# 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): January 27, 2011

# **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

 $\begin{tabular}{ll} No~Change \\ (Former name~or~former~address,~if~changed~since~last~report) \\ \end{tabular}$ 

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))

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

On January 27, 2011, we issued a press release announcing our results of operations for the fourth quarter and fiscal year ended December 31, 2010, including, among other things, an income statement for those periods. In addition, on the same day we held a teleconference for analysts and media to discuss those results. The teleconference was web cast on our web site. The press release and related financial statements are attached to this Form 8-K as <a href="Exhibit 99.1"><u>Exhibit 99.1</u></a>.

For the fourth quarter and fiscal year 2010, the press release attached as Exhibit 99.1 includes a non-GAAP presentation of our results. We use non-GAAP financial measures, such as non-GAAP net income and earnings per share, that differ from financial statements reported in conformity to U.S. generally accepted accounting principles ("GAAP"). In the press release attached as Exhibit 99.1, we used non-GAAP financial measures in comparing the financial results for the fourth quarter and fiscal year of 2010 with the same periods of 2009. Those measures include the following, adjusted to exclude the effect of the items below (described in more detail in the press release attached as Exhibit 99.1): total revenue; gross margin as a percent of total revenue; marketing, selling and administration expenses; research and development expenses; operating income; other income; income before taxes; income taxes; effective tax rate; net income; and earnings per share. The adjustments consist of:

- Restructuring charges in each quarter of 2010 primarily related to severance costs from previously-announced strategic actions that the company is taking
  to reduce its cost structure and global workforce.
- · In-process research and development charges in the first quarter of 2010 associated with an in-licensing transaction with Acrux Ltd.
- The following items in the fourth quarter of 2009:
  - Asset impairments and restructuring charges primarily related to severance costs from previously announced strategic actions.
  - In-process research and development charge associated with a licensing agreement with Incyte Corporation.
- The following items in the first three quarters of 2009:
  - Asset impairments and restructuring primarily related to severance costs from previously announced strategic actions.
  - · Charges related to settlements and potential settlements with the attorneys general of several states of claims related to Zyprexa.

We also provide certain operating results, including earnings-per-share growth, without the impact of changes in foreign exchange rates for the fourth quarter and fiscal year 2010 compared to the same periods in 2009.

In the press release attached as Exhibit 99.1, we provided financial expectations for 2011, including earnings per share growth on a non-GAAP basis and revenue growth excluding the anticipated decline in Zyprexa and Gemzar sales outside of Japan and the incremental impact of U.S. health care reform.

The items that we exclude when we provide adjusted results or adjusted expectations 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 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 would otherwise be masked or distorted by the items subject to the adjustments. 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 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 9.01. Financial Statements and Exhibits

Exhibit Number

Description

99.1

Press release dated January 27, 2011, together with related attachments

### **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/ Arnold C. Hanish

Name: Arnold C. Hanish

Title: Vice President and
Chief Accounting Officer

Dated: January 27, 2011

## EXHIBIT INDEX

Exhibit Number Exhibit

99.1 Press release dated January 27, 2011, together with related attachments.



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

www.lilly.com

Refer to:

**Date:** January 27, 2011

For Release: Immediately

(317) 276-5795 – Mark E. Taylor (Media)

(317) 655-6874 – Philip Johnson (Investors)

### Lilly Reports Fourth-Quarter and Full-Year 2010 Results, Provides 2011 Financial Guidance

- Higher volume drove four percent revenue growth in Q4.
- Gross margin improvements in Q4 led to growth in operating income.
- Fourth quarter earnings per share grew to \$1.05 (reported), or \$1.11 (non-GAAP).
- Full-year 2010 revenue topped \$23 billion as eight human pharmaceutical medicines and the company's animal health business all exceed \$1 billion in annual sales.
- Full-year 2010 earnings per share grew to \$4.58 (reported), or \$4.74 (non-GAAP).
- 2011 earnings per share guidance range set at \$3.92 \$4.07 (reported), or \$4.15 \$4.30 (non-GAAP).

Eli Lilly and Company (NYSE: LLY) today announced financial results for the fourth quarter and full year of 2010.

\$ in millions, except per share data		Quarter	%	Full	%	
	2010	2009	Growth	2010	2009	Growth
Total Revenue – Reported	\$6,187.0	\$5,934.2	4%	\$23,076.0	\$21,836.0	6%
Net Income – Reported	1,169.6	915.4	28%	5,069.5	4,328.8	17%
EPS – Reported	1.05	0.83	27%	4.58	3.94	16%
Net Income – non-GAAP	1,234.9	999.4	24%	5,240.8	4,851.0	8%
EPS – non-GAAP	1.11	0.91	22%	4.74	4.42	7%

Financial results for 2010 and 2009 are presented on both a reported and a non-GAAP basis. Reported results were prepared in accordance with generally accepted accounting principles (GAAP) and include all revenue and expenses recognized during the period. Non-GAAP results exclude the items described in the reconciliation tables. The non-GAAP results are presented in order to provide additional insights into the underlying trends in the company's business. The company's 2011 financial guidance is also being provided on both a reported and a non-GAAP basis.

