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, 1999

COMMISSION FILE NUMBER 1-6351

## 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 $15(\mathrm{~d})$ 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

The number of shares of common stock outstanding as of April 30, 1999:

Class Number of Shares Outstanding

Common
$1,100,883,804$

## Item 1. Financial Statements

## CONSOLIDATED CONDENSED STATEMENTS OF INCOME (Unaudited) <br> Eli Lilly and Company and Subsidiaries

|  | Three Months Ended March 31, |  |
| :---: | :---: | :---: |
|  | 1999 | 1998 |
|  | (Dollars in millions except per-share data) |  |
| Net sales. | \$2,255.6 | \$2, 087.0 |
| Cost of sales. | 493.5 | 457.3 |
| Research and development | 413.1 | 362.9 |
| Marketing and administrative. | 592.9 | 543.5 |
| Asset impairment | 61.4 | - |
| Interest expense. | 43.9 | 47.9 |
| Other (income) expense - net | 107.3 | (27.9) |
|  | 1,712.1 | 1,383.7 |
| Income from continuing operations before income taxes and extraordinary item | 543.5 | 703.3 |
| Income taxes. | 92.1 | 171.7 |
| Income from continuing operations before extraordinary item. | 451.4 | 531.6 |
| Income (loss) from discontinued operations, net of tax...... | 174.3 | (3.3) |
| Extraordinary item - loss on early redemption of debt, net of tax. | - | (7.2) |
| Net income. | \$ 625.7 | \$ 521.1 |
| EARNINGS PER SHARE BASIC: |  |  |
| Income from continuing operations before extraordinary item. | \$ . 41 | \$ . 48 |
| Discontinued operations.. | . 16 | - |
| Extraordinary item. | - | (.01) |
| Net income. | \$ . 57 | \$ . 47 |
| EARNINGS PER SHARE DILUTED: |  |  |
| Income from continuing operations before extraordinary item. | \$ . 40 | \$ . 47 |
| Discontinued operations.................. | . 16 |  |
| Extraordinary item.. | - | (.01) |
| Net income. | \$ . 56 | \$ . 46 |
| Dividends paid per share. | \$ . 23 | \$ . 20 |

See Notes to Consolidated Condensed Financial Statements.

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CONSOLIDATED CONDENSED BALANCE SHEETS
    (Unaudited)
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Eli Lilly and Company and Subsidiaries

| ASSETS |  |  |
| :---: | :---: | :---: |
| CURRENT ASSETS |  |  |
| Cash and cash equivalents. | \$ 2,404.4 | \$ 1,495.7 |
| Short-term investments. | 46.1 | 101.4 |
| Accounts receivable, net of allowances |  |  |
| and \$64.3 (1998). | 1,465.6 | 1,967.9 |
| Other receivables. | 221.3 | 275.8 |
| Inventories. | 929.8 | 999.9 |
| Deferred income taxes | 311.5 | 332.7 |
| Prepaid expenses. | 321.8 | 233.4 |
| TOTAL CURRENT ASSETS. | 5,700.5 | 5,406.8 |
| OTHER ASSETS |  |  |
| Prepaid retirement | 614.9 | 612.3 |
| Investments. | 158.5 | 204.0 |
| Goodwill and other intangibles, net of |  |  |
| \$111.8 (1999) and \$171.4 (1998) | 120.7 | 1,517.9 |
| Sundry............................ | 778.2 | 758.2 |
|  | 1,672.3 | 3,092.4 |
| PROPERTY AND EQUIPMENT |  |  |
| Land, buildings, equipment, and |  |  |
| construction-in-progress.... | 7,036.2 | 7,274.5 |
|  | 3,183.4 | 3,178.2 |
|  | 3,852.8 | 4,096.3 |
|  | \$11, 225.6 | \$12,595. 5 |


| LIABILITIES AND SHAREHOLDERS' EQUITY |  |  |
| :---: | :---: | :---: |
| CURRENT LIABILITIES |  |  |
| Short-term borrowings | \$ 356.7 | \$ 181.4 |
| Accounts payable. | 319.0 | 1,186.0 |
| Employee compensation. | 304.3 | 704.0 |
| Dividends payable. | - | 252.9 |
| Income taxes payable | 1,170.2 | 1,290.2 |
| Other liabilities | 968.7 | 992.7 |
| TOTAL CURRENT LIABILITIES. | 3,118.9 | 4,607.2 |
| LONG-TERM DEBT. | 1,982.2 | 2,185.5 |
| DEFERRED INCOME TAXES. | 234.4 | 247.9 |
| RETIREE MEDICAL BENEFIT OBLIGATION. | 106.8 | 114.7 |
| OTHER NONCURRENT LIABILITIES. | 923.3 | 1,010.6 |
|  | 3,246.7 | 3,558.7 |
| COMMITMENTS AND CONTINGENCIES. | - | - |
| SHAREHOLDERS' EQUITY |  |  |
| Common stock. | 688.3 | 686.5 |
| Retained earnings | 4,797.2 | 4,228.8 |
| Deferred costs-ESOP. | (144.8) | (146.9) |
| Accumulated other comprehensive income | (372.4) | (229.8) |
|  | 4,968.3 | 4,538.6 |
| Less cost of common stock in treasury. | 108.3 | 109.0 |
|  | 4,860.0 | 4,429.6 |
|  | \$11, 225.6 | \$12,595.5 |

