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Lilly Announces Fourth-Quarter Earnings per Share of \$.60, Excluding One-Time Charges

Company Also Announces Full-Year Normalized Earnings of \$2.76 per Share

Eli Lilly and Company (NYSE: LLY) today announced financial results for the fourth quarter and full year of 2001.

Fourth-Quarter Highlights

- Sales decreased 5 percent, to \$2.829 billion, compared with \$2.978 billion in the fourth quarter of the prior year. Excluding Prozac[®], sales increased 15 percent.
- Normalized net income and diluted earnings per share, excluding one-time charges, decreased 14 percent, to \$656.2 million and \$.60 per share, respectively. Reported net income and earnings per share decreased 25 percent and 24 percent, respectively, to \$575.4 million and \$.53 per share. These results compare with \$767.3 million and \$.70 per share in the fourth quarter of the prior year.

2001 Highlights

- Sales increased 6 percent, to \$11.543 billion, compared with reported sales of \$10.862 billion in the prior year. Excluding Prozac, sales increased 17 percent.
- During 2001, Zyprexa[®], Lilly's breakthrough product for schizophrenia and bipolar mania, became the company's first product to surpass \$3 billion in annual sales, a noteworthy accomplishment given its launch just five years ago and increasing competition in the antipsychotic and mood stabilization markets.
- Normalized net income and diluted earnings per share, excluding one-time charges, increased 4 percent, to \$3.014 billion and \$2.76 per share, respectively, compared with prior-year normalized earnings of \$2.905 billion and \$2.65 per share. Reported net income and earnings per share decreased 9 percent, to \$2.780 billion and \$2.55 per share, respectively, compared with prior-year reported earnings of \$3.058 billion and \$2.79 per share.

Pharmaceutical Product Sales Highlights – As Reported

(Dollars in millions)	Fourth Quarter		% Change	Full Year		% Change
	2001	2000	Over/(Under)	2001	2000	Over/(Under)
			2000			2000
Zyprexa	\$900.4	\$695.8	29%	\$3,086.6	\$2,349.5	31%
Diabetes Care Products	548.0	465.7	18%	2,126.0	1,761.3	21%
Prozac, Prozac Weekly [™] and Sarafem [™]	225.4	669.9	(66%)	1,990.0	2,573.7	(23%)
Gemzar [®]	200.9	160.2	25%	722.9	559.3	29%
Evista [®]	165.8	145.7	14%	664.8	521.5	27%
ReoPro [®]	105.5	105.6	0%	431.4	418.1	3%

Significant Operating Events Over the Last Three Months

- In late-November 2001, Lilly received approval from the U.S. Food and Drug Administration (FDA) and launched Xigris[™], the company's breakthrough treatment for adult severe sepsis patients at high risk of death. Initial Xigris sales through December 31, 2001, were \$21.2 million.
- Lilly received a Form 483 outlining 50 additional observations from the FDA following its reinspection of certain Lilly manufacturing facilities in Indianapolis in connection with pending new-product approvals for Zyprexa[®] IntraMuscular and Fortéo[™]. The company holds approvable letters from the FDA for Zyprexa IntraMuscular and Fortéo. However, FDA approval of these products continues to be contingent upon resolving all manufacturing issues to the agency's satisfaction. In addition, Fortéo approval is contingent upon completion of labeling negotiations and agreement on measures to ensure appropriate use of the product.
- Lilly filed a new drug application (NDA) with the FDA for the use of atomoxetine, a highly specific norepinephrine reuptake inhibitor, as a treatment for attention deficit hyperactivity disorder (ADHD) for children, adolescents and adults. If approved for use, atomoxetine would be the first nonstimulant and the first new type of medication for the treatment of

ADHD in more than 30 years.

- Lilly submitted an NDA to the FDA for duloxetine, an investigational dual reuptake inhibitor of both serotonin and norepinephrine being developed for the treatment of depression. Clinical trials suggest that duloxetine's distinctive clinical profile may enable it to address a number of unmet medical needs in the antidepressant market.

