

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

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

FOR THE QUARTER ENDED SEPTEMBER 30, 2003

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 October 20, 2003:

Class	Number of Shares Outstanding
Common	1,122,904,283

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

CONSOLIDATED CONDENSED STATEMENTS OF INCOME
(Unaudited)

ELI LILLY AND COMPANY AND SUBSIDIARIES

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
	(Dollars in millions except per-share data)			
Net sales	\$3,139.4	\$2,785.6	\$9,117.0	\$8,121.9
Cost of sales	679.3	553.7	1,943.6	1,608.7
Research and development	568.1	526.7	1,640.2	1,575.0
Marketing and administrative	963.4	810.7	2,921.2	2,503.2
Acquired in-process research and development	—	84.0	—	84.0
Asset impairment, restructuring, and other special charges	—	—	353.9	—
Interest expense	15.8	22.3	51.2	55.8
Other income—net	(3.1)	(74.6)	(90.8)	(218.5)
	<u>2,223.5</u>	<u>1,922.8</u>	<u>6,819.3</u>	<u>5,608.2</u>
Income before income taxes	915.9	862.8	2,297.7	2,513.7
Income taxes	201.5	178.9	484.1	542.1
Net income	<u>\$ 714.4</u>	<u>\$ 683.9</u>	<u>\$1,813.6</u>	<u>\$1,971.6</u>
Earnings per share – basic	<u>\$.66</u>	<u>\$.64</u>	<u>\$ 1.68</u>	<u>\$ 1.83</u>
Earnings per share – diluted	<u>\$.66</u>	<u>\$.63</u>	<u>\$ 1.68</u>	<u>\$ 1.82</u>
Dividends paid per share	<u>\$.335</u>	<u>\$.31</u>	<u>\$ 1.005</u>	<u>\$.93</u>

See Notes to Consolidated Condensed Financial Statements.

CONSOLIDATED CONDENSED BALANCE SHEETS

ELI LILLY AND COMPANY AND SUBSIDIARIES

	September 30, 2003	December 31, 2002
	(Unaudited)	(Dollars in millions)
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 2,916.1	\$ 1,945.9
Short-term investments	950.9	1,708.8
Accounts receivable, net of allowances of \$71.6 (2003) and \$66.4 (2002)	1,666.2	1,670.3
Other receivables	367.8	403.9
Inventories	1,699.7	1,495.4
Deferred income taxes	424.6	331.7
Prepaid expenses	558.1	248.1
TOTAL CURRENT ASSETS	8,583.4	7,804.1
OTHER ASSETS		
Prepaid pension	1,602.1	1,515.4
Investments	3,325.2	3,150.4
Sundry	1,346.6	1,279.1
	6,273.9	5,944.9
PROPERTY AND EQUIPMENT		
Land, buildings, equipment, and construction-in-progress	10,377.4	9,546.1
Less allowances for depreciation	(4,433.9)	(4,253.1)
	5,943.5	5,293.0
	\$20,800.8	\$19,042.0
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Short-term borrowings	\$ 202.5	\$ 545.4
Accounts payable	588.3	676.9
Employee compensation	336.9	231.7
Dividends payable	—	375.8
Income taxes payable	1,789.7	1,761.9
Other liabilities	1,770.2	1,471.8
TOTAL CURRENT LIABILITIES	4,687.6	5,063.5
LONG-TERM DEBT	4,998.0	4,358.2
OTHER NONCURRENT LIABILITIES	1,630.0	1,346.7
COMMITMENTS AND CONTINGENCIES	—	—
SHAREHOLDERS' EQUITY		
Common stock	701.8	702.1
Additional paid-in capital	2,610.0	2,610.0
Retained earnings	9,438.3	8,500.1
Employee benefit trust	(2,635.0)	(2,635.0)
Deferred costs-ESOP	(119.4)	(123.3)
Accumulated other comprehensive loss	(406.3)	(670.8)
	9,589.4	8,383.1
Less cost of common stock in treasury	104.2	109.5
	9,485.2	8,273.6
	\$20,800.8	\$19,042.0

See Notes to Consolidated Condensed Financial Statements.

CONSOLIDATED CONDENSED STATEMENTS OF CASH FLOWS
(Unaudited)

ELI LILLY AND COMPANY AND SUBSIDIARIES

	Nine Months Ended September 30,	
	2003	2002
	(Dollars in millions)	
CASH FLOWS FROM OPERATING ACTIVITIES		
Net income	\$ 1,813.6	\$ 1,971.6
Adjustments to reconcile net income to cash flows from operating activities:		
Changes in operating assets and liabilities	(199.1)	(1,397.0)
Depreciation and amortization	441.9	393.3
Change in deferred taxes	157.0	343.4
Acquired in-process research and development, net of tax	—	54.6
Asset impairments, restructuring, and other special charges, net of tax	243.3	—
Other, net	23.4	9.8
NET CASH PROVIDED BY OPERATING ACTIVITIES	2,480.1	1,375.7
CASH FLOWS FROM INVESTING ACTIVITIES		
Net purchases of property and equipment	(1,048.8)	(740.0)
Net change in short-term investments	774.0	(499.4)
Purchase of noncurrent investments	(3,897.4)	(3,534.8)
Proceeds from sales and maturities of noncurrent investments	3,663.6	3,210.1
Purchase of in-process research and development	—	(84.0)
Other, net	(77.7)	(163.3)
NET CASH USED FOR INVESTING ACTIVITIES	(586.3)	(1,811.4)
CASH FLOWS FROM FINANCING ACTIVITIES		
Dividends paid	(1,082.1)	(1,002.0)
Purchase of common stock and other capital transactions	(281.1)	(243.9)
Issuances of common stock under stock plans	69.7	48.6
Net change in short-term borrowings	(237.4)	392.9
Net change in long-term debt	562.6	1,203.1
NET CASH PROVIDED BY (USED FOR) FINANCING ACTIVITIES	(968.3)	398.7
Effect of exchange rate changes on cash and cash equivalents	44.7	120.9
NET INCREASE IN CASH AND CASH EQUIVALENTS	970.2	83.9
Cash and cash equivalents at January 1	1,945.9	2,702.3
CASH AND CASH EQUIVALENTS AT SEPTEMBER 30	\$ 2,916.1	\$ 2,786.2

See Notes to Consolidated Condensed Financial Statements.

