



**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 8-K**

**Current Report**

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

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Date of Report (Date of earliest event reported): **January 26, 2005**

**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

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

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**Item 2.02. Results of Operations and Financial Condition**

On January 26, 2005, we issued a press release announcing our results of operations for the quarter and year ended December 31, 2004, including, among other things, an income statement for those periods and a consolidated balance sheet as of December 31, 2004. In addition, on the same day we are holding a teleconference for analysts and media to discuss those results. The teleconference will be web cast on our web site. The press release and related financial statements are attached to this Form 8-K as [Exhibit 99](#).

We use non-GAAP financial measures, such as adjusted net income and diluted earnings per share. Non-GAAP financial measures differ from financial statements reported in conformity with U.S. generally accepted accounting principles ("GAAP"). There are non-GAAP financial measures used in comparing the financial results for the fourth quarter and full year of 2004 with the same periods of 2003. Those measures are operating income, other income—net, earnings, and earnings per share excluding the impact of:

- The following charges recognized in the fourth quarter of 2004 (described in more detail in our Forms 8-K dated October 21, 2004 and December 20, 2004, and in the attached press release):
  - Asset impairments, restructuring, and other special charges
  - Tax expense accrued on the expected repatriation to the U.S. of \$8.0 billion of eligible overseas earnings in 2005 under the American Jobs Creation Act of 2004
  - A charge for acquired in-process research and development related to the in-license of an insomnia compound from Merck KGaA
- Asset impairment charges recognized in the second quarter of 2004 (described in more detail in our Form 8-K dated July 22, 2004)
- 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 (described in more detail in our Form 8-K dated April 19, 2004)
- A gain on the sale of patents of the compound dapoxetine in the fourth quarter of 2003 (described in more detail in our Form 8-K dated January 29, 2004)
- Asset impairments, restructuring and special charges incurred in the first and fourth quarters of 2003 (described in more detail in our Forms 8-K dated April 22, 2003 and January 29, 2004, respectively).

In the press release attached as Exhibit 99, we also provided financial expectations for the first quarter and full year 2005. In addition to providing earnings per share expectations on a GAAP

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basis, we provided earnings per share expectations on an adjusted basis. The adjustments were as follows:

- We excluded the effect of the 2004 items listed above. 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 our reported operations for a period.
- In addition, we provided “adjusted proforma earnings per share” for 2004. Beginning January 1, 2005, we have adopted the Financial Accounting Standard Board’s new accounting standard on share-based payments. We determined that it would be useful for investors to provide a year-over-year comparison between 2004 and 2005 assuming comparable accounting treatment in both years. Therefore, we have provided adjusted proforma earnings per share for 2004 that assumes we expensed stock options in 2004.

We believe that these non-GAAP measures provide useful information to investors. Among other things, they may help investors evaluate our 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.

In particular, given our decision to adopt the new accounting rules for equity compensation for the full year 2005, we believe the best way for investors to understand year-over-year comparisons with 2004 is to adjust 2004 as if we had applied the new accounting rules.

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, our prospective earnings guidance is subject to adjustment for certain matters, such as those identified above, as to which prospective quantification generally is not feasible.

The information in this Item 2.02 and the press released attached as Exhibit 99 are considered furnished to the Commission and are not deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

**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: January 26, 2005

**EXHIBIT INDEX**

Exhibit Number

Exhibit

99

Press release dated January 26, 2005, together with related attachments.



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

[www.lilly.com](http://www.lilly.com)

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**Date:** January 26, 2005 — FINAL as of 1/24 end of day

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**For Release:** DRAFT

**Refer to:** (317) 276-5795 — Terra Fox

**Lilly Delivers 10 Percent Top Line Growth for Full Year 2004**  
*Newer Product Sales Double to \$1.5 Billion or 11 Percent of Total Sales*

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

Fourth-Quarter Highlights

- Sales increased 5 percent, to \$3.644 billion.
- Newer products — Alimta®, Cialis®, Cymbalta®, Forteo®, Strattera®, Symbyaxä, Xigris® and Yentreve® — contributed \$498.7 million to fourth-quarter sales and accounted for 14 percent of total sales, compared with 7 percent of total sales in the fourth quarter of 2003. Also, newer products increased 28 percent sequentially compared to the third quarter of 2004.
- Lilly had a net loss of \$2.4 million and no diluted earnings per share, primarily due to the tax expense on the expected repatriation of overseas earnings under the American Jobs Creation Act as well as charges for the restructuring initiatives.
- Excluding certain items, adjusted net income increased 13 percent, to \$814.3 million, and adjusted diluted earnings per share increased 12 percent, to \$.75.