"Our sales performance, excluding Prozac, continued to be impressive with 15 percent growth in the quarter and 17 percent for the year. This strong sales growth continued to be driven by our five best-in-class growth products – Zyprexa, Gemzar, Actos®, Humalog® and Evista – which grew 32 percent for the quarter and 36 percent for the year. In addition, initial sales from our newest breakthrough product, Xigris, were in line with our expectations," said Sidney Taurel, Lilly chairman, president and chief executive officer. "Our number one priority is to address all the manufacturing issues raised by the FDA to its satisfaction in order to bring our innovative new products to market as quickly as possible."

Fourth-Quarter Results – As Reported

Worldwide sales for the quarter were \$2.829 billion, a decrease of 5 percent compared with the fourth quarter of 2000. The sales decline was primarily due to lower Prozac sales as a result of the August 2001 introduction of generic competition in the U.S. This decrease was partially offset by the strong growth of Zyprexa, Gemzar, Evista, and diabetes care revenue. Worldwide sales volume declined 3 percent and selling prices decreased 2 percent while the impact of exchange rates was negligible.

Gross margins as a percent of sales declined by 1.0 percentage point, to 80.0 percent, due primarily to the decrease in Prozac sales. Overall, marketing and administrative expenses decreased 7 percent, to \$882.7 million, due to lower incentive compensation and direct-to-consumer advertising expenses offset partially by increased investment in underlying sales and marketing, including expansion of the sales force. Research and development expenses increased 8 percent, to \$589.9 million, due to the company's investment in its promising product pipeline offset partially by lower incentive compensation expense.

Operating income decreased to \$689.6 million, a 25 percent decrease over the fourth quarter of 2000, primarily as a result of the decline in Prozac sales, the 8 percent increase in research and development expenses and the one-time in-process research and development charge discussed below. Net income and diluted earnings per share for the fourth quarter were \$575.4 million and \$0.53, respectively, representing decreases of 25 percent and 24 percent. Earnings per share benefited slightly from a lower number of outstanding shares.

One-Time Events

During the quarter, the following one-time events affected reported operating income, net income and earnings per share:

- The company recorded special charges of \$100 million for in-process research and development associated with resiquimod, the Phase III compound for the treatment of genital herpes licensed from 3M.
- In addition, the company is taking advantage of lower interest rates to refinance and thus recorded as an extraordinary item a charge of \$19.7 million (\$12.8 million net of tax) for early retirement of existing higher cost debt.

These fourth-quarter 2001 special charges amounted to \$.07 per share. Excluding these charges, operating income was \$789.6 million, a 14 percent decrease compared with the fourth quarter of 2000, and net income and earnings per share both decreased 14 percent. These decreases were primarily a result of the decline in Prozac sales.

Summary of Fourth-Quarter Earnings per Share

	2001	2000	% Over/(Under)
E.P.S. (as reported, diluted)	\$.53	\$.70	(24)%
Add back one-time charges:			
In-process research & development	.06		
Early retirement of debt	.01		
E.P.S. (normalized, diluted)	\$.60	\$.70	(14)%

Full-Year Results – As Reported

For the year, worldwide sales as reported were \$11.543 billion, an increase of 6 percent, compared with reported sales for 2000. Worldwide sales volume growth of 8 percent was offset by a 2 percent reduction in exchange rates, while global selling prices increased 1 percent. Numbers do not add due to rounding. Worldwide sales increased 5 percent compared with prior year normalized sales of \$10.953 billion, adjusted for prior-year Y2K-related sales.

Gross margins as reported increased by 0.2 percentage points, to 81.3 percent. Marketing and administrative expenses

increased 6 percent, to \$3.417 billion, in 2001 due to sales force expansions and increased marketing efforts in support of the company's growth products and upcoming product launches. Research and development expenses increased 11 percent, to \$2.235 billion, in 2001 as the company continued to invest in its promising product pipeline. Operating expenses were reduced by lower incentive compensation expense.

