

LILLY ELI & CO
Form 10-Q
November 03, 2006

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
Form 10-Q
Quarterly Report Under Section 13 or 15(d) of the
Securities Exchange Act of 1934
FOR THE QUARTER ENDED SEPTEMBER 30, 2006
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 October 20, 2006:

Class	Number of Shares Outstanding
Common	1,131,588,452

TABLE OF CONTENTS**PART I. FINANCIAL INFORMATION**Item 1. Financial StatementsItem 2. Management's Discussion and Analysis of Financial Condition and Results of OperationsItem 4. Controls and Procedures**PART II. OTHER INFORMATION**Item 1. Legal ProceedingsItem 2. Unregistered Sales of Equity Securities and Use of ProceedsItem 6. Exhibits and Reports on Form 8-K**SIGNATURES****INDEX TO EXHIBITS****PART I. FINANCIAL INFORMATION***Item 1. Financial Statements*

CONSOLIDATED CONDENSED STATEMENTS OF INCOME

(Unaudited)

Eli Lilly and Company and Subsidiaries

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
	(Dollars in millions except per-share data)			
Net sales	\$ 3,864.1	\$ 3,601.1	\$ 11,445.7	\$ 10,766.2
Cost of sales	860.4	845.7	2,527.5	2,576.0
Research and development	755.7	751.0	2,271.3	2,215.6
Marketing and administrative	1,198.2	1,070.9	3,579.0	3,307.4
Asset impairments, restructuring, and other special charges				1,073.4
Other income net	(56.0)	(85.0)	(135.1)	(229.0)
	2,758.3	2,582.6	8,242.7	8,943.4
Income before income taxes	1,105.8	1,018.5	3,203.0	1,822.8
Income taxes	232.2	224.1	672.6	543.8
Net income	\$ 873.6	\$ 794.4	\$ 2,530.4	\$ 1,279.0

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

Earnings per share	basic	\$.80	\$.73	\$	2.33	\$	1.18
Earnings per share	diluted	\$.80	\$.73	\$	2.33	\$	1.17
Dividends paid per share		\$.40	\$.38	\$	1.20	\$	1.14

See Notes to Consolidated Condensed Financial Statements.

CONSOLIDATED CONDENSED BALANCE SHEETS
Eli Lilly and Company and Subsidiaries

	September 30, 2006	December 31, 2005
	(Dollars in millions)	
	(Unaudited)	
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 2,169.9	\$ 3,006.7
Short-term investments	1,448.6	2,031.0
Accounts receivable, net of allowances of \$73.1 (2006) and \$62.5 (2005)	2,077.9	2,313.3
Other receivables	399.6	448.4
Inventories	2,199.8	1,878.0
Deferred income taxes	731.2	756.4
Prepaid expenses	744.2	362.0
TOTAL CURRENT ASSETS	9,771.2	10,795.8
OTHER ASSETS		
Prepaid pension	2,450.1	2,419.6
Investments	1,294.5	1,296.6
Sundry	2,182.2	2,156.3
	5,926.8	5,872.5
PROPERTY AND EQUIPMENT		
Land, buildings, equipment, and construction-in-progress	13,731.7	13,136.0
Less allowances for depreciation	(5,516.3)	(5,223.5)
	8,215.4	7,912.5
	\$ 23,913.4	\$ 24,580.8
LIABILITIES AND SHAREHOLDERS EQUITY		
CURRENT LIABILITIES		
Short-term borrowings	\$ 334.2	\$ 734.7
Accounts payable	630.6	781.3
Employee compensation	454.3	548.8
Dividends payable		436.5
Income taxes payable	725.2	884.9
Other current liabilities	1,738.5	2,330.1
TOTAL CURRENT LIABILITIES	3,882.8	5,716.3
LONG-TERM DEBT	4,553.3	5,763.5
DEFERRED INCOME TAXES	847.8	695.1
OTHER NONCURRENT LIABILITIES	1,574.8	1,614.0

SHAREHOLDERS EQUITY

Common stock	707.6	706.9
Additional paid-in capital	3,482.3	3,323.8
Retained earnings	11,692.5	10,027.2
Employee benefit trust	(2,635.0)	(2,635.0)
Deferred costs ESOP	(102.5)	(106.3)
Accumulated other comprehensive income (loss)	12.4	(420.6)
	13,157.3	10,896.0
Less cost of common stock in treasury	102.6	104.1
	13,054.7	10,791.9
	\$ 23,913.4	\$ 24,580.8

See Notes to Consolidated Condensed Financial Statements.

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

	Nine Months Ended September 30,	
	2006	2005
	(Dollars in millions)	
CASH FLOWS FROM OPERATING ACTIVITIES		
Net income	\$ 2,530.4	\$ 1,279.0
Adjustments to reconcile net income to cash flows from operating activities:		
Changes in operating assets and liabilities	(1,318.6)	(1,796.0)
Depreciation and amortization	628.2	501.3
Stock-based compensation expense	274.3	309.5
Change in deferred taxes	130.5	(205.0)
Asset impairments, restructuring, and other special charges, net of tax		979.7
Other, net	(126.6)	30.8
NET CASH PROVIDED BY OPERATING ACTIVITIES	2,118.2	1,099.3
CASH FLOWS FROM INVESTING ACTIVITIES		
Net purchases of property and equipment	(667.8)	(878.5)
Net change in short-term investments	580.4	833.1
Purchase of noncurrent investments	(1,218.7)	(271.9)
Proceeds from sales and maturities of noncurrent investments	1,135.1	327.0
Other, net	124.4	(216.4)
NET CASH USED IN INVESTING ACTIVITIES	(46.6)	(206.7)
CASH FLOWS FROM FINANCING ACTIVITIES		
Dividends paid	(1,301.5)	(1,245.7)
Purchases of common stock	(122.1)	
Issuances of common stock under stock plans	44.2	71.2
Net change in short-term borrowings	(1.8)	(1,984.6)
Net (repayments) issuances of long-term debt	(1,599.0)	1,998.0
Other, net	6.3	33.2
NET CASH USED IN FINANCING ACTIVITIES	(2,973.9)	(1,127.9)
Effect of exchange rate changes on cash and cash equivalents	65.5	(160.3)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(836.8)	(395.6)
Cash and cash equivalents at January 1	3,006.7	5,365.3

CASH AND CASH EQUIVALENTS AT SEPTEMBER 30	\$ 2,169.9	\$ 4,969.7
---	------------	------------

See Notes to Consolidated Condensed Financial Statements.

4

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
	(Dollars in millions)			
Net income	\$ 873.6	\$ 794.4	\$ 2,530.4	\$ 1,279.0
Other comprehensive income (loss) ¹	132.3	48.2	433.0	(468.7)
Comprehensive income	\$ 1,005.9	\$ 842.6	\$ 2,963.4	\$ 810.3

¹ The significant components of other comprehensive income were gains of \$123.4 million and \$346.7 million from foreign currency translation adjustments for the three months and nine months ended September 30, 2006, respectively, and losses of \$421.4 million from foreign currency translation adjustments for the nine months ended September 30, 2005.

