

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

**Current Report
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): **April 19, 2004**

ELI LILLY AND COMPANY

(Exact name of registrant as specified in its charter)

Indiana
(State or Other Jurisdiction
of Incorporation)

001-06351
(Commission
File Number)

35-0470950
(I.R.S. Employer
Identification No.)

**Lilly Corporate Center
Indianapolis, Indiana**
(Address of Principal
Executive Offices)

46285
(Zip Code)

Registrant's telephone number, including area code: (317) 276-2000

No Change

(Former name or former address, if changed since last report)

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Item 12. Results of Operations and Financial Condition.

On April 19, 2004, Eli Lilly and Company (the “registrant” or “company”) issued a press release announcing its results of operations for the quarter ended March 31, 2004, including, among other things, an income statement for that period and a consolidated balance sheet as of March 31, 2004. In addition, on the same day the company will hold a teleconference for analysts and media to discuss these results. The teleconference will be web cast on the company’s web site. The press release and related financial statements are attached to this Form 8-K as Exhibit 99.

The company uses non-GAAP financial measures, such as adjusted (or “normalized”) net income and diluted earnings per share. Non-GAAP financial measures differ from financial statements reported in conformity to U.S. generally accepted accounting principles (“GAAP”). There are non-GAAP financial measures used in comparing the financial results for the first quarter 2004 to the same period of 2003. Those measures are operating income, earnings, and earnings per share excluding the impact of:

- A charge for acquired in-process research and development in connection with the acquisition of Applied Molecular Evolution, Inc. in the first quarter of 2004
- Asset impairments, restructuring and special charges incurred in the first quarter of 2003.

The first quarter 2004 item is described in more detail in the attached press release. The first quarter 2003 items are described in more detail in the company’s Form 8-K dated April 22, 2003.

The items that are subject to the adjustments are typically highly variable, difficult to predict, and of a size that could have a substantial impact on the company’s reported operations for a period. Management believes that these non-GAAP measures provide useful information to investors. Among other things, they may help investors evaluate the company’s ongoing operations. They can assist in making meaningful period-over-period comparisons and in identifying operating trends that could otherwise be masked or distorted by the excluded items. Management uses these non-GAAP measures internally to evaluate the performance of the business, including to allocate resources and to evaluate results relative to incentive compensation targets.

Investors should consider these non-GAAP measures in addition to, not as a substitute for or superior to, measures of financial performance prepared in accordance with GAAP. For the reasons described above for use of non-GAAP measures, the company’s prospective earnings guidance is subject to adjustment for certain matters, such as those identified above, as to which prospective quantification generally is not feasible.

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)

By: /s/ Charles E. Golden

Name: Charles E. Golden
Title: Executive Vice President and
Chief Financial Officer

Dated: April 19, 2004

EXHIBIT INDEX

Exhibit Number

Exhibit

99

Press release dated April 19, 2004, together with related attachments.



Eli Lilly and Company
Lilly Corporate Center
Indianapolis, Indiana 46285
U.S.A.

www.lilly.com

Date: April 19, 2004

For Release: Immediately

Refer to: (317) 276-5795 – Terra L. Fox

Lilly Delivers Strong Double-Digit Sales Growth for the Fifth Consecutive Quarter
Company Continues Its Wave of Innovative Product Launches

Eli Lilly and Company (NYSE: LLY) announced financial results for the first quarter of 2004.

First-Quarter Highlights

- Sales increased a robust 17 percent, to \$3.377 billion, driven primarily by sales growth of major products, including Zyprexa®, Gemzar® and Evista®, as well as growing sales from the newer products.
- Newer products – Alimta®, Cialis®, Forteo®, Strattera®, Symbyax™ and Xigris® – contributed \$309.1 million to first-quarter sales in 2004 and accounted for 9 percent of total sales.
- Net income decreased 2 percent, to \$400.4 million, and diluted earnings per share decreased 3 percent, to \$.37, primarily due to a non-tax-deductible charge of \$362.3 million related to the acquisition of Applied Molecular Evolution, Inc. (AME) in the first quarter of 2004.
- Excluding the \$362.3 million charge for acquired in-process research and development related to the AME acquisition and excluding charges in the first quarter of 2003 related to asset impairments, restructuring and other special charges, net income and diluted earnings per share both increased 15 percent, to \$762.7 million and \$.70, respectively.

