
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

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

Date of Report (Date of earliest event reported): October 23, 2008

ELI LILLY AND COMPANY

(Exact name of registrant as specified in its charter)

Indiana
(State or Other Jurisdiction
of Incorporation)

001-06351
(Commission
File Number)

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

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

46285
(Zip Code)

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

No Change

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

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:

- 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 2.02. Results of Operations and Financial Condition

On October 23, 2008, we issued a press release announcing our results of operations for the quarter ended September 30, 2008, including, among other things, an income statement and balance sheet for those periods. 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 99.1](#).

We provide non-GAAP financial information that differs from financial statements reported in conformity to U.S. generally accepted accounting principles ("GAAP"). In the press release attached as Exhibit 99.1 and in related communications about our results, we use non-GAAP financial measures in comparing the financial results for the third quarter and first nine months of 2008 with the same periods of 2007. Those measures include earnings per share and gross margin as a percent of sales without the effect of several items affecting the relevant accounting periods:

- The following items in the third quarter of 2008 (described in more detail in the press release attached to this Form 8-K as Exhibit 99.1)
 - Charges totaling \$1.477 billion, or \$1.33 per share, related to the pending Zyprexa investigations with the U.S. Attorney for the Eastern District of Pennsylvania, as well as the resolution of a multi-state investigation regarding Zyprexa involving 32 states and the District of Columbia.
 - Asset impairments and restructuring of \$182.4 million, or \$.11 per share, primarily driven by the sale of its Greenfield, Indiana site.
 - Acquired in-process research and development of \$28.0 million, or \$.03 per share, associated with the SGX acquisition.
- The following items in the second quarter of 2008 (described in more detail in our Form 8-K filed July 24, 2008):
 - Restructuring (exit costs) and other special charges of \$88.9 million, primarily associated with previously-announced strategic exit activities related to manufacturing operations.
 - Asset impairments associated with certain manufacturing operations (included in cost of sales) of \$57.1 million.
 - In-process research and development (IPR&D) charges associated with the licensing arrangement with TransPharma Medical Ltd. of \$35.0 million.
- The following items in the first quarter of 2008 (described in more detail in our Form 8-K dated April 21, 2008):
 - A tax benefit from resolution of a substantial portion of an IRS audit of the company's federal income tax returns for the years 2001 to 2004.

- Asset impairments, restructuring (exit costs), and other special charges primarily related to the decision to terminate the development of the company's AIR Insulin program.
- In-process research and development charges associated with an in-licensing transaction with BioMS Medical.
- The following item in the third quarter of 2007 (described in more detail in our Form 8-K dated, October 18, 2007):
 - A charge for a reduction in our expected product liability insurance recoveries in the third quarter of 2007.
- The following item in the second quarter of 2007 (described in more detail in our Form 8-K dated July 24, 2007):
 - In-process research and development charges associated with the acquisitions of Hynion, Inc. and Ivy Animal Health.
- The following items in the first quarter of 2007 (described in more detail in our Form 8-K dated April 16, 2007):
 - Restructuring charges associated with previously announced manufacturing decisions.
 - In-process research and development charges associated with the acquisition of ICOS Corporation (which closed on January 29, 2007) and an in-licensing transaction with OSI Pharmaceuticals.

In the press release attached as Exhibit 99.1, we also provided financial expectations for the full year 2008. In addition to providing earnings per share expectations on a GAAP basis, we provided expectations for earnings per share, effective tax, rate and gross margin as a percent of sales as they would have been without certain items. The relevant items include those described above for the first nine months of 2007 and 2008 and the items below in the fourth quarter of 2007 (described in more detail in our Form 8-K dated January 29, 2008):

- Acquired in-process research and development charges for compounds acquired from Macrogenics and Glenmark.
- Asset impairments and restructuring related primarily to previously announced site closures and other special charges related to Zyprexa product liability.

The items identified above are typically highly variable, difficult to predict, and of a size that could have a substantial impact on our reported operations for a period. We believe that this non-GAAP information is useful to investors and may help them evaluate our ongoing operations. This information can assist in making meaningful period-over-period comparisons and in identifying operating trends that would otherwise be masked or distorted by these types of

items. Management uses this non-GAAP information internally to evaluate the performance of the business, including to allocate resources and to evaluate results relative to incentive compensation targets.

Investors should consider this non-GAAP information 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 information, our prospective earnings may be affected by future matters, similar to those identified above, as to which prospective quantification generally is not feasible.

The information in this Item 2.02 and the press release attached as Exhibit 99.1 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 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers

On October 20, 2008, the board of directors elected Douglas R. Oberhelman, Group President, Caterpillar, Inc., as a director for a term ending in April 2009. The board also nominated Mr. Oberhelman to stand for election at the company's annual meeting of shareholders (to be held on April 20, 2009) for a three-year term ending in April 2012. He will serve on the company's Audit and Finance committees. Mr. Oberhelman, 54, began his career at Caterpillar, Inc. in 1975, and served in a number of leadership positions and was elected group president and member of Caterpillar, Inc.'s executive office in 2002.

Mr. Oberhelman has served as Chairman of the Board of Trustees for Millikin University and Chairman of the Board of Directors for Easter Seals. He also serves on the boards of South Side Bank, The Nature Conservancy — Illinois Chapter, and Millikin University. He is a member of the Board of Directors of the National Association of Manufacturers.

