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**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): **October 18, 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

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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### **Item 1.01. Entry into a Material Definitive Agreement**

On October 18, 2004, the board of directors of Eli Lilly and Company (“we” or “our” or “the company”) approved amendments to the 2002 Lilly Stock Plan, the equity incentive plan for company employees and non-employee directors that was approved by our shareholders on April 15, 2002. The most significant amendments are as follows:

- **Termination Date.** As originally adopted, the plan was to remain in effect indefinitely until terminated by the board of directors. Under the amendment, the plan remains in effect until April 14, 2012, or until earlier terminated by the board of directors.
- **Additional Forms of Awards.** As originally adopted, the plan authorized the compensation committee of the board to grant stock options, performance awards, and restricted stock. Under the amendments, the compensation committee is also authorized to grant stock-settled stock appreciation rights and stock unit awards. The compensation committee has no current plans to make grants of those types of awards.

Under Indiana law and the rules of the New York Stock Exchange, these amendments may be made without shareholder approval.

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

On October 21, 2004, we issued a press release announcing our results of operations for the quarter and nine-month period ended September 30, 2004, including, among other things, an income statement for those periods and a consolidated balance sheet as of September 30, 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 (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 nine months of 2004 to the same period of 2003. Those measures are operating income, earnings, and earnings per share excluding the impact of:

- Asset impairment charges recognized in the second quarter of 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
- Asset impairments, restructuring and special charges incurred in the first quarter of 2003.

The second quarter 2004 items are described in more detail in our Form 8-K dated July 22, 2004. The first quarter 2004 item is described in more detail in our Form 8-K dated April 19, 2004. The first quarter 2003 items are described in more detail in our Form 8-K dated April 22, 2003.

In the press release attached as Exhibit 99, we also provided financial expectations for the fourth quarter and full year 2004. In addition to providing earnings per share expectations on a GAAP basis, we provided earnings per share expectations on an adjusted basis, excluding the effect of the first- and second-quarter 2004 items listed above and also excluding the expected effect of asset impairments, severance and other charges anticipated for the fourth quarter of 2004 as described in more detail under Items 2.05 and 2.06 below.

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. Management believes 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.

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.

**Item 2.05 Costs Associated with Exit or Disposal Activities  
and**

**Item 2.06 Material Impairments**

We have committed to several actions designed to increase the productivity of the company, to address current challenges in the marketplace, and to leverage prior investments in our product portfolio. Except as noted below, the actions were decided by action of the board of directors on October 18, 2004. The actions affect operations primarily in research and development, manufacturing, and sales and marketing components, and will have an impact on both infrastructure and personnel. These decisions are integral parts of our ongoing efforts to implement a highly productive innovation-based strategy that will address challenges in the current business environment as well as provide sustainable growth. The actions are intended to help us offset the short-term challenges created by the performance of Zyprexa® in the U.S. without compromising future growth prospects. More fundamentally, the actions are intended to allow us to successfully compete in the long-term. Our company is now in an environment in

which the increasing pressure on pharmaceutical prices compels us to redouble our efforts to increase productivity and thoughtfully reduce our cost structure.

The principal restructuring actions described below will result in the elimination of nearly 1,000 U.S. positions. The individuals affected by those eliminated positions will be given the opportunity to fill other open positions in the company. Each affected employee will also have the option to elect a voluntary severance package.

The principal actions are as follows:

