approval for generic olanzapine in Canada. We have appealed the decision and sued Novopharm for patent infringement. We anticipate the appeal hearing in the fourth quarter of 2007, if at all. The patent infringement suit has been tentatively scheduled for trial in July 2008. In May 2004, Egis-Gyogyszergyar (Egis), and in May 2006, Neolabs Ltd. (Neolabs), both generic pharmaceutical manufacturers, challenged the validity of our Zyprexa compound and method-of-use patents (expiring in 2011) in Germany. The Egis and Neolabs suits were joined and heard together. In June, the German Federal Patent Court held that our patent is invalid. We are appealing the decision. We have received challenges to Zyprexa patents in a number of other countries as well, including the UK (where a trial is scheduled for July 2008), Spain, and several other European countries. 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 for sale in one or more of these countries could have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

In June 2002, Ariad Pharmaceuticals, Inc., the Massachusetts Institute of Technology, the Whitehead Institute for Biomedical Research, and the President and Fellows of Harvard College in the U.S. District Court for the District of Massachusetts sued us, alleging that sales of two of our products, Xigris and Evista, were inducing the infringement of a patent related to the discovery of a natural cell signaling phenomenon in the human body, and seeking royalties on past and future sales of these products. On May 4, 2006, a jury in Boston issued an initial decision in the case that

Xigris and Evista sales infringe the patent. The jury awarded the plaintiffs approximately \$65 million in damages, calculated by applying a 2.3 percent royalty to all U.S. sales of Xigris and Evista from the date of issuance of the patent through the date of trial. In addition, a separate bench trial with the U.S. District Court of Massachusetts was held the week of August 7, 2006, on our contention that the patent is unenforceable and impermissibly covers natural processes. In a statement issued July 6, 2007, the court indicated that Ariad's claims are patentable, valid, and enforceable. In June 2005, the United States Patent and Trademark Office (USPTO) commenced a reexamination of the patent, and has taken the position that the Ariad claims at issue are unpatentable, subject to Ariad's right to appeal. We are seeking to delay entry of a final judgment in the bench trial pending a final resolution of the reexamination. If it becomes necessary, we will appeal any adverse decision. Should we lose, it is likely that the damages would include a royalty on relevant future U.S. sales of Evista and Xigris; however, 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

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 U.S. Attorney's Office 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.

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:

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

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 350 lawsuits covering approximately 540 claims in the U.S. A tentative trial date has been set for October 15, 2007, in the Eastern District of New York, for five of the U.S. claims. In addition, we have been served with a lawsuit seeking class certification in which the members of the purported class are seeking refunds and medical monitoring. 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.

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 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 raised our earnings guidance for the full year of 2007, and now expect earnings per share to be in the range of \$2.75 to \$2.85. We expect third quarter earnings per share of \$.85 to \$.87. The earnings per share guidance incorporates a number of second-half 2007 issues, including the anticipated impact of the launch of generic olanzapine by competitors in Canada and the potential launch of generic olanzapine in Germany, normally scheduled manufacturing shutdowns, and additional investments in research and development and sales and marketing to drive future growth. We have also raised our full-year 2007 sales guidance, and now expect sales growth percentage to be in the mid-teens. Gross margins as a percent of net sales are expected to improve slightly compared with 2006. In addition, we 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 also expect other income net to contribute less than \$100 million, a reduction from 2006 due to the removal of the Lilly ICOS joint venture after-tax profit. Other income net will primarily include net interest income and income from the partnering and out-licensing of molecules. In terms of cash flow, 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

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 June 30, 2007, and concluded that they are effective.

(b) *Changes in Internal Controls.* During the second 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 and Regulatory Matters, for information on various legal proceedings, including but not limited to:

The patent litigation involving Zyprexa, Evista, and Gemzar

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 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 65 suits involving approximately 120 claimants. In the thimerosal litigation, we have been named as a defendant in approximately 355 suits with approximately 930 claimants.

Shareholder Litigation

Two putative class action lawsuits have been 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 under the federal securities laws (*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). In both lawsuits, plaintiffs request certification of a class of purchasers of our stock from March 28, 2002, through December 22, 2006. The complaints allege that the defendants made false and misleading statements regarding Zyprexa in violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, and seek unspecified compensatory damages and the costs of suit, including attorneys' fees. 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. 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.

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 June 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)
April 2007	5	\$ 59.21		\$ 419.2
May 2007				419.2
June 2007	3	57.93		419.2
Total	8			

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 June 30, 2007, we have purchased \$2.58 billion related to this program. During the second 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 August 3, 2007

s/ James B. Lootens
James B. Lootens
Secretary and Deputy General Counsel

Date August 3, 2007

s/ Arnold C. Hanish
Arnold C. Hanish
Executive Director, Finance, and Chief
Accounting Officer
26

INDEX TO EXHIBITS

The following documents are filed as a part of 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