See Notes to Consolidated Condensed Financial Statements.

SEGMENT INFORMATION

We operate in one significant business segment — pharmaceutical products. Operations of our animal health business segment are not material and share many of the same economic and operating characteristics as our pharmaceutical products. Therefore, they are included with pharmaceutical products for purposes of segment reporting. Our business segments are distinguished by the ultimate end user of the product: humans or animals. Performance is evaluated based on profit or loss from operations before income taxes. Income before income taxes for the animal health business was \$47.8 million and \$55.7 million for the quarters ended September 30, 2006 and 2005, respectively, and \$122.9 million and \$143.0 million for the nine months ended September 30, 2006 and 2005, respectively.

SALES BY PRODUCT CATEGORY

Worldwide sales by product category for the three months and nine months ended September 30, 2006 and 2005 were as follows:

	Three Months Ended September 30, 2006		Nine Months Ended September 30, 2006	
	2005	2005	2005	2005
	(Dollars in millions)			
Net sales to unaffiliated customers				
Neurosciences	\$ 1,676.1	\$ 1,514.9	\$ 4,869.4	\$ 4,490.2
Endocrinology	1,221.0	1,115.9	3,680.9	3,402.2
Oncology	511.8	456.9	1,477.6	1,312.2
Animal health	216.2	215.7	615.5	612.3
Cardiovascular	117.3	135.8	387.9	459.6
Anti-infectives	58.5	104.7	216.0	326.7
Other pharmaceuticals	63.2	57.2	198.4	163.0
Net sales	\$ 3,864.1	\$ 3,601.1	\$ 11,445.7	\$ 10,766.2

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, 2005.

CONTINGENCIES

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. We are now awaiting a decision by the Court of Appeals for the Federal Circuit, which on April 6, 2006, heard Reddy's and Teva's respective appeals of this ruling. We are confident Reddy'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 on appeal. 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 (expiring in 2012-2014) are valid, enforceable, and being infringed by Teva. No trial date has been set in either case. We believe 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), a subsidiary of Teva, submitted ANDAs in November 2005 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. In February 2006, we filed a lawsuit against Sicor in the U.S. District Court for the Southern District of Indiana, seeking a ruling that these patents are valid and are being infringed by Sicor. In response to our lawsuit, Sicor filed a declaratory judgment action in the U.S. District Court for the Central District of California. The California action has since been dismissed. In September 2006, we received notice that Mayne Pharma (USA) Inc. (Mayne) filed a similar ANDA for

Gemzar. In October 2006, we filed a lawsuit against Mayne in the Southern District of Indiana in response to the ANDA filing. We are awaiting the filing of an answer to our complaint against Mayne. In October 2006, we received notice that Sun Pharmaceutical Industries Inc. (Sun) filed a similar ANDA for Gemzar. We are evaluating our option to bring legal action against Sun. 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 such 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.

In March 2004, the office of the U.S. Attorney for the Eastern District of Pennsylvania advised us that it has commenced a civil investigation related to our U.S. marketing and promotional practices, including our communications with physicians and

remuneration of physician consultants and advisors, with respect to Zyprexa, Prozac[®], and Prozac Weekly . 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. We are cooperating with the U.S. Attorney in these investigations, including providing a broad range of documents and information relating to the investigations. 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. 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.

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). The MDL includes three lawsuits requesting certification of class actions on behalf of those who allegedly suffered injuries from the administration of Zyprexa. We have entered into agreements with various plaintiffs' counsel halting the running of the statutes of limitation (tolling agreements) with respect to a number of claimants who do not have lawsuits on file.

Since June 2005, we have entered into agreements with various claimants' attorneys involved in U.S. Zyprexa product liability litigation to settle approximately 10,500 claims, including a large number of previously filed lawsuits (including the three purported class actions mentioned above), tolled claims, and other informally asserted claims. The settlements are being overseen and distributed by court-approved claims administrators.

The U.S. Zyprexa product liability claims not subject to these agreements include approximately 1,500 lawsuits in the U.S. covering approximately 9,700 claimants, and approximately 850 tolled claims. The first trials are scheduled for April 2007 in the Federal District Court for the Eastern District of New York. 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. Finally, 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 certain residents of Quebec. The allegations in the Canadian actions are similar to those in the litigation pending in the United States. We are prepared to continue our vigorous defense of Zyprexa in all remaining cases.

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. In 2006, we were served with

similar lawsuits filed by the states of Alaska, West Virginia, Mississippi, and New Mexico in the courts of the respective states.

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, that 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. Four additional lawsuits were filed in 2006: two in the Eastern District of New York, one in the Southern District of Indiana, and one in Indiana state court, all 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 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 carriers and in arbitration in Bermuda against other carriers. While we believe our position is meritorious, 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.

With respect to the product liability claims currently asserted against us, we have accrued for our estimated exposures to the extent they are both probable and estimable based on the information available to us. In addition, we have accrued for certain product liability claims incurred but not filed to the extent we can formulate a reasonable estimate of their costs. We estimate these expenses based primarily on historical claims experience and data regarding product usage. Legal defense costs expected to be incurred in connection with significant product liability loss contingencies are accrued when probable and reasonably estimable. A portion of the costs associated with defending and disposing of these suits is covered by insurance. We record receivables for insurance-related recoveries when it is probable they will be realized. These receivables are classified as a reduction of the litigation charges on the statement of income. We estimate insurance recoverables based on existing deductibles, coverage limits, our assessment of any defenses to coverage that might be raised by the carriers, and the existing and projected future level of insolvencies among the insurance carriers.

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

The cost of the Zyprexa settlements described above; and,

Reserves for product liability exposures and defense costs regarding currently known and expected claims to the extent we can formulate a reasonable estimate of the probable number and cost of the claims. A substantial majority of these exposures and costs relate to current and expected Zyprexa claims not included in the settlements. We have estimated these charges based primarily on historical claims experience, data regarding product usage, and our historical product liability defense cost experience.

During 2005, \$700.0 million was paid in connection with Zyprexa settlements, while the cash related to other reserves for product liability exposures and defense costs is expected to be paid out over the next several years, including 2006. The timing of our insurance recoveries is uncertain.

We cannot predict with certainty the additional number of lawsuits and claims that may be asserted. In addition, although we believe it is probable, there can be no assurance that the Zyprexa settlements described above will be concluded. 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 claims for other products in the future. We have experienced difficulties in obtaining product liability insurance due to a very restrictive insurance market, and therefore will be largely self-insured for future product liability losses. In addition, as noted above, there is no assurance that we will be able to fully collect from our insurance carriers on past claims.

In June 2002, we were sued by 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 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. We believe that these allegations are without legal merit and that we will ultimately prevail on these issues. In June 2005, the United States Patent and Trademark Office commenced a re-examination of the patent in order to consider certain issues raised by us relating to the validity of the patent. A jury trial commenced in Boston on April 10, 2006 on the patent validity and infringement issues. On May 4, 2006, the jury 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. We will seek to have the jury verdict overturned by the trial court judge, and if unsuccessful, will appeal the decision to the Court of Appeals for the

Federal Circuit. 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. No decision has been rendered.