2004 Highlights

- Sales increased 10 percent, to \$13.858 billion.
  - Newer products — Alimta, Cialis, Cymbalta, Forteo, Strattera, Symbyax, Xigris and Yentreve — contributed \$1.548 billion to full-year sales and accounted for 11 percent of total sales, compared with 5 percent of total sales in 2003.
  - Net income decreased 29 percent, to \$1.810 billion, and diluted earnings per share decreased 30 percent, to \$1.66, primarily due to the tax expense on the expected repatriation of overseas earnings under the American Jobs Creation Act as well as charges for the restructuring initiatives and the acquisition of Applied Molecular Evolution, Inc. (AME).
  - Excluding certain items, adjusted net income increased 10 percent, to \$3.071 billion, and adjusted diluted earnings per share increased 9 percent, to \$2.82.
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## Pharmaceutical Product Sales Highlights

(Dollars in millions)	Fourth Quarter		% Change Over/(Under)	Full Year		% Change Over/(Under)
	2004	2003	2003	2004	2003	2003
Zyprexa®	\$ 1,085.5	\$ 1,145.5	(5)%	\$ 4,419.8	\$ 4,276.9	3%
Diabetes Care Products	673.2	706.1	(5)%	2,609.4	2,568.5	2%
Gemzar®	329.5	282.6	17%	1,214.4	1,021.7	19%
Evista®	257.3	244.6	5%	1,012.7	922.1	10%
Strattera	183.4	132.6	38%	666.7	370.3	80%

### Significant Events Over the Last Three Months

- Lilly and Sankyo Company, Ltd. initiated a Phase III clinical trial to compare the effects of prasugrel, an investigational antiplatelet agent, with the antiplatelet market leader, Plavix®, in patients undergoing a procedure to open clogged arteries.
- Lilly acquired Merck KGaA's 5-HT<sub>2a</sub> antagonist compound EMD 281014, a potential breakthrough treatment for insomnia currently in Phase I clinical trials.
- Lilly launched its publicly available clinical trial registry, [www.lillytrials.com](http://www.lillytrials.com), which is the most comprehensive effort to date by any public or private entity to publicly disclose clinical trial information.
- In late December, Lilly and Boehringer Ingelheim GmbH received European approval for Cymbalta for the treatment of major depressive episodes.

“In 2004, Lilly continued leading the industry in delivering new innovative medicines to patients,” said Sidney Taurel, Lilly chairman, president and chief executive officer. “During the year, Lilly launched five new products plus six new indications or formulations in key markets. Notably, our recent launches of Cymbalta and Alimta are exceeding our sales expectations. Also during 2004, our newer product sales doubled and are expected to again double in 2005, to about 20 percent of total sales. And Lilly’s pipeline remains robust even after the recent surge in launches with two products under U.S. regulatory review, a new product submission planned for 2005 and an additional nine compounds and 10 new indications anticipated to be in mid-to-late-stage development this year.”

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Taurel added, "With our many new products, strong pipeline and no major patent expirations the rest of this decade, we believe Lilly is positioned well to produce growth at or near the top of our peer group in a sustainable fashion."

Fourth-Quarter Results

Worldwide sales for the quarter were \$3.644 billion, an increase of 5 percent compared with the fourth quarter of 2003. Worldwide sales volume increased 1 percent, while selling prices and exchange rates increased sales by 2 percent and 3 percent, respectively. (Numbers do not add due to rounding.)

Gross margins as a percent of sales decreased by 2.7 percentage points, to 76.2 percent. This decrease was due to the continued investment in the company's manufacturing technical capabilities and capacity and the impact of foreign exchange rates.

Overall, marketing and administrative expenses decreased 3 percent, to \$1.098 billion. This decrease was primarily attributable to ongoing marketing cost-containment measures, offset partially by increased charitable contribution funding to the Lilly Foundation, the impact of foreign exchange rates, and increased selling expenses in support of the new and anticipated product launches. Marketing and administrative expenses would have decreased 1 percent if not for ongoing reimbursement from collaboration partners for marketing and selling expenses incurred related to new product launches. Research and development expenses were \$705.5 million, or 19 percent of sales. Compared with the fourth quarter of 2003, research and development expenses declined 1 percent, primarily due to the fourth-quarter 2003 exenatide milestone payments to Amylin Pharmaceuticals, Inc. and the fourth-quarter 2004 reimbursement of research and development expenses from Boehringer Ingelheim triggered by the European approval of Cymbalta, offset partially by increased clinical trial and development expenses.

