



April 16, 2001

Lilly Announces First-Quarter Earnings per Share of \$.74, An Increase of 17 Percent Over the Normalized Results of the Prior Year

Eli Lilly and Company (NYSE: LLY) announced financial results for the first quarter of 2001.

First-Quarter Highlights

- Sales increased 10 percent, adjusted for prior-year Y2K-related sales. Net income and earnings per share increased 17 percent, adjusted for prior-year one-time events. Reported worldwide sales increased 14 percent, to \$2.806 billion. Reported net income decreased 5 percent, to \$806.8 million, and earnings per share decreased 4 percent, to \$.74. The decline is a result of a prior year one-time gain realized on the sale of Kinetra.

Summary of First-Quarter Earnings per Share

2001 2000 % Over/(Under)

E.P.S. (as reported, diluted) \$.74 \$.77 (4%)

Add back one-time Y2K-related sales: .06

Eliminate one-time gain on Kinetra Sale: (.20)

E.P.S. (normalized and diluted) \$.74 \$.63 17%

Pharmaceutical Product Sales Highlights as Reported

Reported % Change

Normalized % Change

(Dollars in millions) First Quarter Over/(Under) First Quarter Over/(Under)

2001 2000 2000 2001 2000 2000

Zyprexa® \$ 637.1 \$ 458.1 39% \$ 637.1 \$ 474.8 34%

Prozac® and Sarafem™ 622.9 596.2 4% 622.9 607.9 2%

Diabetes Care Products 482.9 405.7 19% 482.9 428.7 13%

Gemzar® 174.0 136.0 28% 174.0 138.7 25%

Evista® 149.0 100.5 48% 149.0 101.3 47%

ReoPro® 110.7 110.3 0% 110.7 111.1 0%

Significant Events Over the Last Three Months

- The U.S. Food and Drug Administration's Center for Biologics Evaluation and Research granted a six-month priority review of drotrecogin alfa (activated), proposed brand name, Zovant™. Lilly submitted a biologics license application to the FDA in late January 2001 for drotrecogin alfa (activated) to be used for the treatment of sepsis with associated acute organ dysfunction (known as severe sepsis). The FDA grants priority reviews for compounds that represent significant advances over existing treatments. Currently, there is no drug therapy approved specifically for the treatment of severe sepsis. Phase III clinical trial results show drotrecogin alfa (activated) significantly reduced the relative risk of death from severe sepsis by 19.4 percent. Lilly also has applied for regulatory approval in the European Union, Australia and Canada.
- The FDA approved Prozac Weekly™, the first and only prescription medication administered weekly indicated specifically for the continuation phase of long-term depression treatment. It is for patients whose depressive symptoms have stabilized and who require continuing treatment to prevent a relapse, or return of symptoms. Prozac Weekly was launched in the U.S. during March.
- Phase II data published in the International Journal of Impotence Research demonstrated that on-demand treatment with Cialis™, an oral compound under investigation by Lilly ICOS LLC for the treatment of erectile dysfunction (ED), significantly improved erections in 81 percent of men relative to placebo (17 percent), regardless of ED severity.

Additionally, the first Cialis Phase III data was released, showing a strong response rate among men with difficult-to-treat diabetes-related ED (64 percent response for Cialis 20 mg; 25 percent placebo response). Reports of facial flushing and blue vision were similar to placebo. Cialis is currently in global Phase III studies, with worldwide regulatory submissions expected in the second half of this year.

- The Committee for Proprietary Medicinal Products recommended that the European Medicines Evaluation Agency approve the intramuscular formulation of Zyprexa for the rapid control of agitation and disturbed behaviors in patients with schizophrenia.
- The FDA has granted Lilly an approvable letter for Zyprexa IntraMuscular for the treatment of agitation associated with schizophrenia, bipolar mania and dementia. This follows the unanimous recommendation for approval by the FDA's Psychopharmacologic Drugs Advisory Committee. Lilly is currently working to address the approvable letter requests, including successfully completing an FDA reinspection of the manufacturing facility where the intramuscular formulation of Zyprexa is produced. In March, Lilly announced that it had received a warning letter from the FDA following a routine inspection of its injectable product manufacturing facility in Indianapolis in February 2001 in connection with the company's application for approval of the intramuscular formulation of Zyprexa. The company is working closely with the FDA to resolve all issues raised and prepare for reinspection and continues to anticipate a late summer 2001 launch.
- Subsequent to the March 2001 Form 483 and warning letter, Lilly received an additional Form 483 in April from the FDA following a routine inspection of three manufacturing facilities in Indianapolis in March and early April in connection with the company's application for approval of Fortéo™. As previously stated, this was fully anticipated since the company knew it would face similar issues in the scheduled inspection without having time to make substantive corrective changes. The company has a comprehensive plan underway to improve all FDA regulated sites globally and is confident it can correct all issues. The company continues to anticipate that the timing of new product launches will not be affected, including the launch of Fortéo in late 2001.
- "We continued to deliver on our commitments in the first quarter with strong financial results and a number of product and pipeline milestones," said Sidney Taurel, Lilly chairman, president and chief executive officer. "Despite the challenges we face, we are confident we will be able to implement our plans. We have a terrific opportunity for growth with our fast-rising newer products, including our leading seller Zyprexa, as well as an outstanding pipeline that could produce as many as ten new products over the next four years."

