

SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

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FORM 8-K

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

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Date of Report (Date of earliest event reported): **January 29, 2013**

**ELI LILLY AND COMPANY**  
(Exact name of registrant as specified in its charter)

**Indiana**  
(State or Other Jurisdiction  
of Incorporation)

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

**001-06351**  
(Commission  
File Number)

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

**46285**  
(Zip Code)

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

No Change

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- 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 29, 2013 we issued a press release announcing our results of operations for the fourth quarter and twelve month period ended December 31, 2012, including, among other things, income statements 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 Exhibit 99.

In our press release, 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”). The items that we exclude when we provide non-GAAP results or 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 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**

<u>Exhibit Number</u>	<u>Description</u>
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99	Press release dated January 29, 2013 together with related attachments
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## 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/ Donald A. Zakrowski  
Name: Donald A. Zakrowski  
Title: Vice President, Finance and  
Chief Accounting Officer

Dated: January 29, 2013

**EXHIBIT INDEX**

**Exhibit Number**

99

Exhibit

Press release dated January 29, 2013, together with related attachments.

**Date:** January 29, 2013

**For Release:** Immediately

**Refer to:** (317) 433-9899 – Ed Sagebiel (Media)  
(317) 655-6874 – Philip Johnson (Investors)

### **Lilly Reports Fourth-Quarter and Full-Year 2012 Results, Revises 2013 EPS Guidance**

- *Fourth quarter revenue declined 1 percent driven by Zyprexa patent expiration, largely offset by growth in other products.*
- *Fourth quarter earnings per share were \$0.74 (reported), or \$0.85 (non-GAAP).*
- *Full-year 2012 revenue declined 7 percent to \$22.6 billion.*
- *Full-year 2012 earnings per share totaled \$3.66 (reported), or \$3.39 (non-GAAP).*
- *2013 guidance increased by \$0.07 per share to reflect the estimated benefit from the delayed enactment of the American Taxpayer Relief Act of 2012.*
- *2013 earnings per share now expected to be in the range of \$4.10 to \$4.25 (reported), or \$3.82 to \$3.97 (non-GAAP).*

Eli Lilly and Company (NYSE: LLY) today announced financial results for the fourth quarter and full year of 2012.

\$ in millions, except per share data	<u>Fourth Quarter</u>		<u>%</u>	<u>Full Year</u>		<u>%</u>
	<u>2012</u>	<u>2011</u>	<u>Growth</u>	<u>2012</u>	<u>2011</u>	<u>Growth</u>
Total Revenue – Reported	\$5,957.3	\$6,046.6	(1)%	\$22,603.4	\$24,286.5	(7)%
Net Income – Reported	827.2	858.2	(4)%	4,088.6	4,347.7	(6)%
EPS – Reported	0.74	0.77	(4)%	3.66	3.90	(6)%
Net Income – non- GAAP	945.2	968.9	(2)%	3,784.0	4,913.5	(23)%
EPS – non-GAAP	0.85	0.87	(2)%	3.39	4.41	(23)%

Financial results for 2012 and 2011 are presented on both a reported and a non-GAAP basis. Some numbers in this press release may not add due to rounding. 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 later in the release. The non-GAAP results are presented in order to provide additional insights into the underlying trends in the company's business. The company's 2013 financial guidance is also being provided on both a reported and a non-GAAP basis.

"Lilly delivered solid financial results in the fourth quarter of 2012, as we successfully offset a large part of the revenue decline from the Zyprexa patent expiration with growth in other products such as Cymbalta, Forteo, Alimta, Effient and our animal health portfolio," said John C. Lechleiter, Ph.D., Lilly's chairman, president and chief executive officer. "At the same time, we continued to control costs while investing in R&D in order to replenish and advance our pipeline. Today, Lilly has 13 potential new medicines in Phase III testing. We are well-positioned to deliver on our innovation-based strategy and create long-term value for all of our stakeholders."

#### Key Events Over the Last Three Months

- The company's board of directors authorized a new \$1.5 billion share repurchase program, which the company anticipates completing in 2013. The company repurchased \$400 million of shares in 2012 under this program and also completed a previously authorized share repurchase program.
- The company announced plans to conduct an additional Phase III study of solanezumab in patients with mild Alzheimer's disease. Enrollment is expected to begin no later than the third quarter of 2013.
- The company and its partner, Boehringer Ingelheim, announced top-line results for four completed Phase III clinical trials for empagliflozin, an investigational sodium glucose co-transporter-2 (SGLT-2) inhibitor being studied for treatment of patients with type 2 diabetes. In all four studies, the primary efficacy endpoint, defined as significant change in HbA1c from baseline compared to placebo, was met with empagliflozin (10 and 25 mg) taken once daily.