Item 9.01. Financial Statements and Exhibits

| <u>Exhibit Number</u> | <u>Description</u> |
|-----------------------|---|
| 99.1 | Press release dated October 23, 2008, together with related attachments |
| 99.2 | Press release dated October 20, 2008 |

SIGNATURE

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/ Derica W. Rice
Name: Derica W. Rice
Title: Senior Vice President and Chief
Financial Officer

Dated: October 23, 2008

EXHIBIT INDEX

| <u>Exhibit Number</u> | <u>Exhibit</u> |
|-----------------------|---|
| 99.1 | Press release dated July 24, 2008, together with related attachments. |
| 99.2 | Press release dated October 20, 2008 |



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

www.lilly.com

Date: October 23, 2008

For Release: Immediately

Refer to: (317) 276-5795 – Mark E. Taylor

Lilly Reports Third-Quarter Results

Sales increase 14%; Gross margin improves

Company reports net loss of \$.43 per share as a result of Zyprexa charges

On a pro forma non-GAAP basis, earnings per share rose 14% to \$1.04

Eli Lilly and Company (NYSE: LLY) today announced financial results for the third quarter of 2008.

Due to significant strategic actions taken by the company in 2008, financial results are presented on both a reported basis and a pro forma non-GAAP basis. Reported results were prepared in accordance with generally accepted accounting principles (GAAP) and include all sales and expenses recognized by the company during the period. Pro forma non-GAAP results exclude significant items described in the reconciliation tables and also assume the ICOS acquisition was completed January 1, 2007. The pro forma non-GAAP results are presented in order to provide additional insights into the underlying trends in the company's business. Financial guidance is also provided on both a reported and a pro forma non-GAAP basis.

Third-Quarter Highlights

- o Sales increased 14 percent, to \$5.210 billion.
 - o Products launched this decade – Alimta®, Byetta®, Cialis®, Cymbalta®, Forteo®, Strattera®, Symbax®, Xigris® and Yentreve® – collectively grew 28 percent, to \$1.923 billion, and accounted for 37 percent of total sales, compared with 33 percent of total sales in the third quarter of 2007.
 - o The company recorded charges totaling \$1.477 billion related to the pending Zyprexa® investigations by the U.S. Attorney for the Eastern District of Pennsylvania, as well as the resolution of a multi-state investigation regarding Zyprexa involving 32 states and the District of Columbia.
 - o As a result of the Zyprexa charges, the company reported a net loss of \$465.6 million and a loss per share of \$.43, compared with third-quarter 2007 net income of \$926.3
-

million and earnings per share of \$.85. On a pro forma non-GAAP basis, excluding significant items totaling \$1.47 per share, earnings rose 14 percent to \$1.04 per share.

“Over the past few quarters, Lilly has taken significant actions to advance our pipeline, increase productivity and transform our business model,” commented John Lechleiter, Ph.D., Lilly president and chief executive officer. “These actions include the targeted acquisitions of companies and the in-licensing of promising molecules; the restructuring and impairment of assets resulting from continued productivity initiatives; and the move toward resolution of a significant aspect of pending Zyprexa investigations and litigation. In addition, the proposed acquisition of ImClone would create a leading oncology franchise and strengthen our biotechnology capabilities. Going forward, we will continue to look for other opportunities that align with our business strategy.”

“Importantly, as we execute on our strategy, we continue to deliver on our financial commitments. In the third quarter, the underlying fundamentals of our business remained strong, highlighted by volume-driven sales growth and an expansion in gross margin. Our revised full-year EPS guidance reflects these strong fundamentals.”

Significant Events Over the Last Three Months

- The board of directors approved a definitive merger agreement under which Lilly will acquire ImClone Systems, Inc. through an all cash tender offer of \$70.00 per share, or approximately \$6.5 billion. The company expects the transaction to close in either the fourth quarter of 2008 or the first quarter of 2009.
- The company acquired the worldwide rights to the dairy cow supplement, Posilac®, as well as the product’s supporting operations, from Monsanto Company for a \$300.0 million upfront payment, as well as contingent consideration based on future Posilac sales. The transaction closed in October, and will be reflected in the company’s fourth quarter financial results.
- The company completed the \$64.0 million acquisition of SGX Pharmaceuticals, Inc., a San Diego-based biotechnology company focused on applying state-of-the art structural biology capabilities to drug discovery.
- The company sold its Greenfield Laboratories site in Greenfield, Indiana, to Covance Inc. The two companies also signed a 10-year service agreement. Under this agreement, the company and Covance will broaden their existing strategic collaboration, with Covance

assuming responsibility for Lilly's toxicology testing and other R&D support activities at the site.