See Notes to Consolidated Condensed Financial Statements.

## Eli Lilly and Company and Subsidiaries

M.
Three Months Ended
March 31,

[^0]|  |  |  |
| :---: | :---: | :---: |
|  | 1999 | 1998 |
|  | ( D |  |
| Net income. | \$ 625.7 | \$521.1 |
| Other comprehensive income (loss)/1/. | (142.6) | (11.0) |
| Comprehensive income | \$ 483.1 | \$510.1 |

/1/ The significant component of other comprehensive income was a loss of $\$ 134.2$ million from foreign currency translation adjustments for the three months ended March 31, 1999, as compared to a loss of $\$ 22.1$ million for the three months ended March 31, 1998.

See Notes to Consolidated Condensed Financial Statements.

## BASIS OF PRESENTATION

The accompanying unaudited consolidated condensed financial statements have been prepared in accordance with the requirements of Form 10-Q and therefore 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. In the opinion of management, the financial statements reflect all adjustments, all of which are of a normal recurring nature, that are necessary for a fair statement of the results of operations for the periods shown. The preparation of financial statements in conformity with generally accepted accounting principles requires management to 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 Company operates in one significant business segment pharmaceutical products. Operations of the animal health business are not material.

## CONTINGENCIES

Barr Laboratories, Inc. (Barr), and Geneva Pharmaceuticals, Inc. (Geneva), have each submitted an Abbreviated New Drug Application (ANDA) seeking FDA approval to market generic forms of Prozac before the expiration of the Company's patents. The ANDAs assert that two U.S. patents held by Lilly covering Prozac are invalid and unenforceable. The Company filed suit against Barr and Geneva in federal court in Indianapolis seeking a ruling that Barr's challenge to Lilly's patents is without merit. On January 12, 1999, the trial court granted summary judgment in favor of Lilly on two of the four claims raised by Barr and Geneva against Lilly's patents. That decision has been appealed. On January 25, 1999, Barr and Geneva dismissed their other two claims in exchange for a $\$ 4$ million payment, which Barr and Geneva will share with a third defendant. In late 1998, three additional generic pharmaceutical companies, Zenith Goldline Pharmaceuticals, Inc., Teva Pharmaceuticals USA and Cheminor Drugs, Ltd., together with one of its subsidiaries filed ANDAs for generic forms of Prozac, asserting that the later of the two patents (expiring in December 2003) is invalid and unenforceable. Finally, in early 1999, Novex Pharma, a division of Apotex, Inc., changed its previously-filed ANDA to assert that both the 2001 and 2003 patents are invalid and unenforceable. Lilly has filed suits against the four companies in federal court in Indianapolis. The suits are in a very early stage. While the Company believes that the claims of the six generic companies are without merit, there can be no assurance that the Company will prevail. An unfavorable outcome of this litigation could have a material adverse effect on the Company's consolidated financial position, liquidity and results of operations.

The Company has been named as a defendant in numerous product liability lawsuits involving primarily two products, diethylstilbestrol and Prozac. The Company has accrued for its estimated exposure, including costs of litigation, with respect to all current product liability claims. In addition, the Company has accrued for certain future anticipated product liability claims to the extent the Company can formulate a reasonable estimate of their costs. The Company's estimates of these expenses are based primarily on historical claims experience and data regarding product usage. The Company expects the cash amounts related to the accruals to be paid out over the next several years. The majority of costs associated with defending and disposing of these suits are covered by insurance. The Company's estimate of insurance recoverables is based on existing deductibles, coverage limits, and the existing and projected future level of insolvencies among its insurance carriers.

Under the Comprehensive Environmental Response, Compensation, and Liability Act, commonly known as Superfund, the Company has been designated as one of several potentially responsible parties with respect to certain sites. Under Superfund, each responsible party may be jointly and severally liable for the entire amount of the cleanup. The Company also continues remediation of certain of its own sites. The Company has 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. The Company has reached a settlement with its primary liability insurance carrier providing for coverage for certain environmental liabilities and has instituted litigation seeking coverage from certain excess carriers.