Pharmaceutical Product Sales Highlights

(Dollars in millions)	First Quarter		% Change Over/(Under)
	2004	2003	2003
Zyprexa-Symbyax Franchise	\$1,131.9	\$958.3	18%
Diabetes Care Products	681.1	633.4	8%
Gemzar	279.0	233.9	19%
Evista	232.8	214.0	9%

Significant Events Over the Last Three Months

- Alimta was launched in the U.S. in February following its approval earlier that month by the U.S. Food and Drug Administration (FDA) for the treatment of malignant pleural mesothelioma, a cancer of the lining of the lungs. Alimta in combination with cisplatin is the first and only drug regimen proven to help patients with this asbestos-related cancer live longer.
- The FDA approved Zyprexa IntraMuscular, the rapid-acting injectable formulation of Zyprexa, to control the effects of acute agitation in patients suffering with schizophrenia and bipolar mania. Following its late March approval, Zyprexa IntraMuscular was launched in the U.S. in April.
- Evista was granted approval in January by the Ministry of Health, Labor and Welfare for the treatment of osteoporosis for postmenopausal women in Japan. The company expects to launch Evista in Japan in May.
- 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 stress urinary incontinence (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.
- The FDA granted a six-month priority review for Gemzar in combination with paclitaxel for the treatment of metastatic breast cancer following Lilly's submission in December 2003.
- Lilly is in the process of rolling out the global launches of six important new products, indications or formulations – Alimta, Cialis, Forteo, Symbyax, Zyprexa IntraMuscular and Zyprexa for bipolar maintenance.
- The Zyprexa patent trial was held in January and February. A ruling from the U.S. district court judge is expected this summer.

“In the first quarter, we continued generating strong global sales growth and accelerated our normalized earnings growth,” said Sidney Taurel, Lilly chairman, president and chief executive officer. “Over the last two and a half years, Lilly has launched six new innovative products and five new indications or formulations. We expect to continue this wave of new product launches over the next year with the addition of Cymbalta™ and Yentreve. With our multiple launches and outstanding pipeline, we are positioned well to deliver on our promise of strong, sustained earnings growth.”

First-Quarter Results

Worldwide sales for the quarter were \$3.377 billion, an increase of 17 percent compared with the first quarter of 2003. This robust increase was driven primarily by sales growth of major products, including Zyprexa, Gemzar and Evista, as well as growing sales from the newer products. Worldwide sales volume increased 10 percent, while selling prices and exchange rates increased sales by 2 and 5 percent, respectively.

Gross margins as a percent of sales decreased by 0.8 percentage points, to 77.7 percent. This decrease was due to the impact of foreign exchange rates and continued costs associated with quality improvements and growth in capacity in the company's manufacturing operations, offset partially by a favorable product mix.

Overall, marketing and administrative expenses increased 16 percent, to \$1.064 billion, which was 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. Research and development expenses were \$646.6 million, or 19 percent of sales. Compared with the first quarter of 2003, research and development expenses increased 22 percent due to increased clinical trial expenses, increased incentive compensation and benefits expense, and the impact of foreign exchange rates.

Operating income increased 18 percent, to \$552.4 million. Excluding the \$362.3 million charge in the first quarter of 2004 for acquired in-process research and development related to the AME acquisition and excluding charges in the first quarter of 2003 related to asset impairments, restructuring and other special charges, operating income increased 11 percent, to \$914.7 million, due to strong sales growth offset partially by cost of goods sold and research and development expenses increasing at a greater rate than sales. Net other income increased primarily due to income related to a previously assigned patent arrangement and the outlicensing of legacy products, offset partially by an increase in the net loss of the Lilly ICOS LLC joint venture.