- The company initiated a strategic review of its Tippecanoe Labs facility in Lafayette, Indiana. The three options being considered for the site include continuing operations with a revised site mission, exploring opportunities to sell the facility and ceasing operations altogether. The review is expected to last six to twelve months. No decisions have yet been reached.
- The company's board of directors elected John C. Lechleiter, Ph.D., chairman of the board effective January 1, 2009. Lechleiter will succeed outgoing chairman Sidney Taurel, who had previously announced his retirement from the company and the board effective December 31, 2008.
- The company announced that it is set to become the first pharmaceutical research company to disclose its payments to physicians in the United States. As part of its broader transparency efforts, the company plans to launch an online registry of physician payments in 2009.
- The company, along with its partner Daiichi Sankyo Company, Limited, confirmed that the U.S. Food and Drug Administration (FDA) did not complete its review for the prasugrel new drug application (NDA) by the Prescription Drug User Fee Act goal date of September 26, 2008. The two companies also reiterated that they continue to have discussions with the FDA regarding the review of this application. The companies have not been notified of any regulatory action for the NDA or of any decision to have an advisory committee to review prasugrel.
- The FDA approved the use of Alimta, in combination with cisplatin, in the first-line treatment of locally-advanced and metastatic non-small cell lung cancer (NSCLC), for patients with nonsquamous histology.
- The European Commission approved the use of Cymbalta for the treatment of Generalized Anxiety Disorder (GAD).
- The company submitted tadalafil as a treatment for pulmonary arterial hypertension (PAH) to regulatory authorities in both the United States and Japan.
- The Committee for Medicinal Products for Human Use (CHMP) issued a positive opinion recommending approval of Zypadhera™ (also known as olanzapine long-acting injection) for maintenance treatment of adult patients with schizophrenia sufficiently stabilized during acute treatment with oral olanzapine. The opinion issued by the CHMP

will need to be ratified by the European Commission before the new indication is considered approved.

- The company received a favorable ruling upholding the validity of its Zyprexa patent in the United Kingdom.

Third-Quarter Significant Items Affecting Reported Net Income (Loss)

The reported net loss for the third quarter of 2008 and the reported net income for the third quarter of 2007 were affected by significant items totaling \$1.47 and \$.06 per share, respectively, which are reflected in the company's financial results and are summarized below and in the table that follows:

2008

- The company recognized charges totaling \$1.477 billion, or \$1.33 per share, related to the pending Zyprexa investigations with the U.S. Attorney for the Eastern District of Pennsylvania, as well as the resolution of a multi-state investigation regarding Zyprexa involving 32 states and the District of Columbia.
- The company recognized a charge of \$182.4 million, or \$.11 per share, for asset impairments and restructuring primarily driven by the sale of its Greenfield, Indiana site.
- The company recognized a charge of \$28.0 million, or \$.03 per share, for acquired in-process research and development associated with the SGX acquisition.

2007

- The company recorded a charge of \$81.3 million, or \$.06 per share, related to the reduction in expected insurance recoveries.

| | Third Quarter | | % Growth |
|--|-----------------|---------------|------------|
| | 2008 | 2007 | |
| Earnings (loss) per share (reported) | \$ (.43) | \$.85 | NM |
| Charges related to Zyprexa investigations | 1.33 | — | |
| Asset impairments and restructuring charges | .11 | — | |
| Charge for a reduction in expected insurance recoveries | — | .06 | |
| In-process research and development charge associated with the SGX acquisition | .03 | — | |
| Earnings per share (pro forma non-GAAP) | \$ 1.04 | \$.91 | 14% |

Third-Quarter Results

Worldwide sales for the quarter were \$5.210 billion, an increase of 14 percent compared with the third quarter of 2007. Sales volume increased 6 percent, while exchange rates contributed 4 percent of worldwide sales growth and selling prices contributed 3 percent (numbers do not add due to rounding).

Gross margin as a percent of sales increased by 0.8 percentage points, to 77.8 percent. This increase was primarily due to higher product prices and manufacturing expenses growing at a slower rate than sales.

Marketing, selling and administrative expenses rose 12 percent, to \$1.649 billion. This increase was due to increased marketing and sales force expenses, including prelaunch expenses for prasugrel and marketing costs associated with Cymbalta and Evista®, the impact of foreign exchange rates and increased litigation-related expenses. Research and development expenses were \$953.0 million, or 18 percent of sales. Compared with the third quarter of 2007, research and development expenses grew 13 percent. This increase was primarily due to increased late-stage clinical trial and discovery research costs.

The company recognized a charge of \$28.0 million in the third quarter of 2008 for acquired in-process research and development associated with the acquisition of SGX.

The company recognized asset impairments, restructuring, and other special charges of \$1.659 billion in the third quarter of 2008, primarily associated with charges totaling \$1.477 billion related to Zyprexa investigations with the U.S. Attorney for the Eastern District of Pennsylvania and multiple states. In addition, the company also recognized asset impairments and restructuring charges of \$182.4 million primarily related to the sale of its Greenfield, Indiana site to Covance. In the third quarter of 2007, the company recognized a charge of \$81.3 million for the reduction in expected product liability insurance recoveries.

Other income decreased by \$47.3 million, to \$2.5 million, primarily due to lower out-licensing income and the \$10.9 million write-down of certain investment securities, offset by lower interest expense.

In the third quarter of 2008, due to the uncertainty of the tax treatment of the Zyprexa charges, the company recorded tax expense of \$232.8 million despite a net loss before income taxes. The effective tax rate for the third quarter of 2007 was 21.4 percent.

As a result of the Zyprexa charges, on a reported basis the company recorded a net loss of \$465.6 million, or \$.43 per share in the third quarter of 2008, compared with third-quarter 2007 net income of \$926.3 million and earnings per share of \$.85.