- **Research and Development**  
We will focus our research efforts on the therapeutic areas of neuroscience, endocrine, oncology and cardiovascular and will discontinue our efforts in inflammation. We will close our RTP Laboratory site in Research Triangle Park, North Carolina. This site has historically been our center of excellence for high-throughput screening and combinatorial chemistry, but much of that technology has evolved such that these operations can be more efficiently performed in existing facilities in Indianapolis. These actions are expected to result in asset impairments and severance-related charges.
- **Manufacturing**  
The mission of our Clinton, Indiana, manufacturing site will be narrowed to make products solely for the Elanco Animal Health business. The portion of that site that currently produces human pharmaceutical products will cease operation. Also, we will discontinue our plans to produce the bulk active ingredient for Xigris® at the company's Indianapolis operations. Although we remain committed to this important life-saving product, we have determined that our manufacturing partner, Lonza Biologics plc, has enough capacity to supply anticipated Xigris demand for the foreseeable future. These actions are expected to result in asset impairments and severance-related charges.
- **Sales and Marketing**  
We will close all district and regional sales offices throughout the United States, and these operations will now be managed from home-based offices. This change, which is consistent with standard industry practice, will provide cost savings. In addition, we will reorganize our U.S. sales force to create an organization that better meets customer needs as well as maximizes sales potential. We will also streamline some sales and marketing support activities as well as our field-based operations that support our medical function. The company committed to the U.S. sales and marketing actions in early October, 2004. These actions are expected to result in asset impairments, severance-related charges, and lease termination costs, which are not material individually or in the aggregate.

#### Restructuring and Asset Impairments Charge

The costs associated with the restructuring actions in the aggregate will consist of asset impairments, severance expenses, and other charges estimated in a range of \$320 million to \$420 million (pretax), substantially all of which is expected to be reported in the fourth quarter of 2004. The estimated non-cash charges total approximately \$250 million to \$320 million and consist of asset impairments, which primarily relate to Xigris manufacturing equipment in

Indianapolis, human pharmaceutical manufacturing buildings and equipment at Clinton, Indiana, and the RTP Laboratory building and equipment. We will cease using these assets as described above and they will be disposed of or destroyed. The impairment charges will be necessary to adjust the carrying value of the assets to fair value. The estimated cash expenditures total approximately \$70 million to \$100 million and consist primarily of severance payments, and to a lesser extent, lease termination payments.

We expect to substantially complete the restructuring actions by March 31, 2005. However, certain activities may require additional time for completion throughout 2005.

#### **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

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Name: Charles E. Golden

Title: Executive Vice President and Chief  
Financial Officer

Dated: October 21, 2004

**EXHIBIT INDEX**

<u>Exhibit Number</u>	<u>Exhibit</u>
99	Press release dated October 21, 2004, together with related attachments.



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

WWW.LILLY.COM

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**Date:** October 21, 2004

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**For Release:** Immediately

**Refer to:** (317) 276-2506 — Phil Belt  
(317) 276-5795 — Terra Fox

**Lilly Announces Third-Quarter Earnings Per Share of \$.69; Company Also Details Restructuring Activities**

*Changes in Various Functional Areas Designed to Increase Productivity of Organization*

Eli Lilly and Company (NYSE: LLY) today announced financial results for the third quarter of 2004. The company also announced several actions designed to increase the productivity of the company, to address current challenges in the marketplace, and to leverage prior investments in the company's product portfolio. The actions affect primarily operations in research and development, manufacturing, and sales and marketing components, and will have an impact on both infrastructure and personnel. These decisions are integral parts of the company's ongoing efforts to implement a highly productive innovation-based strategy that will address challenges in the current business environment as well as provide sustainable earnings growth.

**Restructuring**

The restructuring activities described below will result in the elimination of approximately 1,000 positions, of which 575 relate to changes in the sales and marketing component that were announced last week. The individuals affected by the eliminated positions will be given the opportunity to fill other open positions in the company. Each affected employee will also have the option to elect a voluntary severance package.

Said Sidney Taurel, chairman, president and chief executive officer for Lilly, "We have taken these actions at this time for two reasons. First, they will help us offset the short-term challenges created by the performance of Zyprexa® in the U.S. without compromising future growth prospects. Second, and much more important, these actions are part of a strategic mindset that will allow us to successfully compete in the long-term. Specifically, we are now in an

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environment in which the increasing dissatisfaction with pharmaceutical prices compels us to relentlessly identify and eliminate any inefficiency in our business. Therefore, as we move forward, we will be committed to increasing productivity and wisely reducing our cost structure. Today's announcements represent an example of this ongoing commitment. These activities will generate an estimated net savings in the range of \$150 million in 2005, with annual savings thereafter expected to be even larger. These cost savings will be accomplished by natural attrition, the results of a previously announced hiring freeze, employees who accept voluntary severance packages, and modest savings from asset impairments."