The environmental liabilities and litigation accruals have been reflected in the Company's consolidated condensed balance sheet at the gross amount of approximately $\$ 289.5$ million at March 31, 1999. Estimated insurance recoverables of approximately $\$ 232.5$ million at March 31, 1999, 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 the Company or the ultimate cost of environmental matters, the Company believes that, except as noted above, the costs associated with all such matters will not have a material adverse effect on its consolidated financial position or liquidity but could possibly be material to the consolidated results of operations in any one accounting period.

## EARNINGS PER SHARE

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

## ACCOUNTING CHANGES

In June 1998, Statement of Financial Accounting Standards ("SFAS") No. 133, "Accounting for Derivative Instruments and Hedging Activities," was issued. Statement 133 is required to be adopted in years beginning after June 15, 1999. The statement permits early adoption as of the beginning of any fiscal quarter after its issuance. The statement will require the Company to recognize all derivatives on the balance sheet at fair value. Derivatives that are not hedges must be adjusted to fair value through income. If the derivative is a hedge, depending on the nature of the hedge, changes in the fair value of derivatives will either be offset against the change in fair value of the hedged assets, liabilities or firm commitments through earnings or recognized in other comprehensive income until the hedged item is recognized in earnings. Hedge ineffectiveness, the amount by which the change in the value of a hedge does not exactly offset the change in the value of the hedged item, will be immediately recognized in earnings. The Company has not yet determined what the effect of Statement 133 will be on the consolidated earnings and financial position of the Company or when the statement will be adopted.

Effective January 1, 1999, the Company adopted the American Institute of Certified Public Accountants Statement of Position (SOP) 98-5, "Reporting the Costs of Start-up Activities." The SOP requires that start-up costs capitalized prior to January 1, 1999 be written off and any future start-up costs be expensed as incurred. The unamortized balance of start-up costs was written off as of January 1, 1999. The effect of this change in accounting principle on consolidated earnings was immaterial.

## DISCONTINUED OPERATIONS

In November 1998, the Company signed a definitive agreement for Rite Aid
Corporation to acquire PCS, the Company's health-care-management subsidiary, for $\$ 1.6$ billion in cash. The transaction closed on January 22, 1999, and generated a gain of $\$ 174.3$ million ( $\$ .16$ per share), net of $\$ 8.7$ million tax benefit, in the first quarter of 1999. The results of operations from PCS prior to the close of the sale were not material, and have been classified as discontinued operations in the consolidated condensed statements of income. The prior period has been restated.

The consolidated condensed balance sheet and consolidated condensed statements of cash flows include PCS through the date of disposal. Selected balances, excluding intercompany amounts, as of December 31, 1998 were as follows:

| Current assets | \$ 528.7 |
| :---: | :---: |
| Goodwill | 1,397.4 |
| Total assets | 2,026.5 |
| Current liabilities | 886.3 |

## SPECIAL CHARGES

During the first quarter, the Company recognized a pre-tax charge of $\$ 150.0$ million, which resulted from funding commitments made to the Eli Lilly and Company Foundation, the non-profit foundation through which the Company makes charitable contributions. The charge for the funding commitment, which has been
included in other expense in the consolidated condensed statement of income, reduced earnings per share by approximately $\$ .09$ in the first quarter of 1999.

During the first quarter, the Company also recognized a pre-tax asset impairment charge of $\$ 61.4$ million to adjust the carrying value of certain manufacturing assets, in accordance with SFAS No. 121, "Accounting for the Impairment of LongLived Assets and for Long-Lived Assets to be Disposed Of." The asset impairment charge reduced earnings per share by $\$ .04$ in the first quarter of 1999. The major portion of the charge related to the decommissioning of a building previously used for antibiotic manufacturing, which resulted from the consolidation of certain manufacturing processes. The Company has no planned future use for the vacated building. The fair value of the facility was estimated using a discounted cash flow analysis.

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

## SALE OF PCS HEALTH-CARE-MANAGEMENT BUSINESS

In November 1998, the Company signed a definitive agreement to sell to Rite Aid Corporation the Company's PCS health-care-management subsidiary for $\$ 1.6$ billion in cash. The sale, which was completed in January 1999, will allow the Company to further focus on pharmaceutical innovation and the realization of optimal demand for Company products in the marketplace. As a consequence of the divestiture, the operating results of PCS have been reflected as "discontinued operations" in the Company's financial statements for all periods and have been excluded from consolidated sales and expenses reflected therein. The Company recognized a gain on disposal of $\$ 174.3$ million, net of $\$ 8.7$ million tax benefit, which increased earnings per share by approximately $\$ .16$, net of tax, in the first quarter of 1999.