- The company and its partner, Boehringer Ingelheim, adjusted the scope of their diabetes alliance, with Lilly reassuming sole worldwide development and commercialization rights for LY2605541, Lilly's investigational novel basal insulin analog which is currently in Phase III clinical testing.
- The company stopped one of three Phase III rheumatoid arthritis (RA) registration studies of tabalumab, an anti-BAFF monoclonal antibody, due to insufficient efficacy. The decision was not based on safety concerns, and patients currently enrolled in other tabalumab RA studies will continue treatment.
- The European Commission approved Cialis<sup>®</sup> 5 mg for once daily use for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH).
- Amyvid<sup>™</sup> received marketing authorization from the European Commission as a diagnostic radiopharmaceutical indicated for Positron Emission Tomography (PET) imaging of beta-amyloid neuritic plaque density in the brains of adult patients with cognitive impairment who are being evaluated for Alzheimer's disease and other causes of cognitive impairment.
- The company received notification from its partner, Bristol-Myers Squibb, to terminate the collaboration for necitumumab in North America and Japan, which will result in Lilly assuming sole worldwide development and commercialization rights. Necitumumab is currently in Phase III testing as a potential treatment for squamous non-small cell lung cancer.
- The company reached an agreement with the U.S. Securities and Exchange Commission (SEC) to settle the SEC's investigation into the company's compliance with the U.S. Foreign Corrupt Practices Act (FCPA). Without admitting or denying the allegations, Lilly paid a civil settlement amount of \$29.4 million and agreed to have an independent compliance consultant conduct a 60-day review of the company's internal controls and compliance program related to the FCPA.

### Fourth-Quarter Reported Results

In the fourth quarter of 2012, worldwide total revenue was \$5.957 billion, a decrease of 1 percent compared with the fourth quarter of 2011. This 1 percent revenue decline was comprised of a decrease of 3 percent due to lower volume and 1 percent due to the unfavorable effect of foreign exchange rates, partially offset by an increase of 2 percent due to price. (Numbers do not add due to rounding) The decrease in volume was driven primarily by the loss of patent exclusivity for Zyprexa<sup>®</sup> in most major markets, partially offset by volume gains for certain other products. Total revenue in the U.S. decreased 2 percent to \$3.230 billion due primarily to the loss of patent exclusivity for Zyprexa, largely offset by increased prices for pharmaceutical products, as well as higher demand for animal health products. Total revenue outside the U.S. decreased by 1 percent to \$2.728 billion, driven by the loss of patent exclusivity for Zyprexa in markets outside of Japan, the unfavorable effect of foreign exchange rates, and decreased prices, partially offset by increased volume in certain other products.

Gross margin decreased 0.3 percent to \$4.709 billion in the fourth quarter of 2012, as the loss of patent exclusivity for Zyprexa was largely offset by growth in other products. Gross margin as a percent of total revenue was 79.0 percent, an increase of 0.9 percentage points compared with the fourth quarter of 2011. The increase in gross margin percent was primarily due to the impact of foreign exchange rates on international inventories sold which decreased cost of sales in the fourth quarter of 2012 and increased cost of sales in the fourth quarter of 2011, partially offset by lower sales of Zyprexa.

Total operating expense, defined as the sum of research and development, marketing, selling and administrative expenses, decreased 1 percent compared with the fourth quarter of 2011 to \$3.441 billion. Marketing, selling and administrative expenses decreased 7 percent to \$1.978 billion, driven primarily by lower marketing and selling expenses resulting from the company's cost containment efforts. Research and development expenses increased 8 percent to \$1.463 billion, or 25 percent of



total revenue, driven by expenses related to late-stage clinical trials, including a \$50.0 million milestone payment to Incyte Corporation based on the formal initiation of the rheumatoid arthritis (RA) Phase III program for baricitinib.

In the fourth quarter of 2012, the company recognized a \$204.0 million charge for asset impairments, restructuring and other special charges, comprised primarily of \$122.6 million related to an intangible asset impairment for liprotamase and \$64.7 million related to restructuring to reduce the company's cost structure and global workforce. In the fourth quarter of 2011, the company recognized a charge of \$167.6 million for asset impairments, restructuring and other special charges, including a special charge of \$85.0 million related to the withdrawal of Xigris<sup>®</sup> and \$82.6 million related to restructuring to reduce the company's cost structure and global workforce.