Operating income decreased 48 percent, to \$450.9 million, due largely to \$494.1 million in asset impairments, restructuring and other special charges, which is described in footnote (a) in the "Operating Results — Adjusted" income statement later in this press release. These charges exceeded the company's previously announced estimate primarily due to a \$36.0 million charge taken in the fourth quarter in connection with the previously reported Evista marketing and promotional practices investigation. The company has been cooperating with the Office of

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Consumer Litigation, Department of Justice in this investigation. Based on current discussions with the government, the company believes this provision will be sufficient to resolve the matter. Excluding certain items, adjusted operating income increased 10 percent, to \$974.9 million due primarily to increased sales and decreased operating expenses offset partially by cost of goods sold increasing at a faster rate than sales.

Net other income decreased \$26.9 million, which reflects the fourth-quarter 2003 gain related to the sale of dapoxetine patents to PPD, Inc. Excluding this gain, adjusted net other income increased \$38.1 million, primarily due to a milestone payment received from Boehringer Ingelheim related to the European approval of Cymbalta and income related to the outlicense of legacy products outside the U.S.

Lilly had a net loss of \$2.4 million and no diluted earnings per share, primarily due to the \$465.0 million tax expense on the expected repatriation to the United States of \$8.0 billion of eligible overseas earnings in 2005 under the American Jobs Creation Act of 2004 as well as the charges for the previously announced restructuring initiatives. Excluding certain items, adjusted net income and diluted earnings per share increased 13 percent and 12 percent, to \$814.3 million and \$.75, respectively, due to the increase in adjusted operating income and adjusted net other income. Refer to "Operating Results" and "Operating Results — Adjusted" later in this press release for a reconciliation of reported to adjusted operating income, net other income and net income.

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Reconciliation of Reported to AdjustedFourth-Quarter Earnings per Share

	Fourth Quarter		% Over/(Under)
	2004	2003	2003
<b>E.P.S. (reported)</b>	<b>\$ .00</b>	<b>\$ .69</b>	<b>(100%)</b>
Eliminate charges (a):			
Tax expense on the expected repatriation of earnings under the American Jobs Creation Act	.43	—	
Asset impairments, restructuring and other special charges	.30	.02	
Acquired in-process R&D related to inlicense of insomnia compound from Merck KGaA	.02	—	
Eliminate income (a):			
Gain on sale of dapoxetine patents	—	(.04)	
<b>E.P.S. (adjusted)</b>	<b>\$ .75</b>	<b>\$ .67</b>	<b>12%</b>

(a) Refer to "Operating Results — Adjusted" later in this press release for further description.

Full-Year Results

Worldwide sales for the full year of 2004 were \$13.858 billion, an increase of 10 percent compared with 2003. Worldwide sales volume increased 5 percent, while selling prices and exchange rates increased sales by 2 percent and 3 percent, respectively.

Gross margins as a percent of sales decreased by 2.0 percentage points, to 76.7 percent. This decrease was due to the continued investment in the company's manufacturing technical capabilities and capacity and the impact of foreign exchange rates, offset partially by a favorable product mix.

Overall, marketing and administrative expenses increased 6 percent, to \$4.284 billion. This increase was primarily attributable to increased selling expenses in support of the new and anticipated product launches, the impact of foreign exchange rates, and increased incentive compensation and benefits expense, offset partially by ongoing marketing cost-containment measures. Marketing and administrative expenses would have increased 10 percent if not for reimbursement from collaboration partners for marketing and selling expenses incurred related to new product launches. A majority of the reimbursements are ongoing. Research and development expenses were \$2.691 billion, or 19 percent of sales. Compared with 2003,

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research and development expenses increased 15 percent, primarily due to increased clinical trial and development expenses and increased incentive compensation and benefits expense, partially offset by reimbursements for research activities.

Operating income decreased 15 percent, to \$2.664 billion, due largely to the charges related to the previously announced restructuring initiatives and acquired in-process research and development (IPR&D) charge related to the acquisition of AME. Excluding certain items, adjusted operating income increased 4 percent, to \$3.659 billion, due primarily to increased sales offset partially by cost of goods sold and research and development expenses increasing at a greater rate than sales.

Net other income increased \$126.9 million due to income related to the outlicense of legacy products, milestones from collaborations on the duloxetine molecule, and other miscellaneous income, offset partially by an increase in the net loss of the Lilly ICOS LLC joint venture. Excluding the fourth-quarter 2003 gain related to the sale of dapoxetine patents to PPD, Inc., adjusted net other income increased \$191.9 million.

Net income decreased 29 percent, to \$1.810 billion, and diluted earnings per share decreased 30 percent, to \$1.66, primarily due to the tax expense on the expected repatriation of eligible overseas earnings in 2005 under the American Jobs Creation Act of 2004, the charges related to the previously announced restructuring initiatives, and acquired IPR&D charge for the AME acquisition. Excluding certain items, adjusted net income and diluted earnings per share increased 10 percent and 9 percent, to \$3.071 billion and \$2.82, respectively, due to the increase in adjusted operating income and adjusted net other income. Refer to "Operating Results" and "Operating Results — Adjusted" later in this press release for a reconciliation of reported to adjusted operating income, net other income and net income.