First-Quarter Results - as Reported

Reported worldwide sales for the quarter were \$2.806 billion, an increase of 14 percent compared with reported sales for the first quarter of 2000. Adjusting for prior year Y2K-related sales, worldwide sales increased 10 percent. Zyprexa, Evista, Gemzar and diabetes care revenue led the growth. This growth was partially offset by lower sales of anti-infectives. Reported worldwide sales volume growth of 16 percent was partially offset by an unfavorable exchange rate effect of 3 percent while global selling prices increased 1 percent.

Reported gross margins as a percent of sales improved by 2.2 percentage points, to 81.4 percent, primarily due to a favorable mix of product sales. During the quarter, higher margin products, such as Zyprexa, Actos®, Evista and Gemzar, experienced strong growth, while lower margin products, such as anti-infectives, declined. Marketing and administrative expenses increased 12 percent, to \$768.9 million, compared with the first quarter of 2000, primarily due to increased sales and marketing spending to support the company's current growth products and upcoming product launches. Research and development expenses increased 12 percent, to \$515.5 million, as the company continued to invest in its product pipeline.

Reported operating income increased to \$999.0 million, a 26 percent increase over reported operating income during the first quarter of 2000. Adjusting for prior year Y2K-related sales, operating income increased 14 percent. Reported net income and diluted earnings per share for the first quarter were \$806.8 million and \$.74, representing decreases of 5 percent and 4 percent respectively, over the reported results of the first quarter of 2000. The decline is a result of a one-time gain of \$214 million (after-tax) realized on the sale of Kinetra, a joint venture between Lilly and EDS, to WebMD during the first quarter of 2000. Adjusting for both prior year one-time events, net income and earnings per share increased 17 percent.

Zyprexa

In the first quarter of 2001, reported Zyprexa sales totaled \$637.1 million, a 39 percent increase over the first quarter of 2000. U.S. sales of Zyprexa increased 50 percent, to \$450.7 million, while sales outside the United States increased 18 percent, to \$186.4 million. Adjusting for prior-year Y2K-related sales, worldwide Zyprexa sales grew by 34 percent.

Prozac and Sarafem

Overall, reported Prozac and Sarafem combined sales for the quarter increased 4 percent, to \$622.9 million. In the United

States, Prozac and Sarafem combined sales increased 7 percent, to \$541.5 million. Prozac sales outside the United States decreased 8 percent, to \$81.4 million, due to continued generic competition. Adjusting for prior-year Y2K-related Prozac sales, worldwide Prozac and Sarafem combined sales grew by 2 percent.

Diabetes Care Products

Reported diabetes care revenue, composed primarily of Humulin[®], Humalog[®], Actos, and Iletin[®], increased 19 percent, to \$482.9 million, compared with the first quarter of 2000. Diabetes care revenue increased 27 percent in the U.S., to \$303.4 million, and increased 8 percent in international markets, to \$179.5 million. Worldwide Humulin sales were flat at \$273.5 million compared with the first quarter of 2000, due in part to the continued shift by patients to Humalog and Humalog mix products. Worldwide Humalog sales for the first quarter were \$125.2 million, an increase of 74 percent compared with a year ago. Actos generated \$64.0 million of revenue for Lilly in the first quarter, which represents a 51 percent increase. During the quarter, Actos was launched in South Africa, Sweden, Norway and Russia, where Lilly has marketing rights. Adjusting for prior-year Y2K-related sales, worldwide diabetes care revenue grew by 13 percent.

Gemzar

Gemzar reported sales totaling \$174.0 million for the quarter, an increase of 28 percent from the first quarter of 2000. Gemzar sales increased 29 percent in the U.S. and 27 percent outside the U.S., to \$101.5 million and \$72.5 million, respectively. Adjusting for prior-year Y2K-related sales, worldwide Gemzar sales grew by 25 percent.

Gemzar was recently approved in Japan for the treatment of pancreatic cancer. It is the first major effective treatment for pancreatic cancer in Japan, a usually fatal disease affecting 22,000 Japanese patients annually.

Evista

Evista reported sales totaling \$149.0 million, a 48 percent increase compared with the first quarter of 2000. U.S. sales of Evista increased 44 percent, to \$120.3 million, while sales outside the United States increased 67 percent, to \$28.8 million.

Recent findings from Lilly's MORE (Multiple Outcomes of Raloxifene Evaluation) trial showed that postmenopausal women with osteoporosis who used Evista continued to show significantly lower risk of breast cancer through four years of treatment. Specifically, Evista reduced the risk of newly diagnosed invasive breast cancer by 72 percent and estrogen-receptor-positive invasive breast cancer-the most common type occurring in women past menopause-by 84 percent, when compared with placebo. Evista is not indicated for the prevention and/or treatment of breast cancer. However, ongoing large-scale clinical trials may lead to regulatory submissions for a breast cancer risk-reduction indication.