Also, 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 earnings 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

We adopted Statement of Financial Accounting Standards No. 123 (revised 2004), Share-Based Payment (SFAS 123R), effective January 1, 2005. SFAS 123R requires the recognition of the fair value of stock-based compensation in net income. Stock-based compensation primarily consists of stock options and performance awards. We recognized pretax stock-based compensation cost in the amount of \$83.0 million and \$101.3 million in the third quarter of 2006 and 2005, respectively. In the first nine months of 2006 and 2005, we recognized stock-based compensation expense of \$274.3 million and \$309.5 million, respectively.

As of September 30, 2006, the total remaining unrecognized compensation cost related to nonvested stock options and performance awards amounted to \$128.9 million and \$51.2 million, respectively, which will be amortized over the weighted-average remaining requisite service periods, which are approximately 17 months and 3 months, respectively. Under our policy, all stock option awards are approved prior to the date of grant and the exercise price is the average of the high and low market price on the date of grant. The Compensation Committee of the Board of Directors approves the value of the award and the date of grant. Options that are awarded as part of annual total compensation are made on specific grant dates scheduled in advance. With respect to option awards given to new hires, our policy requires approval of such awards prior to the grant date, and the options are granted on a predetermined monthly date immediately following the date of hire.

RETIREMENT BENEFITS

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

	Defined Benefit Pension Plans			
	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
	(Dollars in millions)			
Components of net periodic benefit cost				
Service cost	\$ 67.8	\$ 79.2	\$ 206.1	\$ 233.6
Interest cost	81.8	73.5	244.0	222.5
Expected return on plan assets	(121.2)	(111.8)	(361.5)	(334.8)
Amortization of prior service cost	1.4	1.9	4.3	5.8
Recognized actuarial loss	31.8	25.7	94.9	77.9
Net periodic benefit cost	\$ 61.6	\$ 68.5	\$ 187.8	\$ 205.0

	Retiree Health Benefit Plans			
	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2006	2005	2006	2005
	(Dollars in millions)			
Components of net periodic benefit cost				
Service cost	\$ 18.0	\$ 14.7	\$ 53.9	\$ 44.1
Interest cost	24.4	20.0	73.3	60.1
Expected return on plan assets	(22.5)	(18.7)	(67.4)	(54.4)
Amortization of prior service cost	(3.9)	(3.9)	(11.6)	(11.9)
Recognized actuarial loss	27.0	21.5	80.9	64.6
Net periodic benefit cost	\$ 43.0	\$ 33.6	\$ 129.1	\$ 102.5

In 2006, we contributed approximately \$30 million to our defined benefit pension plans to satisfy minimum funding requirements for the year. In addition, we contributed approximately \$140 million of additional discretionary funding to our defined benefit plans and approximately \$90 million of discretionary funding to our post retirement benefit plans. We do not expect to contribute additional amounts to our plans during the remainder of 2006.

OTHER INCOME NET

Other income net, was comprised of the following:

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2006	2005	2006	2005
	(Dollars in millions)			
Interest expense	\$ 62.7	\$ 24.3	\$ 193.5	\$ 60.9
Interest income	(67.5)	(51.9)	(195.6)	(144.2)
Joint venture (income) loss	(23.8)	(5.8)	(66.1)	7.3
Other	(27.4)	(51.6)	(66.9)	(153.0)
	\$ (56.0)	\$ (85.0)	\$ (135.1)	\$ (229.0)

The joint venture (income) loss represents our share of the Lilly ICOS LLC joint venture results of operations, net of income taxes.

SHAREHOLDERS EQUITY

As of September 30, 2006, we have purchased \$2.58 billion of our previously announced \$3.0 billion share repurchase program. During the nine months ended September 30, 2006, we acquired 2.1 million shares pursuant to this program. We do not expect any share repurchases during the remainder of 2006.

IMPLEMENTATION OF NEW FINANCIAL ACCOUNTING PRONOUNCEMENTS

In September 2006, the FASB issued Statement No. 158, Employers Accounting for Defined Benefit Pension and Other Postretirement Plans an amendment of FASB Statements No. 87, 88, 106, and 132(R). SFAS 158 requires the recognition of the overfunded or underfunded status of a defined benefit postretirement plan (other than a multiemployer plan) as an asset or liability in its statement of financial position, the measurement of a plan's assets and its obligations that determine its funded status as of the end of the employer's fiscal year, and the recognition of changes in that funded status in the year in which the changes occur through comprehensive income. Additional footnote disclosures will also be required. SFAS 158 is effective for us as of December 31, 2006 and is required to be adopted prospectively. Because the impact on our consolidated financial position upon adoption will depend on the facts and circumstances as of December 31, 2006, we cannot determine the impact at this time; however, if we would

have adopted SFAS 158 as of December 31, 2005, there would have been a reduction to our net assets and shareholder's equity of approximately \$1.7 billion. There will be no impact to our statements of income or cash flows. We do not expect the change in the measurement date to have an impact on our financial statements.

In September 2006, the SEC issued Staff Accounting Bulletin (SAB) No. 108, which provides interpretive guidance on how the effects of carryover or reversal of prior year misstatements should be considered in quantifying a current year misstatement. The SEC staff believes that errors should be quantified using both a balance sheet and income statement approach and evaluated as to whether either approach results in quantifying a misstatement that, when all relevant quantitative and qualitative factors are considered, is material. The SEC staff has stated that it will not object if there is a one-time cumulative effect adjustment recorded to correct errors existing in prior years that previously had been considered immaterial - quantitatively and qualitatively - based on appropriate use of the registrant's previous approach. SAB 108 describes the circumstances where this would be appropriate as

well as the required disclosures and is effective for fiscal years ending after November 15, 2006; therefore we will be required to apply this Bulletin in the year ending December 31, 2006. We are currently evaluating SAB 108 and have not yet determined its impact; however, based on currently available information, we do not expect a material impact on our consolidated financial position or results of operations.

In June 2006, the FASB issued FIN 48, Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109. 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. The Interpretation is effective for fiscal years beginning after December 15, 2006; therefore, we will be required to adopt this Interpretation in the first quarter of 2007. We are currently evaluating FIN 48 and have not yet determined the impact the adoption of this Interpretation will have on our consolidated financial position or results of operations.

In the fourth quarter of 2005, we adopted Financial Accounting Standards Board (FASB) Interpretation (FIN) 47, Accounting for Conditional Asset Retirement Obligations, an interpretation of FASB Statement No. 143. FIN 47 requires us to record the fair value of a liability for conditional asset retirement obligations in the period in which it is incurred, which is adjusted to its present value each subsequent period. In addition, we are required to capitalize a corresponding amount by increasing the carrying amount of the related long-lived asset, which is depreciated over the useful life of the related long-lived asset. The adoption of FIN 47 on December 31, 2005, resulted in a cumulative effect of a change in accounting principle of \$22.0 million, net of income taxes of \$11.8 million.