#### Research and Development

Lilly will focus its research efforts on the therapeutic areas of neuroscience, endocrine, oncology and cardiovascular and will discontinue its efforts in inflammation. This will allow Lilly to become increasingly focused in its research and will allow for the positioning of a critical mass of scientific talent and investment in therapeutic areas where the company has the greatest likelihood of continuing its strong record of innovation.

In addition to the narrowing of therapeutic focus, Lilly will close its RTP Laboratory site in Research Triangle Park, North Carolina. This site has historically been the company's center of excellence for high-throughput screening and combinatorial chemistry, but much of that technology has evolved such that these operations can be more efficiently performed in existing facilities in Indianapolis.

#### Manufacturing

The company will also streamline some of its manufacturing operations. Specifically, the mission of the company's Clinton, Indiana, manufacturing site will be narrowed to make products solely for the Elanco Animal Health business. The portion of that site that currently produces human pharmaceutical products will stop operation.

The company will discontinue its plans to produce the bulk active ingredient for Xigris® at the company's Indianapolis operations. Although the company remains committed to this important life-saving product, it has determined that its manufacturing partner, Lonza Biologics plc, has enough capacity to supply anticipated Xigris demand for the foreseeable future.

## Sales and Marketing

As announced last week, the company is making some changes to the sales and marketing component. The company will close all its district and regional sales offices throughout the United States, and these operations will now be managed from home-based offices. This change, which is consistent with standard industry practice, will provide cost savings. In addition, the company will reorganize its U.S. sales force to create an organization that better meets customer needs as well as maximizes sales potential. This rebalancing of sales territories will allow the company to make better use of existing resources. The company will also streamline some of its sales and marketing support activities as well as its field-based operations that support the company's medical function.

## Restructuring and Asset Impairments Charge

The restructuring activities will be substantially completed by March 31, 2005. However, certain activities may require additional time for completion throughout 2005. The estimated costs associated with the various activities will consist of voluntary severance expenses, asset impairment and other charges aggregating \$320 million to \$420 million (pretax), substantially all of which is expected to be reported in the fourth quarter of 2004. The estimated non-cash charges total approximately \$250 million to \$320 million and consist of asset impairments, which primarily relate to Xigris manufacturing equipment in Indianapolis, human pharmaceutical manufacturing buildings and equipment at Clinton, and RTP Laboratory building and equipment. The estimated cash expenditures total approximately \$70 million to \$100 million and consist primarily of voluntary severance payments as well as lease termination payments.

## Financial Results

### Third-Quarter Highlights

- Sales increased 4 percent, to \$3.280 billion.
- Newer products — Alimta®, Cialis®, Cymbalta®, Forteo®, Strattera®, Symbyax™, Xigris and Yentreve® — contributed \$390.1 million to third-quarter sales and accounted for 12 percent of total sales, compared with 6 percent of total sales in the third quarter of last year.
- Net income increased 6 percent, to \$755.2 million, and diluted earnings per share increased 5 percent, to \$.69.

