
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

**Quarterly Report Under Section 13 or 15(d) of the
Securities Exchange Act of 1934**

FOR THE QUARTER ENDED JUNE 30, 2005

COMMISSION FILE NUMBER 001-6351

ELI LILLY AND COMPANY

(Exact name of Registrant as specified in its charter)

INDIANA
(State or other jurisdiction of
incorporation or organization)

35-0470950
(I.R.S. Employer
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 an accelerated filer as defined in Exchange Act Rule 12b-2.

Yes No

The number of shares of common stock outstanding as of July 20, 2005:

<u>Class</u>	<u>Number of Shares Outstanding</u>
Common	1,133,814,071

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(Unaudited)**

ELI LILLY AND COMPANY AND SUBSIDIARIES

	Three Months Ended June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
	(Dollars in millions, except per share data)			
Net sales	\$3,667.7	\$3,556.3	\$7,165.1	\$6,933.2
Cost of sales	871.3	796.4	1,730.3	1,548.1
Research and development	762.4	684.2	1,464.6	1,330.8
Marketing and administrative	1,146.1	1,170.2	2,236.5	2,234.1
Acquired in-process research and development	—	—	—	362.3
Asset impairments, restructuring, and other special charges	1,073.4	108.9	1,073.4	108.9
Interest expense	12.0	7.5	36.6	16.8
Other income – net	(57.4)	(49.1)	(180.6)	(121.5)
	<u>3,807.8</u>	<u>2,718.1</u>	<u>6,360.8</u>	<u>5,479.5</u>
Income (loss) before income taxes	(140.1)	838.2	804.3	1,453.7
Income taxes	111.9	181.3	319.7	396.4
Net income (loss)	<u>\$ (252.0)</u>	<u>\$ 656.9</u>	<u>\$ 484.6</u>	<u>\$1,057.3</u>
Earnings (loss) per share — basic	<u>\$ (.23)</u>	<u>\$.61</u>	<u>\$.45</u>	<u>\$.98</u>
Earnings (loss) per share — diluted	<u>\$ (.23)</u>	<u>\$.60</u>	<u>\$.44</u>	<u>\$.97</u>
Dividends paid per share	<u>\$.38</u>	<u>\$.355</u>	<u>\$.76</u>	<u>\$.71</u>

See Notes to Consolidated Condensed Financial Statements.

CONSOLIDATED CONDENSED BALANCE SHEETS

ELI LILLY AND COMPANY AND SUBSIDIARIES

	June 30, 2005	December 31, 2004
	(Dollars in millions)	
	(Unaudited)	
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 4,642.4	\$ 5,365.3
Short-term investments	760.1	2,099.1
Accounts receivable, net of allowances of \$63.8 (2005) and \$66.1 (2004)	2,085.7	2,058.7
Other receivables	373.8	494.3
Inventories	1,988.8	2,291.6
Deferred income taxes	392.4	255.3
Prepaid expenses	710.6	271.5
TOTAL CURRENT ASSETS	10,953.8	12,835.8
OTHER ASSETS		
Prepaid pension	2,188.2	2,253.8
Investments	502.1	561.4
Sundry	2,037.6	1,665.1
	4,727.9	4,480.3
PROPERTY AND EQUIPMENT		
Land, buildings, equipment, and construction-in-progress	12,730.7	12,338.9
Less allowances for depreciation	(4,992.8)	(4,788.0)
	7,737.9	7,550.9
	\$23,419.6	\$24,867.0
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Short-term borrowings	\$ 230.6	\$ 2,020.6
Accounts payable	608.5	648.6
Employee compensation	454.0	471.6
Dividends payable	420.5	414.4
Income taxes payable	1,844.1	1,703.9
Other current liabilities	2,904.7	2,334.6
TOTAL CURRENT LIABILITIES	6,462.4	7,593.7
LONG-TERM DEBT	4,445.5	4,491.9
DEFERRED INCOME TAXES	480.8	620.4
OTHER NONCURRENT LIABILITIES	1,762.3	1,241.1
SHAREHOLDERS' EQUITY		
Common stock	709.2	708.0
Additional paid-in capital	3,324.0	3,119.4
Retained earnings	9,381.9	9,724.6
Employee benefit trust	(2,635.0)	(2,635.0)
Deferred costs-ESOP	(109.3)	(111.9)
Accumulated other comprehensive income (loss)	(298.4)	218.6
	10,372.4	11,023.7
Less cost of common stock in treasury	103.8	103.8
	10,268.6	10,919.9
	\$23,419.6	\$24,867.0

See Notes to Consolidated Condensed Financial Statements.

CONSOLIDATED CONDENSED STATEMENTS OF CASH FLOWS
(Unaudited)

ELI LILLY AND COMPANY AND SUBSIDIARIES

	Six Months Ended June 30,	
	2005	2004
	(Dollars in millions)	
CASH FLOWS FROM OPERATING ACTIVITIES		
Net income	\$ 484.6	\$ 1,057.3
Adjustments to reconcile net income to cash flows from operating activities:		
Changes in operating assets and liabilities	(369.0)	(599.6)
Depreciation and amortization	317.4	297.6
Stock-based compensation expense	208.2	50.4
Change in deferred taxes	(175.9)	136.1
Acquired in-process research and development	—	362.3
Asset impairments, restructuring, and other special charges, net of tax	979.7	81.7
Other, net	33.9	135.4
NET CASH PROVIDED BY OPERATING ACTIVITIES	1,478.9	1,521.2
CASH FLOWS FROM INVESTING ACTIVITIES		
Net purchases of property and equipment	(619.9)	(971.7)
Net change in short-term investments	1,337.8	(47.0)
Purchase of noncurrent investments	(218.1)	(2,106.5)
Proceeds from sales and maturities of noncurrent investments	270.8	1,737.4
Cash paid for acquisition of Applied Molecular Evolution, net of cash acquired	—	(71.7)
Other, net	(145.1)	(60.5)
NET CASH PROVIDED BY (USED IN) INVESTING ACTIVITIES	625.5	(1,520.0)
CASH FLOWS FROM FINANCING ACTIVITIES		
Dividends paid	(821.2)	(769.2)
Issuances of common stock under stock plans	34.9	75.8
Net change in short-term borrowings	(1,885.9)	324.1
Other, net	7.9	(4.7)
NET CASH USED IN FINANCING ACTIVITIES	(2,664.3)	(374.0)
Effect of exchange rate changes on cash and cash equivalents	(163.0)	13.2
NET DECREASE IN CASH AND CASH EQUIVALENTS	(722.9)	(359.6)
Cash and cash equivalents at January 1	5,365.3	2,756.3
CASH AND CASH EQUIVALENTS AT JUNE 30	\$ 4,642.4	\$ 2,396.7

See Notes to Consolidated Condensed Financial Statements.

CONSOLIDATED CONDENSED STATEMENTS OF COMPREHENSIVE INCOME
(Unaudited)

ELI LILLY AND COMPANY AND SUBSIDIARIES

	Three Months Ended June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
	(Dollars in millions)			
Net income (loss)	\$(252.0)	\$656.9	\$ 484.6	\$1,057.3
Other comprehensive income (loss) ¹	(345.9)	8.2	(517.0)	(16.6)
Comprehensive income (loss)	\$(597.9)	\$665.1	\$ (32.4)	\$1,040.7

¹ The significant components of other comprehensive income (loss) were losses of \$247.9 million and \$386.4 million from foreign currency translation adjustments for the three months and six months ended June 30, 2005, respectively, and losses of \$104.7 million and \$114.3 million from cash flow hedges for the three months and six months ended June 30, 2005, respectively.

See Notes to Consolidated Condensed Financial Statements.

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SEGMENT INFORMATION

We operate in one significant business segment – pharmaceutical products. Operations of our animal health business segment are not material and share many of the same economic and operating characteristics as our pharmaceutical products. Therefore, they are included with pharmaceutical products for purposes of segment reporting. Our business segments are distinguished by the ultimate end user of the product: humans or animals. Performance is evaluated based on profit or loss from operations before income taxes. Income before income taxes for the animal health business for the second quarter of 2005 and 2004 was \$47.3 million and \$35.0 million, respectively, and \$87.3 million and \$88.5 million for the six months ended June 30, 2005 and 2004, respectively.

SALES BY PRODUCT CATEGORY

Worldwide sales by product category for the three months and six months ended June 30, 2005 and 2004 were as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
Net sales – to unaffiliated customers	(Dollars in millions)			
Neurosciences	\$1,547.4	\$1,593.1	\$2,975.2	\$3,091.2
Endocrinology	1,141.8	1,119.0	2,286.5	2,176.3
Oncology	454.4	313.2	855.3	607.2
Animal health	201.0	179.6	396.5	362.0
Cardiovascular	155.7	179.8	323.8	345.6
Anti-infectives	112.8	118.6	222.0	243.7
Other pharmaceuticals	54.6	53.0	105.8	107.2
Net sales	\$3,667.7	\$3,556.3	\$7,165.1	\$6,933.2

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, 2004.