POTENTIAL ASSET IMPAIRMENTS, RESTRUCTURING, AND OTHER SPECIAL CHARGES

As part of our ongoing efforts to maximize performance and efficiencies, including the streamlining of manufacturing operations and research and development activities, as announced in June 2006, we have been considering the future of three European facilities, which include the R&D facilities in Mont St. Guibert, Belgium and Hamburg, Germany, and the dry products manufacturing facility in Basingstoke, England. On October 16, 2006, the Board of Directors approved a plan to close the Hamburg, Germany, facility and also approved a social package, including severance payments that were negotiated with the site works council. Under the agreement, operations will decrease during the rest of 2006 and into the first half of 2007, with the official closing anticipated by mid-2007. This will result in a fourth-quarter charge to asset impairment, restructuring and other special charges of \$40 million to \$50 million (pretax), or \$.02 to \$.03 per share (after-tax), composed of \$35 million to \$40 million in severance related charges and lease termination costs, substantially all of which is expected to be in cash, and \$5 million to \$10 million in non-cash asset impairment charges. We have also been considering the closure of the Basingstoke plant as well as the sale of the plant as an ongoing operation. Several companies have expressed interest in potentially purchasing this site as an ongoing operation, and management intends to diligently pursue the sale option and make a decision by year end. If no viable sale option has been identified by that time, the Board has authorized management to proceed with the closure of the facility and implementation of a severance package negotiated with the employee representatives. No final decisions have been made with respect to the Basingstoke and Mont St. Guibert sites. However, severance and impairment charges as a result of any potential sale or site closure could be significant.

SUBSEQUENT EVENT

On October 17, 2006, we signed an agreement to acquire ICOS Corporation (ICOS) for approximately \$2.1 billion in cash. 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. Consummation of the acquisition is subject to antitrust clearance under the Hart-Scott-Rodino Act, approval of the ICOS shareholders, and other customary closing conditions. Upon the closing of the transaction, which is expected in late 2006 or early 2007, we will incur a one-time charge to earnings for acquired in-process research and development (IPR&D), but it is premature to estimate what that charge will be.

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

OPERATING RESULTS

Executive Overview

I. Financial Results

Our worldwide sales for the third quarter increased 7 percent to \$3.86 billion. Net income was \$873.6 million, or \$.80 per share, for the third quarter of 2006 compared with \$794.4 million, or \$.73 per share, for the third quarter of 2005, representing an increase of 10 percent in both net income and earnings per share. The earnings growth was driven by sales increasing at a faster rate than cost of products sold and research and development expenses, offset partially by higher marketing and administrative expenses and decreased other income. Net income was \$2.53 billion, or \$2.33 per share, for the first nine months of 2006 compared with \$1.28 billion, or \$1.17 per share, for the first nine months of 2005. These amounts include the impact of the product liability litigation charge of \$1.07 billion that was taken in the second quarter of 2005. In addition to this product liability charge, the earnings increase in the nine-month period was driven primarily by increased sales and decreased cost of sales, offset by decreased other income.

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

On October 17, 2006, we announced our acquisition of ICOS Corporation for approximately \$2.1 billion in cash. 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. We expect this acquisition will increase our earnings and earnings growth rate beginning in 2008 and, after a significant addition to sales in 2007, will modestly accelerate our sales growth rate thereafter. Upon the closing of the transaction, which is expected in late 2006 or early 2007, we will incur a one-time charge to earnings for acquired in-process research and development (IPR&D), but it is premature to estimate what that charge will be. In addition, we expect the impact of including the operations of ICOS in our financial results will be modestly dilutive to earnings in 2007. Consummation of the acquisition is subject to antitrust clearance under the Hart-Scott-Rodino Act, approval of the ICOS shareholders, and other customary closing conditions.

We received an approvable letter from the U.S. Food and Drug Administration (FDA) for Arxxant for the treatment of diabetic retinopathy. The FDA has indicated that it will require efficacy data from an additional Phase III study before it will consider approving the molecule. We have decided to appeal the FDA's decision and have recently begun discussions with the agency. We reached this decision by considering the significance of the unmet medical need that diabetic retinopathy represents, the efficacy demonstrated in the completed clinical studies and the safety profile shown in more than 3,300 patient years of clinical trial exposure. There can be no assurance that our appeal will be successful.

The Committee for Medicinal Products for Human Use of the European Medicines Evaluation Agency issued a positive opinion recommending approval of Byetta[®] for the treatment of type 2 diabetes. Marketing authorization by the European Commission is expected later this year. Byetta is already approved in the U.S. for this indication.

We submitted data to the FDA for consideration of a new treatment-resistant depression (TRD) indication for Symbyax[®], available as a range of fixed combinations of Zyprexa and Prozac, as well as for Zyprexa used in combination with Prozac. Symbyax is already approved in the U.S. for the treatment of bipolar depression.

During the second quarter of 2006, Gemzar was approved in the U.S. for the treatment of recurrent ovarian cancer in combination with carboplatin.

During the second quarter of 2006, we submitted a supplemental NDA to the FDA for Cymbalta[®] for the treatment of generalized anxiety disorder. We are also conducting Phase III studies on Cymbalta for the treatment of fibromyalgia, a chronic, often debilitating pain disorder.

During the second quarter of 2006, we initiated a Phase III clinical trial to study enzastaurin as a maintenance therapy to prevent relapse in patients with diffuse large B-cell lymphoma. We initiated a Phase III clinical trial of enzastaurin, a targeted oral agent, during the first quarter of 2006, for the treatment of relapsed glioblastoma multiforme, an aggressive and malignant form of brain cancer.

III. Legal, Regulatory, and Other Matters

Certain generic manufacturers have challenged our U.S. compound patent for Zyprexa and are seeking permission to market generic versions of Zyprexa prior to its patent expiration in 2011. On April 14, 2005, the U.S. District Court in Indianapolis ruled in our favor on all counts, upholding our patents. The decision has been appealed.

We have reached agreements with claimants' attorneys involved in certain U.S. Zyprexa product liability litigation to settle a large number of claims against us relating to the medication. A large number of claims remain. As a result of our product liability exposures, the substantial majority of which were related to Zyprexa, we recorded a net pretax charge of \$1.07 billion in the second quarter of 2005.

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

As previously disclosed, we have been considering the future of three European facilities, which include the R&D facilities in Mont St. Guibert, Belgium, and Hamburg, Germany, and the dry products manufacturing facility in Basingstoke, England. On October 16, 2006, the Board of Directors approved a plan to close the Hamburg, Germany, facility by June 30, 2007. No final decisions have been made with respect to the Basingstoke and Mont St. Guibert sites. However, severance and impairment charges as a result of any potential sale or site closure could be significant. 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. In 2006, we are experiencing a one-time sales benefit as a result of MMA; however, in the long term there is additional risk of increased pricing pressures. While the MMA prohibits the Secretary of Health and Human Services (HHS) from directly negotiating prescription drug prices with manufacturers, we expect continued challenges to that prohibition over the next several years. Also, the MMA retains the authority of the Secretary of HHS to prohibit the importation of prescription drugs, but we expect Congress to consider several measures that could remove that authority and allow for the importation of products into the U.S. regardless of their safety or cost. If adopted, such legislation would likely have a negative effect on our U.S. sales. Recently, language allowing for personal importation of a 90-day supply of medication from Canada only was passed into law via the Homeland Security Appropriations bill. This language only allows for medication to be carried in person from Canada to the U.S. and does not authorize mail or Internet importation. Further, the language disallows certain medications including injectibles. We believe there is some chance that the new and expanded prescription drug coverage for seniors under the MMA will alleviate the perceived need for a federal importation scheme. Additionally, notwithstanding the federal law that continues to prohibit all but the very narrow drug importation detailed above, approximately a dozen states have implemented importation schemes for their citizens, usually involving a website that links patients to selected Canadian pharmacies. One state has such a program for its state employees.