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Reconciliation of Reported to Adjusted

Full-Year Earnings per Share

	Full Year		% Over/(Under)
	2004	2003	2003
<b>E.P.S. (reported)</b>	<b>\$1.66</b>	<b>\$2.37</b>	<b>(30%)</b>
Eliminate charges (a):			
Tax expense on the expected repatriation of earnings under the American Jobs Creation Act	.43	—	
Asset impairments, restructuring and other special charges	.38	.25	
Acquired in-process R&D for AME acquisition and insomnia compound	.35	—	
Eliminate income (a):			
Gain on sale of dapoxetine patents	—	(.04)	
<b>E.P.S. (adjusted)</b>	<b>\$2.82</b>	<b>\$2.58</b>	<b>9%</b>

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

Zyprexa

In the fourth quarter of 2004, Zyprexa sales totaled \$1.086 billion, a 5 percent decrease compared with the fourth quarter of 2003. U.S. sales of Zyprexa decreased 19 percent, to \$547.9 million, driven by a decline in underlying demand due to continued competitive pressures. Zyprexa sales in international markets increased 15 percent, to \$537.6 million, driven by volume growth in a number of major markets outside the U.S. and the impact of foreign exchange rates. Excluding the impact of exchange rates, sales of Zyprexa outside the U.S. increased 8 percent in the fourth quarter.

For the full year of 2004, worldwide Zyprexa sales increased 3 percent, to \$4.420 billion. U.S. Zyprexa sales for 2004 were \$2.422 billion, an 8 percent decrease compared with 2003, and international Zyprexa sales were \$1.998 billion, a 22 percent increase. Excluding the impact of exchange rates, sales of Zyprexa outside the U.S. increased 13 percent in 2004.

While Lilly expects U.S. Zyprexa sales to decline for full-year 2005, the company believes its interventions will enable it to slow the erosion sometime in 2005. In addition, the company continues to expect double-digit growth of Zyprexa sales outside the U.S. As a result, Lilly expects a slight decline in its 2005 worldwide Zyprexa sales.

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#### Diabetes Care Products

In the fourth quarter of 2004, diabetes care revenue, composed primarily of Humalog®, Humulin® and Actos®, decreased 5 percent, to \$673.2 million, compared with the fourth quarter of 2003. Diabetes care revenue decreased 14 percent in the U.S., to \$371.3 million, due primarily to continued competitive pressures in the insulins market. Diabetes care revenue outside the U.S. increased 10 percent, to \$301.9 million.

For the full year of 2004, worldwide diabetes care revenue increased 2 percent, to \$2.609 billion.

For the fourth quarter of 2004, worldwide Humalog sales were \$284.6 million, an increase of 2 percent. Worldwide Humulin sales decreased 18 percent, to \$245.2 million. U.S. Humulin sales decreased 37 percent, to \$96.0 million, primarily due to continued competitive pressures in the insulins market as well as the effect of lower rebates and discounts in the fourth quarter of 2003 and wholesaler destocking in the fourth quarter of 2004. Actos generated \$128.9 million of revenue for Lilly, an increase of 12 percent. As previously disclosed, since Lilly's share of revenue from the agreement with Takeda will vary quarter-to-quarter based on contract terms, Actos revenue will not necessarily track with product sales. As a result, it is difficult to make quarterly comparisons for Actos revenue.

For the full year of 2004, worldwide Humalog sales increased 8 percent, to \$1.102 billion; Humulin sales decreased 6 percent, to \$997.7 million; and Actos revenue to Lilly increased 5 percent, to \$452.9 million.

#### Gemzar

Gemzar had sales totaling \$329.5 million for the quarter, an increase of 17 percent from the fourth quarter of 2003. Gemzar sales in the U.S. increased 8 percent, to \$155.1 million, due primarily to the approval of the metastatic breast cancer indication in the second quarter of 2004. Sales outside the U.S. increased 26 percent, to \$174.4 million.

For the full year of 2004, worldwide Gemzar sales increased 19 percent, to \$1.214 billion.

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#### Evista

Evista sales were \$257.3 million, a 5 percent increase compared with the fourth quarter of 2003. U.S. sales of Evista decreased 3 percent, to \$167.6 million, driven by a decline in underlying demand due to continued competitive pressures, partially offset by price increases. Sales outside the United States increased 25 percent, to \$89.7 million.

For the full year of 2004, worldwide Evista sales increased 10 percent, to \$1.013 billion.