Net income and diluted earnings per share for the first quarter decreased 2 percent and 3 percent, to \$400.4 million and \$.37, respectively, due to the increase in income before taxes being more than offset by higher income taxes in the first quarter of 2004 as a result of the nondeductibility of the acquired in-process research and development charge related to the AME acquisition. Excluding the first-quarter charges shown below, net income and diluted earnings per share

increased 15 percent, to \$762.7 million and \$.70, respectively. Refer to “Operating Results” and “Operating Results – Normalized” later in this press release for a reconciliation of reported to normalized operating income and net income.

Reconciliation of Reported to Normalized
First-Quarter Earnings per Share

	First Quarter		% Over/(Under)
	2004	2003	2003
E.P.S. (as reported, diluted)	\$.37	\$.38	(3%)
Add back charges: (a)			
Acquired in-process R&D related to AME acquisition	.33		
Asset impairments, restructuring and other special charges		.23	
E.P.S. (normalized and diluted)	\$.70	\$.61	15%

(a) Refer to “Operating Results – Normalized” later in this press release for further description.

Zyprexa-Symbyax Franchise

In the first quarter of 2004, Zyprexa sales totaled \$1.098 billion, a 15 percent increase over the first quarter of 2003. U.S. sales of Zyprexa increased 2 percent, to \$620.9 million. The U.S. Zyprexa sales growth was a result of an overall increase in the average dose sold, an increase in volume in the institutional market and a reduction in wholesaler destocking in the first quarter compared with the first quarter of last year. This increase was partially offset by lower prescription volume in the U.S. retail market due to continued competitive pressures.

Zyprexa sales in international markets increased 36 percent, to \$477.4 million, due to strong volume growth in a number of major markets outside the U.S. as well as the impact of foreign exchange rates. Symbyax, which was launched during the quarter in the U.S. for the treatment of bipolar depression, had sales of \$33.7 million, of which approximately \$30 million represents initial wholesaler stocking. While the initial prescription volume for Symbyax is in line with the company’s expectations, stocking levels were higher than expected.

Diabetes Care Products

Diabetes care revenue, composed primarily of Humalog®, Humulin® and Actos®, increased 8 percent, to \$681.1 million, compared with the first quarter of 2003. Diabetes care revenue decreased 1 percent in the U.S., to \$413.3 million. Diabetes care revenue outside the U.S. increased 24 percent, to \$267.8 million.

In the first quarter of 2004, worldwide Humalog sales were \$267.2 million, an increase of 7 percent compared with the first quarter of 2003. Worldwide Humulin sales increased 4 percent, to \$249.4 million. Actos generated \$153.3 million of revenue for Lilly in the first quarter, which represents an increase of 15 percent.

Gemzar

Gemzar had sales totaling \$279.0 million for the quarter, an increase of 19 percent from the first quarter of 2003. Gemzar sales in the U.S. increased 2 percent, to \$128.1 million, while sales outside the U.S. increased 40 percent, to \$150.9 million. A price decrease occurred in the U.S. in January 2004. After being granted an exemption from the new Medicare reimbursement calculations, Gemzar's price was increased April 1, 2004.

Evista

Evista sales were \$232.8 million, a 9 percent increase compared with the first quarter of 2003. U.S. sales of Evista increased 4 percent, to \$160.3 million. The U.S. sales growth was due to price increases and wholesaler buying patterns, offset partially by a decline in U.S. prescription volume resulting from the continued declines in the prevention of postmenopausal osteoporosis market. Sales outside the United States increased 20 percent, to \$72.5 million.

Animal Health

Worldwide sales of animal health products in the first quarter were \$182.4 million, an increase of 6 percent compared with the first quarter of 2003.

Newer Products

Xigris

Sales of Xigris, the first available pharmaceutical treatment for severe sepsis, were \$48.6 million, an increase of 36 percent compared with the first quarter of 2003. During the first quarter of 2004, U.S. sales of Xigris increased 20 percent, to \$32.2 million, while sales outside the United States increased 81 percent, to \$16.4 million.

Forteo

First-quarter sales of Forteo, a new treatment for severe osteoporosis, were \$40.8 million, compared with \$25.9 million in the fourth quarter of 2003. U.S. sales of Forteo were \$36.7 million and initial sales of the product outside the U.S. were \$4.1 million in the first quarter of 2004.