CONTINGENCIES

Three generic pharmaceutical manufacturers, Zenith Goldline Pharmaceuticals, Inc. (Zenith), Dr. Reddy's Laboratories, Ltd. (Reddy), and Teva Pharmaceuticals (Teva), have submitted abbreviated new drug applications (ANDAs) seeking permission to market generic versions of Zyprexa® in various dosage forms several years prior to the expiration of our U.S. patents for the product. The generic companies alleged that our patents are invalid, unenforceable, or not infringed. We filed suit against the three companies in the U.S. District Court for the Southern District of Indiana, seeking a ruling that the challenges to our compound patent (expiring in 2011) are without merit. The cases have been consolidated. A trial before the district court judge was held in January and February of 2004. On April 14, 2005, the district court upheld our 2011 U.S. patent on Zyprexa. In the case of *Eli Lilly and Company v. Zenith Goldline Pharmaceuticals et al.*, the court ruled in our favor on all counts, including the patent doctrines of obviousness, double patenting, inequitable conduct, novelty, and public use. The decision has been appealed. We are confident, and the trial court confirmed, that the generic manufacturers' claims are without merit, and we expect to prevail in this litigation. However, it is not possible to predict or determine the outcome of this litigation and, accordingly, 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.

In October 2002, we were notified that Barr Laboratories, Inc. (Barr), had submitted an ANDA with the FDA seeking permission to market a generic version of Evista® (raloxifene) several years prior to the expiration of our U.S. patents covering the product, alleging that the patents are invalid or not infringed. In November 2002, we filed suit against Barr in the U.S. District Court for the Southern District of Indiana, seeking a ruling that Barr's challenges to our patents claiming the methods of use and pharmaceutical form (expiring from 2012 to 2017) are without merit. Recently, Barr has also asserted that the method of use patents are unenforceable. In the last year, the U.S. Patent and Trademark Office issued to us two new patents (expiring in 2017) directed to pharmaceutical compositions containing raloxifene and a method for preventing post-menopausal osteoporosis and a third (expiring in 2012) directed to methods of inhibiting post-menopausal bone loss by administering a single daily oral dose of raloxifene. These patents have been listed in the FDA's Orange Book. Barr has challenged these patents, alleging that each is invalid, unenforceable, or will not be infringed. These new patents have been added to the pending suit. The suit is in discovery. No trial date has been set at this time. While we believe that Barr's claims are without merit and we expect to prevail, it is not possible to predict or determine the outcome of the litigation. Therefore, 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.

In July 2002, we received a grand jury subpoena for documents from the Office of Consumer Litigation, U.S. Department of Justice, related to our marketing and promotional practices and physician communications with respect to Evista. We received subpoenas seeking additional documents in July 2003, July 2004, and August 2004. We continue to cooperate with the government and have provided a broad range of information concerning our U.S. marketing and promotional practices, including documents relating to communications with physicians and the remuneration of physician consultants and advisers. Based on advanced discussions with the government to resolve this matter, we expensed \$36.0 million during the fourth quarter of 2004, which we believe will be sufficient to resolve the matter. Those discussions are ongoing.

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 with respect to Zyprexa, Prozac®, and Prozac Weekly™. We are cooperating with the U.S. Attorney in this investigation and are providing a broad range of documents and information related to the investigation, including documents relating to communications with physicians and the remuneration of physician consultants and advisers. In June 2005, we received a subpoena from the office of the Attorney General, Medicaid Fraud Control Unit, of the State of

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Florida, seeking production of documents relating to sales of Zyprexa and our marketing and promotional practices with respect to Zyprexa. It is possible that other Lilly products could become subject to investigation and that the outcome of these matters could include criminal charges, fines, penalties, or other monetary or non-monetary 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, and remuneration of health care professionals comply with promotional laws and regulations.

We have been named as a defendant in approximately 230 product liability cases in the United States involving approximately 375 claimants alleging a variety of injuries from the use of Zyprexa. Most of the cases allege that the product caused or contributed to diabetes or high blood-glucose levels. The lawsuits seek substantial compensatory and punitive damages and typically accuse us of inadequately testing for and warning about side effects of Zyprexa. Many of the lawsuits also allege that we improperly promoted the drug. Almost all of the federal cases, involving approximately 345 claimants, 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. In addition, we have entered into agreements with various plaintiffs' counsel halting the running of the statutes of limitation (tolling agreements) with respect to more than 5,875 individuals who do not have lawsuits on file and may or may not eventually file suits.

Two cases requesting certification of nationwide class actions on behalf of those who allegedly suffered injuries from the administration of Zyprexa were filed in the Federal District Court for the Eastern District of New York on April 16, 2004, and May 19, 2004, respectively. Both cases sought damages for alleged personal injuries and compensation for medical monitoring of individuals who have taken Zyprexa. The personal injury claims in both of these lawsuits have been dismissed pursuant to agreement of the parties. A lawsuit was filed on May 4, 2004 that requests a personal injury class action on behalf of Iowa residents who took Zyprexa, and that case is pending before Judge Weinstein. In June 2005, another lawsuit was filed in the Eastern District of New York purporting to be a nationwide class action on behalf of all consumers and third party payors, excluding governmental entities, who have made or will make payments on account of their members or insureds being prescribed Zyprexa. The suit seeks a refund of the cost of Zyprexa; medical expenses paid and to be paid as a result of persons taking Zyprexa; treble damages under certain state consumer protection statutes; punitive damages; and attorney fees.

In June 2005, we announced that we entered into an agreement in principle with plaintiffs' attorneys involved in the U.S. Zyprexa product liability litigation to settle a majority of the claims against us relating to the medication. The parties are negotiating a final settlement agreement. When finalized, the settlement will resolve the majority of Zyprexa claims pending in the United States. This includes a large number of the previously filed federal and state lawsuits; the two nationwide medical monitoring class action lawsuits pending in the Eastern District of New York (neither of which has been certified by a judge); and the majority of the claims subject to tolling agreements, as well as a large number of other potential claims. At this time, the exact number of claimants that will be covered by this settlement is unknown, but is estimated to be about 8,000, which represents approximately 75 percent of claims identified to us to date. The agreement in principle provides us an option to renegotiate or terminate the settlement if we do not receive full releases from a specified number of the covered claimants.

According to the agreement, we will establish a fund of \$690 million for the claimants who agree to settle their claims. Additionally, \$10 million will be paid to cover administration of the settlement. The settlement fund will be overseen and distributed by claims administrators appointed by the court.

The settlement covers claimants who asserted that they developed diabetes-related conditions from their use of Zyprexa. Claimants who are not covered by the final settlement are those represented by attorneys who are not participating in the agreement in principle. We are prepared to continue our vigorous defense of Zyprexa in the 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 early 2005, we were served with five lawsuits seeking class action status in Canada on behalf of patients who took Zyprexa. The allegations in these suits are similar to those in the litigation pending in the United States.

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In connection with the Zyprexa product liability claims, certain of our insurance carriers have raised defenses to their liability under the policies and to date have failed to reimburse us for claim-related costs despite demand from the first-layer carriers for payment. However, in our opinion, the defenses identified to date appear to lack substance. In March 2005, we filed suit against several of the carriers in state court in Indiana to obtain reimbursement of costs related to the Zyprexa product liability litigation. The matter has been removed to the federal court in Indianapolis. Several carriers have asserted defenses to their liability and some carriers are seeking rescission of the coverage. 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 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.

As a result of these matters, in the second quarter of 2005, we recorded a net pre-tax charge of \$1.07 billion for product liability matters, which includes the following:

- The \$700 million Zyprexa settlement and administration fee;
- 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 settlement. We have estimated these charges based primarily on historical claims experience, data regarding product usage, and our historical product liability defense cost experience.

The \$1.07 billion net charge takes into account our estimated recoveries from our insurance coverage related to these matters. The after-tax impact of this net charge is \$.90 per share. We expect the \$700 million for the Zyprexa settlement to be paid during 2005, while the cash related to the other reserves for product liability exposures and defense costs is expected to be paid out over the next several years. 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 proposed Zyprexa settlement will be finalized. The ultimate resolution of Zyprexa product liability litigation could have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

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 previously with respect to the U.S. Zyprexa and Evista patent litigation, the Zyprexa, Prozac, and Prozac Weekly marketing and promotional practices investigations, and the Zyprexa product liability litigation, 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). Loss per-share amounts are presented based on a basic calculation; that is, based on the weighted-average number of outstanding common shares.

