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 MARCH 31, 2004

COMMISSION FILE NUMBER 001-6351

ELI LILLY AND COMPANY

(Exact name of Registrant as specified in its charter)

INDIANA	35-0470950
(State or other jurisdiction of incorporation or organization)	(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 [X] No [ ]

Indicate by check mark whether the Registrant is an accelerated filer as defined in Exchange Act Rule 12b-2.

Yes [X] No [ ]

The number of shares of common stock outstanding as of April 20, 2004:

Class	Number of Shares Outstanding
Common	1,129,485,533

TABLE OF CONTENTS

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

CONSOLIDATED CONDENSED STATEMENTS OF INCOME
(Unaudited)

ELI LILLY AND COMPANY AND SUBSIDIARIES

	Three Months Ended March 31,	
	2004	2003
	(Dollars in millions except per-share data)	
Net sales	$ 3,376.9	$ 2,889.4
Cost of sales	751.7	621.3
Research and development	646.6	529.6
Marketing and administrative	1,063.9	914.5
Acquired in-process research and development	362.3	—
Asset impairments, restructuring, and other special charges	—	353.9
Interest expense	9.3	15.5
Other income — net	(72.4)	(39.3)
	2,761.4	2,395.5
Income before income taxes	615.5	493.9
Income taxes	215.1	86.9
Net income	$ 400.4	$ 407.0
Earnings per share — basic	$ .37	$ .38
Earnings per share — diluted	$ .37	$ .38
Dividends paid per share	$ .355	$ .335

See Notes to Consolidated Condensed Financial Statements.

CONSOLIDATED CONDENSED BALANCE SHEETS

ELI LILLY AND COMPANY AND SUBSIDIARIES

	March 31, 2004	December 31, 2003
	(Dollars in millions) (Unaudited)	
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 2,410.4	$ 2,756.3
Short-term investments	1,065.3	957.0
Accounts receivable, net of allowances of $81.0 (2004) and $79.5 (2003)	1,911.5	1,854.7
Other receivables	500.9	477.6
Inventories	2,039.5	1,963.0
Deferred income taxes	569.1	500.6
Prepaid expenses	302.2	249.5
TOTAL CURRENT ASSETS	8,798.9	8,758.7
OTHER ASSETS		
Prepaid pension	1,598.1	1,613.3
Investments	3,664.8	3,374.6
Sundry	1,494.0	1,392.5
	6,756.9	6,380.4
PROPERTY AND EQUIPMENT		
Land, buildings, equipment, and construction-in-progress	11,401.2	11,068.0
Less allowances for depreciation	(4,554.6)	(4,529.0)
	6,846.6	6,539.0
	$ 22,402.4	$ 21,678.1
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Short-term borrowings	$ 807.1	$ 196.5
Accounts payable	800.5	875.9
Employee compensation	326.3	387.4
Dividends payable	—	398.3
Income taxes payable	1,849.1	1,749.8
Other liabilities	1,768.1	1,942.7
TOTAL CURRENT LIABILITIES	5,551.1	5,550.6
LONG-TERM DEBT	4,503.6	4,687.8
OTHER NONCURRENT LIABILITIES	1,789.2	1,674.9
COMMITMENTS AND CONTINGENCIES	—	—
SHAREHOLDERS' EQUITY		
Common stock	706.4	702.3
Additional paid-in capital	3,008.2	2,610.0
Retained earnings	9,884.9	9,470.4
Employee benefit trust	(2,635.0)	(2,635.0)
Deferred costs-ESOP	(117.3)	(118.6)
Accumulated other comprehensive loss	(184.9)	(160.1)
	10,662.3	9,869.0
Less cost of common stock in treasury	103.8	104.2
	10,558.5	9,764.8
	$ 22,402.4	$ 21,678.1

See Notes to Consolidated Condensed Financial Statements.

CONSOLIDATED CONDENSED STATEMENTS OF CASH FLOWS
(Unaudited)

ELI LILLY AND COMPANY AND SUBSIDIARIES

	Three Months Ended March 31,	
	2004	2003
	(Dollars in millions)	
CASH FLOWS FROM OPERATING ACTIVITIES		
Net income	$ 400.4	$ 407.0
Adjustments to reconcile net income to cash flows from operating activities:		
Changes in operating assets and liabilities, net of effect of acquisition of Applied Molecular Evolution	(412.8)	(358.4)
Depreciation and amortization	147.6	144.6
Change in deferred taxes	13.2	166.2
Acquired in-process research and development	362.3	—
Asset impairments, restructuring, and other special charges, net of tax	—	243.3
Other, net	66.3	(13.7)
NET CASH PROVIDED BY OPERATING ACTIVITIES	577.0	589.0
CASH FLOWS FROM INVESTING ACTIVITIES		
Net purchases of property and equipment	(463.6)	(278.6)
Net change in short-term investments	(88.5)	374.0
Purchase of noncurrent investments	(1,342.2)	(819.1)
Proceeds from sales and maturities of noncurrent investments	1,018.1	782.1
Cash paid for acquisition of Applied Molecular Evolution, net of cash acquired	(71.7)	—
Other, net	1.7	(57.4)
NET CASH (USED IN) PROVIDED BY INVESTING ACTIVITIES	(946.2)	1.0
CASH FLOWS FROM FINANCING ACTIVITIES		
Dividends paid	(384.3)	(360.5)
Purchase of common stock and other capital transactions	—	(65.6)
Issuances of common stock under stock plans	46.5	17.7
Net change in short-term borrowings	358.6	(228.7)
Net (repayments) issuances of long-term debt	(2.3)	294.0
NET CASH PROVIDED BY (USED IN) FINANCING ACTIVITIES	18.5	(343.1)
Effect of exchange rate changes on cash and cash equivalents	4.8	11.3
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(345.9)	258.2
Cash and cash equivalents at January 1	2,756.3	1,945.9
CASH AND CASH EQUIVALENTS AT MARCH 31	$ 2,410.4	$ 2,204.1