"Lilly's fourth quarter results capped a year of solid financial performance in which we achieved volume-driven revenue growth along with good expense control. These results allowed us to deliver attractive earnings growth and a healthy dividend for our shareholders, while still investing in the research and development and business development activities that will enable us to bring the next generation of new medicines to patients," said John C. Lechleiter Ph.D., Lilly's chairman and chief executive officer. "As we begin 2011, we remain committed to our strategy of accelerating the flow of potential new medicines through our pipeline and are prepared to meet the challenges of patent expirations for several of our products."

### Key Events Over the Last Three Months

- The company announced a global agreement with Boehringer Ingelheim to jointly develop and commercialize a portfolio of diabetes compounds currently in mid- and late-stage development. Included are Boehringer Ingelheim's two oral diabetes agents—linagliptin and BI 10773—as well as Lilly's two basal insulin analogues LY2605541 and LY2963016 along with an option to co-develop and co-commercialize Lilly's anti-TGF-beta monoclonal antibody.
- The company completed the acquisition of Avid Radiopharmaceuticals, Inc., a company developing novel molecular imaging compounds intended for the detection and monitoring of chronic human diseases. In addition, the U.S. FDA assigned priority review designation to the marketing application for Amyvid<sup>TM</sup> (florbetapir), Avid's lead program in development. The Peripheral and Central Nervous System Drugs Advisory Committee of the FDA held a meeting to discuss Amyvid's new drug application on January 20, 2011. The Committee decided that it could not recommend approval of Amyvid at this time based on the currently available data (13-3); but, voted unanimously (16-0) to recommend approval of Amyvid conditional on a reader training program that demonstrates reader accuracy and consistency through a re-read of previously acquired scans. The Committee supported that efficacy was established and there were no significant safety concerns raised.
- The U.S. Food and Drug Administration (FDA) Gastrointestinal Drugs Advisory Committee voted to recommend non-approval of liprotamase, a non-porcine pancreatic enzyme

replacement therapy, currently under FDA review for the treatment of exocrine pancreatic insufficiency. During the meeting, the Committee had questions about the degree of efficacy of liprotamase and recommended that additional studies be conducted prior to considering approval of liprotamase for EPI. The company will continue to work with the FDA to address the questions raised in the meeting as the agency moves toward a final decision on the application.

- The U.S. District Court for the District of Delaware ruled that judgment would be entered in the company's favor regarding its Alimta® patent litigation. Including the recently-obtained pediatric exclusivity, the patent provides protection for Alimta until January of 2017.
- The U.S. Court of Appeals for the Federal Circuit heard the company's appeal of a prior district court ruling invalidating the patent for Strattera®. The company is currently awaiting the appeals court's ruling.
- The U.S. FDA approved Cymbalta® for the management of chronic musculoskeletal pain. This has been established in studies in patients with chronic low back pain and chronic pain due to osteoarthritis.
- The U.S. FDA approved Axiron® for replacement therapy in men for certain conditions associated with a deficiency or absence of testosterone. The company, along with its partner Acrux Ltd., expects to launch Axiron in the U.S. by mid-2011.
- The company's Elanco Animal Health division launched two new companion animal products. Assurity™ is a topical flea treatment solely for cats, while Trifexis™ is a broad-spectrum canine parasiticide.
- The company suspended all current studies evaluating tasisulam as a second-line treatment for those with unresectable or metastatic melanoma. Tasisulam, an investigational, small-molecule anti-cancer compound, continues to be studied in other types of cancers.
- The company notified its partner, MacroGenics Inc., of its decision to terminate the collaboration agreement for the development of teplizumab.

### Fourth-Quarter Reported Results

In the fourth quarter of 2010, worldwide total revenue was \$6.187 billion, an increase of 4 percent compared with the fourth quarter of 2009. This 4 percent revenue growth was comprised of an

increase of 3 percent in volume and 2 percent due to higher prices, offset by a 1 percent decrease due to the impact of foreign exchange rates. Total revenue in the U.S. increased 5 percent to \$3.420 billion primarily due to higher prices and, to a lesser extent, increased volume. Total revenue outside the U.S. increased 4 percent to \$2.767 billion due to increased demand, partially offset by the negative impact of foreign exchange rates and lower prices. Fourth-quarter 2010 total revenue was reduced by approximately \$70 million due to the impact of U.S. health care reform.

Gross margin increased 10 percent in the fourth quarter of 2010. Gross margin as a percent of total revenue was 80.1 percent, reflecting an increase of 4.2 percentage points compared with the fourth quarter of 2009. This increase was due to the impact of changes in foreign currencies compared to the U.S. dollar on international inventories sold, which slightly decreased cost of sales in the fourth quarter of 2010, but significantly increased cost of sales in the fourth quarter of 2009. To a lesser extent, the increase in gross margin as a percent of revenue was also due to lower manufacturing costs.