## OPERATING RESULTS FROM CONTINUING OPERATIONS:

The Company's sales for the first quarter of 1999 increased 8 percent from the first quarter of 1998. Sales in the U.S. increased 6 percent, while sales outside the U.S. increased 11 percent. Compared with the first quarter of 1998, worldwide sales reflected volume growth of 10 percent while global selling prices and exchange rates reduced sales growth by one percentage point each.

Worldwide pharmaceutical sales for the quarter were $\$ 2.11$ billion, an increase of 9 percent compared with the same period of 1998. Sales growth was led by Gemzar, ReoPro, and Zyprexa. In addition, the quarter benefited from Evista, which was launched in the first quarter of 1998 in the U.S. for the prevention of osteoporosis in postmenopausal women. Revenue growth was partially offset by lower sales of anti-infectives, Axid and Prozac. Total U.S. pharmaceutical sales increased 7 percent to $\$ 1.29$ billion primarily as a result of increased volume. International pharmaceutical sales increased 12 percent compared with the first quarter of 1998, as sales volume growth of 15 percent was mitigated by the effect of unfavorable selling prices (1 percent) and exchange rates ( 2 percent).

Worldwide sales of Prozac in the first quarter were $\$ 589.9$ million, a decrease of 4 percent from the first quarter of 1998, driven primarily by a decline of 6 percent in the U.S. to $\$ 454.4$ million. Sales of Prozac outside the U.S. experienced an increase of 2 percent to $\$ 135.4$ million. Prozac sales in the U.S. were negatively affected by increased competition from new antidepressants. In addition, U.S. wholesaler stocking that occurred in late 1998 had a larger than expected adverse impact on first-quarter sales as wholesalers reduced excess inventories. The Company expects that some additional reductions of excess inventories are likely to occur in the second quarter. For the full year, the Company anticipates slight growth in worldwide Prozac sales. The actual sales levels will depend on the effectiveness of the Company's marketing efforts in offsetting increased competition, the rate of growth of the antidepressant market, and wholesaler, retailer and consumer stocking patterns.

In the first quarter of 1999, Zyprexa had worldwide sales of $\$ 401.2$ million, led by sales in the United States. This represents a 40 percent, or $\$ 114.2$ million, increase as compared to the same period in 1998. The Company expects continued strong sales growth for Zyprexa for the full year 1999 but at a lower percentage than the 98 percent achieved in 1998.

Worldwide Gemzar sales grew to $\$ 114.4$ million in the first quarter of 1999, an increase of 101 percent from the first quarter of 1998. Sales in the U.S. increased by $\$ 40.4$ million, representing growth of 131 percent. International sales also increased by $\$ 17.0$ million, or 65 percent.

ReoPro had first quarter 1999 sales totaling $\$ 101.0$ million, which reflected an increase of $\$ 31.0$ million (44 percent) as compared with the first quarter of 1998.

Insulin sales, composed of Humulin, Humalog, and Iletin, increased 7 percent compared with the first quarter of 1998. Insulin sales increased 2 percent in the U.S., to $\$ 132.3$ million, and increased 14 percent in international markets to $\$ 121.3$ million. Worldwide Humulin sales of $\$ 202.9$ million increased 4 percent. Worldwide Humalog sales for the first quarter were $\$ 42.5$ million, an increase of 72 percent as compared with a year ago. This increase was due in part to the launch of the pre-filled insulin pen system in the first quarter of 1999.

In the first quarter of 1999, worldwide sales of anti-infectives decreased 15 percent to $\$ 252.4$ million as a result of continuing competitive pressures. U.S and international anti-infectives sales declined 27 percent and 11 percent respectively. Cefaclor and Lorabid accounted for the majority of the decline in anti-infective sales.

Worldwide sales of Axid decreased 23 percent to $\$ 111.5$ million in the first quarter of 1999.

Evista had sales totaling $\$ 54.6$ million in the first quarter, an increase of 63 percent over the first quarter of 1998. Sales of Evista were negatively affected by the U.S. wholesaler stocking in late 1998. The Company anticipates continued strong growth in worldwide Evista sales for 1999.

Worldwide sales of animal health products of $\$ 146.6$ million increased 2 percent as compared to the first quarter of 1998. This sales growth was led by Micotil.