Strattera

Strattera, the only nonstimulant medicine approved for the treatment of attention-deficit hyperactivity disorder 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.

Cialis

Total worldwide sales of Cialis, a new treatment for erectile dysfunction marketed by Lilly ICOS LLC, were \$108.3 million, compared with fourth-quarter 2003 worldwide sales of \$94.2 million, which includes initial stocking for the U.S. launch. The \$108.3 million of worldwide Cialis sales in the first quarter of 2004 is comprised of \$33.3 million of sales in Lilly territories, which is reported in Lilly's revenue, 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.

Alimta

Alimta, which was launched in the U.S. during the first quarter of 2004 for the treatment of malignant pleural mesothelioma, generated \$11.6 million in sales, which includes approximately \$7 million of initial wholesaler stocking. The company is pleased by the early uptake of Alimta.

Financial Expectations for the Second Quarter and Full Year 2004

The company provided second-quarter earnings guidance and confirmed its full-year 2004 financial guidance. Specifically, the company expects earnings per share to be in the range of \$.67 to \$.69 for the second quarter of 2004 and \$2.80 to \$2.85 for the full year 2004. The full-year earnings guidance excludes the \$.33 per share charge for acquired in-process research and development related to the AME acquisition that was incurred in the first quarter of 2004. If this first-quarter charge was not excluded, then the reported earnings-per-share guidance for 2004 would be \$2.47 to \$2.52. In addition, the company's earnings guidance for the second quarter and full year excludes future material, unusual items. The company is not aware at this time of any other material, unusual items that will occur in the remainder of 2004.

For the full year 2004, the company continues to expect low double-digit sales growth. As previously disclosed, despite an increasingly competitive environment, Lilly expects global sales growth for Zyprexa and believes the Zyprexa-Symbyax franchise has growth potential in the U.S. The company expects U.S. sales to benefit from the recent launches of Symbyax as well as the bipolar maintenance indication and injectable formulation of Zyprexa. The company will continue to monitor Zyprexa's U.S. performance. In addition, the company continues 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, the company expects that other income/deductions (net other income less interest expense) will be approximately \$120 million for 2004. The tax rate is expected to increase slightly due to the nondeductibility of the acquired in-process research and development charge related to the AME acquisition.

Webcast of Conference Call

As previously announced, investors and the general public can access a live webcast of the first-quarter 2004 earnings conference call through a link on Lilly's website at www.lilly.com. The conference call will be held today from 9:30 a.m. to 10:30 a.m. Eastern Daylight Savings Time and will be available for replay via the website through May 19, 2004.

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of first-in-class and best-in-class pharmaceutical products by applying the latest research from its own worldwide laboratories and from collaborations with eminent scientific organizations. Headquartered in Indianapolis, Ind., Lilly provides answers – through medicines and information – for some of the world's most urgent medical needs. Additional information about Lilly is available at www.lilly.com.

This press release contains forward-looking statements that are based on management's current expectations, but actual results may differ materially due to various factors. There are significant risks and uncertainties in pharmaceutical research and development. There can be no guarantees with respect to pipeline products that the products will receive the necessary clinical and manufacturing regulatory approvals or that they will prove to be commercially successful. The company's results may also be affected by such factors as competitive developments affecting current growth products, rate of sales growth of recently launched products, the timing of anticipated regulatory approvals and launches of new products, other regulatory developments and government investigations, patent disputes and other litigation involving current and future products (including the outcome of the Zyprexa patent litigation that was held in January and February 2004), the impact of governmental actions regarding pricing, importation, and reimbursement for pharmaceuticals, and the impact of exchange rates. For additional information about the factors that affect the company's business, please see Exhibit 99 to the company's latest Form 10-K filed March 2004. The company undertakes no duty to update forward-looking statements.