CONSOLIDATED CONDENSED STATEMENTS OF COMPREHENSIVE INCOME
(Unaudited)

ELI LILLY AND COMPANY AND SUBSIDIARIES

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
	(Dollars in millions)			
Net income	\$ 714.4	\$ 683.9	\$ 1,813.6	\$ 1,971.6
Other comprehensive income (loss) ¹	35.1	(144.6)	264.6	(26.1)
Comprehensive income	\$ 749.5	\$ 539.3	\$ 2,078.2	\$ 1,945.5

¹For the three and nine months ended September 30, 2003, other comprehensive income (loss) consisted primarily of gains of \$49.6 million from cash flow hedges and \$205.5 million, from foreign currency translation adjustments, respectively. This compares with a loss of \$118.1 million from cash flow hedges for the three months ended September 30, 2002, and a loss of \$198.5 million from cash flow hedges and net unrealized losses on securities, offset by a \$172.4 million gain from foreign currency translation adjustments for the nine months ended September 30, 2002.

See Notes to Consolidated Condensed Financial Statements.

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SEGMENT INFORMATION

We operate in one significant business segment – pharmaceutical products. Operations of the animal health business are not material and share many of the same economic characteristics as pharmaceutical products. Our business segments are distinguished by the ultimate end user of the product: humans or animals. Performance is evaluated based on profit or loss from operations before income taxes. Income before income taxes for the animal health business was \$39 million and \$42 million, respectively, for the quarter ended September 30, 2003 and 2002, and \$149 million and \$145 million, respectively, for the nine months ended September 30, 2003 and 2002.

SALES BY PRODUCT CATEGORY

Worldwide sales by product category for the three months and nine months of 2003 and 2002 were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
	(Dollars in millions)			
Net sales – to unaffiliated customers				
Neurosciences	\$1,454.2	\$1,228.8	\$4,041.0	\$3,447.3
Endocrinology	965.6	871.9	2,890.3	2,515.6
Oncology	253.8	203.8	751.8	628.0
Animal health	174.5	167.6	513.7	497.6
Cardiovascular	160.8	150.2	495.2	455.0
Anti-infectives	111.5	124.7	348.6	438.8
Other pharmaceuticals	19.0	38.6	76.4	139.6
Net sales	\$3,139.4	\$2,785.6	\$9,117.0	\$8,121.9

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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 generally accepted accounting principles accepted in the United States. In our opinion, the financial statements reflect all adjustments that are necessary for a fair presentation of the results of operations for the periods shown. All such adjustments are of a normal recurring nature. In preparing financial statements in conformity with accounting principles generally accepted in the United States, 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.

CONTINGENCIES

In February 2001, we were notified that Zenith Goldline Pharmaceuticals, Inc. (Zenith), had submitted an abbreviated new drug application (ANDA) seeking permission to market a generic version of Zyprexa® in various dosage forms several years prior to the expiration of our U.S. patents for the product. Zenith alleges that our patents are invalid or not infringed. On April 2, 2001, we filed suit against Zenith in federal district court in Indianapolis seeking a ruling that Zenith's challenge to the U.S. compound patent (expiring in 2011) is without merit. In May 2001, we were notified that Dr. Reddy's Laboratories, Ltd. (Reddy), had also filed an ANDA covering two dosage forms, alleging that the patents are invalid or not infringed. On June 26, 2001, we filed a similar patent infringement suit against Reddy in federal district court in Indianapolis. Thereafter, we were notified that Reddy had filed an ANDA for additional dosage forms, and in February 2002, we filed an infringement suit in the same court based on Reddy's additional ANDA. We received notice in August 2002 of a similar ANDA filing by Teva Pharmaceuticals, and in September 2002, we filed suit against Teva in the same court. In February 2003, we received notice that Reddy had filed an ANDA on the Zydis® formulation of Zyprexa, and in March 2003, we filed suit against Reddy in the same court. The cases have been consolidated and are in the discovery stage. In July 2003, Teva and Lilly reached an agreement under which Teva's lawsuit will be governed by the outcome of the Zenith and Reddy lawsuits. As a result, Teva will not be participating in the Zenith and Reddy lawsuit, which is now scheduled to begin on January 26, 2004. We believe 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. 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 U.S. FDA seeking permission to market a generic version of Evista® several years prior to the expiration of our U.S. patents covering the product, alleging that the patents are invalid or not infringed. On November 26, 2002, we filed suit against Barr in federal district court in Indianapolis seeking a ruling that Barr's challenges to our patents claiming the method of use and pharmaceutical form (expiring from 2012 to 2017) are without merit. In June 2003, Barr added a challenge to one of our additional patents (expiring in 2017) claiming a component in the pharmaceutical form of Evista. This patent has now been added to the lawsuit. The trial is currently scheduled to begin in February 2005. While we believe that Barr's claims are without merit and 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.

We have been named as a defendant in numerous product liability lawsuits involving primarily two products, diethylstilbestrol (DES) and thimerosal. We have accrued for the estimated exposure with respect to all current product liability claims. In addition, we have accrued for certain claims incurred, but not filed, to the extent we can formulate a reasonable estimate of their costs. We estimate these expenses based primarily on historical claims experience and data regarding product usage. We expect the cash amounts related to the accruals to be paid out over the next several years. A portion of the costs associated with defending and disposing of these suits is covered by insurance. We estimate insurance recoverables based on existing deductibles, coverage limits, and the existing and projected future level of insolvencies among the insurance carriers.

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, taking 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 primary liability insurance carrier and certain excess carriers providing for coverage for certain environmental liabilities. Litigation seeking coverage from certain other excess carriers is ongoing.

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The environmental liabilities and litigation accruals have been reflected in our consolidated balance sheet at the gross amount of approximately \$293.8 million at September 30, 2003. Estimated insurance recoverables of approximately \$85.2 million at September 30, 2003, have been reflected as assets in the consolidated balance sheet.

While it is not possible to predict or determine the outcome of the patent, product liability, or other legal actions brought against us or the ultimate cost of environmental matters, we believe that, except as noted above with respect to the Zyprexa and Evista patent litigation, the resolution of these 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 our operations in any one accounting period.