Operating income in the fourth quarter of 2012 was \$1.064 billion, which was essentially flat compared to the fourth quarter of 2011, as higher charges (as described in the previous paragraph) and slightly lower gross margin were offset by lower total operating expenses.

Other income (expense) was a net expense of \$52.0 million, compared with net expense of \$26.8 million in the fourth quarter of 2011.

The effective tax rate was 18.3 percent in the fourth quarter of 2012, compared with an effective tax rate of 17.6 percent in the fourth quarter of 2011. The increase in the fourth quarter 2012 effective tax rate reflects the expiration of the R&D tax credit in the U.S. at the end of 2011, partially offset by the tax benefit related to the intangible asset impairment for liprotamase.

Although operating income was essentially flat, higher other expense caused net income and earnings per share to decrease 4 percent to \$827.2 million and \$0.74, respectively, compared with fourth-quarter 2011 net income of \$858.2 million and earnings per share of \$0.77.

### Fourth-Quarter 2012 non-GAAP Results

On a non-GAAP basis, fourth quarter 2012 operating income increased 3 percent to \$1.268 billion, as lower gross margin due to the loss of patent exclusivity for Zyprexa, along with higher research and development expenses, were more than offset by growth in other products and lower marketing, selling and administrative expenses. The effective tax rate was 22.3 percent, compared with 19.9 percent in the fourth quarter of 2011 principally due to the expiration of the R&D tax credit in the U.S. at the end of 2011. Net income and earnings per share both decreased 2 percent to \$945.2 million and \$0.85, respectively. These decreases were driven by higher operating income that was more than offset by higher other expense and a higher tax rate.

Non-GAAP results exclude items totaling \$0.11 and \$0.10 per share of expense in the fourth quarters of 2012 and 2011, respectively. For further detail, see the reconciliation below as well as the footnotes to the non-GAAP income statement later in this press release.

	<u>Fourth Quarter</u>		<u>% Change</u>
	<u>2012</u>	<u>2011</u>	
<b>Earnings per share (reported)</b>	<b>\$0.74</b>	<b>\$0.77</b>	<b>(4)%</b>
Asset impairment, restructuring and other special charges	0.11	0.10	
<b>Earnings per share (non-GAAP)</b>	<b>\$0.85</b>	<b>\$0.87</b>	<b>(2)%</b>

### Full-Year 2012 Reported Results

For the full-year 2012, worldwide total revenue decreased 7 percent to \$22.603 billion compared with 2011, driven by the loss of patent exclusivity for Zyprexa in most major markets, partially offset by growth in other products. This 7 percent revenue decline was comprised of a 7 percent decrease due to lower volume and a 2 percent decrease due to the impact of foreign exchange rates, partially offset by a 2 percent increase due to higher prices. Total revenue in the U.S. decreased 5 percent to \$12.313 billion due to the loss of patent exclusivity for Zyprexa, partially offset by higher prices and demand growth for certain other products. Total revenue outside the U.S. decreased 9 percent to \$10.290 billion due to the loss of patent exclusivity for Zyprexa in markets

outside of Japan, the unfavorable impact of foreign exchange rates, and lower prices, partially offset by demand growth for certain other products.

Gross margin decreased 7 percent to \$17.807 billion in 2012. Gross margin as a percent of total revenue decreased by 0.3 percentage points in 2012 to 78.8 percent. This decrease was due primarily to lower sales of Zyprexa and, to a lesser extent higher miscellaneous manufacturing costs, partially offset by the effect of foreign exchange rates on international inventories sold, which decreased cost of sales in 2012 and increased cost of sales in 2011.

Total operating expense decreased 1 percent in 2012. Marketing, selling and administrative expenses decreased 5 percent to \$7.514 billion driven by lower marketing expenses resulting from the company's cost containment efforts. Research and development expenses increased 5 percent to \$5.278 billion, or 23 percent of total revenue, due to higher late-stage clinical trial costs.

In 2012, the company recognized charges of \$281.1 million for asset impairments, restructuring and other special charges. These charges were comprised of \$122.6 million related to an intangible asset impairment for liprotamase, \$74.5 million related to restructuring to reduce the company's cost structure and global workforce, \$64.0 million related to the asset impairment of a product delivery device platform, and \$20.0 million related to the withdrawal of Xigris. In 2011, the company recognized asset impairment, restructuring and other special charges of \$401.4 million, of which \$316.4 million related primarily to severance costs from the previously announced strategic actions and \$85.0 million related to the withdrawal of Xigris. In 2011, the company also recognized a charge of \$388.0 million related to acquired in-process research and development associated with the Boehringer Ingelheim diabetes collaboration.