See Notes to Consolidated Condensed Financial Statements.

CONSOLIDATED CONDENSED STATEMENTS OF COMPREHENSIVE INCOME
(Unaudited)

ELI LILLY AND COMPANY AND SUBSIDIARIES

	Three Months Ended March 31,	
	2004	2003
	(Dollars in millions)	
Net income	$ 400.4	$ 407.0
Other comprehensive income (loss)[1]	(24.8)	64.9
Comprehensive income	$ 375.6	$ 471.9

[1] The significant components of other comprehensive income (loss) were a loss of $39.9 million from cash flow hedges, partially offset by net unrealized gains on securities of $19.7 million for the three months ended March 31, 2004, compared with $33.2 million from unrealized gains on securities and $30.1 million from foreign currency translation adjustment gains for the three months ended March 31, 2003.

See Notes to Consolidated Condensed Financial Statements.

SEGMENT INFORMATION

We operate in one significant business segment — pharmaceutical products. Operations of our animal health business segment are not material and share many of the same economic and operating characteristics as our pharmaceutical products. Therefore, they are included with pharmaceutical products for purposes of segment reporting. Our business segments are distinguished by the ultimate end user of the product: humans or animals. Performance is evaluated based on profit or loss from operations before income taxes. Income before income taxes for the animal health business for the first quarter of 2004 and 2003 was $53.5 million and $57.2 million, respectively.

SALES BY PRODUCT CATEGORY

Worldwide sales by product category for the first quarter of 2004 and 2003 were as follows:

	Three Months Ended March 31,	
	2004	2003
	(Dollars in millions)	
Net sales — to unaffiliated customers:		
Neurosciences	$ 1,498.1	$ 1,225.0
Endocrinology	1,057.5	936.3
Oncology	294.1	240.7
Animal health	182.4	172.8
Cardiovascular	165.8	165.0
Anti-infectives	125.1	121.8
Other pharmaceutical	53.9	27.8
Net sales	$ 3,376.9	$ 2,889.4

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 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 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, 2003.

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, alleging that our patents are invalid or not infringed. In April 2001, we filed suit against Zenith 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. We filed similar suits in the same court against Reddy in June 2001 and Teva in September 2002. The cases have been consolidated. A trial before a district court judge in Indianapolis was held in January and February of 2004 and the parties are now in the process of submitting posttrial briefs. A ruling from the trial court is expected in the summer of 2004. Regardless of the trial court's ruling, we anticipate that appeals will follow. If we are unsuccessful at the trial court level, we cannot predict whether any of the generic companies would launch generic versions of Zyprexa prior to a final resolution of any appeals. 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., had submitted an ANDA with the U.S. Food and Drug Administration (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. 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 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. That patent has been added to the lawsuit. The suit is in discovery with a trial date currently proposed for August 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 July 2002, we received a grand jury subpoena for documents from the Office of Consumer Litigation, Department of Justice, related to our marketing and promotional practices and physician communications with respect to Evista. We received a second subpoena seeking additional documents in July 2003. 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. 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 relating to our U.S. marketing and promotional practices. Based on the information provided by the U.S. Attorney's office, we believe that the products involved include Prozac® and Zyprexa. We are cooperating with the U.S. Attorney in this investigation. It is possible that other Lilly products could become subject to these investigations. We continue to review and enhance policies and procedures designed to ensure that our marketing and promotional practices and physician communications comply with promotional laws and regulations. It is possible that the outcome of the above matters could include criminal charges and fines and/or civil penalties. We cannot predict or determine the outcome of the above 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 financial position, liquidity, and results of operations.

We have been named as a defendant in numerous product liability lawsuits involving primarily three products, diethylstilbestrol (DES), thimerosal, and Zyprexa. With respect to current claims, 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 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 liability insurance carriers providing for coverage for certain environmental liabilities.