EARNINGS PER SHARE

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

STOCK-BASED COMPENSATION

We have elected to follow Accounting Principles Board (APB) Opinion 25, Accounting for Stock Issued to Employees, and related interpretations in accounting for our stock options and performance awards. Under APB 25, because the exercise price of our employee stock options equals the market price of the underlying stock on the date of grant, no compensation expense is recognized. However, Statement of Financial Accounting Standards (SFAS) 123, Accounting for Stock-Based Compensation, as amended by SFAS 148, Accounting for Stock-Based Compensation-Transition and Disclosure, requires us to present pro forma information as if we had accounted for 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 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 123 to stock-based employee compensation.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
	(Dollars in millions)			
Net income, as reported	\$ 714.4	\$ 683.9	\$1,813.6	\$1,971.6
Deduct: Compensation for stock-based performance awards included in reported net income, net of related tax effects	(13.2)	—	—	—
Deduct: Total stock-based employee compensation expense determined under fair-value-based method for all awards, net of related tax effects	(43.2)	(80.1)	(170.1)	(241.2)
Pro forma net income	\$ 658.0	\$ 603.8	\$1,643.5	\$1,730.4
Earnings per share:				
Basic, as reported	\$.66	\$.64	\$ 1.68	\$ 1.83
Basic, pro forma	\$.61	\$.56	\$ 1.53	\$ 1.61
Diluted, as reported	\$.66	\$.63	\$ 1.68	\$ 1.82
Diluted, pro forma	\$.61	\$.56	\$ 1.52	\$ 1.59

SHAREHOLDERS' EQUITY

As of September 30, 2003, we have purchased \$2.08 billion of our previously announced \$3.0 billion share repurchase program. We purchased approximately 3.0 million shares during the first nine months of 2003 at a net cost of approximately \$281.2 million. As previously disclosed, in connection with the share repurchase program, we entered into agreements to purchase shares of our stock. During the second quarter of 2003, we satisfied all our remaining obligations under the agreements.

IMPLEMENTATION OF NEW FINANCIAL ACCOUNTING PRONOUNCEMENTS

In 2001, the Financial Accounting Standards Board (FASB) issued SFAS 143, Accounting for Asset Retirement Obligations. SFAS 143 requires companies to record the fair value of a liability for an asset retirement obligation in the period in which it is incurred, which is adjusted to its present value each subsequent period. In addition, companies must capitalize a corresponding amount by increasing the carrying amount of the related long-lived asset, which is depreciated over the useful life of the related long-lived asset. The adoption of SFAS 143 on January 1, 2003, had no material impact on our consolidated financial position or results of operations.

In 2002, the FASB issued SFAS 145, Rescission of FASB Statements No. 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Corrections. SFAS 145 eliminates the classification of debt extinguishments as extraordinary items. The adoption of this statement on January 1, 2003, had no impact on these consolidated condensed financial statements.

In 2002, the FASB issued SFAS 146, Accounting for Costs Associated with Exit or Disposal Activities. SFAS 146 requires that a liability for a cost associated with an exit or disposal activity be recognized when the liability is incurred. Severance pay under SFAS 146, in many cases, would be recognized over the remaining service period rather than at the time the plan is communicated. The provisions of SFAS 146 are effective for exit or disposal activities that are initiated after December 31, 2002. We adopted SFAS 146 for any actions initiated after January 1, 2003, and any future exit costs or disposal activities will be subject to this statement.

In 2002, the FASB issued FASB Interpretation (FIN) 45, Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others. FIN 45 requires an issuer of a guarantee to recognize an initial liability for the fair value of the obligations covered by the guarantee. FIN 45 also addresses the disclosures required by a guarantor in interim and annual financial statements regarding obligations under guarantees. We have adopted the requirement for recognition of liabilities for the fair value of guaranteed obligations prospectively for guarantees entered into after January 1, 2003. We adopted the disclosure provisions as of December 31, 2002.

In 2003, the FASB issued FIN 46, Consolidation of Variable Interest Entities. FIN 46 defines a variable interest entity (VIE) as a corporation, partnership, trust, or any other legal structure that does not have equity investors with a controlling financial interest or has equity investors that do not provide sufficient financial resources for the entity to support its activities. FIN 46 requires consolidation of a VIE by the primary beneficiary of the assets, liabilities, and results of activities. FIN 46 also requires certain disclosures by all holders of a significant variable interest in a VIE that are not the primary beneficiary. We do not have any material investments in variable interest entities; therefore, the adoption of this interpretation in the fourth quarter of 2003 will not have a material impact on our consolidated financial position or results of operations.

In 2003, the FASB issued SFAS 150, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity. SFAS 150 establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. Financial instruments within the scope of SFAS 150 will now be required to be classified as a liability. This statement also requires enhanced disclosures regarding alternative methods of settling the instruments and the capital structure of entities. SFAS 150 is effective for all financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. The adoption of this statement had no impact on our consolidated financial position or results of operations.

ASSET IMPAIRMENTS, RESTRUCTURING, AND OTHER SPECIAL CHARGES

In December 2002, we initiated a plan of eliminating approximately 700 positions worldwide in order to streamline our infrastructure. While a substantial majority of affected employees were successfully placed in other positions in the company, severance expenses were incurred in the first quarter for those employees who elected a severance package. The restructuring and other special charges incurred in the first quarter were \$52.5 million, consisting primarily of voluntary severance expenses, which have been included in asset impairments, restructuring, and other special charges in our consolidated statement of income. Approximately \$34.6 million of this charge was expended during the first nine months of 2003 with the majority of the remainder expected to be expended during the next two quarters.

In addition, as part of our previously disclosed ongoing strategic review, management approved global manufacturing strategies across our product portfolio during the first quarter of 2003 to improve plant performance and efficiency, including the out-sourcing of production of certain anti-infective products. These decisions resulted in the impairment of certain assets, primarily manufacturing assets in the U.S. This review did not result in any closure of facilities, but certain assets located at various manufacturing sites were affected. We have ceased using these assets and disposal or destruction has commenced. The impairment charges were necessary to adjust the carrying value of these assets to zero. These asset impairment charges incurred in the first quarter were \$114.6 million and are included in asset impairments, restructuring, and other special charges in our consolidated statement of income.