Operating income in 2012 decreased 14 percent to \$4.734 billion compared to 2011, driven by lower gross margin, partially offset by lower charges in 2012 compared to 2011 (as described in the previous paragraph), as well as lower total operating expenses.

Other income (expense) in 2012 was a net income of \$674.0 million, compared to net expense of \$179.0 million in 2011. The increase in other income (expense) was driven by \$787.8 million of income related to the early payment of the exenatide revenue-sharing obligation from Amylin Pharmaceuticals.

The effective tax rate was 24.4 percent in 2012, compared with 18.7 percent in 2011. The increase in the 2012 effective tax rate reflects the tax impact of the payment received from Amylin and the expiration of the R&D tax credit at the end of 2011, partially offset by the tax benefit related to the intangible asset impairment for liprotamase. The effective tax rate for 2011 was lower due to a tax benefit on the in-process research and development charge associated with the Boehringer Ingelheim diabetes collaboration, as well as a benefit of \$85.3 million primarily from the resolution in 2011 of the IRS audits of tax years 2005-2007, along with certain matters related to 2008-2009.

For the full-year 2012, net income and earnings per share decreased 6 percent to \$4.089 billion and \$3.66, respectively, compared to full-year 2011 net income of \$4.348 billion and earnings per share of \$3.90. The decreases in net income and earnings per share were due to lower operating income, partially offset by higher other income from the early payment of the exenatide revenue-sharing obligation.

#### Full-Year 2012 non-GAAP Results

Operating income decreased 21 percent to \$5.015 billion due to the loss of patent exclusivity for Zyprexa and higher research and development expenses, partially offset by growth in other products and lower marketing, selling and administrative expenses. The effective tax rate for 2012 was 22.8 percent. Net income and earnings per share each decreased 23 percent, to \$3.784 billion and \$3.39, respectively.

For purposes of non-GAAP reporting, items totaling \$0.27 of income and \$0.52 of expense for 2012 and 2011, 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.

	<u>Full-Year</u>		<u>% Change</u>
	<u>2012</u>	<u>2011</u>	
<b>Earnings per share (reported)</b>	<b>\$3.66</b>	<b>\$3.90</b>	<b>(6)%</b>
In-process research and development charges associated with Boehringer Ingelheim collaboration	-	0.23	
Asset impairment, restructuring and other special charges	0.16	0.29	
Income from early payment of exenatide revenue-sharing obligation	(0.43)	-	
<b>Earnings per share (non-GAAP)</b>	<b>\$3.39</b>	<b>\$4.41</b>	<b>(23)%</b>

Numbers in the 2011 full-year column do not add due to rounding.

## Revenue Highlights

(Dollars in millions)	Fourth Quarter		% Change Over/(Under)	Full-Year		% Change Over/(Under)
	2012	2011	2011	2012	2011	2011
Cymbalta <sup>®</sup>	\$1,420.4	\$1,180.7	20%	\$4,994.1	\$4,161.3	20%
Alimta <sup>®</sup>	684.3	638.1	7%	2,594.3	2,461.1	5%
Humalog <sup>®</sup>	616.0	662.0	(7)%	2,395.5	2,367.6	1%
Cialis	513.4	494.2	4%	1,926.8	1,875.6	3%
Zyprexa	384.8	749.6	(49)%	1,701.4	4,622.0	(63)%
Humulin <sup>®</sup>	343.0	345.6	(1)%	1,239.1	1,248.8	(1)%
Forteo <sup>®</sup>	314.6	262.5	20%	1,151.0	949.8	21%
Evista <sup>®</sup>	241.0	267.1	(10)%	1,010.1	1,066.9	(5)%
Strattera <sup>®</sup>	163.9	170.6	(4)%	621.4	620.1	0%
Effient <sup>®</sup>	120.6	90.9	33%	457.2	302.5	51%
Animal Health	554.1	468.2	18%	2,036.5	1,678.6	21%
Total Revenue	\$5,957.3	\$6,046.6	(1)%	\$22,603.4	\$24,286.5	(7)%

### Cymbalta

For the fourth quarter of 2012, Cymbalta generated \$1.420 billion in revenue, an increase of 20 percent compared with the fourth quarter of 2011. U.S. sales of Cymbalta increased 25 percent, to \$1.141 billion, driven by higher prices and, to a lesser extent, increased demand. Revenue outside the U.S. was \$279.8 million, an increase of 5 percent, driven primarily by increased demand, partially offset by the unfavorable impact of foreign exchange rates.