Marketing, selling and administrative expenses increased 2 percent to \$1.989 billion. Higher marketing and selling expenses outside the U.S. were partially offset by lower administrative expenses and company-wide cost containment efforts. Research and development expenses were \$1.438 billion, or 23 percent of total revenue. Compared with the fourth quarter of 2009, research and development expenses grew 18 percent due primarily to charges related to pipeline molecules, including charges related to business development activities and termination of clinical trials. Total operating expense, defined as the sum of research and development, marketing, selling and administrative expenses, increased 8 percent compared with the fourth quarter of 2009.

In the fourth quarter of 2010, the company recognized a charge of \$79.0 million for restructuring primarily related to severance and other related costs from previously announced strategic actions that the company is taking to reduce its cost structure and global workforce. In the fourth quarter of 2009, the company recognized asset impairments, restructuring and other special charges of \$37.9 million, primarily related to the previously announced strategic actions, as well as a \$90.0 million in–process research and development charge associated with the in-licensing of an oral JAK1/JAK2 inhibitor, INCB28050, from Incyte Corporation.

Operating income in the fourth quarter of 2010 increased 20 percent to \$1.449 billion, compared to the fourth quarter of 2009, due primarily to increased gross margin, partially offset by increased research and development expenses.

Other income (expense) improved \$28.4 million, to a net expense of \$39.4 million, primarily driven by increased other miscellaneous income and the net gain on equity investments, as well as lower net interest expense, partially offset by foreign exchange losses.

The effective tax rate was 17.0 percent in the fourth quarter of 2010, compared with an effective tax rate of 19.5 percent in the fourth quarter of 2009. The effective tax rate for the fourth quarter of 2010 reflects a full-year adjustment related to the extension of the R&D tax credit in the U.S. in late December.

Net income and earnings per share increased to \$1.170 billion and \$1.05, respectively, compared with fourth-quarter 2009 net income of \$915 million and earnings per share of \$0.83. The increases in net income and earnings per share were primarily due to higher operating income, improved other income and a lower effective tax rate.

### Fourth-Quarter non-GAAP Results

Operating income increased 15 percent to \$1.528 billion, due to increased gross margin, partially offset by increased research and development expenses. Net income increased 24 percent to \$1.235 billion, while earnings per share increased 22 percent to \$1.11. These increases were primarily driven by sales growth leveraged by gross margin improvements and the tax adjustment related to the extension of the R&D tax credit in the U.S. Excluding the impact of changes in foreign exchange rates, operating income and earnings per share would have increased approximately 3 percent and 10 percent, respectively.

For purposes of non-GAAP reporting, items totaling \$0.06 and \$0.08 in the fourth quarters of 2010 and 2009, respectively, have been excluded. For further detail, see the reconciliation below as well as the footnotes to the non-GAAP income statement later in this press release. Numbers in the 2009 fourth quarter column do not add due to rounding.

	Fourth (	Quarter	
	2010	2009	% Growth
Earnings per share (reported)	\$1.05	\$0.83	27%
In-process research and development charge associated with Incyte licensing agreement	_	.05	
Asset impairments and restructuring charges	.06	.02	
Earnings per share (non-GAAP)	\$1.11	\$0.91	22%

### Full Year 2010 Reported Results

For the full-year 2010, worldwide total revenue increased 6 percent to \$23.076 billion compared with 2009. This 6 percent revenue growth was comprised of a 3 percent increase due to higher volume and a 2 percent increase due to higher prices, while the impact of foreign exchange rates was negligible (numbers do not add due to rounding). Total revenue in the U.S. increased 5 percent to \$12.866 billion due to higher prices. Total revenue outside the U.S. increased 7 percent to \$10.210 billion due to increased demand, partially offset by lower prices. 2010 total revenue was reduced by approximately \$230 million due to the impact of U.S. health care reform.

Gross margin as a percent of total revenue increased by 0.5 percentage points in 2010 to 81.1 percent. This increase was due to lower manufacturing costs and higher selling prices, partially offset by the negative effect of foreign exchange rates on international inventories sold.

Marketing, selling and administrative expenses increased 2 percent in 2010 compared with 2009, to \$7.053 billion. Higher marketing and selling expenses outside the U.S. were partially offset by lower administrative and litigation expenses and company-wide cost containment efforts. Research and development expenses were \$4.884 billion in 2010, or 21 percent of total revenue. Compared with 2009, research and development expenses grew 13 percent due primarily to charges related to pipeline molecules, including charges related to business development activities and termination of clinical trials. Total operating expenses, defined as the sum of research and development, marketing, selling and administrative expenses, increased 6 percent in 2010, compared with 2009.

In 2010, the company recognized a charge of \$50.0 million related to acquired in-process research and development associated with the in-licensing agreement with Acrux Corporation. In 2009, the company recognized charges of \$90.0 million for acquired in-process research and development associated with the in-licensing agreement with Incyte Corporation.