As a result of the passage of the MMA, aged and disabled patients jointly eligible for Medicare and Medicaid began receiving their prescription drug benefits through the Medicare program, instead of Medicaid, on January 1, 2006. This may relieve some state budget pressures but is unlikely to result in reduced pricing pressures at the state level. A majority of states have implemented supplemental rebates and restricted formularies in their Medicaid programs, and these programs are expected to continue in the post-MMA environment. Moreover, under the 2005 federal Deficit Reduction Act, states will have greater flexibility to impose new cost-sharing requirements on Medicaid beneficiaries for non-preferred prescription drugs that will result in certain beneficiaries bearing more of the cost. Several states also are attempting to extend discounted Medicaid prices to non-Medicaid patients. As a result, we expect pressures on pharmaceutical pricing to continue.

As it relates to the new Medicare program, we announced in the second quarter of 2006 that we temporarily extended our U.S. patient assistance program, LillyAnswers. The temporary extension of LillyAnswers allows patients who are not enrolled in Medicare Part D access to the LillyAnswers program until December 31, 2006. We also temporarily extended LillyAnswers for patients who have enrolled in a Medicare Part D plan and need assistance for Zyprexa and Forteo. We have received a favorable opinion from the U.S. Department of Health and Human Services Office of the Inspector General (OIG) for our proposal for an Outside Part D patient assistance program (i.e., the LillyMedicareAnswers program) which will provide assistance for Zyprexa, Forteo, and Humatrope® beyond the end of this year to eligible patients enrolled in a Medicare Part D plan. We currently anticipate that the specific

LillyAnswers program extension involving Zyprexa, Forteo, and Humatrope for patients enrolled in a Medicare Part D plan will continue to be available until December 31, 2006. In order to participate in either the temporary extension as described above or the new LillyMedicareAnswers program, certain eligibility and certification requirements must be met.

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

Sales growth for the third quarter and first nine months of 2006 was 7 percent and 6 percent, respectively. The primary drivers for growth in the third quarter of 2006 were Cymbalta, Byetta, Forteo, Alimta® and Zyprexa. Sales in the U.S. increased by \$178.3 million, or 9 percent for the third quarter of 2006, and \$527.3 million, or 9 percent for the first nine months of 2006, compared with the same periods of 2005. The U.S. growth comparison for the nine-month period also benefited from an estimated \$170 million of wholesaler destocking in the first nine months of 2005 as a result of restructuring our arrangements with our U.S. wholesalers in the first quarter of 2005. We experienced a one-time sales benefit resulting from a shift of certain low-income patients from Medicaid to Medicare and increased access to medical coverage by certain patients previously covered under our LillyAnswers program following the implementation of MMA in 2006. This contributed part of the increases in U.S. net effective sales prices of 11 percent and 9 percent for the third quarter and first nine months of 2006, respectively. Sales outside the U.S. increased \$84.7 million, or 5 percent, and \$152.2 million, or 3 percent, for the third quarter and first nine months of 2006, respectively. Worldwide sales volume and exchange rates both increased by 1 percent and selling prices increased by 5 percent in the third quarter of 2006. For the first nine months of 2006, worldwide sales volume and selling prices increased 4 percent and 3 percent, respectively, while exchange rates decreased 1 percent. The following tables summarize our net sales activity for the three- and nine-month periods ended September 30, 2006 and 2005:

Product	Three Months Ended September 30, 2006			Three Months Ended September 30, 2005	Percent Change From 2005
	U.S. ¹	Outside U.S.	Total	Total	
	(Dollars in millions)				
Zyprexa	\$ 519.0	\$ 565.7	\$1,084.7	\$ 1,035.1	5
Gemzar	153.0	201.6	354.6	334.3	6
Cymbalta	306.5	42.1	348.6	182.8	91
Humalog	199.0	123.2	322.2	306.2	5
Evista	162.8	95.1	257.9	260.3	(1)
Humulin	96.7	133.3	230.0	250.9	(8)
Animal health products	98.0	118.2	216.2	215.7	0
Alimta	89.9	67.3	157.2	122.3	29
Forteo	104.2	44.9	149.1	102.6	45
Strattera®	112.3	14.1	126.4	140.9	(10)
Humatrope	49.3	52.3	101.6	100.2	1
Fluoxetine products	37.8	40.5	78.3	112.4	(30)
Actos®	34.7	42.3	77.0	64.3	20
ReoPro®	26.6	40.3	66.9	70.9	(6)
Byetta	62.1		62.1	10.6	NM
Anti-infectives	1.0	57.5	58.5	104.7	(44)
Cialis ²	1.4	54.2	55.6	40.9	36
Xigris	22.7	19.4	42.1	45.5	(7)
Other pharmaceutical products	29.6	45.5	75.1	100.5	(25)
Total net sales	\$2,106.6	\$1,757.5	\$3,864.1	\$ 3,601.1	

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

Product	Nine Months Ended September 30, 2006			Nine Months Ended September 30, 2005	Percent Change From 2005
	U.S. ¹	Outside U.S.	Total	Total	
	(Dollars in millions)				
Zyprexa	\$1,555.8	\$1,651.3	\$ 3,207.1	\$ 3,170.1	1
Gemzar	452.7	584.2	1,036.9	981.9	6
Humalog	584.2	363.1	947.3	888.6	7
Cymbalta	782.3	110.0	892.3	450.9	98
Evista	486.9	288.1	775.0	770.8	1
Humulin	264.8	403.5	668.3	757.5	(12)
Animal health products	274.7	340.8	615.5	612.3	1
Alimta	255.5	184.9	440.4	327.4	35
Strattera	373.5	49.2	422.7	384.1	10
Forteo	292.4	129.8	422.2	271.3	56
Actos	237.0	121.7	358.7	338.0	6
Humatrope	149.6	156.6	306.2	313.6	(2)
Fluoxetine products	113.4	122.3	235.7	339.1	(30)
Anti-infectives	25.3	190.7	216.0	326.7	(34)
ReoPro	84.5	128.9	213.4	225.4	(5)
Cialis ²	4.6	158.5	163.1	124.9	31
Byetta	150.0		150.0	14.0	NM
Xigris	75.7	65.1	140.8	162.8	(14)
Other pharmaceutical products	76.7	157.4	234.1	306.8	(24)
Total net sales	\$6,239.6	\$5,206.1	\$11,445.7	\$ 10,766.2	

NM Not meaningful

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

² Cialis had worldwide third-quarter and nine-month sales of \$245.6 million and \$701.8 million, respectively, representing increases of 26 percent and 31 percent,

respectively,
compared with
the same
periods of 2005.
The sales shown
in the tables
above represent
results in the
territories in
which we
market Cialis
exclusively. The
remaining sales
relate to the
joint-venture
territories of
Lilly ICOS LLC
(North America,
excluding
Puerto Rico, and
Europe). Our
share of the
joint-venture
territory sales,
net of expenses,
is reported in
other income
net in our
consolidated
condensed
statements of
income.