The litigation accruals and environmental liabilities have been reflected in our consolidated condensed balance sheet at the gross amount of approximately $218.5 million at March 31, 2004. Estimated insurance recoverables of approximately $80.7 million at March 31, 2004, have been reflected as assets in the consolidated condensed 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 and the marketing and promotional practices investigations, the resolution of all such matters will not have a material adverse effect on our consolidated financial position or liquidity but could possibly be material to the consolidated results of operations in any one accounting period.

EARNINGS PER SHARE

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

STOCK-BASED COMPENSATION

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 March 31,	
	2004	2003
	(Dollars in millions)	
Net income, as reported	$ 400.4	$ 407.0
Add: Compensation expense for stock-based performance awards included in reported net income, net of related tax effects	15.2	6.2
Deduct: Total stock-based employee compensation expense determined under fair-value-based method for all awards, net of related tax effects	(67.6)	(65.1)
Pro forma net income	$ 348.0	$ 348.1
Earnings per share:		
Basic, as reported	$ .37	$ .38
Basic, pro forma	$ .32	$ .32
Diluted, as reported	$ .37	$ .38
Diluted, pro forma	$ .32	$ .32

SHAREHOLDERS' EQUITY

As of March 31, 2004, we have purchased $2.08 billion of our previously announced $3.0 billion share repurchase program. During the first quarter of 2004, we did not repurchase any stock pursuant to this program and we do not expect any significant share repurchases during the remainder of 2004.

RETIREMENT BENEFITS

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

	Defined Benefit Pension Plans		Retiree Health Benefit Plans	
	Three Months Ended March 31,		Three Months Ended March 31,	
	2004	2003	2004	2003
	(Dollars in millions)			
Components of net periodic benefit cost				
Service cost	$ 59.2	$ 46.9	$ 11.8	$ 13.0
Interest cost	70.9	66.7	17.4	17.2
Expected return on plan assets	(97.2)	(95.0)	(14.7)	(13.9)
Amortization of prior service cost	2.2	1.9	(3.9)	(3.9)
Recognized actuarial loss	20.9	12.1	16.6	12.8
Net periodic benefit cost	$ 56.0	$ 32.6	$ 27.2	$ 25.2

We previously disclosed in our consolidated financial statements for the year ended December 31, 2003, that we expected to contribute approximately $26.0 million to our defined benefit pension plans in 2004 to satisfy minimum funding requirements and an additional $300.0 million and $125.0 million of discretionary funding for our defined benefit pension plans and postretirement health benefit plans, respectively. We confirm these full-year 2004 minimum and discretionary funding expectations. As of March 31, 2004, a total of $20.0 million of contributions has been made to these plans.

IMPLEMENTATION OF NEW FINANCIAL ACCOUNTING PRONOUNCEMENTS

In 2003, the Financial Accounting Standards Board (FASB) issued FASB Interpretation (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 first quarter of 2004 had no material impact on our consolidated financial position or results of operations.

On January 12, 2004, the FASB issued FASB Staff Position (FSP) FAS106-1 regarding the accounting for the effects of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). The FSP allowed companies an opportunity to assess the effect of the MMA on their retirement-related benefit costs and obligations and reflect the effects in the 2003 financial statements, pursuant to SFAS 106, Employer's Accounting for Postretirement Benefits Other Than Pensions. Companies were also allowed to defer accounting for the effects of the MMA until the first interim or annual period beginning after June 15, 2004. We elected to defer accounting for the effects of the MMA in accordance with the FSP. As a result, the accumulated postretirement benefit obligation and net periodic postretirement benefit cost in the consolidated financial statements do not reflect the effects of the MMA on the plan. Final authoritative guidance on the accounting for the federal subsidy, one of the provisions of the MMA, is pending and that guidance, when issued, could require us to change previously reported information.

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 common stock was derived using a per-share value of $74.14, which was our average closing stock price for February 11 and 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, inflammatory diseases, and critical care as well as 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 of $9.6 million has been recorded as goodwill. 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. Although we do not anticipate any significant adjustments, to the extent that our estimates used in the purchase accounting need to be refined, we will do so upon making that determination but not later than one year from the date of acquisition.

	Estimated Fair Value at February 12, 2004
	(Dollars in millions)
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	$ 442.8

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.

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 of 2003 for those employees who elected a severance package. The restructuring and other special charges incurred in the first quarter of 2003 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 condensed statement of income. As of March 31, 2004, all this charge had been expended.

In addition, as part of our previously disclosed ongoing strategic review, management approved global manufacturing strategies across our product portfolio during 2003 to improve plant performance and efficiency, including the outsourcing 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 all these assets have been disposed of or their destruction commenced by March 31, 2004. The impairment charges were necessary to adjust the carrying value of these assets to zero. These asset impairment charges incurred in the first quarter of 2003 totaled $114.6 million and are included in asset impairments, restructuring, and other special charges in our consolidated condensed statement of income.

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 was other-than-temporarily impaired as defined by generally accepted accounting principles. For the same reasons, it was 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 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 canceled 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 March 31, 2004, substantially all our contractual obligations had been fulfilled. The stock and loan impairments and other special charges incurred in the first quarter of 2003 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 condensed statement of income.