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Actos® (pioglitazone hydrochloride, Takeda), Takeda
Alimta® (pemetrexed, Lilly)
Cialis® (tadalafil, ICOS), Lilly ICOS LLC
Cymbalta™ (duloxetine hydrochloride, Lilly)
Evista® (raloxifene hydrochloride, Lilly)
Forteo® (teriparatide of recombinant DNA origin injection, Lilly)
Gemzar® (gemcitabine hydrochloride, Lilly)
Humalog® (insulin lispro injection of recombinant DNA origin, Lilly)
Humatrope® (somatropin of recombinant DNA origin, Lilly)
Humulin® (human insulin of recombinant DNA origin, Lilly)
Prozac® (fluoxetine hydrochloride, Dista)
ReoPro® (abciximab, Centocor), Lilly
Strattera® (atomoxetine hydrochloride, Lilly)
Symbyax™ (olanzapine fluoxetine combination, or OFC, Lilly)
Xigris® (drotrecogin alfa (activated), Lilly)
Yentreve® (duloxetine hydrochloride, Lilly)
Zyprexa® (olanzapine, Lilly)
Zyprexa® IntraMuscular (olanzapine for injection, Lilly)

Eli Lilly and Company
Operating Results (Unaudited)
(Dollars in millions, except per share data)

	Three Months Ended March 31,	
	2004	2003
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
Operating income	552.4	470.1
Interest expense	(9.3)	(15.5)
Other income – net	72.4	39.3
Income before income taxes	615.5	493.9
Income taxes	215.1	86.9
Net income	\$ 400.4	\$ 407.0
Earnings per share – basic	\$ 0.37	\$ 0.38
Earnings per share – diluted	\$ 0.37	\$ 0.38
Dividends paid per share	\$ 0.355	\$ 0.335
Weighted-average shares outstanding (thousands) – basic	1,080,283	1,076,076
Weighted-average shares outstanding (thousands) – diluted	1,086,950	1,083,217

Eli Lilly and Company
Operating Results (Unaudited) — NORMALIZED
(Dollars in millions, except per share data)

	Three Months Ended March 31,	
	2004 (a)	2003 (b)
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
Operating income	914.7	824.0
Interest expense	(9.3)	(15.5)
Other income – net	72.4	39.3
Income before income taxes	977.8	847.8
Income taxes	215.1	186.5
Net income	\$ 762.7	\$ 661.3
Earnings per share – basic	\$ 0.71	\$ 0.61
Earnings per share – diluted	\$ 0.70	\$ 0.61
Dividends paid per share	\$ 0.355	\$ 0.335
Weighted-average shares		
outstanding (thousands) – basic	1,080,283	1,076,076
Weighted-average shares		
outstanding (thousands) – diluted	1,086,950	1,083,217

- (a) The 2004 first-quarter amounts are adjusted to exclude a \$362.3 million charge or \$.33 per share (no tax benefit), for acquired in-process research and development related to the Applied Molecular Evolution acquisition.
- (b) The 2003 first-quarter amounts are adjusted to exclude \$353.9 million of charges, including 1) \$114.6 million (pretax), or \$.07 per share (after-tax), for asset impairments, primarily manufacturing assets; 2) \$186.8 million (pretax), or \$.13 per share (after-tax), for asset impairments and other charges related primarily to the company's common stock ownership and loan agreements with Isis Pharmaceuticals, Inc.; and 3) \$52.5 million (pretax), or \$.03 per share (after-tax), for severance-related and other charges in order to streamline the company's infrastructure.

Eli Lilly and Company
Major Pharmaceutical Product Sales and Revenues (Unaudited)
(Dollars in millions)

	First Quarter		% Change
	2004	2003	Over/(Under) 2003
Zyprexa	\$1,098.3	\$958.3	15%
Gemzar	279.0	233.9	19%
Humalog	267.2	248.8	7%
Humulin	249.4	241.0	4%
Evista	232.8	214.0	9%
Prozac family	165.0	149.9	10%
Actos	153.3	133.2	15%
Strattera	141.1	55.0	157%
Humatrope	102.8	84.8	21%
ReoPro	93.7	93.1	1%

Eli Lilly and Company
Consolidated Balance Sheets

	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 for doubtful amounts 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
	<u>\$22,402.4</u>	<u>\$21,678.1</u>
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
	6,292.8	6,362.7
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
	<u>\$22,402.4</u>	<u>\$21,678.1</u>