## Pharmaceutical Product Sales Highlights

(Dollars in millions)	Third Quarter			Year-to-Date		
	2004	2003	% Change Over/(Under) 2003	2004	2003	% Change Over/(Under) 2003
Zyprexa	\$1,023.7	\$1,127.6	(9)%	\$3,334.3	\$3,131.4	6%
Diabetes Care Products	580.2	588.7	(1)%	1,936.2	1,862.4	4%
Gemzar®	312.7	250.6	25%	885.0	739.1	20%
Evista®	246.1	240.0	3%	755.4	677.4	12%

### Significant Events Over the Last Three Months

- The U.S. Food and Drug Administration (FDA) approved Cymbalta, a balanced and potent selective serotonin and norepinephrine reuptake inhibitor (SSNRI), for the treatment of major depression. This breakthrough antidepressant, which treats both the emotional and painful physical symptoms of depression, was launched in the U.S. in late August.
- In September, Cymbalta received its second U.S. approval and became the first FDA-approved treatment for pain caused by diabetic peripheral neuropathy. This approval came after a six-month priority review.
- The Committee for Medicinal Products in Human Use (CHMP) of the European Medicines Agency (EMA) issued a positive opinion recommending approval of Cymbalta for the treatment of major depressive episodes. The European Commission is expected to grant marketing authorization by early 2005.
- The European Commission granted marketing authorization throughout the European Union for Yentreve, the first pharmaceutical widely approved for the treatment of moderate to severe stress urinary incontinence (SUI) in women. Yentreve was launched in Germany, Denmark, Finland, Sweden and the United Kingdom in mid-September and is anticipated to launch in additional European countries in the near future.
- Lilly and Boehringer Ingelheim submitted a complete response to the FDA and anticipate U.S. approval for duloxetine for stress urinary incontinence in the first half of 2005.
- In August, the FDA granted accelerated approval for Alimta for the second-line treatment of non-small cell lung cancer. This represents Alimta's second U.S. approval, following its February approval for the treatment of malignant pleural mesothelioma.
- In September, Alimta was granted marketing authorization by the European Commission for both the treatment of malignant pleural mesothelioma and as a second-line treatment for non-

small cell lung cancer. Alimta will be launched in several European countries later this year, with additional European markets launching in 2005.

- In August, Lilly announced that upon product approval it would disclose the results of all clinical trials for which Lilly is a sponsor via a publicly available registry, by the end of the fourth quarter of this year. The registry will include results of all Phase I through Phase IV clinical trials of Lilly's marketed products conducted anywhere in the world. Additionally, the company will begin posting the initiation of all Phase III and Phase IV clinical trials via the registry.

"Our third-quarter financial results were negatively affected by Zyprexa's performance in the U.S.," said Taurel. "However, increased productivity combined with the industry's best new product flow positions Lilly well to deliver sustainable sales and earnings growth. During this quarter alone, Lilly received six approvals in the U.S. and Europe related to Cymbalta, Yentreve and Alimta, and we are very pleased with the initial performance of these products. We expect to continue to build our newer product sales base with the addition next year of duloxetine for stress urinary incontinence and exenatide for type 2 diabetes in the U.S."

#### Third-Quarter Results

Worldwide sales for the quarter were \$3.280 billion, an increase of 4 percent compared with the third quarter of 2003. Worldwide sales volume increased 1 percent, while selling prices and exchange rates increased sales by 1 percent and 2 percent, respectively.

Gross margins as a percent of sales decreased by 3.1 percentage points, to 75.3 percent. This decrease was due to investment in the company's manufacturing technical capabilities and capacity and the impact of foreign exchange rates.

Overall, marketing and administrative expenses decreased 1 percent, to \$951.9 million. This decrease was primarily attributable to ongoing marketing cost-containment measures, offset partially by 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. In addition, marketing and administrative expenses would have increased 6 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 \$654.8 million, or 20 percent of sales. Compared with the third quarter of 2003, research and development expenses increased 15 percent, primarily due to increased clinical trial and development expenses, increased incentive compensation and benefits expense, and reduced third-party reimbursements for research activities.

Operating income decreased 7 percent, to \$863.6 million, due primarily to the impact of cost of goods sold and research and development expenses increasing at a rate greater than sales. Net other income increased \$120 million primarily due to income related to the outlicense of legacy products outside the U.S., milestones from collaborations on the duloxetine molecule, and other miscellaneous income.