For the full year of 2012, worldwide Cymbalta sales increased 20 percent to \$4.994 billion. U.S. Cymbalta sales for 2012 were \$3.918 billion, a 23 percent increase driven by higher prices and, to a lesser extent, increased demand. Cymbalta sales outside the U.S. were \$1.076 billion, a 9 percent increase driven by higher demand, partially offset by the unfavorable impact of foreign exchange rates.

## Alimta

For the fourth quarter of 2012, Alimta generated sales of \$684.3 million, an increase of 7 percent compared with the fourth quarter of 2011. U.S. sales of Alimta increased 19 percent, to \$297.6 million, driven by increased demand and, to a lesser extent, higher prices. Sales outside the U.S. remained relatively flat at \$386.7 million, driven by increased demand, offset by lower prices in Japan and the unfavorable impact of foreign exchange rates.

For the full year of 2012, worldwide Alimta sales increased 5 percent to \$2.594 billion. U.S. Alimta sales for 2012 were \$1.122 billion, a 13 percent increase driven by higher demand and higher prices. Alimta sales outside the U.S. were \$1.472 billion, which was relatively flat with 2011 driven by increased demand offset by lower prices in Japan and the unfavorable effect of foreign exchange rates.

## Humalog

For the fourth quarter of 2012, worldwide Humalog sales decreased 7 percent, to \$616.0 million. Sales in the U.S. decreased 19 percent to \$331.6 million, driven by lower net effective selling prices due to increased government and commercial rebates and changes in estimates for sales rebate reserves based upon updated information. U.S. sales of Humalog have also been negatively impacted by the product's removal from a large formulary in 2012. Sales outside the U.S. increased 12 percent to \$284.4 million, due primarily to increased demand.

For the full year of 2012, worldwide Humalog sales increased 1 percent to \$2.395 billion. U.S. Humalog sales for 2012 were \$1.371 billion, a 2 percent decline due to increased government and commercial rebates. U.S. sales of Humalog have also been negatively impacted by the product's removal from a large formulary in 2012. Humalog sales outside the U.S. were \$1.025 billion, a 6 percent increase driven by higher demand, partially offset by the unfavorable impact of foreign exchange rates.

### Cialis

Cialis sales for the fourth quarter of 2012 increased 4 percent to \$513.4 million. U.S. sales of Cialis were \$211.0 million in the fourth quarter, a 6 percent increase compared with the fourth quarter of 2011, driven by increased demand. Sales of Cialis outside the U.S. increased 2 percent, to \$302.4 million, driven by higher prices, as well as increased demand in Japan, partially offset by the unfavorable impact of foreign exchange rates.

For the full year of 2012, worldwide Cialis sales increased 3 percent to \$1.927 billion. U.S. Cialis sales for 2012 were \$782.2 million, an 11 percent increase driven by higher demand and higher prices. Cialis sales outside the U.S. were \$1.145 billion, a 2 percent decrease driven by the unfavorable impact of foreign exchange rates, partially offset by increased demand and higher prices.

### Zyprexa

In the fourth quarter of 2012, Zyprexa sales totaled \$384.8 million, a decrease of 49 percent compared with the fourth quarter of 2011 due to the loss of patent exclusivity in the U.S. and most major international markets, partially offset by growth in Japan. U.S. sales of Zyprexa decreased 80 percent to \$60.1 million. Zyprexa sales in international markets decreased 29 percent, to \$324.7 million.

For the full year of 2012, worldwide Zyprexa sales totaled \$1.701 billion, a decrease of 63 percent compared with 2011 due to the loss of patent exclusivity in the U.S. and most major international markets, partially offset by growth in Japan. U.S. sales of Zyprexa decreased 83 percent to \$360.4 million. Zyprexa sales in international markets decreased 45 percent, to \$1.341 billion. Zyprexa sales in Japan for the full-year 2012 were approximately \$585 million.

### Humulin



Worldwide Humulin sales decreased 1 percent in the fourth quarter of 2012, to \$343.0 million. U.S. sales decreased 4 percent to \$163.0 million, driven primarily by lower demand, partially offset by higher prices. U.S. sales of Humulin have been negatively impacted by the product's removal from a large formulary in 2012, as well as the continued decline in the market for human insulin and the termination of the Humulin ReliOn agreement. Sales outside the U.S. increased 2 percent, to \$180.0 million, driven primarily by increased demand, partially offset by the unfavorable impact of foreign exchange rates and lower prices.