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In August 2001, we licensed from Isis Pharmaceuticals, Inc. (Isis), Affinitak™, a non-small-cell lung cancer drug candidate and entered into an agreement regarding an ongoing research collaboration. In conjunction with this agreement, we purchased approximately 4.2 million shares of Isis common stock with a cost basis of approximately \$68.0 million and we committed to loan Isis \$100 million over the four-year term of the research agreement. The Isis loan is repayable at the end of the research agreement term in cash or Isis stock, at Isis's option, using a conversion price of \$40 per share. In addition, we committed to loan Isis \$21.2 million for the building of a manufacturing suite for Affinitak. On March 17, 2003, we announced, along with Isis, the results of the Phase III trial that evaluated Affinitak when combined with chemotherapy in patients with advanced non-small-cell lung cancer. No difference was observed in the overall survival of the two groups. Due to this announcement and the decline in Isis's stock price that occurred in the previous 12 months, we concluded in the first quarter of 2003 that our investment in Isis common stock is other-than-temporarily impaired, as defined by generally accepted accounting principles. For the same reasons, it is probable that the value of the consideration that we will be eligible to receive from Isis pursuant to the terms of the loan agreements will be less than the carrying amount of the loans. Therefore, in the first quarter of 2003, we recognized an impairment in our investment in Isis's common stock of \$55.0 million and a reserve related to the loans of \$92.9 million. In addition, we recognized a charge of \$38.9 million for contractual obligations related to Affinitak. The primary portion of this charge resulted from our supply agreement with Isis. The supply agreement obligated us to pay certain costs associated with work-in-process and raw materials and other costs that were triggered when we cancelled our order of Affinitak. The remaining portion of the charge resulted from our contractual obligations related to the conduct of Affinitak clinical trials. As of September 30, 2003, approximately \$8.7 million remained related to the original \$38.9 million. The remaining cash payments associated with the Affinitak clinical trials are expected to be made through mid-2004. The stock and loan impairments and other special charges incurred in the first quarter related to this relationship totaled \$186.8 million and have been included in the asset impairments, restructuring, and other special charges category in our consolidated statement of income.

ACQUIRED IN-PROCESS RESEARCH AND DEVELOPMENT

In the third quarter of 2002, we entered into a collaboration agreement with Amylin Pharmaceuticals, Inc. (Amylin), to jointly develop and commercialize Amylin's synthetic exendin-4 compound, a potential treatment for type 2 diabetes. This compound is in the development phase and no alternative future uses were identified. As with many development-phase compounds, launch of the product, if approved, is not expected in the near term. Our charge for acquired in-process research and development expense related to this arrangement totaled \$84.0 million in the third quarter of 2002.

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

OPERATING RESULTS

Net income was \$714.4 million, or \$.66 per share, for the third quarter of 2003 compared with \$683.9 million, or \$.63 per share, for the third quarter of 2002, representing increases in earnings and earnings per share of 5 percent, primarily due to the acquired in-process research and development charge of \$84.0 million, or \$.05 per share, recognized in the third quarter of 2002. Net income was \$1.81 billion, or \$1.68 per share, for the nine-month period of 2003 compared with \$1.97 billion, or \$1.82 per share, for the nine-month period of 2002. Net income and earnings per share for the nine-month period of 2003 decreased by 8 percent, due primarily to the asset impairments, restructuring, and other special charges recognized in the first quarter of 2003, offset, in part, by acquired in-process research and development recognized in the third quarter of 2002. Our net income was favorably affected in both periods of 2003 by increased sales of Zyprexa, Humalog®, Gemzar®, and Evista and the sales related to the launches of Strattera®, Cialis®, and Forteo®. The favorable impact of increased sales was reduced by increased cost of goods sold, increased marketing and administrative expenses, and lower net other income. Earnings per share benefited slightly from a lower number of shares outstanding, resulting from our share repurchase program.

Comparisons between years for the quarter and the nine-month period are made difficult by the impact of the asset impairments, restructuring, and other special charges that were reflected in our operating results in the first quarter of 2003 and the acquired in-process research and development charge recognized in the third quarter of 2002. These charges are summarized as follows (see Asset Impairments, Restructuring, and Other Special Charges and Acquired In-Process Research and Development in the Notes to Consolidated Condensed Financial Statements for additional information):

- We recognized severance-related and other charges in the first quarter of 2003 in order to streamline our infrastructure of \$52.5 million, which decreased earnings per share by \$.03 in the first quarter of 2003.
- We recognized asset impairments in the first quarter of 2003, primarily relating to manufacturing assets in the U.S., totaling \$114.6 million, which decreased earnings per share by approximately \$.07 in the first quarter of 2003.
- We recognized asset impairments and other charges of \$186.8 million in the first quarter of 2003 related primarily to our common stock ownership and loan agreements with Isis, which decreased earnings per share by \$.13 in the first quarter of 2003.

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- We incurred a charge for acquired in-process research and development expense related to the collaboration arrangement with Amylin in the third quarter of 2002 totaling \$84.0 million, which decreased earnings per share by approximately \$.05 in the third quarter of 2002.

Our sales for the third quarter of 2003 increased 13 percent, to \$3.14 billion, compared with the third quarter of 2002 due primarily to the strong performance of Zyprexa, Humalog, Gemzar, and Evista as well as sales from the launches of Strattera, Cialis, and Forteo. Sales in the U.S. increased 9 percent, to \$1.79 billion, for the third quarter of 2003 compared with the third quarter of 2002. Sales outside the U.S. increased 17 percent, to \$1.35 billion, for the third quarter of 2003 compared with the third quarter of 2002. Worldwide sales for the third quarter reflected a volume increase of 8 percent, a 1 percent increase in global selling prices, and a 3 percent increase due to favorable changes in exchange rates. These numbers do not add due to rounding.

Our sales for the first nine months of 2003 increased 12 percent, to \$9.12 billion, compared with the first nine months of 2002 due primarily to the strong performance of Zyprexa, Humalog, Gemzar, and Evista as well as sales from the launches of Strattera, Cialis, and Forteo. Sales in the U.S. increased 9 percent, to \$5.23 billion, for the first nine months of 2003 compared with the first nine months of 2002. Sales outside the U.S. increased 17 percent, to \$3.89 billion, for the first nine months of 2003 compared with the first nine months of 2002. Worldwide sales reflected a volume increase of 6 percent, a 2 percent increase in global selling prices, and a 4 percent increase due to favorable changes in exchange rates.