Net income and diluted earnings per share for the third quarter increased 6 percent and 5 percent, to \$755.2 million and \$.69, respectively. The decrease in operating income was offset by higher net other income.

#### Zyprexa

In the third quarter of 2004, Zyprexa sales totaled \$1.024 billion, a 9 percent decrease over the third quarter of 2003.

U.S. sales of Zyprexa decreased 22 percent, to \$557.3 million, driven by a decline in underlying demand due to continued competitive pressures and by wholesaler destocking in the third quarter of 2004 and wholesaler stocking during the third quarter of last year. The company expects Zyprexa sales in the U.S. to decline in the fourth quarter of 2004, compared with the fourth quarter of 2003.

Zyprexa sales in international markets increased 12 percent, to \$466.4 million, driven by volume growth in a number of major markets outside the U.S. Zyprexa international sales growth also benefited from the impact of foreign exchange rates. Excluding the impact of exchange rates, sales of Zyprexa outside the U.S. increased by 6 percent in the third quarter. The company expects a stronger international growth rate for Zyprexa in the fourth quarter of 2004.

For the full year 2004, the company expects some growth in worldwide Zyprexa sales.

#### Diabetes Care Products

Diabetes care revenue, composed primarily of Humalog®, Humulin® and Actos®, decreased 1 percent, to \$580.2 million, compared with the third quarter of 2003. Diabetes care revenue decreased 8 percent in the U.S., to \$314.9 million, due primarily to continued competitive pressures in the insulins market. Diabetes care revenue outside the U.S. increased 7 percent, to \$265.3 million.

Worldwide Humalog sales were \$264.6 million, an increase of 10 percent compared with the third quarter of 2003. Worldwide Humulin sales decreased 8 percent, to \$243.7 million. Actos generated \$58.3 million of revenue for Lilly in the third quarter, a decrease of 13 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.

#### Gemzar

Gemzar had sales totaling \$312.7 million for the quarter, an increase of 25 percent from the third quarter of 2003. Gemzar sales in the U.S. increased 25 percent, to \$152.3 million, due primarily to wholesaler destocking in the third quarter of last year as well as the approval of the metastatic breast cancer indication in the second quarter of 2004. Sales outside the U.S. increased 25 percent, to \$160.4 million.

#### Evista

Evista sales were \$246.1 million, a 3 percent increase compared with the third quarter of 2003. U.S. sales of Evista decreased 3 percent, to \$169.2 million, driven by a decline in underlying demand due to continued competitive pressures. Sales outside the United States increased 16 percent, to \$76.9 million.

#### Animal Health

Worldwide sales of animal health products in the third quarter were \$185.4 million, an increase of 6 percent compared with the third quarter of 2003.

## Newer Products

### Xigris

Sales of Xigris, the first available pharmaceutical treatment for severe sepsis, were \$49.3 million, an increase of 30 percent compared with the third quarter of 2003. U.S. sales of Xigris increased 21 percent, to \$29.9 million, while sales outside the United States increased 48 percent, to \$19.4 million.

### Forteo

Third-quarter sales of Forteo, a new treatment for severe osteoporosis, were \$58.1 million, a sequential decrease compared with sales of \$65.3 million in the second quarter of 2004. In the third quarter of 2004, U.S. sales of Forteo were \$47.6 million and sales outside the U.S. were \$10.5 million. Underlying prescription volume for Forteo has sequentially increased. However, Forteo sales have sequentially declined due to U.S. wholesaler destocking in the third quarter of 2004.

### Strattera

During the third quarter of 2004, Strattera, the only non-stimulant medicine approved for the treatment of ADHD in children, adolescents and adults, generated \$163.6 million of sales, a 51 percent increase over sales of \$108.0 million in the third quarter of 2003, but down sequentially compared with sales of \$178.6 million in the second quarter of 2004. Underlying prescription volume for Strattera has sequentially increased. However, Strattera sales have sequentially declined due to U.S. wholesaler destocking in the third quarter of 2004.