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. Stock options are granted to employees at exercise prices equal to the fair market value of our stock at the dates of grant. Generally, options fully vest three years from the grant date and have a term of 10 years. Performance awards are granted to officers and key employees and are payable in shares of our common stock. The number of performance award shares actually issued, if any, varies depending on the achievement of certain earnings-per-share targets. In general, performance awards fully vest at the end of the fiscal year of the grant. We recognize the stock-based compensation expense over the requisite service period of the individual grantees, which generally equals the vesting period. We provide newly issued shares and treasury stock to satisfy stock option exercises and for the issuance of performance awards.

Prior to January 1, 2005, we followed Accounting Principles Board (APB) Opinion 25, Accounting for Stock Issued to Employees, and related interpretations in accounting for our stock-based compensation. Under APB 25, no compensation expense was recognized for stock options since the exercise price of our employee stock options equaled the market price of the underlying stock on the date of grant. We have elected the modified prospective transition method for adopting SFAS 123R. Under this method, the provisions of SFAS 123R apply to all awards granted or modified after the date of adoption. In addition, the unrecognized expense of awards not yet vested at the date of adoption, determined under the original provisions of SFAS 123, shall be recognized in net income in the periods after the date of adoption. We recognized stock-based compensation cost in the amount of \$100.0 million and \$25.2 million in the second quarter of 2005 and 2004, respectively, as well as related tax benefits of \$30.6 million and \$8.8 million, respectively. In the first half of 2005 and 2004, we recognized stock-based compensation expense of \$208.2 million and \$50.4 million, respectively, as well as related tax benefits of \$63.4 million and \$17.6 million, respectively. The amounts for 2004 relate only to expenses for performance awards because no expense was recognized for stock options under APB 25.

As a result of the adoption of SFAS 123R and compensation plan structural changes effective January 1, 2005, the incremental impact on our stock compensation expense caused our loss before income taxes and net loss for the quarter ended June 30, 2005, to be \$78.7 million and \$55.6 million (\$.05 per share) higher, respectively, than if we had continued to account for our equity compensation programs under APB 25. For the first half of 2005, the incremental impact of the adoption of SFAS 123R and compensation plan structural changes caused our income before income taxes and net income to be \$165.6 million and \$117.2 million (\$.11 per share) lower, respectively, than if we had continued to account for our previous equity compensation programs under APB 25.

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SFAS 123R requires us to present pro forma information for periods prior to the adoption as if we had accounted for all our employee stock options and performance awards under the fair value method of that statement. For purposes of pro forma disclosure, the estimated fair value of the options and performance awards at the date of the grant is amortized to expense over the requisite service period, which generally equals the vesting period. The following table illustrates the effect on net income and earnings per share if we had applied the fair value recognition provisions of SFAS 123R to stock-based employee compensation (dollars in millions, except per-share data).

	Three Months Ended June 30, 2004	Six Months Ended June 30, 2004
Net income, as reported	\$656.9	\$1,057.3
Add: Stock-based compensation expense included in reported net income, net of related tax effects	16.4	32.8
Deduct: Total stock-based employee compensation expense determined under fair-value-based method for all awards, net of related tax effects	(73.4)	(181.1)
Pro forma net income	\$599.9	\$ 909.0
Earnings per share:		
Basic, as reported	\$.61	\$.98
Basic, pro forma	\$.55	\$.84
Diluted, as reported	\$.60	\$.97
Diluted, pro forma	\$.55	\$.83

Beginning with the 2005 stock option grant, we utilized a lattice-based option valuation model for estimating the fair value of the stock options. The lattice model allows the use of a range of assumptions related to volatility, risk-free interest rate, and employee exercise behavior. Expected volatilities utilized in the lattice model are based on implied volatilities from traded options on our stock, historical volatility of our stock price, and other factors. Similarly, the dividend yield is based on historical experience and our estimate of future dividend yields. The risk-free interest rate is derived from the U.S. Treasury yield curve in effect at the time of grant. The model incorporates exercise and post-vesting forfeiture assumptions based on an analysis of historical data. The expected life of the 2005 grants is derived from the output of the lattice model.

The weighted-average fair values of the options granted in the first quarter and first half of 2005 were \$16.06 per option, determined using the following assumptions:

Dividend yield	2.0%
Weighted-average volatility	27.8%
Range of volatilities	27.6% - 30.7%
Risk-free interest rate	2.5% - 4.5%
Weighted-average expected life	7.2 years

As of June 30, 2005, the total remaining unrecognized compensation cost related to non-vested stock options and performance awards amounted to \$339.7 million and \$82.6 million, respectively, which will be amortized over the weighted-average remaining requisite service period of 22 months and 6 months, respectively.

SHAREHOLDERS' EQUITY

As of June 30, 2005, we have purchased \$2.08 billion of our previously announced \$3.0 billion share repurchase program. During the six months ended June 30, 2005, we did not repurchase any stock pursuant to this program and we do not expect any share repurchases during the remainder of 2005.

RETIREMENT BENEFITS

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

	Defined Benefit Pension Plans			
	Three Months Ended June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
	(Dollars in millions)			
Components of net periodic benefit cost				
Service cost	\$ 74.3	\$ 61.5	\$ 154.4	\$ 120.7
Interest cost	74.2	71.1	149.0	142.0
Expected return on plan assets	(112.9)	(97.6)	(223.0)	(194.8)
Amortization of prior service cost	1.9	2.2	3.9	4.4
Recognized actuarial loss	26.0	21.1	52.2	42.0
Net periodic benefit cost	\$ 63.5	\$ 58.3	\$ 136.5	\$ 114.3

	Retiree Health Benefit Plans			
	Three Months Ended June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
	(Dollars in millions)			
Components of net periodic benefit cost				
Service cost	\$ 14.7	\$ 10.3	\$ 29.4	\$ 22.1
Interest cost	20.0	15.4	40.1	32.8
Expected return on plan assets	(18.7)	(14.7)	(35.7)	(29.4)
Amortization of prior service cost	(4.0)	(3.9)	(8.0)	(7.8)
Recognized actuarial loss	21.5	12.6	43.1	29.2
Net periodic benefit cost	\$ 33.5	\$ 19.7	\$ 68.9	\$ 46.9

We expect to contribute approximately \$380 million during 2005 to our defined benefit pension plans and post-retirement health benefit plans. As of June 30, 2005, approximately \$52 million in contributions have been made to these plans. The substantial majority of the remaining contributions will be made in the third quarter of 2005. This level of contribution is consistent with our historical practice of making the maximum tax-deductible contribution to our defined benefit pension plan for each plan year.

IMPLEMENTATION OF NEW FINANCIAL ACCOUNTING PRONOUNCEMENTS

In 2004, the FASB issued FASB Staff Position (FSP) 106-2, which provides guidance regarding accounting for the effects of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). The FSP specifies that, for plans with benefits that are determined to be actuarially equivalent to the Medicare Part D benefits, the plan sponsor will be entitled to a tax-free subsidy under the MMA. We have determined that our plan is actuarially equivalent and, therefore, we are entitled to the subsidy. Following our adoption of the provisions of FSP 106-2 in the second quarter of 2004, we remeasured the accumulated postretirement benefit obligation (APBO) to reflect the effects of the MMA as of the effective date of the MMA (December 8, 2003), and recognized the financial statement effect retroactively. This had no material impact on the APBO, our consolidated financial position, or results of operations.

As discussed previously, we adopted SFAS 123(R) effective January 1, 2005. The adoption of this standard requires the recognition of the fair value of stock-based compensation in net income.

APPLIED MOLECULAR EVOLUTION ACQUISITION

On February 12, 2004, we acquired all the outstanding common stock of Applied Molecular Evolution, Inc. (AME) in a tax-free merger. Under the terms of the merger agreement, each outstanding share of AME common stock was exchanged for our common stock or a combination of cash and our stock valued at \$18. The aggregate purchase price of approximately \$442.8 million consisted of issuance of 4.2 million shares of our common stock valued at \$314.8 million, issuance of 0.7 million replacement options to purchase shares of our common stock in exchange for the remaining outstanding AME options valued at \$37.6 million, cash of \$85.4 million for AME common stock and options for certain AME employees, and transaction costs of \$5.0 million. The fair value of our

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common stock was derived using a per-share value of \$74.14, which was our average closing stock price for February 11 and February 12, 2004. The fair value for the options granted was derived using a Black-Scholes valuation method using assumptions consistent with those we used in valuing employee options. Replacement options to purchase our common stock granted as part of this acquisition have terms equivalent to the AME options being replaced.