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

OPERATING RESULTS

Executive Overview

Net income was $400.4 million, or $.37 per share, for the first quarter of 2004 compared with $407.0 million, or $.38 per share, for the first quarter of 2003. Income before income taxes increased 25 percent, to $615.5 million, driven by growth in sales of 17 percent and an increase in net other income. This increase was more than offset by higher income taxes in the first quarter of 2004 as a result of the nondeductibility of the acquired IPR&D charge related to the AME acquisition. As a result, net income and diluted earnings per share decreased 2 and 3 percent, respectively, in the first quarter of 2004.

Comparisons between the three-month periods ended March 31, 2004 and 2003, are also influenced by the following items that are reflected in our operating results (see Notes to Consolidated Condensed Financial Statements for additional information).

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.

2003

- We streamlined our infrastructure in the first quarter of 2003, resulting in severance-related and other charges of $52.5 million (pretax), which decreased earnings per share by $.03.
- We recognized asset impairments, primarily relating to manufacturing assets in the U.S., totaling $114.6 million (pretax) in the first quarter of 2003, which decreased earnings per share by $.07.
- Separately, we recognized asset impairments and other charges of $186.8 million (pretax) in the first quarter of 2003 related primarily to our common stock ownership and loan agreements with Isis Pharmaceuticals, Inc. (Isis), which decreased earnings per share by $.13.

Recent product launches and other significant events impacting our business:

- Alimta®, a treatment for malignant pleural mesothelioma, was launched in the U.S. in February.
- Zyprexa IntraMuscular, the rapid-acting injectable formulation of Zyprexa to control acute agitation in patients suffering from schizophrenia and bipolar mania, was launched in the U.S. in April.
- Evista was granted approval by Japan's Ministry of Health, Labor and Welfare in January for the treatment of osteoporosis for postmenopausal women and we expect to launch the product in Japan in May.
- Duloxetine for the treatment of moderate-to-severe stress urinary incontinence (SUI) in women was recommended for approval by the European Committee for Proprietary Medicinal Products in March. Marketing authorization by the European Commission and subsequent launch of the product is expected later this year.
- We are in the process of rolling out the global launches of six important products, indications, or formulations — Alimta, Cialis®, Forteo®, Symbyax™, Zyprexa IntraMuscular, and Zyprexa for bipolar maintenance.
- Cymbalta™, a treatment for depression, received an approvable letter from the FDA in the fall of 2003. We currently anticipate an approval and launch in the summer of 2004.
- The Zyprexa patent trial was held in January and February. A ruling from the U.S. district court judge is expected this summer.

- 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. We believe that the products involved include Prozac and Zyprexa.

Additional information regarding these significant events is included in the Notes to Consolidated Condensed Financial Statements and elsewhere in Part I, Item 2, Management's Discussion and Analysis of Financial Condition and Results of Operations.

Sales

First quarter 2004 sales growth of 17 percent was primarily driven by sales growth of our major products, including Zyprexa, Gemzar®, and Evista as well as growing sales from our newer products, consisting of Alimta, Cialis, Forteo, Strattera®, Symbyax, and Xigris®. Sales in the U.S. increased by $204.4 million, or 12 percent, for the first quarter of 2004 compared with the first quarter of 2003. Sales outside the U.S. increased $283.1 million, or 24 percent, for the first quarter of 2004. Worldwide sales volume increased 10 percent, while exchange rates and selling prices increased sales by 5 and 2 percent, respectively.

The following table summarizes our net sales activity for the three-month periods ended March 31, 2004 and 2003:

Product	Three Months Ended March 31, 2004			Three Months Ended March 31, 2003	Percent Change
	U.S.[1]	Outside U.S.	Total	Total	from 2003
			(Dollars in millions)		
Zyprexa	$ 620.9	$ 477.4	$ 1,098.3	$ 958.3	15
Gemzar	128.1	150.9	279.0	233.9	19
Humalog	167.6	99.6	267.2	248.8	7
Humulin	109.1	140.3	249.4	241.0	4
Evista	160.3	72.5	232.8	214.0	9
Animal health products	69.4	113.0	182.4	172.8	6
Fluoxetine products	103.4	61.6	165.0	149.9	10
Actos	130.0	23.3	153.3	133.2	15
Strattera	140.4	0.7	141.1	55.0	NM
Anti-infectives	27.9	97.2	125.1	121.8	3
ReoPro	45.4	48.3	93.7	93.1	1
Xigris	32.2	16.4	48.6	35.9	36
Forteo	36.7	4.1	40.8	4.1	NM
Symbyax	33.7	—	33.7	—	NM
Cialis[2]	0.3	33.0	33.3	4.9	NM
Alimta	11.6	—	11.6	—	NM
Other pharmaceutical products	79.7	141.9	221.6	222.7	—
Total net sales	$ 1,896.7	$ 1,480.2	$ 3,376.9	$ 2,889.4	17