#### Animal Health

Worldwide sales of animal health products in the fourth quarter were \$251.2 million, an increase of 18 percent compared with the fourth quarter of 2003, primarily driven by strong volume growth. For the full year of 2004, animal health sales increased 10 percent, to \$798.7 million.

#### Newer Products

##### Strattera

During the fourth quarter of 2004, Strattera, the only nonstimulant medicine approved for the treatment of ADHD in children, adolescents and adults, generated \$183.4 million of sales, a 38 percent increase over sales of \$132.6 million in the fourth quarter of 2003, and up sequentially compared with sales of \$163.6 million in the third quarter of 2004. The sequential growth was due to an increase in underlying prescription volume and U.S. wholesaler destocking in the third quarter of 2004.

For the full year of 2004, Strattera sales were \$666.7 million, compared with \$370.3 million in 2003.

##### Cialis

Total worldwide sales of Cialis, a treatment for erectile dysfunction marketed by Lilly ICOS LLC, were \$152.7 million, a sequential decrease compared with third-quarter 2004 worldwide sales of \$154.1 million. The \$152.7 million of worldwide Cialis sales in the fourth quarter of 2004 comprises \$34.0 million of sales in Lilly territories, which is reported in Lilly's revenue, and \$118.7 million of sales in the joint venture territories. The sequential decrease in worldwide



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Cialis sales was a result of a sequential decrease in U.S. sales in the fourth quarter as described below.

Within the joint venture territories, the U.S. sales of Cialis were \$52.8 million in the fourth quarter, a sequential decline compared with third-quarter 2004 U.S. sales of \$70.2 million. Although underlying U.S. prescription volume for Cialis has sequentially increased, Cialis U.S. sales sequentially declined due to wholesaler destocking in the fourth quarter of 2004.

For the full year of 2004, Cialis worldwide sales were \$552.3 million, of which \$130.6 million represents sales in Lilly territories and \$421.7 million relates to sales in the joint venture territories. This compares to 2003 worldwide Cialis sales of \$203.3 million, which comprised \$73.5 million of sales in Lilly territories and \$129.8 million of sales in the joint venture territories. Within the joint venture territories, the U.S. sales of Cialis were \$206.6 million in 2004, Cialis' first full year on the U.S. market.

#### Forteo

Fourth-quarter sales of Forteo, a treatment for severe osteoporosis, were \$74.3 million, a sequential increase compared with sales of \$58.1 million in the third quarter of 2004. The sequential growth was due to an increase in underlying prescription volume and U.S. wholesaler destocking in the third quarter of 2004. In the fourth quarter of 2004, U.S. sales of Forteo were \$56.8 million and sales outside the U.S. were \$17.5 million.

For the full year of 2004, Forteo sales were \$238.6 million, compared with \$65.3 million in 2003.

#### Xigris

Sales of Xigris, the first available pharmaceutical treatment for severe sepsis, were \$55.3 million, an increase of 9 percent compared with the fourth quarter of 2003. U.S. sales of Xigris decreased 5 percent, to \$31.6 million, while sales outside the United States increased 37 percent, to \$23.7 million.

For the full year of 2004, Xigris sales were \$201.8 million, an increase of 26 percent compared with 2003.

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#### Alimta

In the U.S., Alimta was launched during the first quarter of 2004 for the treatment of malignant pleural mesothelioma and approved during August for second-line treatment of non-small cell lung cancer, while in Europe it was approved for both indications in September. For the fourth quarter of 2004, Alimta generated sales of \$73.1 million, representing a significant sequential increase compared with third-quarter 2004 sales of \$40.0 million. U.S. sales of Alimta were \$59.3 million and sales outside the U.S. were \$13.8 million in the fourth quarter.

For 2004, Alimta's first year on the market, sales were \$142.6 million.

#### Cymbalta

Launched in the U.S. in late August for the treatment of depression and in September for the treatment of diabetic peripheral neuropathic pain, Cymbalta generated \$61.3 million in sales in the fourth quarter. Sales are up sequentially compared with third-quarter 2004 sales of \$32.5 million, which was predominately due to initial wholesaler stocking. Cymbalta received European approval for the treatment of major depressive episodes in late December and is expected to be available in the first European countries during the first quarter of 2005.

Year-to-date 2004 sales for Cymbalta were \$93.9 million.

#### Symbyax

Symbyax, which was launched during the first quarter of 2004 in the U.S. for the treatment of bipolar depression, had sales of \$15.2 million in the fourth quarter, compared with sales of \$13.5 million in the third quarter of 2004.

Symbyax sales were \$70.2 million in 2004, the product's first year on the U.S. market.