In 2010, the company recognized charges of \$192.0 million for asset impairments, restructuring and other special charges primarily related to severance costs from previously announced strategic actions. In 2009, the company recognized charges totaling \$692.7 million for asset impairments, restructuring and other special charges.

Operating income in 2010 rose 17 percent to \$6.530 billion compared to 2009, due primarily to increased gross margin, and lower asset impairments, restructuring and other special charges, partially offset by increased research and development expenses.

Other income (expense) in 2010 was a net expense of \$5.0 million, compared to a net expense of \$229.5 million in 2009, due primarily to net gains on equity investments, lower net interest expense, damages recovered from generic pharmaceutical companies following Zyprexa® patent litigation in Germany, and an insurance recovery associated with the theft of product at the company's Enfield distribution center.

The effective tax rate was 22.3 percent for the full-year 2010. In 2009, the effective tax rate was 19.2 percent. The 2010 effective tax rate increased due to \$85.1 million in additional tax expense in the first quarter related to U.S. health care reform. The 2009 effective tax rate was reduced due to the tax benefit of asset impairment and restructuring charges associated with the sale of the Tippecanoe manufacturing site.

For the full-year 2010, net income and earnings per share increased to \$5.070 billion and \$4.58, respectively, compared to full-year 2009 net income of \$4.329 billion and earnings per share of \$3.94. The increases in net income and earnings per share were primarily due to higher operating income and improved other income, partially offset by a higher effective tax rate.

### Full-Year 2010 non-GAAP Results

Operating income increased 6 percent to \$6.772 billion due primarily to increased gross margin, partially offset by increased research and development expenses. The effective tax rate for 2010 was 22.6 percent, up from 21.0 percent in 2009. Net income and earnings per share increased 8 percent and 7 percent, to \$5.241 billion and \$4.74, respectively. Excluding the impact of changes in foreign exchange rates, operating income would have increased approximately 7 percent and earnings per share would have increased approximately 8 percent.

For purposes of non-GAAP reporting, items totaling \$0.16 and \$0.48 for 2010 and 2009, respectively, have been excluded. For further detail, see the reconciliation below as well as the footnotes to the non-GAAP income statement later in this press release. Numbers in the 2009 full year column do not add due to rounding.

	Full-		
	2010	2009	% Growth
Earnings per share (reported)	<b>\$4.58</b>	\$3.94	16%
Charges related to Zyprexa litigation		.13	
In-process research and development charge associated with licensing			
agreements with Acrux (2010) and Incyte (2009)	.03	.05	
Asset impairment and restructuring charges	.13	.29	
Earnings per share (non-GAAP)	\$4.74	\$4.42	7%

### Revenue Highlights

(75. W	Parada	0	% Change Over/(Under)	E.11	% Change	
(Dollars in millions)		Fourth Quarter		Full-	Over/(Under)	
	2010	2009	2009	2010	2009	2009
Zyprexa	\$1,335.8	\$1,366.5	(2)%	\$ 5,026.4	\$ 4,915.7	2%
Cymbalta	984.6	830.8	19%	3,480.7	3,074.7	13%
Alimta	569.0	523.6	9%	2,208.6	1,706.0	29%
Humalog®	549.1	530.8	3%	2,054.2	1,959.0	5%
Cialis®	465.9	439.5	6%	1,699.4	1,559.1	9%
Gemzar®	243.6	310.5	(22)%	1,149.4	1,363.2	(16)%
Humulin <sup>®</sup>	287.9	273.0	5%	1,088.9	1,022.0	7%
Evista®	266.5	262.7	1%	1,024.4	1,030.4	(1)%
Forteo®	226.3	212.8	6%	830.1	816.7	2%
Strattera	155.4	162.2	(4)%	576.7	609.4	(5)%
Animal Health	424.3	353.1	20%	1,391.4	1,207.2	15%
Total Revenue	\$6,187.0	\$5,934.2	4%	\$23,076.0	\$21,836.0	6%

### **Zyprexa**

In the fourth quarter of 2010, Zyprexa sales totaled \$1.336 billion, a decrease of 2 percent compared with the fourth quarter of 2009. U.S. sales of Zyprexa increased 4 percent to \$669.3 million, driven primarily by higher prices, partially offset by lower demand. Zyprexa sales in international markets decreased 8 percent, to \$666.5 million, driven primarily by lower demand, and to a lesser extent the unfavorable impact of foreign exchange rates.

For the full year of 2010, worldwide Zyprexa sales increased 2 percent to \$5.026 billion. U.S. Zyprexa sales for 2010 were \$2.496 billion, a 7 percent increase driven by higher prices, partially offset by lower demand. Zyprexa sales outside the U.S. were \$2.531 billion, a 2 percent decrease driven by lower prices and decreased demand in Europe and Canada, partially offset by the favorable impact of foreign exchange rates and increased demand in Japan.