NM — Not meaningful

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

[2] Cialis had worldwide first-quarter 2004 sales of $108.3 million compared with fourth-quarter 2003 sales of $94.2 million. Fourth-quarter 2003 sales also included stocking activity to prepare for the launch in the U.S. The sales shown in the table 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-Symbyax franchise sales increased 18 percent, to $1.13 billion, in the first quarter of 2004 compared with the first quarter of 2003. Zyprexa sales in the U.S. increased 2 percent in the first quarter of 2004 compared with the first quarter of 2003. This increase was a result of the overall increase in the average dose sold, an increase in volume in the institutional market, and a

reduction in wholesaler destocking, partially offset by lower prescription volume in the U.S. retail market due to continuing competitive pressures. Sales outside the U.S. increased 36 percent, primarily driven by strong volume growth in a number of major markets and a favorable impact of exchange rates. Excluding the impact of exchange rates, sales of Zyprexa outside the U.S. increased by 20 percent. Zyprexa IntraMuscular has recently been launched in the U.S., Australia, Canada, and Europe. In addition, we launched Zyprexa for bipolar maintenance in the U.S. in January 2004 and we are currently launching Zyprexa for bipolar maintenance in Europe.

Symbyax was launched in the U.S. in January 2004. Symbyax combines olanzapine (the active ingredient in Zyprexa) and fluoxetine (the active ingredient in Prozac) to treat bipolar depression. Symbyax is the first FDA-approved medication for this difficult-to-treat condition. The first-quarter sales included approximately $30 million of initial stocking. Initial prescription volume was in line with our expectations.

Diabetes care products, composed primarily of Humalog®, Humulin®, and Actos®, had worldwide net sales of $681.1 million in the first quarter of 2004, an increase of 8 percent compared with the same period last year. Diabetes care revenues in the U.S. decreased 1 percent, to $413.3 million, while revenues outside the U.S. increased 24 percent, to $267.8 million. Humalog and Humulin sales in the U.S. decreased 1 percent and 9 percent, respectively, in the first quarter of 2004 due to continuing competitive pressures. Humalog and Humulin sales outside the U.S. increased 27 percent and 16 percent, respectively, during the first quarter of 2004. Actos revenues, the majority of which represent service revenues from a copromotion agreement in the U.S. with Takeda Pharmaceuticals North America (Takeda), increased 15 percent in 2004. 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.

The growth in Gemzar sales in the first quarter of 2004 comprised a 2 percent increase in the U.S. and a 40 percent increase outside the U.S. A price decrease for Gemzar in the U.S. occurred in January 2004. After being granted an exemption from the new Medicare reimbursement calculations, the price of Gemzar was increased April 1, 2004. The FDA granted a six-month review for Gemzar in combination with paclitaxel for the treatment of metastatic breast cancer following our submission in December 2003.

Evista sales in the U.S. increased 4 percent in the first quarter of 2004, driven by price increases and wholesaler buying patterns, offset partially by a decline in U.S. prescription volume resulting from the continued declines in the postmenopausal osteoporosis prevention market. Evista sales outside the U.S. increased 20 percent in the first quarter of 2004 compared with 2003. We expect to launch Evista in Japan in the second quarter of 2004 for the treatment of osteoporosis for postmenopausal women.

Strattera, the only nonstimulant medicine approved for the treatment of attention-deficit hyperactivity disorder (ADHD) in both children and adults, generated $141.1 million of sales during the first quarter of 2004 compared with $132.6 million of sales in the fourth quarter of 2003. Strattera was launched in the U.S. in January 2003. The American Academy of Child and Adolescent Psychiatry recently issued guidelines for the diagnosis and treatment of ADHD. The guidelines list Strattera as a first-line therapy option for ADHD.

Xigris had first-quarter 2004 sales growth of 20 percent in the U.S., while sales outside the U.S. increased 81 percent during the same period.

Forteo, a treatment for both men and postmenopausal women suffering from osteoporosis, was launched in December 2002. First-quarter 2004 sales were $40.8 million compared with fourth-quarter 2003 sales of $25.9 million, representing a sequential increase of 58 percent. The sales growth of the product has benefited slightly from the phased launch in major European countries.

Cialis was launched in the U.S. in December 2003. The $108.3 million of worldwide Cialis sales in the first quarter of 2004 comprises $33.3 million of sales in our territories, which are reported in our net sales, and $75.0 million of sales in the joint-venture territories. Within the joint-venture territories, the U.S. sales of Cialis were $32.8 million in its first full quarter on the market. After only four months on the U.S. market, Cialis surpassed Levitra®* (vardenafil HCl) in weekly share of new and total prescriptions written.

*Levitra® is a registered trademark of Bayer Pharmaceuticals Corporation

Alimta, a treatment for malignant pleural mesothelioma, was launched in the U.S. in February 2004. In addition, we have submitted Alimta for approval for second-line non-small-cell lung cancer (NSCLC) in the U.S. and malignant pleural mesothelioma

and second-line NSCLC in Europe. First-quarter 2004 results in the U.S. included approximately $7 million of wholesaler stocking activities. We are pleased by initial sales results for Alimta.