In addition to acquiring the rights to two compounds currently under development, we expect the acquisition of AME's protein optimization technology to create synergies that will accelerate our ability to discover and optimize biotherapeutic drugs for cancer, critical care, diabetes, and obesity, areas in which proteins are of great therapeutic benefit.

In accordance with SFAS 141, Business Combinations, the acquisition has been accounted for as a purchase business combination. Under the purchase method of accounting, the assets acquired and liabilities assumed from AME at the date of acquisition are recorded at their respective fair values as of the acquisition date in our consolidated financial statements. The excess of the purchase price over the fair value of the acquired net assets has been recorded as goodwill in the amount of \$9.6 million. Goodwill resulting from this acquisition has been fully allocated to the pharmaceutical products segment. No portion of this goodwill is expected to be deductible for tax purposes. AME's results of operations are included in our consolidated financial statements from the date of acquisition.

As of the date of acquisition, we determined the following estimated fair values for the assets purchased and liabilities assumed. The determination of estimated fair value requires management to make significant estimates and assumptions. We hired independent third parties to assist in the valuation of assets that were difficult to value.

	Estimated Fair Value at February 12, 2004
Cash and short-term investments	\$ 38.7
Acquired in-process research and development	362.3
Platform technology	17.9
Goodwill	9.6
Other assets and liabilities — net	14.3
Total estimated purchase price	<u>\$ 442.8</u>

The acquired in-process research and development (IPR&D) represents compounds currently under development that have not yet achieved regulatory approval for marketing. The estimated fair value of these intangible assets was derived using a valuation from an independent third party. AME's two lead compounds for the treatment of non-Hodgkin's lymphoma and rheumatoid arthritis represent approximately 80 percent of the estimated fair value of the IPR&D. In accordance with FIN 4, Applicability of FASB Statement No. 2 to Business Combinations Accounted for by the Purchase Method, these IPR&D intangible assets have been written off by a charge to income immediately subsequent to the acquisition because the compounds do not have any alternative future use. This charge is not deductible for tax purposes. The ongoing activity with respect to each of these compounds under development is not material to our research and development expenses.

There are several methods that can be used to determine the estimated fair value of the acquired IPR&D. We utilized the "income method," which applies a probability weighting to the estimated future net cash flows that are derived from projected sales revenues and estimated costs. These projections are based on factors such as relevant market size, patent protection, historical pricing of similar products, and expected industry trends. The estimated future net cash flows are then discounted to the present value using an appropriate discount rate. This analysis is performed for each project independently. The discount rate we used in valuing the acquired IPR&D projects was 18.75 percent.

ASSET IMPAIRMENTS AND PRODUCT LIABILITY CHARGES

As discussed further in the Contingencies Note, in June 2005 we entered into an agreement in principle with plaintiffs' attorneys involved in the U.S. Zyprexa product liability litigation to settle a majority of the claims against us relating to the medication. According to the agreement, we will establish a fund of \$690 million for the claimants who agree to settle their claims. Additionally, \$10 million will be paid to cover administration of the settlement. In the second quarter of 2005, we recorded a net pre-tax charge of \$1.07 billion for product liability matters, which includes the following:

- The \$700 million Zyprexa settlement and administration fee;
- 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

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exposures and costs relate to current and expected Zyprexa claims not included in the settlement. We have estimated these charges based primarily on historical claims experience, data regarding product usage, and our historical product liability defense cost experience.

The \$1.07 billion net charge takes into account our estimated recoveries from our insurance coverage related to these matters. The after-tax impact of this net charge is \$.90 per share. We expect the \$700 million for the Zyprexa settlement to be paid during 2005, while the other product liability exposures and defense costs are expected to be paid out over the next several years. The timing of our insurance recoveries is uncertain.

In the second quarter of 2004, as part of our ongoing review of our manufacturing and research and development strategies to maximize performance and efficiencies, including the streamlining of manufacturing operations and research and development activities, we made decisions that resulted in the impairment of certain assets. This review did not result in any closure of facilities or layoffs, but certain assets located at various sites were affected. We have ceased using these assets, written down their carrying value to zero, and are in the process of disposing of or destroying all of the assets. The asset impairment charges incurred in the second quarter of 2004 aggregated \$108.9 million.

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

OPERATING RESULTS

Executive Overview

I. Financial Summary

The second quarter 2005 net loss was \$252.0 million, or \$.23 per share, compared with net income of \$656.9 million, or \$.60 per share, for the second quarter of 2004. The net loss and loss per share in the second quarter of 2005 was caused by the product liability litigation charges of \$1.07 billion in the quarter. Net income was \$484.6 million, or \$.44 per share, for the first half of 2005 compared with \$1.06 billion, or \$.97 per share, for the first half of 2004, representing decreases in net income and earnings per share of 54 percent and 55 percent, respectively. Sales growth of 3 percent for both the second quarter and first half of 2005 was more than offset by costs of goods sold and research and development expenses increasing at a rate greater than sales. Comparisons between the three- and six-month periods ended June 30, 2005 and 2004, were also affected by the following items that are reflected in our operating results (see Notes to Consolidated Condensed Financial Statements for additional information):

2005

- We incurred a charge related to product liability litigation matters of \$1.07 billion (pretax) net of estimated insurance recoveries, which decreased earnings per share by \$.90 in the second quarter of 2005.
- In 2005, we began to expense stock options in accordance with SFAS 123(R). Had we expensed stock options in 2004, our second quarter and first half of 2004 net income would have been lower by \$57.0 million and \$148.3 million, which would have decreased earnings per share by \$.05 per share in the second quarter and \$.14 per share for the first half of 2004.

2004

- We recognized asset impairment charges of \$108.9 million (pretax), which decreased earnings per share by \$.08 in the second quarter of 2004.
- We incurred a charge for acquired IPR&D of \$362.3 million (no tax benefit) related to the acquisition of AME, which decreased earnings per share by \$.33 in the first quarter of 2004.

II. Product Launches and Other Significant Events Affecting our Business

- We are in the process of rolling out the global launches of a number of new products, including Alimta[®], Byetta[™], Cialis[®], Cymbalta[®], Forteo[®], Strattera[®], Symbyax[®], and Yentreve[®]. In addition, we have launched new indications or formulations of Alimta, Cymbalta, Gemzar[®], Humatrope[®], and Zyprexa.
- We launched Cymbalta, a balanced and potent selective serotonin and norepinephrine reuptake inhibitor, for the treatment of major depressive disorder in the U.S. in August 2004. In September 2004, Cymbalta received its second U.S. approval and became the first FDA-approved treatment for pain caused by diabetic peripheral neuropathy (DPNP). Cymbalta was launched in the United Kingdom and Germany in the first quarter of 2005 for the treatment of major depressive episodes. Other launches in the European Union are expected to occur throughout 2005 and 2006.

The European Commission also granted marketing authorization of Cymbalta for the treatment of DPNP in adults in July 2005.

- In August 2004, the European Commission granted marketing authorization throughout the European Union for Yentreve for the treatment of moderate-to-severe stress urinary incontinence (SUI) in women. Yentreve has been launched in several European countries and will be available in many additional countries in the coming months. To date, we have received marketing authorization for the product in 29 countries worldwide. In January 2005, we withdrew the New Drug Application from the FDA for duloxetine for the treatment of SUI. This decision was based on discussions with the FDA suggesting the agency was not prepared at that time to grant approval for the product for the treatment of the SUI patient population based on the data package submitted. With our marketing partner, Boehringer Ingelheim, we are continuing to evaluate our options for next steps for the SUI indication in consultation with the FDA. Ongoing clinical trials for the product's treatment of SUI will continue.
- In June 2005, Lilly and Amylin Pharmaceuticals, Inc. launched Byetta™ (exenatide), the first in a new class of medicines known as incretin mimetics, in the U.S. for the treatment of type 2 diabetes.
- In the first quarter of 2005, we restructured our arrangements with our U.S. wholesalers. The new arrangements are expected to provide us competitive distribution costs, reduce the speculative wholesaler buying seen in the past, and provide improved data on inventory levels at our U.S. wholesalers.

III. Legal and Regulatory 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. The decision has been appealed.

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. marketing and promotional practices. The products involved include Zyprexa, Prozac, and Prozac Weekly.

In June 2005, we entered into an agreement in principle with plaintiffs' attorneys involved in the U.S. Zyprexa product liability litigation to settle a majority of the claims against us relating to the medication. According to the agreement, we will establish a fund of \$690 million for the claimants who agree to settle their claims. Additionally, \$10 million will be paid to cover administration of the settlement. As a result of our product liability exposures, the substantial majority of which are the current and expected Zyprexa claims, we recorded a net pretax charge of \$1.07 billion in the second quarter of 2005.