For the full year of 2012, worldwide Humulin sales decreased 1 percent to \$1.239 billion. U.S. Humulin sales for 2012 were \$592.1 million, a 1 percent increase driven by higher prices, largely offset by decreased demand. U.S. sales of Humulin have been negatively impacted by the product's removal from a large formulary in 2012, as well as the continued decline in the market for human insulin and the termination of the Humulin ReliOn agreement. Humulin sales outside the U.S. were \$647.0 million, a 2 percent decrease driven by the unfavorable impact of foreign exchange rates, partially offset by higher volume.

### Forteo

Fourth-quarter sales of Forteo were \$314.6 million, a 20 percent increase compared with the fourth quarter of 2011. U.S. sales of Forteo were relatively flat at \$120.8 million, due to lower volume, offset by higher prices. Sales outside the U.S. increased 37 percent, to \$193.8 million, due primarily to increased demand in Japan, partially offset by the unfavorable impact of foreign exchange rates.

For the full year of 2012, worldwide Forteo sales increased 21 percent to \$1.151 billion. U.S. Forteo sales for 2012 were \$488.2 million, an 8 percent increase driven by higher prices, partially offset by decreased volume. Forteo sales outside the U.S. were \$662.8 million, a 33 percent increase driven primarily by higher demand in Japan.

### Evista

Evista sales for the fourth quarter of 2012 decreased 10 percent to \$241.0 million. U.S. sales of Evista decreased 3 percent to \$177.0 million, driven by decreased demand, partially offset by higher prices. Sales outside the U.S. decreased 25 percent to \$64.0 million, driven by lower volume.

For the full year of 2012, worldwide Evista sales decreased 5 percent to \$1.010 billion. U.S. Evista sales for 2012 were \$699.5 million, a 1 percent decrease driven by lower demand, largely offset by higher prices. Evista sales outside the U.S. were \$310.6 million, a 14 percent decrease driven by decreased volume and, to a lesser extent, the unfavorable impact of foreign exchange rates.

### Strattera

During the fourth quarter of 2012, Strattera generated \$163.9 million of sales, a decrease of 4 percent compared with the fourth quarter of 2011. U.S. sales decreased 14 percent to \$95.8 million, due to lower net effective selling prices and decreased demand. Sales outside the U.S. increased 15 percent to \$68.1 million driven by increased demand in Japan, partially offset by lower prices.

For the full year of 2012, worldwide Strattera sales were relatively flat at \$621.4 million. U.S. Strattera sales for 2012 were \$384.1 million, a 2 percent decrease driven by lower demand, partially offset by higher prices. Strattera sales outside the U.S. were \$237.3 million, a 4 percent increase driven by higher demand in Japan, partially offset by lower prices and the unfavorable impact of foreign exchange rates.

### Effient

Effient sales were \$120.6 million in the fourth quarter of 2012, an increase of 33 percent compared with the fourth quarter of 2011. U.S. Effient sales increased 31 percent to \$87.8 million, driven by increased demand and, to a lesser extent, higher prices. Sales outside the U.S. increased 37 percent to \$32.8 million driven by higher demand.

For the full year of 2012, worldwide Effient sales increased 51 percent to \$457.2 million. U.S. Effient sales for 2012 were \$339.0 million, a 52 percent increase driven by higher demand and, to a lesser extent, higher prices. Effient sales outside the U.S. were \$118.2 million, a 47 percent increase driven by higher demand, partially offset by the unfavorable impact of foreign exchange rates.

#### Erbitux<sup>®</sup>

Lilly recognizes net royalties received from its Erbitux collaboration partners and revenue from manufactured product sold to these partners. For the fourth quarter of 2012, Lilly recognized total revenue of \$87.0 million for Erbitux, a decrease of 19 percent from the fourth quarter of 2011, due to the timing of product shipments to collaboration partners. For the full-year of 2012, Lilly recognized total Erbitux revenue of \$397.0 million, a decrease of 3 percent from 2011.

#### Animal Health

Worldwide sales of animal health products in the fourth quarter of 2012 were \$554.1 million, an increase of 18 percent compared with the fourth quarter of 2011. U.S. sales grew 31 percent, to \$312.2 million, due primarily to increased demand for companion animal products. Sales outside the U.S. increased 5 percent, to \$241.9 million, driven primarily by increased volume.

For the full year of 2012, worldwide animal health sales increased 21 percent to \$2.036 billion. Animal health sales in the U.S. increased 30 percent to \$1.162 billion, driven primarily by increased demand for companion animal products. Animal health sales outside the U.S. increased 12 percent to \$874.7 million, driven primarily by the acquisition of certain Janssen animal health assets in Europe and the growth of other products, partially offset by the unfavorable impact of foreign exchange rates.