### Cymbalta

For the fourth quarter of 2010, Cymbalta generated \$984.6 million in revenue, an increase of 19 percent compared with the fourth quarter of 2009. U.S. sales of Cymbalta increased 13 percent, to \$770.3 million, driven by higher prices, and to a lesser extent, increased demand. Sales outside the U.S. were \$212.0 million, an increase of 41 percent, primarily driven by higher demand resulting from recent launches in Japan and other international markets. In addition, the company recognized \$2.3 million of other revenue associated with the reacquisition of duloxetine rights from Boehringer Ingelheim.

For the full year of 2010, worldwide Cymbalta revenue increased 13 percent to \$3.481 billion. U.S. Cymbalta sales for 2010 were \$2.772 billion, a 9 percent increase, driven primarily by higher prices. Cymbalta sales outside the U.S. were \$687.2 million, a 31 percent increase, driven primarily by increased demand in Japan, Europe and Canada. In addition, the company recognized \$21.5 million of other revenue associated with the reacquisition of duloxetine rights from Boehringer Ingelheim.

### Alimta

For the fourth quarter of 2010, Alimta generated sales of \$569.0 million, an increase of 9 percent compared with the fourth quarter of 2009. U.S. sales of Alimta increased 3 percent, to \$235.3 million, driven by higher prices, partially offset by decreased demand due to competitive pressures. Sales outside the U.S. increased 13 percent, to \$333.8 million, due to increased demand.

For the full year of 2010, worldwide Alimta sales increased 29 percent to \$2.209 billion. U.S. Alimta sales for 2010 were \$957.1 million, a 17 percent increase driven primarily by higher demand. Alimta sales outside the U.S. were \$1.251 billion, a 41 percent increase driven by increased demand.

#### Humalog

For the fourth quarter of 2010, worldwide Humalog sales increased 3 percent, to \$549.1 million. Sales in the U.S. increased 1 percent to \$324.0 million, driven by increased prices, partially offset by the impact of wholesaler buying patterns. Sales outside the U.S. increased 7 percent to \$225.2 million, driven by higher demand, partially offset by the unfavorable impact of foreign exchange rates.

For the full year of 2010, worldwide Humalog sales increased 5 percent to \$2.054 billion. U.S. Humalog sales for 2010 were \$1.222 billion, a 1 percent increase driven by higher prices, partially offset by the impact of wholesaler buying patterns. Humalog sales outside the U.S. were \$831.8 million, an 11 percent increase driven by increased demand primarily in Japan and China.

### **Cialis**

Cialis sales for the fourth quarter of 2010 increased 6 percent to \$465.9 million. U.S. sales of Cialis were \$189.5 million in the fourth quarter, a 14 percent increase compared with the fourth quarter of 2009, driven primarily by increased demand and higher prices. Sales of Cialis outside the U.S. increased 1 percent, to \$276.4 million, driven by increased demand and higher prices, partially offset by the unfavorable impact of foreign exchange rates and increased competitive pressures.

For the full year of 2010, worldwide Cialis sales increased 9 percent to \$1.699 billion. U.S. Cialis sales for 2010 were \$658.1 million, a 6 percent increase driven by higher prices. Cialis sales outside the U.S. were \$1.041 billion, an 11 percent increase driven primarily by increased demand, and to a lesser extent, higher prices.

### Gemzar

Gemzar sales totaled \$243.6 million in the fourth quarter of 2010, a decrease of 22 percent from the fourth quarter of 2009. Sales in the U.S. decreased 27 percent, to \$140.1 million, due to the impact of generic competition which began November 15, 2010. Sales outside the U.S. decreased 13 percent, to \$103.5 million, due primarily to generic competition in most major markets.

For the full year of 2010, worldwide Gemzar sales decreased 16 percent to \$1.149 billion. U.S. Gemzar sales for 2010 were \$723.3 million, a 3 percent decrease due to the impact of generic competition. Gemzar sales outside the U.S. were \$426.1 million, a 31 percent decrease due primarily to generic competition in most major markets.

### Humulin

Worldwide Humulin sales increased 5 percent in the fourth quarter of 2010, to \$287.9 million. U.S. sales increased 17 percent to \$120.4 million, driven by increased demand resulting from the new partnership with Walmart for Humulin® ReliOn®. Sales outside the U.S. decreased 2 percent, to \$167.5 million, driven by lower prices and the unfavorable impact of foreign exchange rates, partially offset by increased demand.

For the full year of 2010, worldwide Humulin sales increased 7 percent to \$1.089 billion. U.S. Humulin sales for 2010 were \$470.8 million, a 17 percent increase driven primarily by higher prices and higher demand. Humulin sales outside the U.S. were \$618.0 million, essentially flat when compared to 2009, due to lower prices offset by increased demand and the favorable impact of foreign exchange rates.

### **Evista**

Evista sales were \$266.5 million in the fourth quarter of 2010, a 1 percent increase compared with the fourth quarter of 2009. U.S. sales of Evista increased 3 percent to \$181.6 million, as a result of higher prices, partially offset by decreased demand. Sales outside the U.S. decreased 2 percent to \$84.9 million, driven by reduced prices, partially offset by increased demand and the favorable impact of foreign exchange rates.