#### Financial Guidance for 2005 Reconfirmed

As previously announced, the company plans to adopt stock option expensing, effective January 1, 2005, instead of the mandatory July 1, 2005, adoption under the Financial Accounting Standards Board's recently issued accounting standard on share-based payments. Lilly is taking this step because it will provide comparable accounting treatment for the full year and facilitates

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a change the company is making beginning in 2005 in its incentive compensation structure. Specifically, to align with market-based compensation trends while maintaining a strong pay-for-performance philosophy, the company will adjust its incentives for management by decreasing the use of stock options in favor of an increase in stock grants that are contingent on achieving specified earnings goals. Overall this change will not increase the value of the equity compensation program for company management. The company estimates its incremental equity compensation expense due to these accounting and compensation changes will reduce diluted earnings per share by approximately \$.25 in 2005. For comparison purposes, 2004 diluted earnings per share would have been reduced by \$.23 if stock options had been expensed.

To facilitate year-to-year comparisons, the company is providing 2005 earnings-per-share guidance, both including as well as excluding the impact of the incremental equity compensation expense. In addition, to facilitate year-to-year comparisons, the company is providing 2004 adjusted earnings-per-share proforma as if stock options had been expensed in 2004.

Excluding the 2005 incremental equity compensation expense, the company expects 2005 earnings per share of \$3.05 to \$3.15, representing 8 percent to 12 percent growth compared with 2004 adjusted earnings per share of \$2.82. Including the 2005 incremental equity compensation expense, the company expects 2005 earnings per share of \$2.80 to \$2.90, representing 8 percent to 12 percent growth compared with 2004 adjusted proforma earnings per share of \$2.59. On a reported basis, the company's 2005 earnings-per-share guidance of \$2.80 to \$2.90 compares with 2004 earnings per share of \$1.66, representing growth of 69 percent to 75 percent. A more complete reconciliation follows:

	2005 Expectations	2004 Actual	% Change Over/(Under)
<b>E.P.S. (reported)</b>	<b>\$2.80 to \$2.90</b>	<b>\$1.66</b>	<b>69% to 75%</b>
Eliminate charges:			
Tax expense on the expected repatriation of earnings under the American Jobs Creation Act	—	.43	
Asset impairments, restructuring and other special charges	—	.38	
Acquired in-process R&D for AME acquisition and insomnia compound	—	.35	
Eliminate incremental equity compensation expense	.25	—	
<b>E.P.S. (adjusted)</b>	<b>\$3.05 to \$3.15</b>	<b>\$2.82</b>	<b>8% to 12%</b>
Include incremental equity compensation expense for 2005 and proforma stock option expense for 2004	(.25)	(.23)	
<b>E.P.S. (with options expensed)</b>	<b>\$2.80 to \$2.90</b>	<b>\$2.59</b>	<b>8% to 12%</b>

For the full year of 2005, the company expects sales to grow 8 percent to 10 percent (with sales acceleration in the second half), gross margins as a percent of sales to decline by roughly 50 basis points to 75 basis points, marketing and administrative expenses to grow in the low-single digits, research and development expense to grow in the mid-single digits, other income to contribute approximately \$175 million to \$225 million and the effective tax rate to be about 22 percent.

#### Financial Guidance for First-Quarter 2005 Provided

For the first quarter of 2005, the company expects earnings per share of \$.65 to \$.67, compared with first-quarter 2004 adjusted proforma earnings per share of \$.64; this first-quarter 2004 adjusted proforma earnings per share assumes stock options had been expensed in 2004 and eliminates the first-quarter 2004 acquired IPR&D charge related to the AME acquisition. Excluding the first-quarter 2005 incremental equity compensation expense, earnings per share would be \$.71 to \$.73, compared with first-quarter 2004 adjusted earnings per share of \$.70. On a reported basis, the first-quarter 2004 earnings per share was \$.37. A more complete reconciliation follows:

	First-Quarter 2005 Expectations	First-Quarter 2004 Actual	% Change Over/(Under)
<b>E.P.S. (reported)</b>	<b>\$.65 to \$.67</b>	<b>\$.37</b>	<b>76% to 81%</b>
Eliminate charges:			
Acquired in-process R&D for AME acquisition	—	.33	
Eliminate incremental equity compensation expense	.06	—	
<b>E.P.S. (adjusted)</b>	<b>\$.71 to \$.73</b>	<b>\$.70</b>	<b>1% to 4%</b>
Include incremental equity compensation expense for Q1 2005 and proforma stock option expense for Q1 2004	(.06)	(.06)	
<b>E.P.S. (with options expensed)</b>	<b>\$.65 to \$.67</b>	<b>\$.64</b>	<b>2% to 5%</b>

#### Webcast of Conference Call

As previously announced, investors and the general public can access a live webcast of the fourth-quarter and full-year 2004 earnings conference call through a link on Lilly's website at [www.lilly.com](http://www.lilly.com). The conference call will be held today from 9:00 a.m. to 10:00 a.m. EST and will be available for replay via the website through February 25, 2005.