Sales

Second-quarter and first-half 2005 sales growth of 3 percent was primarily driven by sales growth of Cymbalta, Alimta, Gemzar, and Forteo. This growth was partially offset by an estimated \$30 million and \$160 million of wholesaler destocking in the second quarter and first six months of 2005, respectively, as a result of restructuring our arrangements with our U.S. wholesalers in the first quarter of 2005, and by decreased sales of Zyprexa. Sales in the U.S. decreased by \$37.1 million, or 2 percent, and \$89.1 million, or 2 percent, for the second quarter and first half of 2005, respectively, compared with the same periods of 2004. The decline in U.S. sales was driven primarily by decreased sales of Zyprexa and reductions in wholesaler inventory levels, partially offset by increased sales of Cymbalta, Alimta, and Gemzar. Sales outside the U.S. increased \$148.4 million, or 9 percent, and \$321.0 million, or 10 percent, for the second quarter and first half of 2005, respectively. Exchange rates increased sales in the second quarter by 2 percent, while the remaining growth resulted from slight increases in selling price and volume. For the first six months of 2005, worldwide sales volume was essentially flat while exchange rates and selling prices increased 2 percent, and 1 percent, respectively.

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The following tables summarize our net sales activity for the three- and six-month periods ended June 30, 2005 and 2004:

Product	Three Months Ended June 30, 2005			Three Months Ended June 30, 2004	Percent Change From 2004
	U.S. ¹	Outside U.S.	Total	Total	
	(Dollars in millions)				
Zyprexa	\$ 549.4	\$ 547.4	\$1,096.8	\$1,212.3	(10)
Gemzar	154.5	188.5	343.0	293.3	17
Humalog	181.8	114.4	296.2	285.3	4
Evista	162.9	98.7	261.6	276.6	(5)
Humulin	102.6	147.2	249.8	259.3	(4)
Animal health products	80.5	120.5	201.0	179.6	12
Cymbalta	151.2	10.2	161.4	—	NM
Strattera	111.0	12.5	123.5	178.6	(31)
Fluoxetine products	59.0	55.2	114.2	129.8	(12)
Anti-infectives	35.3	77.5	112.8	118.6	(5)
Alimta	69.4	41.8	111.2	17.8	NM
Humatrope	46.4	62.5	108.9	102.1	7
Actos	71.5	33.5	105.0	112.4	(7)
Forteo	70.8	31.1	101.9	65.3	56
ReoPro	31.7	46.0	77.7	101.8	(24)
Xigris	33.3	24.4	57.7	48.6	19
Cialis ²	0.6	44.5	45.1	32.2	40
Symbyax	14.5	0.4	14.9	7.9	89
Other pharmaceutical products	12.9	72.1	85.0	134.8	(37)
Total net sales	\$1,939.3	\$1,728.4	\$3,667.7	\$3,556.3	3

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Product	Six Months Ended June 30, 2005			Six Months Ended June 30, 2004	Percent Change From 2004
	U.S. ¹	Outside U.S.	Total	Total	
	(Dollars in millions)				
Zyprexa	\$1,066.8	\$1,068.2	\$2,135.0	\$2,310.6	(8)
Gemzar	281.4	366.2	647.6	572.3	13
Humalog	358.0	224.4	582.4	552.5	5
Evista	321.4	189.1	510.5	509.4	—
Humulin	207.6	299.1	506.7	508.7	—
Animal health products	155.1	241.4	396.5	362.0	10
Strattera	223.2	20.0	243.2	319.7	(24)
Actos	209.5	64.1	273.6	265.7	3
Cymbalta	253.6	14.6	268.2	—	NM
Fluoxetine products	116.3	110.4	226.7	294.9	(23)
Anti-infectives	70.0	152.0	222.0	243.7	(9)
Humatrope	94.5	118.9	213.4	204.8	4
Alimta	133.0	72.1	205.1	29.4	NM
Forteo	113.0	55.7	168.7	106.1	59
ReoPro	60.4	94.0	154.4	195.5	(21)
Xigris	68.1	49.2	117.3	97.2	21
Cialis ²	1.1	82.9	84.0	65.5	28
Symbyax	26.9	0.6	27.5	41.6	(34)
Other pharmaceutical products	24.1	158.2	182.3	253.6	(28)
Total net sales	\$3,784.0	\$3,381.1	\$7,165.1	\$6,933.2	3

NM – Not meaningful

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

² Cialis had worldwide second-quarter and first-half 2005 sales of \$190.9 million and \$341.1 million, respectively, representing an increase of 39 percent compared with both periods of 2004. 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 net other income in our consolidated condensed income statement.

Product Highlights

Zyprexa sales in the U.S. decreased 21 percent and 19 percent in the second quarter and first-half of 2005 compared with the same periods of 2004. This decrease was a result of a decline in the underlying demand due to continuing competitive pressures. U.S. Zyprexa sales for the second quarter of 2005 increased sequentially compared to the first quarter of 2005 by \$32.0 million. We expect these more stable prescription trends to continue, which will result in an improvement in year-on-year growth rate comparisons in the last two quarters of 2005. Sales outside the U.S. increased 6 percent and 8 percent for the second quarter and first half of 2005, respectively, driven primarily by favorable impact of exchange rates. Excluding the impact of exchange rates, sales of Zyprexa outside the U.S. increased by 1 percent in the second quarter and 2 percent in the first half of 2005. Full-year 2005 Zyprexa sales outside the U.S. are expected to grow in the single digits compared with 2004. We continue to expect a slight decline in our 2005 worldwide Zyprexa sales.

Diabetes care products, composed primarily of Humalog[®], Humulin[®], and Actos[®], had worldwide net sales of \$669.4 million and \$1.39 billion in the second quarter and first-half of 2005, respectively, a decrease of 1 percent and an increase of 3 percent compared with the same periods last year. Diabetes care revenues in the U.S. decreased 5 percent and 1 percent, to \$370.7 million and \$799.0 million for the second quarter and first-half of 2005, primarily driven by decline in underlying demand due to continued competitive pressures in the insulins market and reductions in wholesaler inventory levels of insulins during the first half of 2005, offset partially by price increases for insulins. Diabetes care revenues outside the U.S. increased 5 percent and 8 percent, to \$298.6 million and \$595.0 million in the second quarter and first-half of 2005, respectively. Humalog sales increased 1 percent and 3 percent, while Humulin sales decreased 9 percent and 7 percent in the U.S. in the second quarter and first-half of 2005, respectively. Humalog and Humulin

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sales outside the U.S. increased 9 percent and 1 percent during the second quarter of 2005 and 10 percent and 4 percent during the first-half of 2005, respectively. Actos revenues, the majority of which represent service revenues from a copromotion agreement in the U.S. with Takeda Pharmaceuticals North America (Takeda), decreased 15 percent and 2 percent in the second quarter and first-half of 2005 in the U.S. 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 vary from quarter to quarter based on contract terms, Actos revenue will not necessarily track with product sales. As a result, it is difficult to make quarterly comparisons for Actos revenue.

Gemzar sales, driven by increases in demand, increased 19 percent and 9 percent in the U.S. for the second quarter and first-half of 2005, respectively. Sales growth comparisons in the U.S. in the second quarter were benefited by wholesaler destocking in the second quarter of 2004. Sales growth in the U.S. in the first half of 2005 was negatively affected by reductions in wholesaler inventory levels in the first quarter of 2005. Gemzar sales outside the U.S. increased 15 and 16 percent for the second quarter and first-half of 2005, respectively.

Evista sales in the U.S. decreased 5 percent and 3 percent in the second quarter and first-half of 2005, respectively, due primarily to a decline in U.S. underlying demand resulting from continued competitive pressures and reductions in wholesaler inventory levels, partially offset by price increases. Evista sales outside the U.S. decreased 7 percent and increased 6 percent in the second quarter and first-half of 2005 compared with the same periods of 2004. The decline in Evista sales outside the U.S. was primarily due to stocking related to the launch of Evista in Japan in the second quarter of 2004.

Strattera, the only nonstimulant medicine approved for the treatment of attention-deficit hyperactivity disorder (ADHD) in children, adolescents, and adults, generated \$123.5 million and \$243.2 million of sales during the second quarter and first-half of 2005, compared with \$178.6 million and \$319.7 million of sales in the second quarter and first-half of 2004. The decline in sales was due to a decline in demand and reductions in wholesaler inventory levels during the first half of 2005. We expect Strattera sales for 2005 to decrease primarily due to greater than anticipated wholesaler destocking resulting from the recently restructured arrangements with our U.S. wholesalers, as well as sales pressures in the children's ADHD market.