Gross Margin, Costs, and Expenses

For the first quarters of 2004, gross margins declined 0.8 percentage points, to 77.7 percent of net sales. This decrease was due to foreign exchange rates, costs associated with quality improvements, and growth in capacity in our manufacturing operations, offset partially by a favorable sales mix of higher margin products.

Operating expenses (the aggregate of research and development and marketing and administrative expenses) increased 18 percent for the first quarter of 2004 compared with the first quarter of 2003. Investment in research and development increased 22 percent, to $646.6 million, due to increased clinical trial expenses, increased incentive compensation and benefits expense, and the impact of foreign exchange rates. Marketing and administrative expenses increased 16 percent, to $1.06 billion, in the first quarter of 2004, primarily attributable to selling and marketing expenses in support of the new and anticipated product launches, the impact of foreign exchange rates, and increased incentive compensation and benefits expense.

Net other income for the first quarter of 2004 increased $33.1 million, to $72.4 million. This increase was primarily due to income related to a previously assigned patent arrangement of $30.0 million and the outlicensing of legacy products, offset partially by an increase in the net loss of the Lilly ICOS LLC joint venture, due primarily to increased marketing costs.

For the first quarters of 2004 and 2003, the effective tax rates were 34.9 percent and 17.6 percent, respectively. The first-quarter 2004 effective tax rate was affected by the charge for acquired IPR&D related to the AME acquisition, which is not deductible for tax purposes.

FINANCIAL CONDITION

As of March 31, 2004, cash, cash equivalents, and short-term investments totaled $3.48 billion compared with $3.71 billion at December 31, 2003. Cash flow from operations of $577.0 million was more than offset by dividends paid of $384.3 million and net capital expenditures of $463.6 million. Total debt at March 31, 2004, was $5.31 billion, an increase of $426.4 million from December 31, 2003. The increase in debt was primarily due to the issuance of commercial paper.

We believe that cash to be generated from operations in 2004, along with available cash and cash equivalents, will be sufficient to fund most of our remaining 2004 operating needs, including debt service, capital expenditures, and dividends. We will likely issue additional debt in the remainder of 2004 to fund remaining cash requirements. We believe that, if necessary, amounts available through existing commercial paper programs should be adequate to fund maturities of short-term borrowings. Various risks and uncertainties, including those discussed in the Other Matters and Financial Expectations for 2004 sections, may affect our operating results and cash generated from operations.

OTHER 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, alleging that our patents are invalid or not infringed. In April 2001, we filed suit against Zenith 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. We filed similar suits in the same court against Reddy in June 2001 and Teva in September 2002. The cases have been consolidated. A trial before a district court judge in Indianapolis was held in January and February of 2004 and the parties are now in the process of submitting posttrial briefs. A ruling from the trial court is expected in the summer of 2004. Regardless of the trial court’s ruling, we anticipate that appeals will follow. If we are unsuccessful at the trial court level, we cannot predict whether any of the generic companies would launch generic versions of Zyprexa prior to a final resolution of any appeals. 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 July 2002, we received a grand jury subpoena for documents from the Office of Consumer Litigation, Department of Justice, related to our marketing and promotional practices and physician communications with respect to Evista. We received a second subpoena seeking additional documents in July 2003. 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. 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 relating to our U.S. marketing and promotional practices. Based on the information provided by the U.S. Attorney's office, we believe that the products involved include Prozac and Zyprexa. We are cooperating with the U.S. Attorney in this investigation. It is possible that other Lilly products could become subject to these investigations. We continue to review and enhance policies and procedures designed to ensure that our marketing and promotional practices and physician communications comply with promotional laws and regulations. It is possible that the outcome of the above matters could include criminal charges and fines and/or civil penalties. We cannot predict or determine the outcome of the above 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 financial position, liquidity, and results of operations.

Cymbalta, a treatment for depression, received an approvable letter from the FDA in the fall of 2003. The FDA has indicated that it does not currently believe a preapproval inspection for Cymbalta will be necessary. However, a preapproval inspection remains at the discretion of the FDA. We have submitted our complete response to the approvable letter and we expect U.S. approval and launch in the summer of 2004.

In March, the European Committee for Proprietary Medicinal Products recommended to the European Commission that approval should be granted for duloxetine for the treatment of moderate-to-severe SUI in women. If approved, duloxetine will be the first widely approved pharmaceutical treatment for SUI and will be marketed in the European Union by Lilly under the brand name Yentreve® and by Boehringer Ingelheim. Marketing authorization by the European Commission and subsequent launch of the product is expected later this year.