In the first quarter, gross margins were 78.1 percent, the same as the first quarter of 1998. This was a result of the offsetting effects of unfavorable product sales mix, increases in production efficiencies and the expiration of Humulin and Humalog royalties in August 1998.

During the first quarter, the Company recognized two one-time charges that affect the comparisons with 1998. The first charge relates to a pre-tax asset impairment charge of approximately $\$ 61.4$ million to adjust the carrying value of certain manufacturing assets. The major portion of the charge related to the write-down of a manufacturing facility to its fair value, which was estimated using a discounted cash flow analysis. This asset impairment charge reduced earnings per share by approximately $\$ .04$ in the quarter. The second pre-tax charge of $\$ 150.0$ million resulted from funding commitments made to the Eli Lilly and Company Foundation, the non-profit foundation through which the Company makes charitable contributions. The charge for the funding commitment reduced earnings per share by approximately $\$ .09$ in the first quarter of 1999 . See "Special Charges" in the Notes to Consolidated Condensed Financial Statements for additional information.

Operating expenses for 1999, excluding the effect of the asset impairment charge, increased 11 percent for the first quarter. Investment in research and development increased 14 percent, to $\$ 413.1$ million, for the first quarter. This growth is a result of the Company continuing to build internal and external capabilities. Marketing and administrative expenses increased 9 percent from the first quarter of 1998. This increase was driven by increased expenditures to support continued new product launches around the world, enhancements of the Company's global information technology capabilities, including expenditures relating to the Company's development and implementation of the year 2000 computer initiatives, and direct-to-consumer advertising campaigns in the U.S.

Compared with the first quarter of 1998, interest expense decreased $\$ 4$ million ( 8 percent). The decrease was primarily due to a decrease in the Company's borrowings.

Net other income for the first quarter of 1999, excluding the charge for the funding commitment to the Eli Lilly and Company Foundation, was $\$ 42.7$ million, an increase of $\$ 14.8$ million. The quarter benefited from decreased goodwill amortization expense and increased interest income.

For the first quarter of 1999, the Company's effective tax rate was 17 percent, which was lowered by the impact of the $\$ 61.4$ million asset impairment charge and the $\$ 150.0$ million funding commitment to Eli Lilly and Company Foundation. Excluding these items, the effective tax rate for the first quarter of 1999 was 22 percent, which was 2.4 percentage points below the first quarter of 1998 but was consistent with the tax rate estimate provided by the Company at year-end 1998.

During the first quarter of 1998, the Company refinanced an ESOP debenture, which resulted in a one-time extraordinary charge of $\$ 7.2$ million ( $\$ .01$ per share), net of a $\$ 4.8$ million tax benefit.

First quarter net income was $\$ 625.7$ million, or $\$ .56$ per share, compared with $\$ 521.1$ million for the first quarter of 1998 , or $\$ .46$ per share. The first quarter 1999 results were affected by the previously mentioned gain on disposal of the PCS health-care-management business of $\$ 174.3$ million, the pre-tax asset impairment charge of $\$ 61.4$ million and the pre-tax $\$ 150.0$ million charge for funding commitments to the Eli Lilly and Company Foundation. Excluding these non-recurring items and discontinued operations in 1998, first quarter net income and earnings per share increased 12 percent and 15 percent, respectively, as compared to 1998. For the first quarter of 1999, net income was favorably impacted by increased sales, a lower effective tax rate and increased other income, offset somewhat by higher research and development expenses as a percent of sales. Earnings per share for the first quarter 1999 benefited from a lower number of shares outstanding resulting from the Company's share repurchase programs.

## FINANCIAL CONDITION

As of March 31, 1999, cash, cash equivalents and short-term investments totaled $\$ 2.45$ billion as compared with $\$ 1.60$ billion at December 31, 1998. The net increase in cash was due primarily to $\$ 1.6$ billion received from the sale of PCS, which was offset by $\$ 251.6$ million in dividends paid and $\$ 399.2$ million in shares repurchased. Total debt at March 31, 1999, was $\$ 2.34$ billion, a decrease of $\$ 28$ million from December 31, 1998. The purchase of shares was pursuant to the Company's previously announced plan to repurchase shares of approximately $\$ 1.0$ billion in 1999.

The Company believes that cash generated from operations in 1999, along with available cash and cash equivalents, will be sufficient to fund essentially all of the 1999 operating needs, including debt service, capital expenditures, share repurchases, and dividends.

## YEAR 2000 READINESS DISCLOSURE

Many of the Company's global information technology (IT) systems and non-IT systems, including laboratory and process automation devices, will require modification or replacement in order to render the systems ready for the year 2000 (Y2K). In late 1996, the Company initiated a comprehensive program to reduce the likelihood of a material impact on the business. The numerous activities that are intended to enable the Company to obtain Y2K readiness utilize both internal and external resources and are being centrally managed through a program office. Monthly reports are made to senior management and a business council comprising various management representatives. In addition, regular reports are made to the audit committee of the board of directors.