On a pro forma non-GAAP basis, the company recorded net income of \$1.135 billion, or \$1.04 per share in the third quarter of 2008, compared with third-quarter 2007 net income of \$996.4 million, or \$.91 per share.

Product Sales Highlights

| (Dollars in millions) | Third Quarter | | % Change Over/(Under) 2007 | Year-to-Date | | % Change Over/(Under) 2007 |
|-------------------------|---------------|-----------|----------------------------------|--------------|------------|----------------------------------|
| | 2008 | 2007 | | 2008 | 2007 | |
| Zyprexa | \$1,189.5 | \$1,166.1 | 2% | \$ 3,549.5 | \$ 3,487.1 | 2% |
| Cymbalta | 716.4 | 513.2 | 40% | 1,975.9 | 1,474.6 | 34% |
| Gemzar® | 440.2 | 394.4 | 12% | 1,306.5 | 1,166.9 | 12% |
| Humalog® | 432.6 | 362.5 | 19% | 1,277.8 | 1,060.4 | 21% |
| Cialis ¹ | 376.6 | 311.4 | 21% | 1,075.7 | 797.6 | 35% |
| Alimta | 313.9 | 215.0 | 46% | 836.0 | 610.0 | 37% |
| Evista | 265.7 | 263.2 | 1% | 806.6 | 805.0 | 0% |
| Humulin® | 271.6 | 243.3 | 12% | 800.8 | 711.9 | 12% |
| Forteo | 192.7 | 180.5 | 7% | 584.3 | 511.1 | 14% |
| Strattera | 149.5 | 130.5 | 15% | 432.7 | 412.6 | 5% |
| Total Sales – Reported | \$5,209.5 | \$4,586.8 | 14% | \$15,167.5 | \$13,443.9 | 13% |
| Total Sales – Pro forma | \$5,209.5 | \$4,586.8 | 14% | \$15,167.5 | \$13,516.6 | 12% |

¹ The 2007 year-to-date amount for Cialis represents the reported Cialis sales in Lilly's financial statements and does not include Cialis sales from the joint-venture countries prior to the ICOS acquisition on January 29, 2007. Total worldwide Cialis sales for the first nine months of 2007 were \$870.3 million, resulting in 2008 year-to-date growth of 24 percent.

Zyprexa

In the third quarter of 2008, Zyprexa sales totaled \$1.190 billion, a 2 percent increase compared with the third quarter of 2007. U.S. sales of Zyprexa increased 3 percent to \$555.6 million, driven by increased net effective selling prices, partially offset by lower demand. Zyprexa sales in international markets increased 1 percent, to \$633.9 million, driven by the favorable impact of foreign exchange rates, partially offset by decreased demand and lower prices. Demand outside the U.S. was unfavorably impacted by generic competition in Canada and Germany, offset by growth in Japan and several European markets.

Cymbalta

For the third quarter of 2008, Cymbalta generated \$716.4 million in sales, an increase of 40 percent compared with the third quarter of 2007. U.S. sales of Cymbalta increased 34 percent, to \$597.1 million, driven primarily by higher demand and, to a lesser extent, increased prices. Sales outside the U.S. were \$119.3 million, an increase of 73 percent, driven primarily by higher demand and, to a lesser extent, the favorable impact of foreign exchange rates. Higher demand outside the U.S. reflects both increased demand in established markets, as well as recent launches in new markets.

Gemzar

Gemzar sales totaled \$440.2 million in the third quarter of 2008, an increase of 12 percent from the third quarter of 2007. Sales in the U.S. increased 14 percent, to \$189.2 million, due to increased demand and higher prices, while sales outside the U.S. increased 10 percent, to \$250.9 million, as a result of the favorable impact of foreign exchange rates.

Humalog

For the third quarter of 2008, worldwide Humalog sales increased 19 percent, to \$432.6 million. Sales in the U.S. increased 13 percent to \$245.1 million, driven by higher demand and, to a lesser extent, increased net effective selling prices. Sales outside the U.S. increased 28 percent to \$187.5 million, driven by increased demand and the favorable impact of foreign exchange rates.

Cialis

Cialis sales for the third quarter of 2008 were \$376.6 million, representing growth of 21 percent compared with third-quarter 2007. U.S. sales of Cialis were \$139.8 million in the third quarter, a 20 percent increase compared with the third quarter of 2007, driven by higher prices and, to a lesser extent, increased demand. Sales of Cialis outside the U.S. increased 22 percent, to \$236.8 million, driven primarily by the favorable impact of foreign exchange rates and higher demand.

Alimta

For the third quarter of 2008, Alimta generated sales of \$313.9 million, an increase of 46 percent compared with the third quarter of 2007. U.S. sales of Alimta increased 35 percent, to \$149.3 million, due primarily to increased demand. Sales outside the U.S. increased 58 percent, to \$164.6 million, due primarily to increased demand and, to a lesser extent, the favorable impact of foreign exchange rates.

Evista

Evista sales were \$265.7 million in the third quarter of 2008, a 1 percent increase compared with the third quarter of 2007. U.S. sales of Evista increased 1 percent at \$170.8 million, as a result of higher prices, offset by lower demand. Sales outside the U.S. increased 1 percent to \$94.9 million, driven by favorable exchange rates and higher prices offset by lower demand.