Zyprexa had worldwide sales of \$1.13 billion and \$3.13 billion for the third quarter and nine-month period of 2003, respectively, representing increases of 16 percent compared with the same periods of 2002. U.S. sales increased 4 percent, to \$707.4 million, for the quarter and 5 percent, to \$1.96 billion, for the nine-month period. Continuing competitive pressures contributed to the slower sales growth in the U.S. U.S. Zyprexa sales growth during the third quarter of 2003 benefited slightly due to wholesaler stocking. Sales outside the U.S. increased 44 percent, to \$420.2 million, for the quarter and 41 percent, to \$1.17 billion, for the nine-month period. Zyprexa's strong international sales growth was primarily driven by increased unit volume attributable to the bipolar mania indication and the ongoing conversion from typical to atypical antipsychotics, and, to a lesser extent, the impact of exchange rates. Zyprexa recorded strong growth in several key markets, including Germany, United Kingdom, France, and Japan. In September 2003, the FDA requested updated product labeling for all atypical antipsychotics that includes a warning statement about the risk of diabetes. The FDA's decision to implement class labeling reinforces our long-standing position that the risk for diabetes should be considered among patients with severe mental illness regardless of medication choice.

Diabetes care products, composed primarily of Humulin®, Humalog®, and Actos®, had worldwide revenues of \$588.7 million and \$1.86 billion for the third quarter and nine-month period of 2003, respectively, representing increases of 3 percent and 10 percent compared with the same periods of 2002. Diabetes care revenues in the U.S. decreased 2 percent, to \$335.3 million, for the quarter due primarily to a decline in Actos revenues as discussed below and increased 7 percent, to \$1.14 billion, for the nine-month period. Sales outside the U.S. increased 10 percent, to \$253.4 million, for the quarter and 16 percent, to \$724.1 million, for the nine-month period. Worldwide Humulin sales of \$264.5 million for the quarter and \$761.0 million for the nine-month period increased 3 percent and 2 percent, respectively. Worldwide Humalog sales of \$240.2 million for the quarter and \$743.1 million for the nine-month period, increased 12 and 25 percent, respectively, compared with the same periods of 2002 despite increasing competition. We expect continued increasing competition in the future for both Humulin and Humalog. We received service revenues related to sales of Actos of \$67.1 million and \$316.6 million for the third quarter and nine-month period of 2003, respectively, representing a decrease of 18 percent and an increase of 7 percent compared with the same periods of 2002. Actos is manufactured and sold in the U.S. by Takeda Chemical Industries, Ltd. (Takeda), and we copromote the product with 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 had worldwide sales of \$250.6 million and \$739.1 million for the third quarter and nine-month period of 2003, respectively, representing increases of 27 and 20 percent compared with the same periods of 2002. Sales in the U.S. increased 30 percent, to \$121.2 million, for the quarter and 14 percent, to \$378.4 million, for the nine-month period. U.S. Gemzar sales growth benefited, in part, from wholesaler destocking in the third quarter of 2002. Sales outside the U.S. increased 24 percent, to \$129.4 million, for the quarter and 28 percent, to \$360.7 million, for the nine-month period.

Evista had worldwide sales of \$240.0 million and \$677.4 million for the third quarter and nine-month period of 2003, respectively, representing increases of 10 percent and 16 percent compared with the same periods of 2002. U.S. sales increased 4 percent, to \$172.3 million, for the quarter and 9 percent, to \$484.3 million, for the nine-month period. The U.S. growth was negatively affected primarily by the continued declines in the postmenopausal health market segment due to the results of the Women's Health Initiative study and the resulting exit of patients from the osteoporosis prevention market. Sales outside the U.S. increased 32 percent, to \$67.7 million, for the quarter and 39 percent, to \$193.1 million, for the nine-month period.

Prozac®, Prozac Weekly™, and Sarafem™ (collectively "fluoxetine products") had combined worldwide sales of \$154.2 million and \$479.2 million for the third quarter and nine-month period of 2003, respectively, representing decreases of 19 percent and 16 percent

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compared with the same periods of 2002, primarily due to continued generic competition. Fluoxetine product sales in the U.S. decreased 22 percent, to \$93.1 million, for the quarter and 17 percent, to \$293.9 million, for the nine-month period. Sales outside the U.S. decreased 13 percent, to \$61.1 million, for the quarter and 15 percent, to \$185.3 million, for the nine-month period.

Anti-infectives had worldwide sales of \$111.5 million and \$348.6 million for the third quarter and nine-month period of 2003, respectively, representing decreases of 16 percent and 21 percent compared with the same periods of 2002. Lower sales of anti-infectives for both periods were due primarily to continuing competitive pressures. Sales in the U.S. increased 69 percent and decreased by 7 percent for the quarter and nine-month period to \$21.6 million and \$44.5 million, respectively. Sales outside the U.S. decreased 25 percent for the quarter and 22 percent for the nine-month period, to \$89.9 million and \$304.1 million, respectively.

ReoPro® had worldwide sales of \$88.2 million and \$275.8 million for the third quarter and nine-month period of 2003, respectively, representing decreases of 5 percent and 3 percent compared with the same periods of 2002. These decreases are primarily due to continuing competitive pressures.

In December 2002, we launched Strattera in the U.S. for the treatment of attention-deficit hyperactivity disorder (ADHD) in children, adolescents, and adults. Strattera is the first FDA-approved treatment for ADHD that is not a stimulant under the Controlled Substances Act. Strattera sales were \$108.0 million and \$237.7 million for the third quarter and nine-month period of 2003, respectively. The cumulative number of prescriptions written for Strattera doubled during the third quarter, from roughly 1 million in the first half of 2003 to more than 2 million by the end of September 2003.

Xigris® had worldwide sales of \$37.8 million and \$109.7 million for the third quarter and nine-month period of 2003, respectively, representing increases of 78 percent and 67 percent compared with the same periods of 2002. Total Xigris sales in the third quarter of 2003 were largely unchanged when compared with the second quarter of 2003. Sales in the U.S. increased 24 percent, to \$24.4 million, for the quarter and 22 percent, to \$76.1 million, for the nine-month period. Sales outside the United States were \$13.4 million for the quarter and \$33.6 million for the nine-month period.