Operating income as reported was \$3.418 billion, a 4 percent decrease, as a result of the decline in Prozac sales, the 11 percent increase in research and development expenses and the one-time in-process research and development and asset impairment charges referred to below. Other income declined primarily due to the one-time gain realized on the sale of Kinetra in 2000. Net income and diluted earnings per share for the year, as reported, were \$2.780 billion and \$2.55, both representing decreases of 9 percent, compared with 2000 reported results. Adjusting for one-time events in 2000 and 2001 as described below, operating income was \$3.730 billion, a 3 percent increase, and net income and earnings per share both increased 4 percent.

Summary of 2001 Earnings per Share

	<u>2001</u>	<u>2000</u>	<u>% Over/(Under)</u>
E.P.S. (as reported, diluted)	\$2.55	\$2.79	(9)%
Adjust for Y2K-related sales:		.06	
Eliminate one-time gains:			
Sale of Kinetra		(.20)	
Add back one-time charges:			
In-process research & development	.11		
Asset impairments and other site charges	.07		
Early retirement of debt	<u>.03</u>		
E.P.S. (normalized, diluted)	\$2.76	\$2.65	4%

Zyprexa

In the fourth quarter of 2001, Zyprexa sales totaled \$900.4 million, a 29 percent increase over the fourth quarter of 2000. U.S. sales of Zyprexa increased 20 percent, to \$624.4 million, while sales outside the United States increased 56 percent, to \$276.1 million. For the full year of 2001, worldwide Zyprexa sales increased 31 percent, to \$3.087 billion. Since its market entry five years ago, Zyprexa has been prescribed for eight million patients in 85 countries worldwide.

Diabetes Care Products

Diabetes care revenue, composed of Humulin[®], Humalog, Actos, and Iletin[®], increased 18 percent, to \$548.0 million, compared with the fourth quarter of 2000.

Diabetes care revenue increased 18 percent in the U.S., to \$337.5 million, and increased 17 percent in international markets, to \$210.5 million. Worldwide Humulin sales decreased 9 percent, to \$267.8 million, compared with the fourth quarter of 2000, due to the continued shift by patients to Humalog and Humalog mix products as well as increased competition. Worldwide Humalog sales for the fourth quarter were \$192.7 million, an increase of 74 percent compared with a year ago. Actos generated \$67.4 million of revenue for Lilly in the fourth quarter, which represents a 53 percent increase. For the full year of 2001, worldwide diabetes care revenue increased 21 percent, to \$2.126 billion.

Prozac, Prozac Weekly and Sarafem

Overall, combined Prozac, Prozac Weekly and Sarafem sales for the quarter decreased 66 percent, to \$225.4 million. Prozac sales in the United States decreased 84 percent, to \$95.4 million, due to the introduction of generic competition in August 2001. Prozac Weekly and Sarafem combined sales in the U.S. were \$45.0 million. Prozac sales outside the United States increased 1 percent, to \$84.5 million. For the full year of 2001, worldwide combined Prozac, Prozac Weekly and Sarafem sales decreased 23 percent, to \$1.990 billion.

On January 14, 2002, the U.S. Supreme Court issued an order indicating it will not hear the Prozac patent case of Eli Lilly and Company v. Barr Laboratories, et al. On October 16, 2001, Lilly filed a petition for a writ of certiorari requesting the Supreme Court to review the May 30, 2001, decision by the Court of Appeals for the Federal Circuit of Washington, D.C. In that decision, the Federal Circuit ruled that Claim 7 of the 2003 Prozac method of use patent is invalid because of double patenting.

Gemzar

Gemzar had sales totaling \$200.9 million for the quarter, an increase of 25 percent from the fourth quarter of 2000. Gemzar sales increased 23 percent in the United States and 29 percent outside the United States, to \$117.3 million and \$83.6 million, respectively. For the full year of 2001, worldwide Gemzar sales increased 29 percent, to \$722.9 million.