Humulin

Worldwide Humulin sales increased 12 percent in the third quarter of 2008, to \$271.6 million. U.S. sales increased 5 percent, to \$95.1 million, due to higher net effective selling prices. Sales outside the U.S. increased 16 percent, to \$176.6 million, driven by the favorable impact of foreign exchange rates and increased demand.

Forteo

Third-quarter sales of Forteo were \$192.7 million, a 7 percent increase compared with the third quarter of 2007. U.S. sales of Forteo decreased 6 percent, to \$117.0 million, driven by changes in wholesaler buying patterns, partially offset by higher net effective selling prices. Sales outside the U.S. grew 36 percent, to \$75.7 million, due to higher demand and the favorable impact of foreign exchange rates.

Strattera

During the third quarter of 2008, Strattera generated \$149.5 million of sales, an increase of 15 percent compared with the third quarter of 2007. U.S. sales increased 6 percent, to \$109.5 million, due primarily to higher prices. Sales outside the U.S. increased 49 percent, to \$40.0 million, due primarily to higher net effective selling prices, increased demand, and, to a lesser extent, the favorable impact of foreign exchange rates.

Byetta

Worldwide sales of Byetta were \$201.2 million in the third quarter of 2008, a 22 percent increase compared with the third quarter of 2007. U.S. Byetta sales grew 12 percent, to \$179.9 million. Byetta sales outside the U.S. were \$21.3 million. Lilly reports as revenue its 50 percent share of Byetta's gross margin in the U.S., 100 percent of Byetta sales outside the U.S., and its sales of Byetta pen delivery devices to its partner, Amylin Pharmaceuticals. For the third quarter, Lilly

recognized revenue totaling \$109.2 million, representing a 25 percent increase compared with the third quarter of 2007.

Animal Health

Worldwide sales of animal health products in the third quarter of 2008 were \$277.1 million, an increase of 17 percent compared with the third quarter of 2007. U.S. sales grew 14 percent, to \$127.9 million, driven by increased demand and the launch of Comfortis™. Sales outside the U.S. grew 20 percent, to \$149.2 million, driven primarily by increased demand and the favorable impact of exchange rates.

Year-to-Date Results

For the first nine months of 2008, worldwide reported sales increased 13 percent and pro forma non-GAAP sales increased 12 percent, to \$15.168 billion, compared with sales for the same period in 2007. Reported net income and earnings per share were \$1.558 billion and \$1.42, respectively. On a pro forma non-GAAP basis, net income and earnings per share were \$3.222 billion and \$2.95, respectively.

Year-to-Date Significant Items Affecting Reported Net Income

In addition to the third-quarter 2008 and 2007 significant items previously mentioned, reported net income for the first nine months of 2008 and the first nine months of 2007 were also affected by significant items occurring in the first and second quarters of the respective years that are reflected in the company's financial results and are summarized below and included in the table that follows:

2008

- The company recognized asset impairments, restructuring and other special charges of \$145.7 million, primarily associated with certain impairment, termination, and wind-down costs resulting from the termination of the AIR® Insulin program, and a charge of \$88.9 million, primarily associated with previously-announced strategic exit activities related to manufacturing operations. These two charges decreased earnings per share by \$.14 in total.
- The company recognized asset impairments associated with certain manufacturing operations (included in cost of sales) of \$57.1 million, which decreased earnings per share by \$.04.

- The company incurred in-process research and development (IPR&D) charges associated with the licensing arrangement with BioMS Medical Corp. of \$87.0 million and the licensing arrangement with TransPharma Medical Ltd. of \$35.0 million, which decreased earnings per share by \$.07 in total.
- The company recognized a discrete income tax benefit of \$210.3 million as a result of the resolution of a substantial portion of the IRS audit of its federal income tax returns for years 2001 through 2004, which increased earnings per share by \$.19.

2007

- The company recognized asset impairments, restructuring, and other special charges associated with previously announced decisions affecting manufacturing and research facilities of \$123.0 million, which decreased earnings per share by \$.08.
- The company incurred IPR&D charges associated with the acquisitions of ICOS (\$303.5 million), Hypnion (\$291.1 million) and Ivy Animal Health (\$37.0 million), as well as the licensing arrangement with OSI Pharmaceuticals (\$25.0 million), which decreased earnings per share by \$.58 in total.

| | Year-to-date | | % Growth |
|---|----------------|----------------|--------------|
| | 2008 | 2007 | |
| Earnings per share (reported) | \$ 1.42 | \$ 1.93 | (26)% |
| Charges related to Zyprexa investigations | 1.33 | — | |
| Asset impairments and restructuring charges (included in asset impairments, restructuring and other special charges) | .25 | .08 | |
| Asset impairments (included in cost of sales) | .04 | — | |
| In-process research and development charges associated with SGX acquisition (2008), ICOS, Hypnion, and Ivy acquisitions (2007) and in-licensing transactions with BioMS and TransPharma (2008) and OSI (2007) | .10 | .58 | |
| Benefit from resolution of IRS audit | (.19) | — | |
| Charge for a reduction in expected insurance recoveries | — | .06 | |
| Include pro forma as if the ICOS acquisition was completed on January 1, 2007 | — | (.01) | |
| Earnings per share (pro forma non-GAAP) | \$ 2.95 | \$ 2.64 | 12% |