### Cialis

Total worldwide sales of Cialis, a new treatment for erectile dysfunction marketed by Lilly ICOS LLC, were \$154.1 million, a sequential increase compared with second-quarter 2004 worldwide sales of \$137.2 million. The \$154.1 million of worldwide Cialis sales in the third quarter of 2004 comprises \$31.1 million of sales in Lilly territories, which is reported in Lilly's revenue, and \$123.0 million of sales in the joint venture territories. Within the joint venture territories, the U.S. sales of Cialis were \$70.2 million in the third quarter.

## Symbyax

Symbyax, which was launched during the first quarter of 2004 in the U.S. for the treatment of bipolar depression, had sales of \$13.5 million in the third quarter, compared with sales of \$7.9 million in the second quarter of 2004.

## Alimta

The company is very pleased with the early sales results for Alimta, which was launched in the U.S. 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. Third-quarter sales of \$40.0 million increased sequentially compared with second-quarter 2004 sales of \$17.8 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 \$32.5 million in sales, predominately due to initial wholesaler stocking. The company is very encouraged by early prescription trends for Cymbalta, which are above the company's expectations. The company is also pleased with the trial rates among both primary care physicians and psychiatrists and by the amount of use of Cymbalta as a first-line therapy in a competitive antidepressant market.

## Year-to-Date Results

For the first nine months of the year, worldwide sales increased 12 percent, to \$10.214 billion, compared with sales for the same period in 2003. Net income was flat and diluted earnings per share for the first nine months decreased 1 percent, to \$1.813 billion and \$1.66, respectively, compared with results for the first nine months in 2003. Excluding the charges shown below, adjusted net income and diluted earnings per share for the first nine months increased 9 percent and 8 percent, respectively, to \$2.257 billion and \$2.07, compared with the same period in the prior year. The adjusted earnings growth was driven by sales growth and net other income offset partially by cost of goods sold and research and development expenses increasing at a rate greater than sales. Refer to the tables titled "Operating Results" and "Operating Results — Adjusted" attached to this press release for a reconciliation of reported to adjusted operating income and net income.



**Reconciliation of Reported to Adjusted  
Year-to-Date Earnings per Share**

	Year-to-Date		% Change Over/(Under) 2003
	2004	2003	
<b>E.P.S. (as reported, diluted)</b>	<b>\$1.66</b>	<b>\$1.68</b>	<b>(1%)</b>
Add back charges: (a)			
Acquired in-process R&D related to AME acquisition	.33	—	
Asset impairments, restructuring and other special charges	.08	.23	
<b>E.P.S. (adjusted and diluted)</b>	<b>\$2.07</b>	<b>\$1.91</b>	<b>8%</b>

(a) Refer to the tables titled "Operating Results — Adjusted" attached to this press release for further description of these charges.

**Financial Expectations for the Fourth Quarter and Full Year 2004**

The company expects adjusted earnings per share of \$.73 to \$.75 for the fourth quarter of 2004 and adjusted earnings per share of \$2.80 to \$2.82 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 and the \$.08 per share charge for asset impairments that was incurred in the second quarter.

In addition, the company's earnings guidance for the fourth quarter and full year excludes future material, unusual items. As discussed in detail earlier in this press release, in the fourth quarter of 2004 the company will incur restructuring and asset impairment charges, which are not included in the above guidance, in the estimated amount of \$.19 to \$.24 per share. If these charges were not excluded, then the reported earnings-per-share guidance for fourth quarter and full year 2004 would be \$.49 to \$.56 per share and \$2.15 to \$2.22 per share, respectively.

The company expects sales growth in the low single digits for the fourth quarter of 2004, resulting in 9 to 10 percent sales growth for the full year 2004. While the weaker revenue trend may persist into the first half of 2005, the company anticipates accelerating overall revenue growth during the second half of 2005 based on the strength of the newer products.