The Company's inventory of IT systems, including software applications, has been divided into various categories. Those most critical to the Company's global operations are generally being assessed and renovated, when necessary, first. The Company has instituted a process to monitor all critical and essential replacement and upgrade projects of existing systems to assist in managing them toward completion in a timely manner. The Company has completed renovation of approximately 98 percent of its critical applications. The Company anticipates that substantially all the remaining critical applications will be completed by June 30, 1999. Of applications deemed essential, the Company anticipates Y2K readiness of approximately 90 percent to 95 percent by June 30, 1999.

The most important non-IT systems are various laboratory and process automation devices. The Company has completed a global assessment of all devices. Based on this assessment, only a small percentage (10 percent to 13 percent) of all automation devices appear to require upgrade or replacement. The Company has begun the process of either remediating or replacing these devices and anticipates that this process will be substantially complete by mid-1999.

The representatives of the program office have visited numerous global sites to assess the progress being made toward site readiness. In addition, several global training programs have occurred to foster the consistent application of the chosen methodologies. In addition, the Company is actively participating in industry efforts in the U.S. to communicate with advocacy groups, as well as governmental groups, about the readiness of the Company and industry as a whole.

The Company has also mailed letters to thousands of vendors, service providers and customers to determine the extent to which they are prepared for the Year 2000 issue. These activities are being coordinated through a global network of regional site and functional coordinators. Many responses have been received and the Company is identifying the vendors, service providers and customers that are critical to Lilly through a business impact analysis. Follow-up interviews are more thoroughly assessing their readiness.

The Company has begun, but not yet completed, a comprehensive risk management analysis of the operational problems and costs (including loss of revenues) that would be reasonably likely to result from the failure by the Company and certain third parties to complete efforts necessary to achieve Year 2000 compliance on a timely basis or from abnormal wholesaler or consumer buying patterns in anticipation of the Year 2000. Contingency plans are beginning to be developed for the Company and its critical vendors, customers and suppliers to address the flow of products to the consumer. The contingency planning involves a multifaceted approach, which may include additional purchases of raw materials and/or locating inventories of products closer to the consumer. The Company has made the decision to increase inventories of certain key products in order to have additional finished stock in the event excessive consumer purchasing occurs in late 1999. Business continuity plans will be developed to address the Company's approach for dealing with extended disruptions. In addition, "rapid response" teams will be established to respond to any issues that occur around the millennium. The Company currently plans to complete analysis and have contingency plans in place by September 30, 1999.

The costs of the Company's Year 2000 efforts are based upon management's best estimates, which are derived using numerous assumptions regarding future events, including the continued availability of certain resources, third-party remediation plans and other factors. There can be no assurance that these estimates will prove to be accurate, and actual results could differ materially from those currently anticipated. The Company currently estimates it will spend between $\$ 160$ and $\$ 180$ million over the life of the program and that approximately 65 percent to 70 percent of the anticipated costs were incurred by March 31, 1999. Expenses associated with addressing the Year 2000 issues are being recognized as incurred.

The failure to correct a material Year 2000 problem could result in an interruption in, or a failure of, certain normal business activities or operations. Such failures could materially and adversely affect the Company's results of operations. Due to the uncertainty inherent in the Year 2000 problem, the Company is unable to determine, at this time, whether the consequences of Year 2000 failures will have a material impact on the Company's results of operations. The Year 2000 project is expected to significantly reduce the Company's level of uncertainty about the Year 2000 problem and, in particular, about the Year 2000 compliance and readiness of its vendors, service suppliers and customers. The Company believes that, with the completion of the project as scheduled, the possibility of a material interruption of normal operations should be reduced.

## EURO CONVERSION

On January 1, 1999, 11 European nations adopted a common currency, the euro, and formed the European Economic and Monetary Union (EMU). For a three-year transition period, both the euro and individual participants' currencies will remain in circulation. After July 1, 2002, at the latest, the euro will be the sole legal tender for EMU countries. The adoption of the euro will affect a multitude of financial systems and business applications as the commerce of these nations will be transacted in the euro and the existing national currency.

The Company is currently addressing euro-related issues and their impact on information systems, currency exchange rate risk, taxation, contracts, competition and pricing. Action plans currently being implemented are expected to result in compliance with all laws and regulations; however, there can be no certainty that such plans will be successfully implemented or that external factors will not have an adverse effect on the Company's operations. Any costs of compliance associated with the adoption of the euro will be expensed as incurred and the Company does not expect these costs to be material to its results of operations, financial condition or liquidity.

## PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995

Under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, the Company cautions investors that any forward-looking statements or projections made by the Company, 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 the Company's operations and prospects are discussed in Exhibit 99 to this Form 10-Q filing.

## Item 1. Legal Proceedings

## PROZAC PATENT LITIGATION

In March 1996 the Company was informed by Barr Laboratories, Inc. ("Barr"), a generic pharmaceutical manufacturer, that it had submitted an abbreviated new drug application ("ANDA") to the U.S. FDA seeking to market a generic form of Prozac in the United States several years before the expiration of the Company's patents. Barr has alleged that the Company's U.S. patents covering Prozac are invalid and unenforceable. The compound patent expires in February 2001 and a method of use patent expires in December 2003. These patents are material to the Company.

On April 11, 1996, the Company filed suit in the United States District Court for the Southern District of Indiana seeking a ruling that Barr's challenge to the Company's patents is without merit. In 1997, the Company was informed that Geneva Pharmaceuticals, Inc. ("Geneva"), another generic manufacturer, had submitted a similar ANDA and, like Barr, had asserted that the Company's U.S. Prozac patents are invalid and unenforceable. On June 23, 1997, the Company sued Geneva in the same court seeking a similar ruling as in the Barr suit. Th two suits have been consolidated. On January 12, 1999, the trial court judge for the Southern District of Indiana granted partial summary judgment in favor of the Company, dismissing the claims of Barr and Geneva based on the patent doctrines of "best mode" and "double patenting". On January 25, 1999 (the day trial was to have begun), Barr and Geneva agreed to abandon their remaining two claims (based on the patent doctrines of "anticipation" and "inequitable conduct") in exchange for a payment of $\$ 4$ million to be shared among Barr, Geneva, and a third defendant, Apotex, Inc. Barr and Geneva have appealed the trial court's January 12, 1999 rulings to the Court of Appeals for the Federal Circuit.

In late 1998, three additional generic manufacturers, Zenith Goldline Pharmaceuticals, Inc., Teva Pharmaceuticals USA, and Cheminor Drugs, Ltd. together with one of its subsidiaries filed ANDAs for generic forms of Prozac, asserting that the Company's December 2003 patent is invalid and unenforceable. Finally, in early 1999, Novex Pharma, a division of Apotex, Inc. changed its previously-filed ANDA to assert that both the 2001 and 2003 patents are invalid and unenforceable. The Company has filed lawsuits in the United States District Court of the Southern District of Indiana seeking rulings that the four companies' challenges to the patent(s) are without merit. These suits are in the preliminary stages.

The Company believes that the claims of the six generic manufacturers are without merit and that the Company should be successful in this litigation. However, it is not possible to predict or determine the outcome of this litigation and accordingly there can be no assurance that the Company will prevail. An unfavorable outcome could have a material adverse effect on the Company's consolidated financial position, liquidity, and results of operations.

## PRICING LITIGATION

Reference is made to the discussion of the retail pharmacy antitrust litigation, In re Brand Name Prescription Drugs Antitrust Litigation (MDL No. 997) and related cases, contained in the Part I, Item 3 of the Company's Form $10-\mathrm{K}$ for the year ended December 31, 1998. An additional case has been filed in state court in North Dakota that purports to be a class action on behalf of pharmaceutical consumers in that state.

Item 6. Exhibits and Reports on Form 8-K
(a) Exhibits. The following documents are filed as exhibits to this Report:
11. Statement re: Computation of Earnings Per Share
12. Statement re: Computation of Ratio of Earnings from Continuing Operations to Fixed Charges
27. Financial Data Schedule
99. Cautionary Statement Under Private Securities Litigation Reform Act of 1995 - "Safe Harbor" for Forward-Looking Disclosures
(b) Reports on Form 8-K.

On February 9, 1999, the Company filed a Form 8-K relating to the consummation of the sale of all of the outstanding capital stock of its wholly-owned subsidiary, PCS Holding Corporation, a Delaware corporation, to Rite Aid Corporation, a Delaware corporation.