Cialis, a treatment for erectile dysfunction was launched earlier this year by us and ICOS Corporation (ICOS). Cialis has been used to treat more than 1 million patients and is now being sold in more than 45 countries outside the U.S. Cialis had total sales of \$50.2 million and \$109.1 million for the third quarter and nine-month period, respectively. Of these total Cialis sales, \$21.8 million for the third quarter and \$42.2 million for the nine-month period of 2003 represent sales in our exclusive territories and are reported in our net sales. The remaining Cialis sales relate to the joint-venture territories of Lilly ICOS LLC and are reported in the Lilly ICOS joint venture income statement along with related expenses. We reported our 50 percent share of the net loss of the joint venture in net other income.

On November 26, 2002, the FDA approved Forteo for the treatment of osteoporosis in postmenopausal women who are at high risk for a fracture. Forteo was also approved to increase bone mass in men with primary osteoporosis who are at high risk for a fracture. Forteo was officially launched in December 2002. We received an approval in Europe during June of 2003. We expect the first launch in Europe to commence in the near future. Forteo sales were \$21.6 million in the third quarter and \$39.4 million for the nine-month period of 2003.

For the third quarter of 2003, gross margins declined to 78.4 percent compared with 80.1 percent for the third quarter of 2002. For the nine-month period of 2003, gross margins declined to 78.7 percent compared with 80.2 percent for the nine-month period of 2002. During the quarter and nine-month period, the decline was primarily due to costs associated with quality improvements as well as growth in capacity in our manufacturing operations and to the impact of foreign exchange rates, offset partially by a favorable product mix.

Operating expenses (the aggregate of research and development and marketing and administrative expenses) increased 15 percent, to \$1.53 billion, and 12 percent, to \$4.56 billion, for the third quarter and nine-month period of 2003, respectively. Investment in research and development increased 8 percent, to \$568.1 million, for the third quarter and increased 4 percent, to \$1.64 billion, for the nine-month period largely due to increased clinical trial expenses. We invested approximately 18 percent of our sales in research and development efforts in the third quarter and nine-month period of 2003. Marketing and administrative expenses increased 19 percent from the third quarter of 2002 and 17 percent from the nine-month period of 2002 attributable primarily to increased marketing expenses in support of the new and anticipated product launches.

Net other income for the third quarter of 2003 decreased \$71.5 million, to \$3.1 million. Net other income for the nine-month period of 2003 decreased \$127.7 million, to \$90.8 million. Net other income decreased in both periods primarily as a result of less income from out-licensing of development-stage products and partnered products in development and lower interest income. Also contributing to the decline were miscellaneous asset write-offs or write-downs in the normal course of business, including certain equity investments that have been determined to be other-than-temporarily impaired.

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For the third quarters of 2003 and 2002, the effective tax rate was 22.0 percent and 20.7 percent, respectively. For the nine-month periods of 2003 and 2002, the effective tax rate was 21.1 percent and 21.6 percent, respectively.

FINANCIAL CONDITION

As of September 30, 2003, cash, cash equivalents, and short-term investments totaled \$3.87 billion compared with \$3.65 billion at December 31, 2002. Cash flow from operations of \$2.48 billion was offset, to a large extent, by dividends paid of \$1.08 billion, net capital expenditures of \$1.05 billion, and net share repurchases of \$281.1 million. Total debt at September 30, 2003, was \$5.20 billion, an increase of \$296.9 million from December 31, 2002. The increase in long-term debt was due primarily to the issuance of a \$330.0 million private placement note with a financial institution in July 2003. Principal and interest are due semiannually over the five-year term of the note. In conjunction with this note, we entered into an interest rate swap agreement with the same financial institution that converts the fixed rate into a variable rate of interest at essentially LIBOR over the term of the note. Additionally, we issued \$300 million of 2.9 percent 5-year notes and \$200 million of 4.5 percent 15-year notes in March 2003. We used the net proceeds from the sale of those notes primarily for the repayment of (i) \$250 million aggregate principal amount of 4.23 percent one-year resettable notes due March 22, 2011, and (ii) \$200 million aggregate principal amount of 6.25 percent notes due March 15, 2003.

We believe that cash generated from operations in 2003, along with available cash and cash equivalents, will be sufficient to fund most of our remaining 2003 operating needs, including debt service, capital expenditures, share repurchases, and dividends. We believe that, if necessary, amounts available through existing commercial paper programs should be adequate to fund any short-term cash requirements. Various risks and uncertainties, including those discussed in the Other Matters and Financial Expectations for 2003 sections, may affect our operating results and cash generated from operations.

Our inventories increased by \$204.3 million during the nine-month period of 2003, to \$1.70 billion, due primarily to the impact of the strength of the euro and the buildup of our inventory for new product launches and our growth products.

Our prepaid expenses increased by \$310.0 million during the nine-month period of 2003, to \$558.1 million, due primarily to the funding of employee benefit plans in January 2003.

OTHER MATTERS

As a result of plant inspections for Zyprexa IntraMuscular and Forteo in early 2001, the U.S. Food and Drug Administration (FDA) informed us of a number of observations and issued a warning letter regarding adherence to current Good Manufacturing Practices (cGMP) regulations. In response, we have been implementing comprehensive, companywide improvements in our manufacturing operations. In the fall of 2002, we provided the FDA with a comprehensive plan to upgrade our manufacturing and quality operations, particularly at our injectable and dry products facilities in Indianapolis, and have been engaged since then in interactions with the agency on our plan and its ongoing implementation.

In late October 2003, the FDA advised us that the agency now considers our injectable and dry products facilities in Indianapolis to have reached a level of cGMP compliance that will allow preapproval site inspections to occur for Cymbalta™ and Zyprexa IntraMuscular, as the agency deems necessary. No further regulatory action is expected at this time. Although the FDA assessment is an important milestone, we still have considerable work to do to reach our ultimate goal of building and sustaining world-class manufacturing and quality capabilities.

Final FDA approval of Zyprexa IntraMuscular is now contingent upon successfully completing a preapproval site inspection, if necessary.

On September 29, 2003, we received an approvable letter for Cymbalta from the FDA indicating that approval was contingent upon resolution of manufacturing issues, a preapproval site inspection at the Indianapolis dry products facility, and the completion of label negotiations. Final FDA approval is now contingent upon completion of label negotiations and a preapproval site inspection. Based on resolution of these items as well as ensuring that sufficient inventory levels are in place to satisfy market demand, our best estimate for U.S. approval and launch is the summer of 2004.

With respect to Cialis, Lilly and ICOS continue to anticipate FDA approval by the end of this year.

We received an approvable letter from the FDA for Symbyax™ for the treatment of bipolar depression. We filed with the FDA our complete response letter and we expect final FDA approval in early 2004.