During the quarter, AstraZeneca and Lilly announced their clinical collaboration to evaluate the benefits of Iressa[™] (ZD1839)

in combination with Gemzar for the treatment of various cancers.

Evista

Evista had sales totaling \$165.8 million, a 14 percent increase compared with the fourth quarter of 2000. U.S. sales of Evista increased 4 percent, to \$123.8 million. The U.S. sales growth was affected by continued competition and, to a lesser extent, wholesaler purchasing patterns. Evista sales outside the United States increased 58 percent, to \$41.9 million. For the full year of 2001, worldwide Evista sales increased 27 percent, to \$664.8 million.

Animal Health

Worldwide sales of animal health products in the fourth quarter were \$188.3 million, a decrease of 5 percent compared with the fourth quarter of 2000. For the full year of 2001, animal health sales increased 3 percent, to \$686.1 million. Excluding the effect of exchange rates, sales decreased by 3 percent for the quarter and grew by 6 percent for the year.

Financial Expectations for First Quarter and Full Year 2002

Looking forward to full-year 2002 results, excluding any unusual items, the company anticipates earnings per share to be in the range of \$2.70 to \$2.80, compared with normalized 2001 earnings per share of \$2.76. The company continues to expect a decline in earnings per share in the first half of 2002 followed by a return to earnings growth in the second half. For the first quarter of 2002, the company expects earnings per share to be in the range of \$.56 to \$.58, which compares with \$.74 in the first quarter of 2001. For 2003, the company continues to target high-teens earnings-per-share growth, excluding unusual items.

In addition, the company expects to post sales growth in the low-to-mid single digits in 2002. Several key products are expected to contribute to this growth, including Zyprexa, Gemzar, Evista, diabetes care products and Xigris. Growth in all these products is anticipated to more than offset the decline of Prozac sales and anti-infectives. The company's plans also include a number of new product launches, including Fortéo, Cialis™, atomoxetine and duloxetine for depression. As previously disclosed, the approval of Zyprexa IntraMuscular and Fortéo as well as additional new products continues to be dependent on resolution of all manufacturing issues to the FDA's satisfaction.

Gross margins as a percent of sales are expected to decline in 2002 approximately 1 percentage point as a result of the decline in Prozac sales. The company anticipates marketing and administrative expenses will grow at least in the mid single digits. Research and development expenses are expected to grow in the low single digits. Non-operating income is expected to contribute up to \$100 million in 2002. The tax rate is expected to remain at approximately 22 percent for the full year.

These forward-looking statements 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 the continuing impact of generic fluoxetine on Prozac sales in the United States, competitive developments affecting current growth products, the timing of anticipated regulatory approvals and launches of new products, other regulatory developments involving current and future products, the impact of governmental actions regarding coverage 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-Q filed November 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 fourth-quarter and full-year earnings conference call through a link that will be posted on Lilly's website at www.lilly.com. The conference call begins today at 10:30 a.m. Eastern Time and will be available for replay through January 31, 2002.

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.

Actos® (pioglitazone hydrochloride, Takeda)

Axid® (nizatidine, Lilly)

Cialis™ (tadalafil), Lilly-ICOS LLC

Evista® (raloxifene hydrochloride, Lilly)

Fortéo™ (teriparatide injection of rDNA origin, Lilly)

Gemzar® (gemcitabine hydrochloride, Lilly)

Humalog® (insulin lispro, Lilly)

Humulin® (human insulin of recombinant DNA origin, Lilly)
Humatrope® (somatropin of recombinant DNA origin, Lilly)
Iletin® (insulin, Lilly)
Prozac® (fluoxetine hydrochloride, Dista)
Prozac® Weekly™ (fluoxetine hydrochloride, Lilly)
ReoPro® (abciximab, Centocor), Lilly
Sarafem™ (fluoxetine hydrochloride, Lilly)
Xigris™ (drotrecogin alfa (activated), Lilly)
Zyprexa® (olanzapine, Lilly)