FINANCIAL EXPECTATIONS FOR 2004

For the second quarter of 2004, excluding unusual items, we expect earnings per share to be in the range of $.67 to $.69. Including the per-share impact of $.33 for the acquired IPR&D charge related to the acquisition of AME in the first quarter of 2004, we expect earnings per share for 2004 to be in the range of $2.47 to $2.52, excluding future unusual items. We are not currently aware of any material unusual items that will occur in the remainder of 2004. For the full-year 2004, we expect low double-digit sales growth. As previously disclosed, despite an increasingly competitive environment, we expect global sales growth for Zyprexa and believe the Zyprexa-Symbyax franchise has growth potential in the U.S. We expect U.S. sales to benefit from the recent launches of Symbyax as well as the bipolar maintenance indication and injectable formulation for Zyprexa. We will continue to monitor the U.S. performance of Zyprexa. In addition, we continue to expect gross margins as a percent of sales to be essentially flat compared with the prior year, marketing and administrative expenses to grow in the low double digits, and research and development expenses to grow in the mid-teens. Further, we expect that other income/deductions (net other income less interest expense) will be approximately $120 million for 2004. We expect the effective tax rate for the remaining three quarters of 2004 to return to a rate of approximately 22 percent. As a result, we expect the reported tax rate for 2004 to increase slightly from 2003, due to the nondeductibility of the acquired IPR&D charge related to the AME acquisition in the first quarter of 2004.

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; other regulatory developments and government investigations; and the impact of governmental actions regarding pricing, importation, and reimbursement for pharmaceuticals. In particular, as described below under Legal Proceedings, certain generic pharmaceutical manufacturers have challenged our U.S. compound patent for Zyprexa. A trial court decision on the challenge is expected during the summer. If the decision is unfavorable and the generic companies launch generic olanzapine prior to resolution of appeals, our financial results would be very negatively affected.

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.

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 March 31, 2004, and concluded that they are effective.

(b) *Changes in Internal Controls.* During the first quarter of 2004, there were no changes in our internal control over financial reporting that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

Certain generic manufacturers have challenged our U.S. compound patent for Zyprexa and are seeking permission to market generic versions of Zyprexa prior to the patent expiration in 2011. The trial regarding the defense of these patents was held in January and February 2004 and a ruling is expected in the summer of 2004. Regardless of the outcome of the court's ruling, we anticipate that appeals will follow. If we are unsuccessful at the trial court level, it is possible that some of the generic manufacturers would launch generic versions of Zyprexa prior to a final resolution of the appeals. While we cannot predict or determine the outcome of this litigation, an unfavorable outcome would have a material adverse effect on our consolidated financial position, liquidity, and results of operations.

In 2002, the Office of Consumer Litigation, Department of Justice instituted a grand jury investigation related to our U.S. marketing and promotional practices and physician communications with respect to Evista. That investigation is ongoing. In addition, in March 2004, we were notified that the office of the U.S. Attorney for the Eastern District of Pennsylvania has commenced a civil investigation relating to our U.S. marketing and promotional practices. Based on the information provided by the U.S. Attorney's office, we believe that the products involved include Prozac and Zyprexa. We are cooperating with the government in these investigations. It is possible that the outcome of these investigations could include criminal charges and fines and/or civil penalties. While we cannot predict or determine the outcome of these matters, it is possible that an adverse outcome could have a material adverse effect on our consolidated financial position, liquidity, and results of operations.

See Part I, Item 2, Other Matters, for more information on these matters.

In October 2002, we were notified that Barr Laboratories, Inc., had submitted an ANDA with the U.S. Food and Drug Administration (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. 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 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. That patent has been added to the lawsuit. The suit is in discovery with a trial date currently proposed for August 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 refer to Part I, Item 3, of our Form 10-K annual report for 2003 for the discussion of product liability litigation involving vaccines containing the preservative thimerosal. We have been named as a defendant in approximately 340 such suits with 915 claimants.

We have been named in approximately 25 product liability cases in the United States involving plaintiffs claiming a variety of injuries from the administration of Zyprexa. Most of the cases allege that the product caused or contributed to diabetes or high blood glucose levels. We are vigorously defending these suits. All the federal cases will be transferred to Judge Jack Weinstein in the Federal District Court for the Eastern District of New York for pretrial proceedings. A motion requesting certification of a nationwide class action on behalf of those who allegedly suffered injuries from the administration of Zyprexa was filed in the Federal District Court for the Eastern District of New York on April 16, 2004.

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 and the marketing and promotional practices investigations, 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. Changes in Securities, Use of Proceeds and Issuer Purchases of Equity Securities

The following table summarizes the activity related to repurchases of our equity securities during the three-month period ended March 31, 2004:

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)
January 1, 2004, through January 31, 2004	11	$ 69.25	—	$ 920.0
February 1, 2004, through February 29, 2004	73	71.90	—	920.0
March 1, 2004, through March 31, 2004	44	65.62	—	920.0
Total	128		—	

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 March 31, 2004, we have purchased $2.08 billion related to this program. During the first quarter of 2004, no shares were repurchased pursuant to this program and we do not expect to purchase any shares under this program during the remainder of 2004. The amounts presented in columns (a) and (b) above represent purchases of common stock related to employee stock option exercises.