In September 2003, we received an approvable letter from the FDA for duloxetine for the treatment of stress urinary incontinence (SUI). Final FDA approval is contingent upon successful completion of additional acute preclinical and clinical pharmacology studies,

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completion of a preapproval site inspection, and completion of label negotiations. We currently anticipate a U.S. approval of duloxetine for SUI in late 2004 or the first half of 2005.

In September 2003, we received an approvable letter from the FDA for Zyprexa for the bipolar maintenance indication. Final approval is contingent upon label negotiations, including an additional analysis of existing data to support desired label claims. We expect final FDA approval for Zyprexa for bipolar maintenance in the first half of 2004. In addition, we received approval for Zyprexa for the prevention of the recurrence of bipolar disorder in the European Union in October 2003.

We completed three submissions during the third quarter of 2003, including the first European submission for Strattera for the treatment of attention-deficit hyperactivity disorder (ADHD), the U.S. submission for Alimta® for malignant pleural mesothelioma, and the European submission for Cymbalta for major depression. We remain on track to complete our U.S. submission for Alimta for second-line non-small-cell lung cancer (NSCLC) and European submissions for mesothelioma and second-line NSCLC by the end of this year.

On July 25, 2003, the U.S. House of Representatives approved H.R. 2427, a bill that would legalize wholesale and individual importation of prescription drugs. The FDA has opposed this bill, stating that it cannot guarantee the safety of imported medicines. The bill is now in a House-Senate conference committee that is considering the House and Senate versions of a proposed Medicare prescription drug benefit. Among other differences, the Senate importation provisions contain a requirement that the Secretary of Health and Human Services certify the safety of imported medicines. The House bill, if enacted, would adversely affect U.S. sales of our products.

FINANCIAL EXPECTATIONS FOR 2003

We are now comfortable with the Wall Street analysts' consensus per Thomson First Call. This implies earnings per share of \$2.35 for 2003, including the asset impairments, restructuring, and other special charges recognized in the first quarter of 2003 amounting to \$.23 per share, and earnings per share for the fourth quarter of \$0.67, excluding any additional unusual items. We are not aware at this time of any material unusual items that will occur in the remainder of 2003.

For the full year 2003, we expect low double-digit sales growth, gross margins as a percent of sales to contract by about 200 basis points (which includes our previously disclosed \$200 million incremental annual costs to ensure quality improvements and growth in manufacturing capacity), marketing and administrative expenses to increase in the mid-to-high teens, and research and development expenses to increase in the high-single digits. Further, we expect that other income - net, less interest expense, should contribute approximately \$70 million to \$90 million for 2003, and that the tax rate should remain essentially constant.

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 for new products, including the necessary FDA approvals of manufacturing operations in connection with pending NDAs; regulatory actions or litigation; the timing and success of new-product launches; foreign exchange rates; and the impact of state, federal, and foreign government pricing and reimbursement measures. We undertake no duty to update these forward-looking statements.

AVAILABLE INFORMATION ON OUR WEBSITE

We make available through our company website, free of charge, our company filings with the Securities and Exchange Commission (SEC) as soon as reasonably practicable after we electronically file them with or furnish them to the SEC. The reports we make available include annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements, registration statements, and any amendments to those documents.

The website link to our SEC filings is <http://investor.lilly.com/edgar.cfm>

PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995

Under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, we caution investors that any forward-looking statements or projections made by us, including those made in this document, are based on management's expectations at the time they are made, but they are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Economic, competitive, governmental, technological, and other factors that may affect our operations and prospects are discussed above and in Exhibit 99 to this Form 10-Q filing. We have no obligation to update forward-looking statements.

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Item 4. Controls and Procedures

- (a) *Evaluation of Disclosure Controls and Procedures.* Under applicable Securities and Exchange Commission 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 September 30, 2003, and concluded that they are effective.

- (b) *Changes in Internal Controls.* During the last fiscal quarter, there have been no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

In February 2001, we were notified that Zenith Goldline Pharmaceuticals, Inc. (Zenith), had submitted an abbreviated new drug application (ANDA) seeking permission to market a generic version of Zyprexa in various dosage forms several years prior to the expiration of our U.S. patents for the product. Zenith alleges that our patents are invalid or not infringed. On April 2, 2001, we filed suit against Zenith in federal district court in Indianapolis seeking a ruling that Zenith's challenge to the U.S. compound patent (expiring in 2011) is without merit. In May 2001, we were notified that Dr. Reddy's Laboratories, Ltd. (Reddy), had also filed an ANDA covering two dosage forms, alleging that the patents are invalid or not infringed. On June 26, 2001, we filed a similar patent infringement suit against Reddy in federal district court in Indianapolis. Thereafter, we were notified that Reddy had filed an ANDA for additional dosage forms, and in February 2002, we filed an infringement suit in the same court based on Reddy's additional ANDA. We received notice in August 2002 of a similar ANDA filing by Teva Pharmaceuticals, and in September 2002, we filed suit against Teva in the same court. In February 2003, we received notice that Reddy had filed an ANDA on the Zydys formulation of Zyprexa, and in March 2003, we filed suit against Reddy in the same court. The cases have been consolidated and are in the discovery stage. In July 2003, Teva and Lilly reached an agreement under which Teva's lawsuit will be governed by the outcome of the Zenith and Reddy lawsuits. As a result, Teva will not be participating in the Zenith and Reddy lawsuit, which is now scheduled to begin on January 26, 2004. We believe 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. 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 U.S. FDA seeking permission to market a generic version of Evista several years prior to the expiration of our U.S. patents covering the product, alleging that the patents are invalid or not infringed. On November 26, 2002, we filed suit against Barr in federal district court in Indianapolis seeking a ruling that Barr's challenges to our patents claiming the method of use and pharmaceutical form (expiring from 2012 to 2017) are without merit. In June 2003, Barr added a challenge to one of our additional patents (expiring in 2017) claiming a component in the pharmaceutical form of Evista. The patent has now been added to the lawsuit. The trial is currently scheduled to begin in February 2005. While we believe that Barr's claims are without merit and 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 February 2003, a law firm in San Francisco, California, issued a press release claiming that it has filed "several" lawsuits and is in the process of filing "numerous" other suits against us on behalf of plaintiffs who claim that they suffered various illnesses as a result of administration of Zyprexa. Currently, we have been served with 10 suits. We intend to vigorously defend all such suits.