Cymbalta was launched in the U.S. in late August 2004 for the treatment of major depressive disorder and in September 2004 for the treatment of diabetic peripheral neuropathic pain. Despite launching in a challenging antidepressant category, Cymbalta continues to make steady prescription volume and share of market gains. Cymbalta launches began in Europe for the treatment of major depressive episodes during the first quarter of 2005, with additional launches expected through 2005 and 2006. Cymbalta has been well accepted, generating \$161.4 million in sales in the second quarter of 2005 and \$268.2 million in sales in the first half of 2005.

Alimta was launched in the U.S. during the first quarter of 2004 for the treatment of malignant pleural mesothelioma and approved during August 2004 for second-line treatment of non-small-cell lung cancer, while in Europe it was approved for both indications in September 2004. For the second quarter of 2005, Alimta generated sales of \$111.2 million, representing a sequential increase compared with first quarter 2005 sales of \$93.9 million. Alimta will continue to be launched in a number of European countries in 2005. We are pleased with the U.S. and European launches of Alimta.

Forteo, a treatment for both men and postmenopausal women suffering from osteoporosis, increased 25 and 21 percent in the U.S. in the second quarter and first-half of 2005, driven by strong growth in underlying demand, but offset, in part, by wholesaler destocking related to our new arrangements with U.S. wholesalers.

Xigris had second-quarter and first-half 2005 sales growth of 13 percent and 10 percent in the U.S., while sales outside the U.S. increased 28 percent in the second quarter of 2005 and 39 percent during the first half of 2005. Xigris sales in the U.S. benefited from wholesaler stocking in the second quarter of 2005 due to a change in distribution arrangements.

Cialis was launched in the U.S. in December 2003. The \$190.9 million of worldwide Cialis sales in the second quarter of 2005 comprised \$45.1 million of sales in our territories, which are reported in our net sales, and \$145.8 million of sales in the joint-venture territories. The \$341.1 million of worldwide Cialis sales in the first half of 2005 comprised \$84.0 million of sales in our territories, which are reported in our net sales, and \$257.1 million of sales in the joint-venture territories. Within the joint-venture territories, the U.S. sales of Cialis were \$71.1 million and \$113.9 million in the second quarter and first-half of 2005, respectively, compared with \$50.8 million and \$83.6 million in the same periods of 2004. The increase was due to an increase in the underlying demand, offset partially by reductions in wholesaler inventory levels during the first quarter of 2005.

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Gross Margin, Costs, and Expenses

For the second quarter of 2005, gross margins declined 1.4 percentage points, to 76.2 percent of net sales, compared with the second quarter of 2004. For the first half of 2005, gross margins declined 1.8 percentage points, to 75.9 percent of net sales, compared with the first half of 2004. This decrease was primarily due to the continued investment in our manufacturing capacity, other cost increases, and the impact of foreign exchange rates, partially offset by a favorable product mix.

Operating expenses (the aggregate of research and development and marketing and administrative expenses) increased 3 percent and 4 percent for the second quarter and first half of 2005, respectively, compared with the same periods of 2004. Investment in research and development increased 11 percent, to \$762.4 million, and 10 percent, to \$1.46 billion, for the second quarter and first half of 2005, respectively, due to increased clinical trial and development expenses and the adoption of stock option expensing in 2005. Marketing and administrative expenses decreased 2 percent, to \$1.15 billion, and was flat at \$2.24 billion, for the second quarter and first half of 2005, respectively, primarily due to ongoing marketing cost-containment measures, offset partially by increased expense related to the adoption of stock option expensing in 2005 and the impact of foreign exchange rates. Research and development expenses would have increased by 7 percent and 5 percent, and marketing and administrative expenses would have decreased by 6 percent and 5 percent for the second quarter and first-half of 2005, respectively, if the comparative periods in 2004 would have been restated as if stock options had been expensed.

Net other income for the quarter and six-month period ended June 30, 2005, increased \$8.3 million, to \$57.4 million, and \$59.1 million, to \$180.6 million, respectively. This increase was primarily due to income earned from the restructuring of our royalty arrangements with Ligand Pharmaceuticals Incorporated and Cubist Pharmaceuticals, Inc. during the first quarter of 2005, and a decreased loss from the Lilly ICOS LLC joint venture for both the second quarter and first half of 2005.

For the second quarter, we incurred a tax expense of \$111.9 million despite reporting a net loss before income taxes for the quarter. The product liability litigation charge of \$1.07 billion in the second quarter resulted in a tax benefit that was less than our effective tax rate, as the tax benefit was calculated based upon existing tax laws in the countries in which we reasonably expect to deduct the charge. For the first half of 2005, the effective tax rate was 39.7 percent, while the tax rates were 21.6 percent and 27.3 percent for the second quarter and first half of 2004, respectively. The effective tax rates for the 2004 periods were affected by the charge for acquired IPR&D related to the AME acquisition, which is not deductible for tax purposes.

FINANCIAL CONDITION

As of June 30, 2005, cash, cash equivalents, and short-term investments totaled \$5.40 billion compared with \$7.46 billion at December 31, 2004. Cash flow from operations of \$1.48 billion was more than offset by net repayments of short-term debt of \$1.89 billion, dividends paid of \$821.2 million and net capital expenditures of \$619.9 million. Total debt at June 30, 2005, was \$4.68 billion, a decrease of \$1.84 billion from December 31, 2004. The decrease in debt was primarily due to the reduction of commercial paper using available U.S. funds.

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 in 2005. We believe that amounts available through our existing commercial paper program should be adequate to fund maturities of short-term borrowings, if necessary. Although we repaid approximately \$1.8 billion of debt in the first six months of 2005, we will likely incrementally increase our debt during the remainder of 2005 by approximately \$2 billion from June 30, 2005 balances, as business needs require, and as a result of our Zyprexa product liability settlement and a recently reached resolution with the Internal Revenue Service (IRS) for the tax years 1998 to 2000. The resolution of the IRS examination will not have an impact on our net income. We currently expect to repay this \$2 billion of incremental debt by the end of 2006. Various risks and uncertainties, including those discussed in the Financial Expectations for 2005 section, may affect our operating results and cash generated from operations.

We have commenced repatriation of the incentive dividends as defined in the American Jobs Creation Act of 2004. We will repatriate a total of approximately \$8.00 billion of incentive dividends during 2005 pursuant to this Act.

LEGAL AND REGULATORY MATTERS

Three generic pharmaceutical manufacturers, Zenith Goldline Pharmaceuticals, Inc. (Zenith), Dr. Reddy's Laboratories, Ltd. (Reddy), and Teva Pharmaceuticals (Teva), have submitted abbreviated new drug applications (ANDAs) seeking permission to market generic versions of Zyprexa® in various dosage forms several years prior to the expiration of our U.S. patents for the product. The generic companies alleged that our patents are invalid, unenforceable, or not infringed. We filed suit against the three companies in the U.S. District Court for the Southern District of Indiana, seeking a ruling that the challenges to our compound patent (expiring in 2011) are

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without merit. The cases have been consolidated. A trial before the district court judge was held in January and February of 2004. On April 14, 2005, the district court upheld our 2011 U.S. patent on Zyprexa. In the case of *Eli Lilly and Company v. Zenith Goldline Pharmaceuticals et al.*, the court ruled in our favor on all counts, including the patent doctrines of obviousness, double patenting, inequitable conduct, novelty, and public use. The decision has been appealed. We are confident, and the trial court confirmed, that the generic manufacturers' claims are without merit, and we expect to prevail in this litigation. However, it is not possible to predict or determine the outcome of this litigation and, accordingly, 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.

In October 2002, we were notified that Barr Laboratories, Inc. (Barr), had submitted an ANDA with the FDA seeking permission to market a generic version of Evista® (raloxifene) several years prior to the expiration of our U.S. patents covering the product, alleging that the patents are invalid or not infringed. In November 2002, we filed suit against Barr in the U.S. District Court for the Southern District of Indiana, seeking a ruling that Barr's challenges to our patents claiming the methods of use and pharmaceutical form (expiring from 2012 to 2017) are without merit. Recently, Barr has also asserted that the method of use patents are unenforceable. In the last year, the U.S. Patent and Trademark Office issued to us two new patents (expiring in 2017) directed to pharmaceutical compositions containing raloxifene and a method for preventing post-menopausal osteoporosis and a third (expiring in 2012) directed to methods of inhibiting post-menopausal bone loss by administering a single daily oral dose of raloxifene. These patents have been listed in the FDA's Orange Book. Barr has challenged these patents, alleging that each is invalid, unenforceable, or will not be infringed. These new patents have been added to the pending suit. The suit is in discovery. No trial date has been set at this time. While we believe that Barr's claims are without merit and we expect to prevail, it is not possible to predict or determine the outcome of the litigation. Therefore, 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.