Item 4. Submission of Matters to a Vote of Security Holders

We held our annual meeting of shareholders on April 19, 2004. The following is a summary of the matters voted on at the meeting:

(a) The four nominees for director were elected to serve three-year terms ending in 2007, as follows:

Nominee	For	Withhold Vote
Steven C. Beering, M.D.	966,216,149	23,059,251
Sir Winfried Bischoff	959,712,071	29,563,329
Franklyn G. Prendergast, M.D., Ph.D.	960,996,129	28,279,271
Kathi P. Seifert	960,544,185	28,731,215

(b) The appointment of Ernst & Young LLP as our principal independent auditors was ratified by the following shareholder vote:

For:	957,312,540
Against:	26,124,624
Abstain:	5,838,236

(c) By the following vote, the shareholders approved the Eli Lilly and Company Bonus Plan:

For:	933,937,494
Against:	46,427,417
Abstain:	8,910,489

(d) By the following vote, the shareholders did not approve the proposal requesting specified limits on the compensation of senior executives:

For:	56,661,544
Against:	801,724,611
Abstain:	11,207,140
Broker Nonvote:	119,682,105

(e) By the following vote, the shareholders did not approve the proposal requesting that the board of directors report on how the company will respond to pressure to increase access to and affordability of prescription drugs:

For:	61,759,668
Against:	738,350,079
Abstain:	69,483,548
Broker Nonvote:	119,682,105

Item 6. Exhibits and Reports on Form 8-K

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

EXHIBIT 10. Eli Lilly and Company Bonus Plan

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 January 29, 2004, which furnished a copy of our press release announcing our fourth-quarter and full-year 2003 financial results as well as informing readers of our upcoming webcast to discuss our fourth-quarter and full-year 2003 financial results on the same date.

We filed a Form 8-K on March 9, 2004, consisting of our 2003 audited consolidated financial statements and management’s discussion and analysis, as this financial information was made available at an investor conference in which we were participating.

We filed a Form 8-K on March 25, 2004, reporting that we had been advised that the U.S. Attorney for the Eastern District of Pennsylvania had commenced an investigation relating to the company’s U.S. marketing and promotional practices.

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 May 7, 2004

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

Date May 7, 2004

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

INDEX TO EXHIBITS

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

Exhibit	
10.	Eli Lilly and Company Bonus Plan*
11.	Statement re: Computation of Earnings per Share
12.	Statement re: Computation of Ratio of Earnings From Continuing Operations to Fixed Charges
31.1	Rule 13a-14(a) Certification of Sidney Taurel, Chairman of the Board, President, and Chief Executive Officer
31.2	Rule 13a-14(a) Certification of Charles E. Golden, Executive Vice President and Chief Financial Officer
32.	Section 1350 Certification
99.	Cautionary Statement Under Private Securities Litigation Reform Act of 1995 — “Safe Harbor” for Forward-Looking Disclosures

* Incorporated by reference from Appendix B to our Proxy Statement dated March 12, 2004.

EXHIBIT 11. STATEMENT RE: COMPUTATION OF EARNINGS PER SHARE

(Unaudited)

ELI LILLY AND COMPANY AND SUBSIDIARIES

	Three Months Ended March 31,	
	2004	**2003**
BASIC		
Net income	$ 400.4	$ 407.0
Average number of common shares outstanding	1,080.3	1,076.1
Contingently issuable shares	—	—
Adjusted average shares	1,080.3	1,076.1
Basic earnings per share	$ .37	$ .38
DILUTED		
Net income	$ 400.4	$ 407.0
Average number of common shares outstanding	1,080.3	1,076.1
Incremental shares — stock options and contingently issuable shares	6.7	7.1
Adjusted average shares	1,087.0	1,083.2
Diluted earnings per share	$ .37	$ .38

Dollars and shares in millions except per-share data.

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)

	Three Months Ended March 31, 2004	Years Ended December 31, 2003	2002	2001	2000	1999
Consolidated pretax income from continuing operations	$ 615.5	$ 3,261.7	$ 3,457.7	$ 3,506.9	$ 3,858.7	$ 3,245.4
Interest from continuing operations and other fixed charges	32.3	121.9	140.0	253.3	225.4	213.1
Less interest capitalized during the period from continuing operations	(23.0)	(60.9)	(60.3)	(61.5)	(43.1)	(29.3)
Earnings	$ 624.8	$ 3,322.7	$ 3,537.4	$ 3,698.7	$ 4,041.0	$ 3,429.2
Fixed charges	$ 32.3	$ 121.9	$ 140.0	$ 253.3	$ 225.4	$ 213.2
Ratio of earnings to fixed charges	19.3	27.3	25.3	14.6	17.9	16.1

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

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 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 that 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: April 30, 2004

By: /s/ Sidney Taurel
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

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 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 that 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: April 30, 2004

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 March 31, 2004 (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 April 30, 2004

/s/ Sidney Taurel

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

Date April 30, 2004

/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-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, 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.

– 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 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

– 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

– 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, that could cause us to lose market exclusivity for, or preclude commercialization of, our products

– 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

– other legal factors, including product liability or other liability claims, marketing and promotional practices investigations, antitrust and pricing litigation, and environmental matters

– 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

– 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

– 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.