Product Highlights

Zyprexa sales in the U.S. increased 3 percent in the third quarter and decreased 1 percent in first nine months of 2006, respectively, compared with the same periods of 2005. The increase resulted from an increase in prices, partially offset by lower demand. However, U.S. prescription volume has held steady during the first nine months of 2006. The increase in net effective selling prices was partially due to the transition of certain low-income patients from Medicaid to Medicare. Sales outside the U.S. increased 6 percent in the third quarter of 2006, driven by increased demand as well as the favorable impact of exchange rates, offset partially by lower prices. International sales for the first nine months of 2006 increased 3 percent, which was due to increased demand.

Diabetes care products, composed primarily of Humalog, Humulin, Actos, and Byetta, had worldwide net sales of \$712.4 million and \$2.18 billion in the third quarter and first nine months of 2006, respectively, representing increases of 9 percent and 6 percent compared with the same periods last year. Diabetes care revenues in the U.S. increased 14 percent and 10 percent, to \$408.6 million and \$1.28 billion for the third quarter and first nine months of 2006, respectively. These increases were primarily driven by sales of Byetta for both periods. Diabetes care revenues outside the U.S. increased 3 percent and 1 percent, to \$303.8 million and \$900.8 million in the third quarter and first nine months of 2006, respectively. Results from our primary diabetes care products are as follows:

Humalog sales in the U.S. increased 3 percent and 6 percent during the third quarter and first nine months of 2006, respectively, due to higher prices, which were partially offset by a decline in demand. Humalog sales outside the U.S. increased 10 percent during the third quarter primarily due to increased demand, as well as a favorable impact of exchange rates, offset partially by lower prices. Humalog sales outside the U.S. increased 8 percent for the first nine months of 2006, primarily due to increased demand, offset by the unfavorable impact of exchange rates.

Humulin sales decreased 10 percent and 16 percent in the U.S. for the third quarter and first nine months of 2006, respectively, driven primarily by the decline in demand due to continued competitive pressures, offset partially by higher prices. Humulin sales outside the U.S. decreased 7 and 9 percent during the third quarter and first nine months of 2006, respectively, due to a decline in demand.

Actos revenues in the U.S., the majority of which represent service revenues from a copromotion agreement in the U.S. with Takeda Pharmaceuticals North America (Takeda), increased 17 percent and decreased 1 percent in the third quarter and first nine months of 2006, respectively. Actos is manufactured by Takeda Chemical Industries, Ltd., and sold in the U.S. by Takeda. As previously disclosed, since our share of revenue from the agreement with Takeda will not necessarily track with product sales, it is difficult to make quarterly comparisons for Actos revenue. Our U.S. marketing rights with respect to Actos expired in September 2006; however, we will continue receiving royalties from Takeda at a declining rate through September 2009. The arrangement outside the U.S. continues.

Sales of Byetta, a first-in-class treatment for type 2 diabetes we market with Amylin Pharmaceuticals (Amylin), launched in the U.S. in June 2005, were \$126.4 million and \$293.2 million during the third quarter and first nine months of 2006, respectively. We report as revenue our 50 percent share of Byetta's gross margins and our sales of Byetta pen delivery devices to Amylin.

Gemzar sales increased 2 percent and 5 percent in the U.S. for the third quarter and first nine months of 2006, respectively, as compared to the same periods in 2005. This increase is attributable to higher prices in both periods, offset partially by lower demand in the third quarter due to competitive pressures. Gemzar sales outside the U.S. increased 9 percent and 6 percent for the third quarter and first nine months of 2006, respectively, which was due to increased demand, offset partially by lower prices. The third quarter also benefited from the favorable impact of exchange rates.

U.S. sales of Cymbalta, a treatment of major depressive disorder and diabetic peripheral neuropathic pain, increased 80 percent and 85 percent for the third quarter and first nine months of 2006, respectively, as compared to the same periods last year, due to strong demand. Cymbalta sales outside the U.S. continue to reflect significant growth due to recent international launches.

Evista sales in the U.S. increased 1 percent for both the third quarter and first nine months of 2006, as compared to the same periods in 2005, due to higher prices, offset by a decline in demand. Evista sales outside the U.S. decreased 4 percent and remained flat in the third quarter and nine month periods of 2006, due primarily to lower prices in both periods, offset by an increase in demand during the first nine months of 2006.

Alimta, a treatment of malignant pleural mesothelioma and second-line treatment of non-small-cell lung cancer, generated an increase in U.S. sales of 17 percent and 22 percent for the third quarter and first nine months of 2006, respectively, as compared to the same periods in 2005. Alimta sales outside the U.S. increased 48 percent and

57 percent during the third quarter and first nine months of 2006, respectively. These increases are attributable to growth in U.S. and international demand.

Forteo, a treatment for severe osteoporosis, increased 48 and 59 percent in the U.S. in the third quarter and first nine months of 2006, respectively, as compared to the same periods in 2005. In addition to increased demand, U.S. sales significantly benefited from access to medical coverage through the Medicare Part D program and from decreased utilization of our U.S. patient assistance program, LillyAnswers. Sales outside the U.S. increased 39 percent and 48 percent for the third quarter and first nine months of 2006, respectively, which was driven by increased demand along with a favorable impact in exchange rates during the third quarter, offset by a decrease in prices.

U.S. sales of Strattera, a treatment of attention-deficit hyperactivity disorder (ADHD) in children, adolescents, and adults, decreased 10 percent during the third quarter and increased 7 percent for the first nine months of 2006, compared with the same periods in 2005. The decline in sales in the third quarter was attributable to a decline in demand, offset by an increase in prices. The increase for the first nine months of 2006 was the result of higher prices as well as the reductions in the U.S. wholesaler inventory levels in 2005, offset by decline in demand.

Total worldwide product sales of Cialis in the third quarter and first nine months of 2006 were composed of \$55.0 million and \$161.2 million of sales in our territories, respectively, which are reported in our net sales, and \$190.6 million and \$540.5 million of sales in the joint-venture territories. Within the joint-venture territories, the U.S. sales of Cialis were \$94.9 million and \$271.3 million in the third quarter and first nine months of 2006, respectively, representing increases of 23 percent and 42 percent from the same periods of 2005. Cialis sales in our territories are reported in revenue, while our 50 percent share of the joint-venture net income is reported in other income net. Cialis sales growth reflects both gains in market share and growth of the erectile dysfunction market during the third quarter and first nine months of 2006.