For the fourth quarter and full year of 2004, the company expects gross margins as a percent of sales to be in line with gross margins as a percent of sales for the first nine months of 2004. The company anticipates marketing and administrative expenses to decline in the fourth quarter, resulting in annual market and administrative expense growth in the low single digits. Research and development expenses are expected to grow in the single digits in the fourth quarter of 2004 and in the mid-teens for the full year 2004. The company expects a modest contribution of other income (i.e. net other income less interest expense) in the fourth quarter of 2004 and approximately \$220 million to \$250 million for the full year 2004.

The reported 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. If the American Jobs Creation Act of 2004, which includes an incentive for companies to reinvest their foreign earnings in the United States, were signed by the President of the United States in the fourth quarter of 2004, the company would anticipate accruing tax on the eligible overseas earnings expected to be repatriated to the United States in 2005. Any such additional tax is not included in the above guidance. The tax impact of the American Jobs Creation Act on the company remains under consideration.

#### Webcast of Conference Call

As previously announced, investors and the general public can access a live webcast of the third-quarter 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 10 a.m. to 11 a.m. EDT and will be available for replay via the website through November 18, 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](http://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. There can be no guarantee that the restructuring activities described here will achieve the results anticipated by the company. 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 August 2004. The company undertakes no duty to update forward-looking statements.

# # #

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)

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

	Three Months Ended September 30		Nine Months Ended September 30	
	2004	2003	2004	2003
Net sales	\$ 3,280.4	\$ 3,139.4	\$ 10,213.6	\$ 9,117.0
Cost of sales	810.1	679.3	2,358.2	1,943.6
Research and development	654.8	568.1	1,985.6	1,640.2
Marketing and administrative	951.9	963.4	3,186.0	2,921.2
Acquired in-process research and development	—	—	362.3	—
Asset impairments, restructuring, and other special charges	—	—	108.9	353.9
Operating income	863.6	928.6	2,212.6	2,258.1
Interest expense	(18.5)	(15.8)	(35.3)	(51.2)
Other income — net	123.1	3.1	244.6	90.8
Income before income taxes	968.2	915.9	2,421.9	2,297.7
Income taxes	213.0	201.5	609.4	484.1
Net income	\$ 755.2	\$ 714.4	\$ 1,812.5	\$ 1,813.6
Earnings per share — basic	\$ 0.70	\$ 0.66	\$ 1.67	\$ 1.68
Earnings per share — diluted	\$ 0.69	\$ 0.66	\$ 1.66	\$ 1.68
Dividends paid per share	\$ 0.355	\$ 0.335	\$ 1.065	\$ 1.005
Weighted-average shares outstanding (thousands)				
— basic	1,084,809	1,076,276	1,082,983	1,076,382
Weighted-average shares outstanding (thousands)				
— diluted	1,089,227	1,081,815	1,088,924	1,082,023

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

	Three Months Ended September 30		Nine Months Ended September 30	
	2004	2003	2004 (a)	2003 (b)
Net sales	\$ 3,280.4	\$ 3,139.4	\$ 10,213.6	\$ 9,117.0
Cost of sales	810.1	679.3	2,358.2	1,943.6
Research and development	654.8	568.1	1,985.6	1,640.2
Marketing and administrative	951.9	963.4	3,186.0	2,921.2
Operating income	863.6	928.6	2,683.8	2,612.0
Interest expense	(18.5)	(15.8)	(35.3)	(51.2)
Other income — net	123.1	3.1	244.6	90.8
Income before income taxes	968.2	915.9	2,893.1	2,651.6
Income taxes	213.0	201.5	636.5	583.3
Net income	\$ 755.2	\$ 714.4	\$ 2,256.6	\$ 2,068.2
Earnings per share — basic	\$ 0.70	\$ 0.66	\$ 2.08	\$ 1.92
Earnings per share — diluted	\$ 0.69	\$ 0.66	\$ 2.07	\$ 1.91
Dividends paid per share	\$ 0.355	\$ 0.335	\$ 1.065	\$ 1.005
Weighted-average shares outstanding (thousands)				
— basic	1,084,809	1,076,276	1,082,983	1,076,382
Weighted-average shares outstanding (thousands)				
— diluted	1,089,227	1,081,815	1,088,924	1,082,023