## 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 11, 1999

S/Daniel P. Carmichael

Daniel P. Carmichael
Secretary and Deputy General Counsel

Date May 11, 1999 S/Arnold C. Hanish
Arnold C. Hanish
Director, Corporate Accounting and Chief Accounting Officer

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

## Exhibit

11. Statement re: Computation of Earnings Per Share
12. Statement re: Computation of Ratio of Earnings from Continuing Operations to Fixed Charges
13. Financial Data Schedule
14. Cautionary Statement Under Private Securities Litigation Reform Act of 1995 - "Safe Harbor" for Forward-Looking Disclosures

## Eli Lilly and Company and Subsidiaries

|  |  |  | E |  |
| :---: | :---: | :---: | :---: | :---: |
|  |  | 1999 |  | 1998 |
| BASIC |  |  |  |  |
| Net income. | \$ | 625.7 | \$ | 521.1 |
| Preferred stock dividends. |  | (.1) |  | (.6) |
| Adjusted net income. | \$ | 625.6 | \$ | 520.5 |
| Average number of common shares outstanding |  | 092.1 |  | 101.1 |
| Contingently issuable shares |  | 1.1 |  | 1.2 |
| Adjusted average shares |  | 093.2 |  | 102.3 |
| Basic earnings per share. | \$ | . 57 | \$ | . 47 |
| DILUTED |  |  |  |  |
| Net income. | \$ | 625.7 | \$ | 521.1 |
| Preferred stock dividends. |  | (.1) |  | (.6) |
| Adjusted net income. | \$ | 625.6 |  | 520.5 |
| Average number of common shares outstanding |  | 092.1 |  | 101.1 |
| Incremental shares - stock options and contingently issuable shares........ |  | 22.6 |  | 29.5 |
| Adjusted average shares. |  | 114.7 |  | 130.6 |
| Diluted earnings per share. | \$ | . 56 | \$ | . 46 |

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,
1999

Consolidated Pretax
Income from Continuing
Operations before Accounting
Changes \& Extraordinary Item..... \$451.4 \$2,665.0 \$2,901.1 \$2,131.3 \$1,866.6 \$1,693.3
Interest from Continuing
Operations and Other
Fixed Changes................................. 48.7



| Fixed Charges /1/ | 48.8 | \$ 200.5 | \$ 256.8 | \$ 328.5 | \$ 323.9 | \$ 128.7 |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| Ratio of Earnings to |  |  |  |  |  |  |
| Fixed Charges | 10.1 | 14.2 | 12.2 | 7.4 | 6.6 | 14.0 |

/1/ Fixed charges include interest from continuing operations for all years presented and beginning in 1996, preferred stock dividends.

Amounts include research and development, marketing and administrative expenses, and asset impairment charge.
The information called for is not given as the balances are not
individually significant.

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 $10-\mathrm{K}$ and may be made by Company spokespersons based on current expectations of management. All forward-looking statements made by the Company are subject to risks and uncertainties. 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 generic competition as patents on key products, such as Prozac, expire; pricing pressures, both in the U.S. and abroad, primarily from managed care groups and government agencies; and new patented products or expanded indications for existing products introduced by competitors, which can lead to declining demand for the Company's products.

Changes in inventory levels maintained by pharmaceutical wholesalers as a result of wholesaler buying patterns, which can cause reported sales for a particular period to differ significantly from underlying prescriber demand.

Economic factors over which the Company has no control, including changes in inflation, interest rates and foreign currency exchange rates, and overall economic conditions in volatile areas such as Latin America.

Governmental factors, including laws and regulations and judicial decisions at the state and federal level related to Medicare, Medicaid and health care reform that could adversely affect pricing and reimbursement of the Company's products; and laws and regulations affecting international operations.

The difficulties and uncertainties inherent in new product development. 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.

Delays and uncertainties in the FDA approval process and the approval processes in other countries, resulting in 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.

Legal factors including unanticipated litigation of product liability or other liability claims; antitrust litigation; environmental matters; and patent disputes with competitors which could preclude commercialization of products or negatively affect the profitability of existing products. In particular, while the Company believes that its U.S. patents on Prozac are valid and enforceable, there can be no assurance that the Company will prevail in the various legal challenges to those patents.

Future difficulties obtaining or the inability to obtain existing levels of product liability insurance.

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, and the American Institute of Certified Public Accountants which are adverse to the Company.

Internal factors such as changes in business strategies and the impact of restructurings and business combinations.

The Company's statement that it expects to complete the Year 2000 modifications before December 31, 1999, is based on management's best estimate, which was derived utilizing numerous assumptions of future events, including the continued availability of certain resources, third party modification plans and other factors. However, there can be no guarantee that timely completion will be achieved and actual results could differ materially from those anticipated. Specific factors that might cause such material differences include, but are not limited to, the availability and cost of personnel trained in this area, the ability to locate and correct all relevant computer codes, and the successful completion by key third parties of their own Year 2000 modifications.


[^0]:    See Notes to Consolidated Condensed Financial Statements.