Gross Margin, Costs, and Expenses

For the third quarter of 2006, gross margins improved 1.2 percentage points, to 77.7 percent of net sales, compared with the third quarter of 2005. For the first nine months of 2006, gross margins increased 1.8 percentage points, to 77.9 percent of net sales, compared with the first nine months of 2005. The increase for the quarter was primarily due to increased product prices and increased production volume, partially offset by higher manufacturing expenses. This increase for the nine-month period was primarily due to favorable product prices and the favorable impact of foreign exchange rates, partially offset by higher manufacturing expenses.

Operating expenses (the aggregate of research and development and marketing and administrative expenses) increased 7 percent and 6 percent for the third quarter and first nine months of 2006, respectively, compared with the same periods of 2005. Investment in research and development increased 1 percent, to \$755.7 million, and 3 percent, to \$2.27 billion, for the third quarter and first nine months of 2006, respectively, and represent 20 percent of sales in both periods. Marketing and administrative expenses increased 12 percent, to \$1.20 billion, and 8 percent, to \$3.58 billion, for the third quarter and first nine months of 2006, respectively, driven largely by increased marketing expenses in support of key products, primarily Cymbalta.

Other income net consists of interest expense, interest income, the after-tax operating results of the Lilly ICOS joint venture, and all other income and expense items.

Interest expense for the third quarter and nine-month period in 2006 increased \$38.4 million, to \$62.7 million, and \$132.6 million to \$193.5 million, respectively, as compared to the same periods in 2005. These increases are a result of higher interest rates and less capitalized interest due to the completion in late 2005 of certain manufacturing facilities.

Interest income increased \$15.6 million, to \$67.5 million and \$51.4 million to \$195.6 million for the third quarter and first nine months of 2006, respectively, as compared to the same periods in 2005, due to higher short-term interest rates.

The Lilly ICOS joint-venture income was \$23.8 million in the third quarter of 2006, compared with \$5.8 million in the third quarter of 2005. For the first nine months of 2006, income was \$66.1 million, compared with a loss of \$7.3 million in the first nine months of 2005. The increase in both periods was due to increased Cialis sales and decreased selling and marketing expenses.

Net other income and expense items decreased \$24.2 million to \$27.4 million for third-quarter 2006 and decreased \$86.1 million to \$66.9 million for the first nine months of 2006, as compared to the same periods in 2005. The decreases are largely a result of less income from business development transactions.

We incurred tax expense of \$232.2 million and \$672.6 million, for the third quarter and first nine months of 2006, respectively, representing an effective tax rate of 21 percent in both periods. Tax expense for the third quarter of 2005 was \$224.1 million, representing an effective tax rate of 22 percent. Year-to-date comparisons to prior year are not

meaningful due to the net loss before income taxes experienced in the second quarter of 2005.

FINANCIAL CONDITION

As of September 30, 2006, cash, cash equivalents, and short-term investments totaled \$3.62 billion compared with \$5.04 billion at December 31, 2005. Cash flow from operations of \$2.12 billion was more than offset by net repayments of long-term debt of \$1.60 billion, dividends paid of \$1.30 billion and net capital expenditures of \$667.8 million. Total debt at September 30, 2006, was \$4.89 billion, a decrease of \$1.61 billion as compared to December 31, 2005. We currently expect to repay additional debt of approximately \$500 million by the end of 2006. We also intend to incur approximately \$2.4 billion of debt to finance the ICOS acquisition at the time the transaction is completed.

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, dividends, and taxes for the remainder of 2006. We believe that amounts available through our existing commercial paper program should be adequate to fund maturities of short-term borrowings, if necessary. Various risks and uncertainties, including those discussed in the Financial Expectations for 2006 section, may affect our operating results and cash generated from operations.

LEGAL AND REGULATORY MATTERS

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. We are now awaiting a decision by the Court of Appeals for the Federal Circuit, which on April 6, 2006, heard Reddy's and Teva's respective appeals of this ruling. We are confident Reddy'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 on appeal. 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 (expiring in 2012-2014) are valid, enforceable, and being infringed by Teva. No trial date has been set in either case. We believe 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), a subsidiary of Teva, submitted ANDAs in November 2005 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. In February 2006, we filed a lawsuit against Sicor in the U.S. District Court for the Southern District of Indiana, seeking a ruling that these patents are valid and are being infringed by Sicor. In response to our lawsuit, Sicor filed a declaratory judgment action in the U.S. District Court for the Central District of California. The California action has since been dismissed. In September 2006, we received notice that Mayne Pharma (USA) Inc. (Mayne) filed a similar ANDA for Gemzar. In October 2006, we filed a lawsuit against Mayne in the Southern District of Indiana in response to the ANDA filing. We are awaiting the filing of an answer to our complaint against Mayne. In October 2006, we received notice that Sun Pharmaceutical Industries Inc. (Sun) filed a similar ANDA for Gemzar. We are evaluating our option to bring legal action against Sun. 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 such 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.

In March 2004, the office of the U.S. Attorney for the Eastern District of Pennsylvania advised us that it has commenced a civil investigation related to our U.S. marketing and promotional practices, including our communications with physicians and remuneration of physician consultants and advisors, with respect to Zyprexa, Prozac, and Prozac Weekly. 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. We are cooperating with the U.S. Attorney in these investigations, including providing a broad range of documents and information relating to the investigations. 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. 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.

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). The MDL includes three lawsuits requesting certification of class actions on behalf of those who allegedly suffered injuries from the administration of Zyprexa. We have entered into agreements with various plaintiffs' counsel halting the running of the statutes of limitation (tolling agreements) with respect to a number of claimants who do not have lawsuits on file.

Since June 2005, we have entered into agreements with various claimants' attorneys involved in U.S. Zyprexa product liability litigation to settle approximately 10,500 claims, including a large number of previously filed lawsuits (including the three purported class actions mentioned above), tolled claims, and other informally asserted claims. The settlements are being overseen and distributed by court-approved claims administrators.

The U.S. Zyprexa product liability claims not subject to these agreements include approximately 1,500 lawsuits in the U.S. covering approximately 9,700 claimants, and approximately 850 tolled claims. The first trials are scheduled for April 2007 in the Federal District Court for the Eastern District of New York. 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. Finally, 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 certain residents of Quebec. The allegations in the Canadian actions are similar to those in the litigation pending in the United States. We are prepared to continue our vigorous defense of Zyprexa in all remaining cases.

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. In 2006, we were served with similar lawsuits filed by the states of Alaska, West Virginia, Mississippi, and New Mexico in the courts of the respective states.

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, that 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. Four additional lawsuits were filed in 2006: two in the Eastern District of New York, one in the Southern District of Indiana, and one in Indiana state court, all 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 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 carriers and in arbitration in Bermuda against other carriers. While we believe our position is meritorious, 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.