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 with respect to Zyprexa, Prozac®, and Prozac Weekly™. We are cooperating with the U.S. Attorney in this investigation and are providing a broad range of documents and information related to the investigation, including documents relating to communications with physicians and the remuneration of physician consultants and advisers. 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. 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 non-monetary 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, and remuneration of health care professionals comply with promotional laws and regulations.

We have been named as a defendant in approximately 230 product liability cases in the United States involving approximately 375 claimants alleging a variety of injuries from the use of Zyprexa. Most of the cases allege that the product caused or contributed to diabetes or high blood-glucose levels. The lawsuits seek substantial compensatory and punitive damages and typically accuse us of inadequately testing for and warning about side effects of Zyprexa. Many of the lawsuits also allege that we improperly promoted the drug. Almost all of the federal cases, involving approximately 345 claimants, 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. In addition, we have entered into agreements with various plaintiffs' counsel halting the running of the statutes of limitation (tolling agreements) with respect to more than 5,875 individuals who do not have lawsuits on file and may or may not eventually file suits.

Two cases requesting certification of nationwide class actions on behalf of those who allegedly suffered injuries from the administration of Zyprexa were filed in the Federal District Court for the Eastern District of New York on April 16, 2004, and May 19, 2004, respectively. Both cases sought damages for alleged personal injuries and compensation for medical monitoring of individuals who have taken Zyprexa. The personal injury claims in both of these lawsuits have been dismissed pursuant to agreement of the parties. A lawsuit was filed on May 4, 2004 that requests a personal injury class action on behalf of Iowa residents who took Zyprexa, and that case is pending before Judge Weinstein. In June 2005, another lawsuit was filed in the Eastern District of New York purporting to be a nationwide class action on behalf of all consumers and third party payors, excluding governmental entities, who have made or will make payments on account of their members or insureds being prescribed Zyprexa. The suit seeks a refund of the cost of Zyprexa; medical expenses paid and to be paid as a result of persons taking Zyprexa; treble damages under certain state consumer protection statutes; punitive damages; and attorney fees.

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In June 2005, we announced that we entered into an agreement in principle with plaintiffs' attorneys involved in the U.S. Zyprexa product liability litigation to settle a majority of the claims against us relating to the medication. The parties are negotiating a final settlement agreement. When finalized, the settlement will resolve the majority of Zyprexa claims pending in the United States. This includes a large number of the previously filed federal and state lawsuits; the two nationwide medical monitoring class action lawsuits pending in the Eastern District of New York (neither of which has been certified by a judge); and the majority of the claims subject to tolling agreements, as well as a large number of other potential claims. At this time, the exact number of claimants that will be covered by this settlement is unknown, but is estimated to be about 8,000, which represents approximately 75 percent of claims identified to us to date. The agreement in principle provides us an option to renegotiate or terminate the settlement if we do not receive full releases from a specified number of the covered claimants.

According to the agreement, we will establish a fund of \$690 million for the claimants who agree to settle their claims. Additionally, \$10 million will be paid to cover administration of the settlement. The settlement fund will be overseen and distributed by claims administrators appointed by the court.

The settlement covers claimants who asserted that they developed diabetes-related conditions from their use of Zyprexa. Claimants who are not covered by the final settlement are those represented by attorneys who are not participating in the agreement in principle. We are prepared to continue our vigorous defense of Zyprexa in the 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 early 2005, we were served with five lawsuits seeking class action status in Canada on behalf of patients who took Zyprexa. The allegations in these suits are similar to those in the litigation pending in the United States.

In connection with the Zyprexa product liability claims, certain of our insurance carriers have raised defenses to their liability under the policies and to date have failed to reimburse us for claim-related costs despite demand from the first-layer carriers for payment. However, in our opinion, the defenses identified to date appear to lack substance. In March 2005, we filed suit against several of the carriers in state court in Indiana to obtain reimbursement of costs related to the Zyprexa product liability litigation. The matter has been removed to the federal court in Indianapolis. Several carriers have asserted defenses to their liability and some carriers are seeking rescission of the coverage. 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 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.

As a result of these matters, in the second quarter of 2005, we recorded a net pre-tax charge of \$1.07 billion for product liability matters, which includes the following:

- The \$700 million Zyprexa settlement and administration fee;
- 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 settlement. We have estimated these charges based primarily on historical claims experience, data regarding product usage, and our historical product liability defense cost experience.

The \$1.07 billion net charge takes into account our estimated recoveries from our insurance coverage related to these matters. The after-tax impact of this net charge is \$.90 per share. We expect the \$700 million for the Zyprexa settlement to be paid during 2005, while the other product liability exposures and defense costs is expected to be paid out over the next several years. The timing of our insurance recoveries is uncertain.

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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 proposed Zyprexa settlement will be finalized. The ultimate resolution of Zyprexa product liability litigation could have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

FINANCIAL EXPECTATIONS FOR 2005

We expect third-quarter 2005 earnings per share of \$.70 to \$.72, which represents up to 4 percent growth compared with reported third-quarter 2004 earnings per share of \$.69 (which excluded stock option expensing). For the full year of 2005, we currently expect earnings per share to be in the range of \$1.90 to \$1.96 per share, including the \$.90 per share product liability charge recognized in the second quarter of 2005, and the incremental equity compensation expense as a result of expensing stock options (see Notes to the Consolidated Condensed Financial Statements for additional information) and compensation structural changes. For the full year 2005, we expect sales to grow 6 percent to 8 percent (with acceleration in the second half of the year), gross margins as a percentage of sales to decline by roughly 50 to 75 basis points, marketing and administrative expenses to remain essentially flat, and research and development expenses to grow in the high single-digits compared with full-year 2004. Further, we expect other income, net of interest expense, to contribute approximately \$270 million to \$300 million. Excluding the tax benefit realized for the product liability litigation charge in the second quarter of 2005, the effective income tax rate is expected to be about 22 percent.

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; foreign exchange rates; wholesaler inventory changes; other regulatory developments, litigation, and government investigations; and the impact of governmental actions regarding pricing, importation, and reimbursement for pharmaceuticals. Other factors that may affect our operations and prospects are discussed in Exhibit 99 to this Form 10-Q. We undertake no duty to update 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, president, and chief executive officer, and Charles E. Golden, executive vice president and chief financial officer, evaluated our disclosure controls and procedures as of June 30, 2005, and concluded that they are effective.

(b) During the first half of 2005, we completed the implementation of new software applications for our Geneva, Switzerland Service Center. The implementation included, among others, our Order to Cash, General Accounting, and Purchase to Pay processes. The Service Center processes transactional activity and performs financial reporting primarily for our Middle Eastern, African, and Eastern European operations, as well as some processing for Japanese and European affiliates. Additionally, we implemented new software applications in the U.S. pertaining to the processing of various discounts and rebates to public and private health care payors. These systems will enhance operational effectiveness and efficiencies and are expected to further improve internal controls that were previously considered effective.

During the remainder of 2005, we will perform appropriate testing, under Section 404 of the Sarbanes-Oxley Act, to ensure the effectiveness of internal controls as they relate to the reliability of financial reporting and the fair presentation of our consolidated financial statements. We anticipate other implementations of software applications as part of our global enterprise-wide software conversion to occur during 2005.

Except for the preceding changes, there was no change in the Company's internal control over financial reporting during the most recently completed calendar quarter that has materially affected, or is reasonably likely to materially affect, the company's 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. Zyprexa patent litigation
- The U.S. Evista patent litigation
- The civil investigation by the U.S. Attorney for the Eastern District of Pennsylvania relating to our U.S. marketing and promotional practices for Zyprexa, Prozac, and Prozac Weekly
- The Zyprexa product liability litigation, including the agreement in principle to settle the majority of the U.S. claims
- The suits we have filed against several of our product liability insurance carriers with respect to our coverage for the Zyprexa claims

That information is incorporated into this Item by reference.

We refer to Part I, Item 3, of our Form 10-K annual report for 2004 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 110 suits involving approximately 200 claimants. In the thimerosal litigation, we have been named as a defendant in approximately 360 suits with approximately 970 claimants.

We refer to Part I, Item 3, of our Form 10-K annual report for 2004, and Part II, Item 1 of our Form 10-Q for the quarter ended March 31, 2005, for the discussion of litigation brought against us and many other pharmaceutical manufacturers by several counties in New York relating generally to the calculation and reporting of average wholesale prices for purposes of Medicaid reimbursement. A consolidated amended complaint has now been filed that includes us as a defendant.