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](http://www.lilly.com). F-LLY

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 tried in front of the federal district court in Indianapolis in January and February 2004); the impact of governmental actions regarding pricing, importation, and reimbursement for pharmaceuticals; changes in tax law; 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 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)  
Plavix® is a registered trademark of Sanofi-Synthelabo Inc.  
Prozac® (fluoxetine hydrochloride, Dista)  
ReoPro® (abciximab, Centocor), Lilly  
Strattera® (atomoxetine hydrochloride, Lilly)  
Symbyax<sup>à</sup> (olanzapine fluoxetine combination, or OFC, Lilly)  
Xigris® (drotrecogin alfa (activated), Lilly)  
Yentreve® (duloxetine hydrochloride, Lilly)  
Zyprexa® (olanzapine, Lilly)

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

	Three Months Ended December 31		Twelve Months Ended December 31	
	2004	2003	2004	2003
Net sales	\$ 3,644.3	\$ 3,465.5	\$ 13,857.9	\$ 12,582.5
Cost of sales	865.7	731.5	3,223.9	2,675.1
Research and development	705.5	710.0	2,691.1	2,350.2
Marketing and administrative	1,098.2	1,134.2	4,284.2	4,055.4
Acquired in-process research and development	29.9	—	392.2	—
Asset impairments, restructuring, and other special charges	494.1	28.3	603.0	382.2
Operating income	450.9	861.5	2,663.5	3,119.6
Interest expense	(16.3)	(9.8)	(51.6)	(61.0)
Other income — net	85.4	112.3	330.0	203.1
Income before income taxes	520.0	964.0	2,941.9	3,261.7
Income taxes	522.4	216.8	1,131.8	700.9
Net income (loss)	\$ (2.4)	\$ 747.2	\$ 1,810.1	\$ 2,560.8
Earnings per share — basic	\$ 0.00	\$ 0.69	\$ 1.67	\$ 2.38
Earnings per share — diluted	\$ 0.00	\$ 0.69	\$ 1.66	\$ 2.37
Dividends paid per share	\$ 0.355	\$ 0.335	\$ 1.42	\$ 1.34
Weighted-average shares outstanding (thousands) — basic	1,086,599	1,077,043	1,083,887	1,076,547
Weighted-average shares outstanding (thousands) — diluted	1,086,599	1,083,113	1,088,936	1,082,230

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

	Three Months Ended December 31		Twelve Months Ended December 31	
	2004 (a)	2003 (c)	2004 (b)	2003 (d)
Net sales	\$ 3,644.3	\$ 3,465.5	\$ 13,857.9	\$ 12,582.5
Cost of sales	865.7	731.5	3,223.9	2,675.1
Research and development	705.5	710.0	2,691.1	2,350.2
Marketing and administrative	1,098.2	1,134.2	4,284.2	4,055.4
Operating income	974.9	889.8	3,658.7	3,501.8
Interest expense	(16.3)	(9.8)	(51.6)	(61.0)
Other income — net	85.4	47.3	330.0	138.1
Income before income taxes	1,044.0	927.3	3,937.1	3,578.9
Income taxes	229.7	204.0	866.2	787.4
Net income	\$ 814.3	\$ 723.3	\$ 3,070.9	\$ 2,791.5
Earnings per share — basic	\$ 0.75	\$ 0.67	\$ 2.83	\$ 2.59
Earnings per share — diluted	\$ 0.75	\$ 0.67	\$ 2.82	\$ 2.58
Dividends paid per share	\$ 0.355	\$ 0.335	\$ 1.42	\$ 1.34
Weighted-average shares outstanding (thousands) — basic	1,086,599	1,077,043	1,083,887	1,076,547
Weighted-average shares outstanding (thousands) — diluted	1,089,227	1,083,113	1,088,936	1,082,230

- (a) The 2004 fourth-quarter amounts are adjusted to eliminate the following charges: \$29.9 million (pretax), or \$.02 per share (after-tax) charge for acquired in-process research and development related to the incense of an insomnia compound from Merck KGaA; \$494.1 million (pretax), or \$.30 per share (after-tax) for asset impairments, restructuring and other special charges (These charges exceeded the company's prior estimate primarily due to a \$36.0 million charge taken in the fourth quarter in connection with the previously reported Evista marketing and promotional practices investigation. The company has been cooperating with the Office of Consumer Litigation, Department of Justice in this investigation. Based on current discussions with the government, the company believes this provision will be sufficient to resolve the matter.); and \$465.0 million, or \$.43 per share, tax expense on the expected repatriation to the United States of \$8.0 billion of eligible overseas earnings in 2005 under the American Jobs Creation Act of 2004.
- (b) The 2004 full-year amounts are adjusted to eliminate the fourth-quarter charges outlined in (a) above and to eliminate the following additional charges: a \$108.9 million (pretax), or \$.08 per share (after-tax), second-quarter charge for asset impairments related to manufacturing and research and development; and a \$362.3



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million, or \$.33 per share (no tax benefit), first-quarter charge for acquired in-process research and development related to the Applied Molecular Evolution acquisition.