2008 Financial Guidance

The company's full-year 2008 reported earnings guidance is now \$2.44 to \$2.49 per share. The change from earlier guidance of \$3.79 to \$3.94 per share results from the previously mentioned third-quarter 2008 significant items totaling \$1.47 per share as well as from an expected increase in underlying EPS. Excluding significant items, the company has raised its pro forma non-GAAP EPS guidance to \$3.97 to \$4.02 per share, an increase from its previous guidance of \$3.85 to \$4.00 per share. The company's full-year 2008 earnings per share guidance on both a reported basis and a pro forma non-GAAP basis do not reflect any impact related to the proposed acquisition of ImClone Systems, including any potential charges.

2008 Earnings Per Share Expectations:

| | 2008 Expectations | 2007 Results | % Growth |
|---|-------------------------|-----------------|----------------------|
| Earnings per share (reported) | \$2.44 to \$2.49 | \$ 2.71 | (10%) to (8%) |
| Charges related to Zyprexa investigations | 1.33 | — | |
| Asset impairments and restructuring charges (included in asset impairments, restructuring and other special charges) | .25 | .15 | |
| Asset impairments (included in cost of sales) | .04 | — | |
| In-process research and development charges associated with SGX acquisition (2008), ICOS, Hypnion, and Ivy acquisitions (2007) and in-licensing transactions with BioMS and TransPharma (2008) and OSI, MacroGenics and Glenmark (2007) | .10 | .63 | |
| Benefit from resolution of IRS audit | (.19) | — | |
| Charge for a reduction in expected insurance recoveries | — | .06 | |
| Pro forma as if the ICOS acquisition was completed on January 1, 2007 | — | (.01) | |
| | \$3.97 to | | |
| Earnings per share (pro forma non-GAAP) | \$4.02 | \$ 3.54 | 12% to 14% |

The company has also revised other aspects of its previously-issued 2008 full-year financial guidance. Specifically, guidance for gross margin as a percent of sales, other income and deductions, and the effective tax rate has been revised. All other line-item guidance remains unchanged.

Pro forma sales are still expected to grow in the high-single to low-double digits. As a result of the weakening of foreign currencies, the company now expects significant improvement in gross margin as a percent of sales. The sum of marketing, selling and administrative expenses and research and development expenses is still expected to grow in the high-single digits. Marketing, selling and administrative expenses are still expected to grow in the high-single digits and the company still expects research and development expenses to grow in the high-single to low-double digits. Other income and deductions are now expected to contribute approximately \$50 million, a change from the previous guidance of less than \$100 million. As a result of the Zyprexa charge, the effective tax rate is now expected to be approximately 23 percent on a reported basis, while on a pro forma non-GAAP basis, the effective tax rate is still expected to be approximately 22 percent.

Webcast of Conference Call

As previously announced, investors and the general public can access a live webcast of the third-quarter 2008 financial results conference call through a link on Lilly's website at www.lilly.com. The conference call will be held today from 9:00 a.m. to 10:00 a.m. Eastern Daylight Time (EDT) and will be available for replay via the website through November 21, 2008. 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; Lilly's clinical trial registry is available at www.lillytrials.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. The company cannot guarantee that the ImClone merger will close or that the company will realize anticipated operational efficiencies following any such merger with ImClone. The current credit market may increase the cost of financing the ImClone transaction. 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 products; rate of sales growth of recently launched products; the timing of anticipated regulatory approvals and launches of new products; regulatory actions regarding currently marketed products; other regulatory developments and government investigations; patent disputes and other litigation involving current and future products; the impact of governmental actions regarding pricing, importation, and reimbursement for pharmaceuticals; changes in tax law; asset impairments and restructuring charges; acquisitions and business development transactions; and the impact of exchange rates. For additional information about the

factors that affect the company's business, please see the company's latest Form 10-Q filed August 2008. The company undertakes no duty to update forward-looking statements.

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Alimta® (pemetrexed, Lilly)
Byetta® (exenatide injection, Amylin Pharmaceuticals)
Cialis® (tadalafil, Lilly)
Comfortis™ (Lilly)
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)
Humulin® (human insulin of recombinant DNA origin, Lilly)
Posilac® (recombinant bovine somatotropin, Lilly)
Strattera® (atomoxetine hydrochloride, Lilly)
Symbyax® (olanzapine fluoxetine combination, or OFC, Lilly)
Xigris® (drotrecogin alfa (activated), Lilly)
Yentreve® (duloxetine hydrochloride, Lilly)
Zypadhera™ (Lilly)
Zyprexa® (olanzapine, Lilly)

AIR® is a trademark of Alkermes, Inc.