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 previously with respect to the U.S. Zyprexa and Evista patent litigation, the Zyprexa, Prozac, and Prozac Weekly marketing and promotional practices investigation, and the Zyprexa product liability litigation, 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 June 30, 2005:

Period	Total Number of Shares Purchased (a)	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)
	(in thousands)			(Dollars in millions)
April 2005	5	\$54.61	—	\$920.0
May 2005	12	57.42	—	920.0
June 2005	4	58.25	—	920.0
Total	<u>21</u>		<u>—</u>	

The amounts presented in columns (a) and (b) above represent purchases of common stock related to employee stock option exercises. The amounts presented in columns (c) and (d) in the above table represent activity related to our \$3.0 billion share repurchase program announced in March 2000. As of June 30, 2005, we have purchased \$2.08 billion related to this program. During the second quarter of 2005, no shares were repurchased pursuant to this program and we do not expect to purchase any shares under this program during the remainder of 2005.

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Item 6. Exhibits and Reports on Form 8-K

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

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, President, and Chief Executive Officer
EXHIBIT 31.2	Rule 13a-14(a) Certification of Charles E. Golden, Executive Vice President and Chief Financial Officer
EXHIBIT 32.	Section 1350 Certification
EXHIBIT 99.	Cautionary Statement Under Private Securities Litigation Reform Act of 1995 – “Safe Harbor” for Forward-Looking Disclosures

SIGNATURES

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

ELI LILLY AND COMPANY
(Registrant)

Date August 2, 2005

/s/ Alecia A. DeCoudreaux
Alecia A. DeCoudreaux
Secretary and Deputy General Counsel

Date August 2, 2005

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

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INDEX TO EXHIBITS

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EXHIBIT 11. STATEMENT RE: COMPUTATION OF EARNINGS (LOSS) PER SHARE
(Unaudited)

ELI LILLY AND COMPANY AND SUBSIDIARIES

	Three Months Ended June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
	(Dollars and shares in millions except per share data)			
BASIC				
Net income (loss)	\$ (252.0)	\$ 656.9	\$ 484.6	\$1,057.3
Average number of common shares outstanding	1,087.6	1,083.9	1,087.2	1,082.1
Basic earnings (loss) per share	\$ (.23)	\$.61	\$.45	\$.98
DILUTED				
Net income (loss)	\$ (252.0)	\$ 656.9	\$ 484.6	\$1,057.3
Average number of common shares outstanding	1,087.6	1,083.9	1,087.2	1,082.1
Incremental shares – stock options	—	6.8	2.5	6.8
Adjusted average shares	1,087.6	1,090.7	1,089.7	1,088.9
Diluted earnings (loss) per share	\$ (.23)	\$.60	\$.44	\$.97

EXHIBIT 12. STATEMENT RE: COMPUTATION OF RATIO OF EARNINGS TO FIXED CHARGES
(Unaudited)

ELI LILLY AND COMPANY AND SUBSIDIARIES
(Dollars in millions)

	Six Months Ended June 30, 2005	Years Ended December 31,				
		2004	2003	2002	2001	2000
Consolidated pretax income	\$484.6	\$2,941.9	\$3,261.7	\$3,457.7	\$3,506.9	\$3,858.7
Interest	105.1	162.9	121.9	140.0	253.3	225.4
Less interest capitalized during the period	(68.5)	(111.3)	(60.9)	(60.3)	(61.5)	(43.1)
Earnings	\$521.2	\$2,993.5	\$3,322.7	\$3,537.4	\$3,698.7	\$4,041.0
Fixed charges	\$105.1	\$ 162.9	\$ 121.9	\$ 140.0	\$ 253.3	\$ 225.4
Ratio of earnings to fixed charges	5.0	18.4	27.3	25.3	14.6	17.9

CERTIFICATIONS

I, Sidney Taurel, chairman of the board, president, and chief executive officer, certify that:

1. I have reviewed this report on Form 10-Q of Eli Lilly and Company;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

- a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
- b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
- c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
- d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):

- a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize, and report financial information; and
- b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

Date: August 2, 2005

By: /s/Sidney Taurel
Sidney Taurel
Chairman of the Board, President,
and Chief Executive Officer

CERTIFICATIONS

I, Charles E. Golden, executive vice president and chief financial officer, certify that:

1. I have reviewed this report on Form 10-Q of Eli Lilly and Company;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

- a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
- b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
- c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
- d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):

- a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize, and report financial information; and
- b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

Date: August 2, 2005

By: /s/Charles E. Golden
Charles E. Golden
Executive Vice President
and Chief Financial Officer

EXHIBIT 32. Section 1350 Certification

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of Eli Lilly and Company, an Indiana corporation (the "Company"), does hereby certify that, to the best of their knowledge:

The Quarterly Report on Form 10-Q for the quarter ended June 30, 2005 (the "Form 10-Q") of the Company fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 and information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date August 2, 2005

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

Date August 2, 2005

/s/Charles E. Golden
Charles E. Golden
Executive Vice President and
Chief Financial Officer

EXHIBIT 99. Cautionary Statement Under Private Securities Litigation Reform Act of 1995 – “Safe Harbor” for Forward-Looking Disclosures

Certain forward-looking statements are included in this Form 10-K and may be made by spokespeople based on then-current expectations of management. All forward-looking statements made by us are subject to risks and uncertainties. One can identify forward-looking statements by the use of words such as “expects,” “plans,” “will,” “estimates,” “forecasts,” “projects,” “believes,” “anticipates,” and other words of similar meaning. Forward-looking statements do not relate strictly to historical or current facts. They are likely to address our growth strategy, financial results, regulatory issues, and status of product approvals, development programs, litigation, and investigations.

Certain factors, including but not limited to those listed below, may cause actual results to differ materially from current expectations and historical results. These factors may include:

- Competitive factors can lead to declining demand for our products. These factors include new patented products or expanded indications for existing products introduced by competitors; generic competition as patents on key products expire; and pricing pressures, both in the U.S. and abroad.
- Government health care cost-containment measures can significantly affect our sales and profitability. These include federal, state, and foreign laws and regulations that negatively affect pharmaceutical pricing, such as Medicaid and Medicare; pharmaceutical importation laws; and other laws and regulations that, directly or indirectly, impose governmental controls on the prices at which our products are sold.
- There are many difficulties and uncertainties inherent in new product development and introduction of new products. New product candidates that appear promising in development may fail to reach the market or may have only limited commercial success because of efficacy or safety concerns, inability to obtain necessary regulatory approvals, limited scope of approved uses, difficulty or excessive costs to manufacture, or infringement of the patents or intellectual property rights of others. In addition, it can be very difficult to predict sales growth rates of new products.
- Delays and uncertainties in the FDA approval process and the approval processes in other countries can result in delays in product launches and lost market opportunity.
- Unexpected safety or efficacy concerns can arise with respect to marketed products, whether or not scientifically justified, leading to product recalls, withdrawals, or declining sales.
- Patent challenges, including challenges to our patents by generic pharmaceutical manufacturers under the Hatch-Waxman Act or patent infringement suits brought against us by other patent holders, can cause us to prematurely lose market exclusivity for, or preclude commercialization of, our products. In particular, see Part I, Item 2, “Legal and Regulatory Matters”, for a discussion of Hatch-Waxman Act challenges to our patents for Zyprexa and Evista.
- Changes in inventory levels maintained by pharmaceutical wholesalers can cause reported sales for a particular period to differ significantly from underlying prescriber demand.
- Regulatory issues concerning compliance with current Good Manufacturing Practice (cGMP) regulations for pharmaceutical products can lead to product recalls and seizures, interruption of production, and delays in the approvals of new products pending resolution of the cGMP issues.
- Other legal factors, including product liability or other liability claims, claims related to marketing and promotional practices asserted by federal and state governmental authorities and private payors, antitrust and pricing litigation, environmental matters, and privacy regulations can result in significant additional expense to the company. In particular, See Part I, Item 2, “Legal and Regulatory Matters”, for the discussions of the U.S. marketing practices investigations and the Zyprexa product liability litigation.
- 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, there is no assurance that we will be able to fully collect from our insurance carriers on past claims.

- Changes in tax laws, including laws related to the remittance of foreign earnings or investments in foreign countries with favorable tax rates, and settlements of federal, state, and foreign tax audits, can affect our net income.
- Economic factors over which we have no control, including changes in inflation, interest rates and foreign currency exchange rates, and overall economic conditions in volatile areas can affect our results of operations.
- Changes in accounting standards promulgated by the Financial Accounting Standards Board, the Securities and Exchange Commission, and the Emerging Issues Task Force can affect reported results.
- Our results can also be affected by internal factors, such as changes in business strategies and the impact of restructurings, asset impairments, technology acquisition and disposition transactions, and business combinations.

We undertake no duty to update forward-looking statements.