We refer to Part I, Item 3 of our Form 10-K annual report for 2002 for the discussion of product liability litigation involving vaccines containing the preservative thimerosal. We have been named as a defendant in approximately 290 such suits in the U.S., involving approximately 800 claimants.

In July 2002, we received a grand jury subpoena for documents from the Office of Consumer Litigation, Department of Justice, related to our marketing practices and physician communications with respect to Evista. We received a second subpoena for documents in July 2003. We are in the process of responding to the subpoenas. We have established a number of policies and procedures designed to ensure that our marketing practices and physician communications comply with all promotional laws and regulations. However, it is possible that criminal penalties could be sought in this matter.

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In August 2003, we received notice that the staff of the U.S. Securities and Exchange Commission (SEC) is conducting an informal inquiry into the compliance by Polish subsidiaries of certain pharmaceutical companies with the U.S. Foreign Corrupt Practices Act of 1977. The staff has requested voluntary production of documents related to our Polish subsidiary. We are cooperating with the SEC in responding to its inquiry.

While it is not possible to predict or determine the outcome of the patent, product liability, or other legal actions brought against us or the ultimate cost of environmental matters, we believe that, except as noted above with respect to the Zyprexa and Evista patent litigation, the resolution of these 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 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 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

(b) Reports on Form 8-K.

We filed a Form 8-K on July 24, 2003, which furnished a copy of our press release announcing our second-quarter financial results as well as informing readers of our upcoming webcast to discuss our second-quarter financial results on the same date.

SIGNATURES

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

ELI LILLY AND COMPANY
(Registrant)

Date November 12, 2003

/S/ Alecia A. DeCoudreaux

Alecia A. DeCoudreaux
Secretary and Deputy General Counsel

Date November 12, 2003

/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 PER SHARE

(Unaudited)

ELI LILLY AND COMPANY AND SUBSIDIARIES

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
(Dollars and shares in millions except per-share data)				
BASIC				
Net income	\$ 714.4	\$ 683.9	\$1,813.6	\$1,971.6
Average number of common shares outstanding	1,076.3	1,076.8	1,076.4	1,077.0
Contingently issuable shares	—	—	—	.1
Adjusted average shares	1,076.3	1,076.8	1,076.4	1,077.1
Basic earnings per share	\$.66	\$.64	\$ 1.68	\$ 1.83
DILUTED				
Net income	\$ 714.4	\$ 683.9	\$1,813.6	\$1,971.6
Average number of common shares outstanding	1,076.3	1,076.8	1,076.4	1,077.0
Incremental shares – stock options and contingently issuable shares	5.5	8.9	5.6	9.0
Adjusted average shares	1,081.8	1,085.7	1,082.0	1,086.0
Diluted earnings per share	\$.66	\$.63	\$ 1.68	\$ 1.82

EXHIBIT 12. STATEMENT RE: COMPUTATION OF RATIO OF EARNINGS FROM CONTINUING

OPERATIONS TO FIXED CHARGES
(Unaudited)ELI LILLY AND COMPANY AND SUBSIDIARIES
(Dollars in millions)

	Nine Months Ended September 30, 2003	2002	2001	Years Ended December 31, 2000	1999	1998
Consolidated pretax income from continuing operations	\$2,297.7	\$3,457.7	\$3,506.9	\$3,858.7	\$3,245.4	\$2,653.0
Interest from continuing operations and other fixed charges	92.5	140.0	253.3	225.4	213.1	210.3
Less interest capitalized during the period from continuing operations	(41.3)	(60.3)	(61.5)	(43.1)	(29.3)	(17.0)
Earnings	\$2,348.9	\$3,537.4	\$3,698.7	\$4,041.0	\$3,429.2	\$2,846.3
Fixed charges ¹	\$ 92.5	\$ 140.0	\$ 253.3	\$ 225.4	\$ 213.2	\$ 212.5
Ratio of earnings to fixed charges	25.4	25.3	14.6	17.9	16.1	13.4

¹ Fixed charges include interest from continuing operations for all years presented and preferred stock dividends for 1998 and 1999.

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)) 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) 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
 - c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer 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 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: October 31, 2003

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)) 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) 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
 - c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer 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 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: October 31, 2003

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 September 30, 2003 (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 October 31, 2003

/S/ Sidney Taurel

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

Date October 31, 2003

/S/ Charles E. Golden

Charles E. Golden
Executive Vice President and
Chief Financial Officer

A signed original of this written statement required by Section 906 has been provided to Eli Lilly and Company and will be retained by Eli Lilly and Company and furnished to the Securities and Exchange Commission or its staff upon request.

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-Q and may be made by spokespersons 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. One can also identify them by the fact that they do not relate strictly to historical or current facts. These statements are likely to address our growth strategy, financial results, regulatory issues, 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.

- competitive factors, including new patented products or expanded indications for existing products introduced by competitors, which can lead to declining demand for our products; generic competition as patents on key products, such as Prozac®, expire; and pricing pressures, both in the U.S. and abroad, primarily from managed care groups and government agencies
- governmental factors, including federal, state, and foreign laws and regulations that affect pharmaceutical pricing, such as Medicaid, Medicare, pharmaceutical importation laws, and other laws and regulations that could, directly or indirectly, impose governmental controls on the prices at which our products are sold
- the 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, 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, resulting in delays in product launches and lost market opportunity
- regulatory issues concerning compliance with current Good Manufacturing Practice (cGMP) regulations for pharmaceutical products that can lead to product recalls and seizures, interruption of production, and delays in the approvals of new products pending resolution of the cGMP issues
- unexpected safety or efficacy concerns arising with respect to marketed products, whether or not scientifically justified, leading to product recalls, withdrawals, or declining sales
- changes in inventory levels maintained by pharmaceutical wholesalers that can cause reported sales for a particular period to differ significantly from underlying prescriber demand
- 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, such as Latin America
- legal factors, including unanticipated litigation of product liability or other liability claims, antitrust and pricing litigation, environmental matters, and patent disputes with competitors that could preclude commercialization of products or negatively affect the profitability of existing products
- 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
- changes in accounting standards promulgated by the Financial Accounting Standards Board, the Securities and Exchange Commission, the American Institute of Certified Public Accountants, and the Emerging Issues Task Force
- 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.