Eli Lilly and Company Employment Information

| | <u>September 30, 2008</u> | <u>December 31, 2007</u> |
|---------------------|---------------------------|--------------------------|
| Worldwide Employees | 39,600 | 40,600 |

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

| | Three Months Ended | | | Nine Months Ended | | |
|--|--------------------|----------------------|--------|-------------------|----------------------|--------|
| | 2008 | September 30 2007 | % Chg. | 2008 | September 30 2007 | % Chg. |
| Net sales | \$ 5,209.5 | \$ 4,586.8 | 14% | \$ 15,167.5 | \$ 13,443.9 | 13% |
| Cost of sales | 1,155.2 | 1,054.6 | 10% | 3,467.4 | 2,976.0 | 17% |
| Research and development | 953.0 | 844.5 | 13% | 2,781.6 | 2,533.1 | 10% |
| Marketing, selling and administrative | 1,649.2 | 1,477.8 | 12% | 4,899.8 | 4,339.3 | 13% |
| Acquired in-process research and development | 28.0 | — | NM | 150.0 | 656.6 | (77)% |
| Asset impairments, restructuring and other special charges | <u>1,659.4</u> | <u>81.3</u> | NM | <u>1,894.0</u> | <u>204.3</u> | NM |
| Operating income (loss) | (235.3) | 1,128.6 | NM | 1,974.7 | 2,734.6 | (28)% |
| Net interest income (expense) | 9.2 | (6.2) | | 10.4 | (10.9) | |
| Joint-venture income | — | — | | — | 11.0 | |
| Net other income (loss) | <u>(6.7)</u> | <u>56.0</u> | | <u>44.7</u> | <u>89.8</u> | |
| Other income | 2.5 | 49.8 | | 55.1 | 89.9 | |
| Income (loss) before income taxes | (232.8) | 1,178.4 | NM | 2,029.8 | 2,824.5 | (28)% |
| Income taxes (benefit) | <u>232.8</u> | <u>252.1</u> | (8%) | <u>472.3</u> | <u>725.9</u> | (35)% |
| Net income (loss) | <u>\$ (465.6)</u> | <u>\$ 926.3</u> | NM | <u>\$ 1,557.5</u> | <u>\$ 2,098.6</u> | (26)% |
| Earnings (loss) per share – basic | <u>\$ (0.43)</u> | <u>\$ 0.85</u> | NM | <u>\$ 1.42</u> | <u>\$ 1.93</u> | (26)% |
| Earnings (loss) per share – diluted | <u>\$ (0.43)</u> | <u>\$ 0.85</u> | NM | <u>\$ 1.42</u> | <u>\$ 1.93</u> | (26)% |
| Dividends paid per share | \$.47 | \$.425 | 11% | \$ 1.41 | \$ 1.275 | 11% |
| Weighted-average shares outstanding (thousands) – basic | 1,093,977 | 1,090,067 | | 1,093,872 | 1,089,809 | |
| Weighted-average shares outstanding (thousands) – diluted | 1,093,977 | 1,090,228 | | 1,093,927 | 1,090,095 | |

N/M – not meaningful

Eli Lilly and Company

Operating Results (Unaudited) – Pro forma Non-GAAP

(Dollars in millions, except per share data)

| | Three Months Ended September 30 2007(c) | | | Nine Months Ended September 30 2007(c)(d) | | |
|--|---|-----------------|--------|---|-------------------|--------|
| | 2008 (a) | | % Chg. | 2008 (a)(b) | | % Chg. |
| Net sales | \$ 5,209.5 | \$ 4,586.8 | 14% | \$ 15,167.5 | \$ 13,516.6 | 12% |
| Cost of sales | 1,155.2 | 1,054.6 | 10% | 3,410.3 | 2,991.9 | 14% |
| Research and development | 953.0 | 844.5 | 13% | 2,781.6 | 2,545.1 | 9% |
| Marketing, selling and administrative | 1,649.2 | 1,477.8 | 12% | 4,899.8 | 4,375.2 | 12% |
| Acquired in-process research and development | — | — | NM | — | — | NM |
| Asset impairments, restructuring and other special charges | — | — | NM | — | — | NM |
| Operating income (loss) | 1,452.1 | 1,209.9 | 20% | 4,075.8 | 3,604.4 | 13% |
| Net interest income (expense) | 9.2 | (6.2) | | 10.4 | (23.4) | |
| Joint-venture income | — | — | | — | — | |
| Net other income (loss) | (6.7) | 56.0 | | 44.7 | 91.8 | |
| Other income | 2.5 | 49.8 | | 55.1 | 68.4 | |
| Income (loss) before income taxes | 1,454.6 | 1,259.7 | 15% | 4,130.9 | 3,672.8 | 12% |
| Income taxes (benefit) | 320.0 | 263.3 | 21% | 908.8 | 795.8 | 14% |
| Net income (loss) | <u>\$ 1,134.6</u> | <u>\$ 996.4</u> | 14% | <u>\$ 3,222.1</u> | <u>\$ 2,877.0</u> | 12% |
| Earnings (loss) per share – basic | <u>\$ 1.04</u> | <u>\$ 0.91</u> | 14% | <u>\$ 2.95</u> | <u>\$ 2.64</u> | 12% |
| Earnings (loss) per share – diluted | <u>\$ 1.04</u> | <u>\$ 0.91</u> | 14% | <u>\$ 2.95</u> | <u>\$ 2.64</u> | 12% |
| Dividends paid per share | \$.47 | \$.425 | 11% | \$ 1.41 | \$ 1.275 | 11% |
| Weighted-average shares outstanding (thousands) – basic | 1,093,977 | 1,090,067 | | 1,093,872 | 1,089,809 | |
| Weighted-average shares outstanding (thousands) – diluted | 1,094,024 | 1,090,228 | | 1,093,927 | 1,090,095 | |

N/M – not meaningful

- (a) The 2008 third-quarter and year-to-date amounts are adjusted to eliminate a charge of \$28.0 million (no tax benefit), or \$0.03 per share, for acquired in-process research and development related to the SGX acquisition; a charge of \$182.4 million (pre-tax), or \$0.11 per share (after-tax), for asset impairments and restructuring primarily associated with the sale of the Greenfield site; and charges totaling \$1.477 billion (pre-tax), or \$1.33 per share (after-tax), related to pending and resolved Zyprexa investigations.