For the full year of 2010, worldwide Evista sales decreased 1 percent to \$1.024 billion. U.S. Evista sales for 2010 were \$681.8 million, essentially flat due to decreased demand offset by increased prices. Evista sales outside the U.S. were \$342.6 million, a 2 percent decrease driven by lower prices and decreased demand, partially offset by a favorable impact of foreign exchange rates.

#### <u>Forteo</u>

Fourth-quarter sales of Forteo were \$226.3 million, a 6 percent increase compared with the fourth quarter of 2009. U.S. sales of Forteo increased 2 percent to \$132.0 million due to higher prices, partially offset by lower demand. Sales outside the U.S. increased 13 percent, to \$94.2 million, due to increased demand and to a lesser extent, higher prices, partially offset by the unfavorable impact of foreign exchange rates.

For the full year of 2010, worldwide Forteo sales increased 2 percent to \$830.1 million. U.S. Forteo sales for 2010 were \$499.0 million, a 4 percent decrease driven by lower demand, partially offset by higher prices. Forteo sales outside the U.S. were \$331.0 million, an 11 percent increase driven by increased demand, and to a lesser extent, higher prices.

#### Strattera

During the fourth quarter of 2010, Strattera generated \$155.4 million of sales, a decrease of 4 percent compared with the fourth quarter of 2009. U.S. sales decreased 14 percent to \$101.4 million, due to lower net effective selling prices and lower demand. Sales outside the U.S. increased 21 percent, to \$53.9 million, driven by increased demand, partially offset by lower prices. Demand outside the U.S. was favorably impacted by continued strong demand in Japan.

For the full year of 2010, worldwide Strattera sales decreased 5 percent to \$576.7 million. U.S. Strattera sales for 2010 were \$389.8 million, a 13 percent decrease driven by lower demand, and to a lesser extent, lower net effective selling prices. Strattera sales outside the U.S. were \$186.9 million, a 14 percent increase driven by increased demand, partially offset by lower prices.

#### Byetta®

Lilly recognizes in 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 fourth quarter of 2010, Lilly recognized total revenue of \$105.3 million for Byetta, a decrease of 13 percent.

Worldwide sales of Byetta were \$174.6 million in the fourth quarter of 2010, a 14 percent decrease compared with the fourth quarter of 2009, due to competitive pressures in the U.S. and European markets. U.S. sales of Byetta decreased 17 percent to \$136.4 million compared with the fourth quarter of 2009, while sales of Byetta outside the U.S. decreased 4 percent to \$38.2 million.

For the full year of 2010, worldwide Byetta sales decreased 11 percent to \$710.2 million. U.S. Byetta sales for 2010 decreased 16 percent to \$559.3 million, while sales outside the U.S. increased 17 percent to \$150.9 million. For the full-year of 2010, Lilly recognized revenue totaling \$430.6 million, representing a 4 percent decrease compared with 2009.

### Erbitux®

Lilly recognizes net royalties received from its Erbitux collaboration partners and revenue from manufactured product sold to these partners. For the fourth quarter of 2010, Lilly recognized total revenue of \$94.5 million for Erbitux, a decrease of 1 percent from the fourth quarter of 2009. For the full-year of 2010, Lilly recognized total Erbitux revenue of \$386.1 million, a decrease of 1 percent from 2009.

### $Effient^{TM}$

Worldwide Effient sales were \$47.0 million in the fourth quarter of 2010, up from \$36.3 million in the third quarter of 2010. U.S. Effient sales were \$35.8 million. Sales outside the U.S. were \$11.3 million.

For the full year of 2010, worldwide Effient sales were \$115.0 million. U.S. Effient sales for 2010 were \$84.6 million. Sales outside the U.S. were \$30.4 million.

### **Animal Health**

Worldwide sales of animal health products in the fourth quarter of 2010 were \$424.3 million, an increase of 20 percent compared with the fourth quarter of 2009. U.S. sales grew 25 percent, to \$234.5 million, due to increased demand. Sales outside the U.S. increased 15 percent, to \$189.8 million, driven by increased demand and the impact of a recent acquisition.

For the full year of 2010, worldwide animal health sales increased 15 percent to \$1.391 billion. Animal health sales in the U.S. and outside the U.S. increased 15 percent to \$775.1 million and \$616.3, respectively, driven primarily by increased demand.

### **2011 Financial Guidance**

The company is providing financial guidance for 2011. The company expects full-year 2011 earnings per share to be in the range of \$3.92 to \$4.07 on a reported basis and \$4.15 to \$4.30 on a non-GAAP basis. The company's guidance includes the dilutive impact of the upfront fee and other anticipated expenses related to the collaboration with Boehringer Ingelheim, but excludes potential restructuring charges primarily related to severance and other related costs from previously announced strategic actions that the company is taking to reduce its cost structure and global workforce.