- (c) The 2003 fourth-quarter amounts are adjusted to eliminate \$65 million (pretax), or \$.04 per share (after-tax), of other income for the gain on the sale of dapoxetine patents to PPD, Inc., and \$28.3 million (pretax), or \$.02 per share (after-tax), charge related primarily to impairment of manufacturing assets.
- (d) The 2003 full-year amounts are adjusted to eliminate the fourth-quarter income and charge outlined in (c) above and to eliminate the \$353.9 million (pretax), or \$.23 per share (after-tax), first-quarter charges as follows: (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)

	Fourth Quarter		% Change Over/(Under)	Full Year		% Change Over/(Under)
	2004	2003	2003	2004	2003	2003
Zyprexa	\$ 1,085.5	\$ 1,145.5	(5%)	\$ 4,419.8	\$ 4,276.9	3%
Gemzar	329.5	282.6	17%	1,214.4	1,021.7	19%
Humalog	284.6	278.2	2%	1,101.6	1,021.2	8%
Evista	257.3	244.6	5%	1,012.7	922.1	10%
Humulin	245.2	299.3	(18%)	997.7	1,060.4	(6%)
Strattera	183.4	132.6	38%	666.7	370.3	80%
Prozac® family	123.1	166.0	(26%)	559.0	645.1	(13%)
Actos	128.9	114.6	12%	452.9	431.2	5%
Humatrope	121.9	102.0	19%	430.3	370.9	16%
ReoPro®	77.6	88.6	(12%)	362.9	364.4	0%

Eli Lilly and Company  
Consolidated Balance Sheet  
(Dollars in millions)

	December 31, 2004 (Unaudited)	December 31, 2003
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	5,365.3	2,756.3
Short-term investments	2,099.1	957.0
Accounts receivable, net of allowances for doubtful amounts of \$66.1 (2004) and \$69.3 (2003)	2,058.7	1,864.9
Other receivables	494.3	477.6
Inventories	2,291.6	1,963.0
Deferred income taxes	255.3	500.6
Prepaid expenses	271.5	249.5
<b>TOTAL CURRENT ASSETS</b>	<b>12,835.8</b>	<b>8,768.9</b>
<b>OTHER ASSETS</b>		
Prepaid pension	2,253.8	1,613.3
Investments	561.4	3,374.6
Sundry	1,665.1	1,392.5
	<u>4,480.3</u>	<u>6,380.4</u>
<b>PROPERTY AND EQUIPMENT</b>		
Land, buildings, equipment, and construction-in-progress	12,728.4	11,068.0
Less allowances for depreciation	5,177.5	4,529.0
	<u>7,550.9</u>	<u>6,539.0</u>
	<u><u>24,867.0</u></u>	<u><u>21,688.3</u></u>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY CURRENT LIABILITIES</b>		
Short-term borrowings	2,020.6	196.5
Accounts payable	648.6	875.9
Employee compensation	471.6	387.4
Dividends payable	414.4	398.3
Income taxes payable	1,703.9	1,749.8
Other liabilities	2,334.6	1,952.9
<b>TOTAL CURRENT LIABILITIES</b>	<b>7,593.7</b>	<b>5,560.8</b>
<b>LONG-TERM DEBT</b>	<b>4,491.9</b>	<b>4,687.8</b>
<b>DEFERRED INCOME TAXES</b>	<b>620.4</b>	<b>386.1</b>
<b>OTHER NONCURRENT LIABILITIES</b>	<b>1,241.1</b>	<b>1,288.8</b>
	<u>6,353.4</u>	<u>6,362.7</u>
<b>COMMITMENTS AND CONTINGENCIES</b>		
	—	—
<b>SHAREHOLDERS' EQUITY</b>		
Common stock	708.0	702.3
Additional paid-in capital	3,119.4	2,610.0
Retained earnings	9,724.6	9,470.4
Employee benefit trust	(2,635.0)	(2,635.0)
Deferred costs-ESOP	(111.9)	(118.6)
Accumulated other comprehensive loss	218.6	(160.1)
	<u>11,023.7</u>	<u>9,869.0</u>
Less cost of common stock in treasury	103.8	104.2
	<u>10,919.9</u>	<u>9,764.8</u>
	<u><u>24,867.0</u></u>	<u><u>21,688.3</u></u>