- (b) In addition to items in (a), the 2008 year-to-date amounts are also adjusted to eliminate charges totaling \$122.0 million (pre-tax), or \$0.07 per share (after-tax), for acquired in-process research and development associated with the in-licensing of compounds from BioMS, and TransPharma; a charge of \$291.7 million (pre-tax), or \$0.18 per share (after-tax), for asset impairments, restructuring, and other special charges; and a discrete income tax benefit of \$210.3 million, or \$(0.19) per share related to the resolution of a substantial portion of an IRS audit.
- (c) The 2007 third-quarter and year-to-date amounts are adjusted to eliminate a \$81.3 million (pretax) charge, or \$0.06 per share (after-tax), for special charges related to an adjustment to insurance recoverables on product liability litigation; the 2007 year-to-date amounts are also adjusted to eliminate a second-quarter charge of \$328.1 million (pretax), or \$0.29 per share (after-tax), for acquired in-process research and development related to the Hypnion and Ivy acquisitions; a \$328.5 million (pretax) first-quarter charge, or \$0.29 per share (after-tax), for acquired in-process research and development for compounds acquired from ICOS and OSI; and a \$123.0 million (pretax) charge, or \$0.08 per share (after-tax), for asset impairments, restructuring, and other special charges.
- (d) In accordance with generally accepted accounting principles (GAAP), the year-to-date 2007 financial statement has been restated assuming the acquisition of ICOS was completed by Lilly effective January 1, 2007.



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

www.lilly.com

Date: October 20, 2008

For Release: Immediately

Refer to: (317) 276-5795 – Mark E. Taylor

Douglas Oberhelman Elected to Lilly Board of Directors

The Board of Directors of Eli Lilly and Company (NYSE:LLY) has elected Douglas R. Oberhelman as a new member, effective December 1, 2008. Oberhelman, 55, currently serves as a group president of Caterpillar Inc. and is a member of Caterpillar's executive office. As a member of Lilly's board, Oberhelman will serve on both the board's audit committee and finance committee. He will stand for election by Lilly shareholders at the company's next annual meeting in April, 2009.

"We are very pleased to welcome Doug Oberhelman to the Lilly board," said Sidney Taurel, Lilly's chairman. "Doug has demonstrated strong leadership in his 33 years with Caterpillar, a global leader in the manufacturing and sales of industrial machinery and equipment. Doug's international management experience, particularly in Asia, will serve Lilly shareholders well as the company moves to expand its presence in this key region. In addition, Doug's financial acumen and prior role as CFO at Caterpillar will bring valuable insights to our board's audit and finance committees."

"I look forward to working together with Doug and the other Lilly board members to deliver increased value for our shareholders," commented John Lechleiter, Ph.D., Lilly president and chief executive officer. On January 1, 2009, Lechleiter will succeed outgoing chairman Taurel, who had previously announced his retirement from the company and the board effective December 31, 2008. "Doug's experiences will directly support several key aspects of our strategy, including our commitment to be more customer-focused, more productive and more global in our scope and reach."

As group president of Caterpillar since 2002, Oberhelman has responsibility for the company's human services and sustainable development functions, as well as Caterpillar's growing remanufacturing business. He also oversees machinery marketing operations in North America and worldwide manufacturing, marketing and support of industrial and large power systems.

Oberhelman was elected a vice president in 1995, serving as Caterpillar's Chief Financial Officer with administrative responsibility for the corporation's accounting, information services, tax, treasury, investor relations and marketing support services areas from 1995 to November 1998. In 1998, he became vice president with responsibility for the Engine Products Division, including the market development, strategic planning, supplier management, electric power generation and worldwide marketing and administration for Caterpillar's engine business. He was elected a group president and member of Caterpillar's executive office in 2002.

Oberhelman joined Caterpillar in 1975 and has held a variety of positions, including senior finance representative based in South America for Caterpillar Americas Co; region finance manager and district manager for the company's North American Commercial Division; and managing director and vice general manager for strategic planning at Shin Caterpillar Mitsubishi, Caterpillar's affiliated company in Tokyo, Japan.

Oberhelman has a bachelor's degree from Millikin University. He is a director for the boards of The Nature Conservancy — Illinois Chapter and Ameren Corporation, serving as chairman of the Ameren Corporation Audit Committee. He is a member of the board of directors of the Association of Equipment Manufacturers, the National Association of Manufacturers, the Manufacturing Institute and the Wetlands America Trust. He has served as chairman of the board of trustees for Millikin University and chairman of the board of directors for Easter Seals, and he is a former director for the boards of South Side Bank, Millikin University and Easter Seals.

About Lilly

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.

C-LLY