2011 Earnings Per Share Expectations:

	2011 Expectations	2010 Results	% Growth
Earnings per share (reported)	\$3.92 to \$4.07	\$4.58	(11)% to (14)%
In-process research and development charge associated with Boehringer Ingelheim			
collaboration (2011 estimate) and Acrux licensing agreement (2010)	.23	.03	
Asset impairments and restructuring charges	_	.13	
Earnings per share (non-GAAP)	\$4.15 to \$4.30	\$4.74	(9)% to (12)%

The company expects total revenue growth will be flat to slightly increasing. The company anticipates that the impact of U.S. health care reform will lower 2011 revenue by \$400 million to \$500 million. 2011 revenue guidance assumes the company maintains its patent exclusivity for U.S. Strattera sales, and also assumes rapid and severe erosion of global Zyprexa sales after patent expirations in major markets, including the U.S. starting in October 2011, and the continued severe erosion of U.S. Gemzar sales. The company expects these reductions in revenue to be offset by sales growth of Alimta, Cialis, Cymbalta, Effient, Humalog and animal health products. Excluding the anticipated decline in Zyprexa and Gemzar sales outside of Japan, and the incremental impact of U.S. health care reform, the company would expect 2011 revenue to grow in the mid- to high-single digits.

The company anticipates that gross margin as a percent of revenue will decline approximately 2 percentage points.

Marketing, selling and administrative expenses are projected to grow in the low- to mid-single digits and include an estimated \$150 million to \$200 million in non-tax deductible expense for the mandatory pharmaceutical manufacturers fee associated with U.S. health care reform. Research and development expense growth is projected to be relatively flat.

Other income is expected to be a net expense of between \$50 million and \$150 million, and the tax rate is expected to be approximately 21.5 percent.

Earnings per share are expected to decline and be in the range of \$3.92 to \$4.07 on a reported basis and \$4.15 to \$4.30 on a non-GAAP basis. Compared with 2010, the company anticipates that the Zyprexa and Gemzar sales erosion will lower EPS growth by approximately 15 to 17 percentage points, while the incremental impact of U.S. health care reform is expected to reduce EPS growth by approximately 4.5 to 5.5 percentage points. The collaboration with Boehringer Ingelheim is expected to reduce EPS growth by approximately 4.5 to 5.5 percentage points.

Cash flows are expected to be sufficient to fund capital expenditures of between \$800 million and \$900 million, as well as anticipated business development activity and the company's dividend.

### Webcast of Conference Call

As previously announced, investors and the general public can access a live webcast of the fourth-quarter and full-year 2010 financial results conference call through a link on Lilly's website at <a href="https://www.lilly.com">www.lilly.com</a>. The conference call will be held today from 9:00 a.m. to 10:00 a.m. Eastern Standard Time (EST) and will be available for replay via the website through February 25, 2011.

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of 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 <a href="https://www.lilly.com">www.lilly.com</a>; Lilly's clinical trial registry is available at <a href="https://www.lillytrials.com">www.lilly.com</a>; Lilly's clinical trial registry is available at <a href="https://www.lillytrials.com">www.lillytrials.com</a>.

#### F-LLY

This press release contains forward-looking statements that are based on management's current expectations, but actual results may differ materially due to various factors. There are significant risks and uncertainties in pharmaceutical

research and development. There can be no guarantees with respect to pipeline products that the products will receive the necessary clinical and manufacturing regulatory approvals or that they will prove to be commercially successful. The company's results may also be affected by such factors as competitive developments affecting current 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, including U.S. health care reform; changes in tax law; asset impairments and restructuring charges; acquisitions and business development transactions; and the impact of exchange rates and global macroeconomic conditions. For additional information about the factors that affect the company's business, please see the company's latest Form 10-Q filed October 2010 and Form 10-K filed February 2010. The company undertakes no duty to update forward-looking statements.

# # #

Alimta® (pemetrexed, Lilly)

Amyvid™ (florbetapir, Lilly),

Assurity<sup>TM</sup> (spinetoram, Lilly)

Axiron® (testosterone, Acrux Corp.)

Byetta® (exenatide injection, Amylin Pharmaceuticals)

Cialis® (tadalafil, Lilly)

Cymbalta® (duloxetine hydrochloride, Lilly)

Effient<sup>TM</sup> (prasugrel, Lilly)

Erbitux® (cetuximab, ImClone Systems, 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)

Strattera® (atomoxetine hydrochloride, Lilly)

Trifexis™ (spinosad + milbemycin oxime, Lilly)

Zyprexa® (olanzapine, Lilly)