With respect to the product liability claims currently asserted against us, we have accrued for our estimated exposures to the extent they are both probable and estimable based on the information available to us. In addition, we have accrued for certain product liability claims incurred but not filed to the extent we can formulate a reasonable estimate of their costs. We estimate these expenses based primarily on historical claims experience and data regarding product usage. Legal defense costs expected to be incurred in

connection with significant product liability loss contingencies are accrued when probable and reasonably estimable. A portion of the costs associated with defending and disposing of these suits is covered by insurance. We record receivables for insurance-related recoveries when it is probable they will be realized. These receivables are classified as a reduction of the litigation charges on the statement of income. We estimate insurance recoverables based on existing deductibles, coverage limits, our assessment of any defenses to coverage that might be raised by the carriers, and the existing and projected future level of insolvencies among the insurance carriers.

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

The cost of the Zyprexa settlements described above; and,

Reserves for product liability exposures and defense costs regarding currently known and expected claims to the extent we can formulate a reasonable estimate of the probable number and cost of the claims. A substantial majority of these exposures and costs relate to current and expected Zyprexa claims not included in the settlements. We have estimated these charges based primarily on historical claims experience, data regarding product usage, and our historical product liability defense cost experience.

During 2005, \$700.0 million was paid in connection with Zyprexa settlements, while the cash related to other reserves for product liability exposures and defense costs is expected to be paid out over the next several years, including 2006. The timing of our insurance recoveries is uncertain.

We cannot predict with certainty the additional number of lawsuits and claims that may be asserted. In addition, although we believe it is probable, there can be no assurance that the Zyprexa settlements described above will be concluded. 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 claims for other products in the future. We have experienced difficulties in obtaining product liability insurance due to a very restrictive insurance market, and therefore will be largely self-insured for future product liability losses. In addition, as noted above, there is no assurance that we will be able to fully collect from our insurance carriers on past claims.

In June 2002, we were sued by 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 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. We believe that these allegations are without legal merit and that we will ultimately prevail on these issues. In June 2005, the United States Patent and Trademark Office commenced a re-examination of the patent in order to consider certain issues raised by us relating to the validity of the patent. A jury trial commenced in Boston on April 10, 2006 on the patent validity and infringement issues. On May 4, 2006, the jury 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. We will seek to have the jury verdict overturned by the trial court judge, and if unsuccessful, will appeal the decision to the Court of Appeals for the Federal Circuit. 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. No decision has been rendered.

Also, 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 2006

For the full year of 2006, we expect earnings per share to be in the range of \$3.07 to \$3.18. This guidance reflects the closure of the Hamburg, Germany research and development facility previously discussed, which will result in a fourth-quarter charge to asset impairment, restructuring and other special charges of \$40 million to \$50 million (pretax), or \$.02 to \$.03 per share (after tax). It does not, however, reflect any other future material unusual items, such as the impact of the ICOS acquisition, including the IPR&D charge, if the transaction closes in 2006. Nor does it include any charges that may occur if further decisions are reached related to our other two European sites.

We expect full-year 2006 sales to grow at approximately the low end of 7 percent to 9 percent growth range. In addition, we expect gross margins as a percent of sales to improve, operating expenses to grow in the mid-single digits in the aggregate, and other income net, to contribute approximately \$175 million to \$250 million. Excluding the tax associated with the potential charges discussed above, we also anticipate the effective tax rate to be approximately 21 percent. In terms of cash flow, we expect capital expenditures to be at approximately \$1.2 billion in 2006.

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, restructurings, and acquisitions of compounds under development resulting in acquired in-process research and development charges; foreign exchange rates; wholesaler inventory changes; the outcome of the Zyprexa patent appeal; other regulatory developments, government investigations, patent disputes, and litigation; and the impact of governmental actions regarding pricing, importation, and reimbursement for pharmaceuticals. Other factors that may affect our operations and prospects are discussed in Item 1A of our 2005 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 September 30, 2006, and concluded that they are effective.

(b) *Changes in Internal Controls.* During the third quarter of 2006, 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 U.S. patent litigation involving Zyprexa, Evista, and Gemzar

The civil investigation by the U.S. Attorney for the Eastern District of Pennsylvania 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 2005 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 70 suits involving approximately 120 claimants. In the thimerosal litigation, we have been named as a defendant in approximately 360 suits with approximately 975 claimants.

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 quarter ended September 30, 2006:

Period	Total Number of Shares Purchased (a) (in thousands)	Average Price Paid per Share (b)	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs (c)	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs (d)
				(Dollars in millions)
July 2006	4	\$ 55.66		\$ 419.2
August 2006	16	53.75		419.2
September 2006	24	55.86		419.2
Total	44			

The amounts presented in columns (a) and (b) above represent purchases of common stock related to employee stock option exercises. The amounts presented in columns (c) and (d) in the above table represent activity related to our \$3.0 billion share repurchase program announced in March 2000. As of September 30, 2006, we have purchased \$2.58 billion related to this program. During the third quarter of 2006, no shares were repurchased pursuant to this program and we do not expect to purchase any shares under this program during the remainder of 2006.

Item 6. Exhibits and Reports on Form 8-K

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

(a) Exhibits. The following documents are filed as exhibits to this Report:

EXHIBIT The Eli Lilly and Company Bonus Plan, as amended
10.1

EXHIBIT 2007 Change In Control Severance Pay Plan for Select Employees, as amended
10.2

EXHIBIT Agreement and Plan of Merger by and among Eli Lilly and Company, Tour Merger Sub, Inc., and
10.3 ICOS Corporation, which is incorporated by reference from Exhibit 2.1 to the Form 8-K filed by
 ICOS Corporation on October 17, 2006

EXHIBIT 11. Statement re: Computation of Earnings (Loss) per Share

EXHIBIT 12. Statement re: Computation of Ratio of Earnings From Continuing Operations to Fixed Charges

EXHIBIT 31.1 Rule 13a-14(a) Certification of Sidney Taurel, Chairman of the Board and Chief Executive Officer

EXHIBIT 31.2 Rule 13a-14(a) Certification of Derica W. Rice, Senior Vice President and Chief Financial Officer

EXHIBIT 32. Section 1350 Certification

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned thereunto duly authorized.

ELI LILLY AND COMPANY
(Registrant)

Date November 1, 2006

/s/James B. Lootens

James B. Lootens
Secretary and Deputy General
Counsel

Date November 1, 2006

/s/Arnold C. Hanish

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

INDEX TO EXHIBITS

The following documents are filed as a part of this Report:

Exhibit

- | | |
|-----------------|---|
| EXHIBIT
10.1 | The Eli Lilly and Company Bonus Plan, as amended |
| EXHIBIT
10.2 | 2007 Change In Control Severance Pay Plan for Select Employees, as amended |
| EXHIBIT
10.3 | Agreement and Plan of Merger by and among Eli Lilly and Company, Tour Merger Sub, Inc., and ICOS Corporation, which is incorporated by reference from Exhibit 2.1 to the Form 8-K filed by ICOS Corporation on October 17, 2006 |
| EXHIBIT 11. | Statement re: Computation of Earnings (Loss) per Share |
| EXHIBIT 12. | Statement re: Computation of Ratio of Earnings From Continuing Operations 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 |