## **2013 Financial Guidance**

The company has revised certain elements of its 2013 financial guidance to reflect an estimated \$0.07 per share benefit from the one-time impact associated with the R&D tax credit for 2012 that will be recorded in the first quarter of 2013 resulting from the delay in the enactment of the American Taxpayer Relief Act of 2012. The company now expects full-year 2013 earnings per share to be in the range of \$4.10 to \$4.25 on a reported basis, or \$3.82 to \$3.97 on a non-GAAP basis.

	2013 Expectations	2012 Results	% Change
<b>Earnings per share (reported)</b>	<b>\$4.10 to \$4.25</b>	<b>\$3.66</b>	<b>12% to 16%</b>
Asset impairments, restructuring and other special charges	-	0.16	
Income from early payment of Amylin revenue-sharing obligation	(0.28)	(0.43)	
<b>Earnings per share (non-GAAP)</b>	<b>\$3.82 to \$3.97</b>	<b>\$3.39</b>	<b>13% to 17%</b>

The company still anticipates 2013 revenue of between \$22.6 billion and \$23.4 billion. Despite the initial impact of the U.S. Cymbalta patent expiration in the fourth quarter of 2013 and the loss of the anticipated 15 percent revenue sharing obligation on worldwide exenatide sales, the company expects overall revenue growth, driven by a portfolio of products including Humalog, Humulin, Cialis, Strattera, Forteo, Alimta, Cymbalta outside the U.S., Effient, Tradjenta<sup>®</sup> and Axiron<sup>®</sup>, as well as animal health products. In addition, significant revenue growth is expected in Japan and the emerging markets, particularly China.

The company still anticipates that gross margin as a percent of revenue will be approximately 78 percent.

Marketing, selling and administrative expenses are still expected in the range of \$7.1 billion to \$7.4 billion. Research and development expenses are still expected to be in the range of \$5.2 billion to \$5.5 billion.

On a reported basis, other income and deductions is still expected to be in a range between \$340 million and \$490 million of net income in 2013. On a non-GAAP basis, other income and deductions is still expected to be in a range between \$0 and \$150 million of net expense, which excludes an estimated \$490 million of deferred exenatide-related income contingent upon the transfer of exenatide commercial rights outside the U.S. to Amylin, which is expected to be largely complete by the end of the first quarter of 2013.

On a reported basis, the 2013 tax rate is now expected to be approximately 21.0 percent, assuming a full-year 2013 benefit of the R&D tax credit. On a non-GAAP basis, the 2013 tax rate is now expected to be approximately 19.5 percent. Both tax rates for 2013 include an estimated \$0.07 per share one-time impact associated with the R&D tax credit for 2012 that will be recorded in 2013 resulting from the delay in the enactment of the American Taxpayer Relief Act of 2012.

Operating cash flows are still expected to be more than sufficient to allow for capital expenditures of approximately \$900 million, fund potential business development activity, pay the company's dividend, and complete the company's previously announced \$1.5 billion share repurchase program.

#### **Webcast of Conference Call**

As previously announced, investors and the general public can access a live webcast of the fourth-quarter and full-year 2012 financial results conference call through a link on Lilly's website at [www.lilly.com](http://www.lilly.com). The conference call will be held today from 9:00 a.m. to 10:00 a.m. Eastern Standard Time (EDT) and will be available for replay via the website.

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

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This press release contains management's current intentions and expectations for the future, all of which are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. The words "estimate", "project", "intend", "expect", "believe", "target" and similar expressions are intended to identify forward-looking statements. 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. Pharmaceutical products can develop unexpected safety or efficacy concerns. The company's results may also be affected by such factors as competitive developments affecting current products; market uptake of recently launched products; the timing of anticipated regulatory approvals and launches of new products; regulatory actions regarding currently marketed products; issues with product supply; regulatory changes or other developments; regulatory compliance problems or government investigations; patent disputes; changes in patent law or regulations related to data-package exclusivity; other litigation involving current or future products; the impact of governmental actions regarding pricing, importation, and reimbursement for pharmaceuticals, including U.S. health care reform and deficit-reduction measures; changes in tax laws, including the American Taxpayer Relief Act of 2012; 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 could cause actual results to differ materially from forward-looking statements, please see the company's latest Form 10-Q and Form 10-K filed with the U.S. Securities and Exchange Commission. You should not place undue reliance on forward-looking statements, which speak only as of the date of this release. Except as is required by law, the company expressly disclaims any obligation to publicly release any revisions to forward-looking statements to reflect events after the date of this release.