ReoPro

ReoPro first-quarter sales were flat at \$110.7 million, compared with the first quarter of 2000. Relative to the fourth quarter of 2000, sales have improved following the release of the Merck-sponsored TARGET data which showed that ReoPro was superior to Aggrastat in reducing the risk of death, myocardial infarction and urgent intervention based on 30-day data.

Animal Health

Worldwide sales of animal health products in the first quarter were \$164.1 million, an increase of 6 percent when compared with the first quarter of 2000. Excluding the effect of exchange rates, sales grew by 9 percent for the quarter.

Financial Expectations for Second-Quarter and Full-Year 2001

For the second quarter of 2001, the company expects earnings per share to be in the range of \$.73 to \$.75, excluding any unusual items. The company reiterated Lilly's previously disclosed full-year 2001 earnings-per-share guidance of \$2.75 to \$2.85, excluding any unusual items.

These forward-looking statements are based on management's current expectations but actual results may differ materially due to various factors. In particular, the company's expectations for the year 2001 may be affected by the pricing and timing of the entry of generic fluoxetine in the U.S., by competitive developments affecting its current growth products, and by the timing of approvals and launches of new products such as drotrecogin alfa activated (proposed trade name Zovant) and Fortéo. 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 2001. The company undertakes no duty to update forward-looking statements.

Webcast of Conference Call

As previously announced, investors can access a live Webcast of the first-quarter earnings conference call through a link that will be posted on Lilly's website at www.lilly.com. The conference call begins today at 10:00 a.m. Eastern Daylight Savings Time (9:00 a.m. local Indianapolis time) and will be available for replay through April 23, 2001.

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of 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.

Operating Results (Unaudited)

(Dollars in millions except per share data)

Three Months Ended

March 31

2001 2000

Net sales \$ 2,805.7 \$ 2,451.1

Cost of sales 522.3 508.7

Research and development 515.5 458.5

Marketing and administrative 768.9 688.3

Operating income 990.0 795.6

Interest expense (41.4) (46.8)

Other income - net 76.8 273.7

Income from continuing operations

before income taxes 1,034.4 1,022.5

Income taxes 227.6 177.0

Net Income \$ 806.8 \$ 845.5

Earnings per share -basic: \$ 0.75 \$ 0.78

Earnings per share -diluted: \$ 0.74 \$ 0.77

Dividends paid per share 0.28 0.26

Weighted-average shares

outstanding (thousands) 1,078,505 1,084,199

Weighted-average shares

outstanding (thousands) -diluted 1,092,101 1,094,688

Major Pharmaceutical Product Sales (Unaudited)

(Dollars in millions)

% Change

First Quarter Over/(Under)

2001 2000 2000

Prozac and Sarafem \$ 622.9 \$ 596.2 4%

Zyprexa 637.1 458.1 39%

Humulin 273.5 273.7 0%

Gemzar 174.0 136.0 28%

Evista 149.0 100.5 48%

Humalog 125.2 72.1 74%

Reopro 110.7 110.3 0%

Axid 75.8 67.9 12%

Humatrope 74.2 69.0 8%

Ceclor/cefaclor 69.4 77.5 (11%)

Operating Results (Unaudited) -Normalized

(Dollars in millions except per share data)

Three Months Ended

March 31

2001 2000a

Net sales \$ 2,805.7 \$ 2,541.8

Cost of sales 522.3 520.9

Research and development 515.5 458.5

Marketing and administrative 768.9 688.3

Operating income 999.0 874.1

Interest expense (41.4) (46.8)

Other income - net 76.8 60.3

Income before income taxes

1,034.4 887.6

Income taxes 227.6 195.3

Net Income \$ 806.8 \$ 692.3

Earnings per share - basic: \$ 0.75 \$ 0.64

Earnings per share - diluted: \$ 0.74 \$ 0.63

Dividends paid per share 0.28 0.26

Weighted-average shares

outstanding (thousands) 1,078,505 1,084,199

Weighted-average shares

outstanding (thousands) - diluted 1,092,101 1,097,688

a2000 first quarter amounts are adjusted for the fourth quarter 1999 impact of Y2K related sales and \$214.4 million in net gain related to the sale of the investment in the Kinetra joint venture.

Major Pharmaceutical Product Sales (Unaudited) -
Normalized

(Dollars in millions)

% Change

First-Quarter Over/(Under)

2001 2000a 2000

Prozac and Sarafem \$ 622.9 \$ 607.9 2%

Zyprexa 637.1 474.8 34%

Humulin 273.5 296.7 (8%)

Gemzar 174.0 138.7 25%

Evista 149.0 101.3 47%

Humalog 125.2 72.1 74%

Reopro 110.7 111.1 0%

Axid 75.8 72.8 4%

Humatrope 74.2 71.6 4%

Ceclor/cefaclor 69.4 84.3 (18%)

a2000 first quarter amounts are adjusted for the fourth quarter 1999 net impact of additional product sales as a result of Y2K related wholesaler buying.