Eli Lilly and Company Employment Information

 December 31, 2010
 December 31, 2009

 Worldwide Employees
 38,350
 40,360

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

	Three Months Ended December 31				Twelve Months Ended December 31					
	2010 2009 % Chg.				2010		2009	% Chg.		
Total Revenue	\$	6,187.0	\$	5,934.2	4%	\$ 2	23,076.0	\$	21,836.0	6%
Cost of sales		1,232.2		1,431.3	-14%		4,366.2		4,247.0	3%
Research and development		1,438.1		1,216.7	18%		4,884.2		4,326.5	13%
Marketing, selling and administrative		1,988.7		1,953.3	2%		7,053.4		6,892.5	2%
Acquired in-process research and development		0		90.0	-100%		50.0		90.0	-44%
Asset impairments, restructuring and other special charges		79.0		37.9	NM		192.0		692.7	-72%
Operating income		1,449.0		1,205.0	20%		6,530.2		5,587.3	17%
Net interest income (expense)		(29.2)		(36.4)			(133.6)		(186.1)	
Net other income (expense)		(10.2)		(31.4)			128.6		(43.4)	
Other income (expense)		(39.4)		(67.8)	-42%		(5.0)		(229.5)	-98%
Income before income taxes		1,409.6		1,137.2	24%		6,525.2		5,357.8	22%
Income taxes		240.0		221.8	8%		1,455.7		1,029.0	41%
Net income	\$	1,169.6	\$	915.4	28%	\$	5,069.5	\$	4,328.8	17%
Earnings per share – Basic and diluted	\$	1.05	\$	.83	27%	\$	4.58	\$	3.94	16%
Dividends paid per share	\$	.49	\$	.49	NM	\$	1.96	\$	1.96	NM
Weighted-average shares outstanding (thousands) – basic	1,1	109,336	1	,101,420		1,	105,788	1	,098,338	
Weighted-average shares outstanding (thousands) – diluted		109,361	1	,101,447		1,	105,813	1	,098,367	

 $NM-not\ meaningful$ 

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

	T	Three Months Ended December 31		Twelve Months Ended December 31			
	2010(a)	2009(b)	2010(a)	2009(b)	% Chg.		
Total Revenue	\$ 6,187.0	\$ 5,934.2	4%	\$ 23,076.0	\$ 21,836.0	6%	
Cost of sales	1,232.2	1,431.3	-14%	4,366.2	4,247.0	3%	
Research and development	1,438.1	1,216.7	18%	4,884.2	4,326.5	13%	
Marketing, selling and administrative	1,988.7	1,953.3	2%	7,053.4	6,892.5	2%	
Operating income	1,528.0	1,332.9	15%	6,772.2	6,370.0	6%	
Net interest income (expense)	(29.2)	(36.4)		(133.6)	(186.1)		
Net other income (expense)	(10.2)	(31.4)		128.6	(43.4)		
Other income (expense)	(39.4)	(67.8)	-42%	(5.0)	(229.5)	-98%	
Income before income taxes		1,265.1	18%	6,767.2	6,140.5	10%	
Income taxes	253.7	265.7	-5%	1,526.4	1,289.5	18%	
Net income	\$ 1,234.9	\$ 999.4	24%	\$ 5,240.8	\$ 4,851.0	8%	
Earnings per share – basic and diluted	\$ 1.11	\$ .91	22%	\$ 4.74	\$ 4.42	7%	
Dividends paid per share	\$ .49	\$ .49	NM	\$ 1.96	\$ 1.96	NM	
Weighted-average shares outstanding (thousands) – basic		1,101,420		1,105,788	1,098,338		
Weighted-average shares outstanding (thousands) – diluted	1,109,361	1,101,447		1,105,813	1,098,367		

### NM - not meaningful

- (a) The fourth-quarter and full-year 2010 financial statements have been adjusted to eliminate restructuring charges of \$79.0 million (pretax), or \$0.06 (after-tax). The year-to-date 2010 financial statements have also been adjusted to eliminate restructuring charges of \$113.0 million (pretax), or \$0.07 (after-tax). These charges are primarily related to severance costs from previously announced strategic actions that the company is taking to reduce its cost structure and global workforce. In addition, the year-to-date 2010 financial statements have been adjusted to eliminate a charge of \$50.0 million (pretax), or \$0.03 per share (after-tax), for acquired in-process research and development associated with the in-licensing agreement with Acrux Ltd.
- (b) The fourth- quarter and full-year 2009 financial statements have been adjusted to eliminate an asset impairment and restructuring charge of \$37.9 million (pretax), or \$0.02 (after-tax). This charge is primarily related to severance costs from previously announced strategic actions. In addition, the fourth quarter and full-year 2009 financial statements have been adjusted to eliminate a charge of \$90.0 million

(pretax), of \$0.05 per share (after-tax) for acquired in-process research and development associated with the licensing agreement with Incyte. The year-to-date 2009 financial statements have been adjusted to eliminate an additional special pretax charge of \$230.0 million, or \$0.13 per share (after-tax), related with several states' litigation claims involving Zyprexa. In addition, the full-year 2009 financial statements have also been adjusted to eliminate an asset impairment and restructuring charge of \$424.8 million (pretax), or \$0.26 (after-tax) primarily related to severance costs from previously announced strategic actions.