- (a) The 2004 year-to-date amounts are adjusted to exclude a \$108.9 million (pretax) second-quarter charge, or \$.08 per share (after-tax), for asset impairments related to manufacturing and research and development and a \$362.3 million first-quarter 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 year-to-date amounts are adjusted to exclude \$353.9 million (pretax) first-quarter charges, or \$.23 per share (after-tax), 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)

	Third Quarter		% Change Over/(Under) 2003	Nine Months Ended September 30		% Change Over/(Under) 2003
	2004	2003		2004	2003	
Zyprexa	\$1,023.7	\$1,127.6	(9%)	\$3,334.3	\$3,131.4	6%
Gemzar	312.7	250.6	25%	885.0	739.1	20%
Humalog	264.6	240.2	10%	817.1	743.1	10%
Evista	246.1	240.0	3%	755.4	677.4	12%
Humulin	243.7	264.5	(8%)	752.5	761.0	(1%)
Strattera	163.6	108.0	51%	483.3	237.7	103%
Prozac® family	141.0	154.2	(9%)	435.9	479.2	(9%)
Actos	58.3	67.1	(13%)	324.0	316.6	2%
Humatrope	103.6	93.5	11%	308.4	268.9	15%
ReoPro	89.8	88.2	2%	285.3	275.8	3%

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

	September 30, 2004	December 31, 2003
	(Unaudited)	
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$ 2,577.4	\$ 2,756.3
Short-term investments	1,596.9	957.0
Accounts receivable, net of allowances for doubtful amounts of \$62.8 (2004) and \$69.3 (2003)	1,913.1	1,864.9
Other receivables	429.7	477.6
Inventories	2,092.0	1,963.0
Deferred income taxes	643.6	500.6
Prepaid expenses	333.0	249.5
<b>TOTAL CURRENT ASSETS</b>	<b>9,585.7</b>	<b>8,768.9</b>
<b>OTHER ASSETS</b>		
Prepaid pension	1,873.6	1,613.3
Investments	3,665.3	3,374.6
Sundry	1,578.4	1,392.5
	7,117.3	6,380.4
<b>PROPERTY AND EQUIPMENT</b>		
Land, buildings, equipment, and construction-in-progress	12,191.2	11,068.0
Less allowances for depreciation	4,708.3	4,529.0
	7,482.9	6,539.0
	<u>\$24,185.9</u>	<u>\$21,688.3</u>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES</b>		
Short-term borrowings	\$ 1,668.6	\$ 196.5
Accounts payable	680.4	875.9
Employee compensation	466.1	387.4
Dividends payable	—	398.3
Income taxes payable	1,874.4	1,749.8
Other liabilities	1,852.4	1,952.9
<b>TOTAL CURRENT LIABILITIES</b>	<b>6,541.9</b>	<b>5,560.8</b>
<b>LONG-TERM DEBT</b>	<b>4,510.5</b>	<b>4,687.8</b>
<b>OTHER NONCURRENT LIABILITIES</b>	<b>1,823.5</b>	<b>1,674.9</b>
	6,334.0	6,362.7
<b>COMMITMENTS AND CONTINGENCIES</b>	—	—
<b>SHAREHOLDERS' EQUITY</b>		
Common stock	707.6	702.3
Additional paid-in capital	3,093.3	2,610.0
Retained earnings	10,526.9	9,470.4
Employee benefit trust	(2,635.0)	(2,635.0)
Deferred costs-ESOP	(114.7)	(118.6)
Accumulated other comprehensive loss	(164.9)	(160.1)
	11,413.2	9,869.0
Less cost of common stock in treasury	103.2	104.2
	11,310.0	9,764.8
	<u>\$24,185.9</u>	<u>\$21,688.3</u>