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Alimta<sup>®</sup> (pemetrexed, Lilly)  
Amyvid<sup>™</sup> (florbetapir, Lilly)  
Axiron<sup>®</sup> (testosterone, Acrux Corp.)  
Cialis<sup>®</sup> (tadalafil, Lilly)  
Cymbalta<sup>®</sup> (duloxetine hydrochloride, Lilly)  
Effient<sup>®</sup> (prasugrel, Lilly)  
Erbitux<sup>®</sup> (cetuximab, ImClone Systems, Lilly)  
Evista<sup>®</sup> (raloxifene hydrochloride, Lilly)  
Forteo<sup>®</sup> (teriparatide of recombinant DNA origin injection, Lilly)  
Humalog<sup>®</sup> (insulin lispro injection of recombinant DNA origin, Lilly)  
Humulin<sup>®</sup> (human insulin of recombinant DNA origin, Lilly)  
Strattera<sup>®</sup> (atomoxetine hydrochloride, Lilly)  
Tradjenta<sup>®</sup> (linagliptin, Boehringer Ingelheim)  
Xigris<sup>®</sup> (drotrecogin alfa (activated), Lilly)

Zyprexa® (olanzapine, Lilly)

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Eli Lilly and Company Employment Information

	<u>December 31, 2012</u>	<u>December 31, 2011</u>
Worldwide Employees	38,350	38,080

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		
	2012	2011	% Chg.	2012	2011	% Chg.
Total Revenue	\$ 5,957.3	\$ 6,046.6	(1)%	\$ 22,603.4	\$ 24,286.5	(7)%
Cost of sales	1,248.3	1,321.7	(6)%	4,796.5	5,067.9	(5)%
Research and development	1,463.1	1,355.3	8%	5,278.1	5,020.8	5%
Marketing, selling and administrative	1,977.5	2,133.4	(7)%	7,513.5	7,879.9	(5)%
Acquired in-process research and development	-	-	NM	-	388.0	NM
Asset impairments, restructuring and other special charges	<u>204.0</u>	<u>167.6</u>	22%	<u>281.1</u>	<u>401.4</u>	(30)%
Operating income	1,064.4	1,068.6	0%	4,734.2	5,528.5	(14)%
Net interest income (expense)	(16.5)	(25.6)		(72.8)	(106.1)	
Other income (expense) – Special	-	-		787.8	-	
Net other income (expense)	<u>(35.50)</u>	<u>(1.20)</u>		<u>(41.00)</u>	<u>(72.90)</u>	
Other income (expense)	<u>(52.00)</u>	<u>(26.80)</u>	94%	<u>674.0</u>	<u>(179.00)</u>	NM
Income before income taxes	1,012.4	1,041.8	(3)%	5,408.2	5,349.5	1%
Income taxes	<u>185.2</u>	<u>183.6</u>	1%	<u>1,319.6</u>	<u>1,001.8</u>	32%
Net income	<u>\$ 827.2</u>	<u>\$ 858.2</u>	(4)%	<u>4088.6</u>	<u>4,347.7</u>	(6)%
Earnings per share – diluted	<u>\$ 0.74</u>	<u>\$ 0.77</u>	(4)%	<u>3.66</u>	<u>3.90</u>	(6)%
Dividends paid per share	\$ 0.49	\$ 0.49	NM	1.96	1.96	NM
Weighted-average shares outstanding (thousands) – diluted	1,113,880	1,115,883		1,117,294	1,113,967	

NM – not meaningful



Eli Lilly and Company

Operating Results (Unaudited) – Non-GAAP

(Dollars in millions, except per share data)

	Three Months Ended			Twelve Months Ended		
	December 31			December 31		
	2012(a)	2011(b)	% Chg.	2012(a)	2011(b)	% Chg.
Total Revenue	\$ 5,957.3	\$ 6,046.6	(1)%	\$ 22,603.4	\$ 24,286.5	(7)%
Cost of sales	1,248.3	1,321.7	(6)%	4,796.5	5,067.9	(5)%
Research and development	1,463.1	1,355.3	8%	5,278.1	5,020.8	5%
Marketing, selling and administrative	1,977.5	2,133.4	(7)%	7,513.5	7,879.9	(5)%
Operating income	1,268.4	1,236.2	3%	5,015.3	6,317.9	(21)%
Net interest income (expense)	(16.50)	(25.60)		(72.80)	(106.10)	
Net other income (expense)	(35.50)	(1.20)		(41.00)	(72.90)	
Other income (expense)	(52.00)	(26.80)	94%	(113.80)	(179.00)	(36)%
Income before income taxes	1,216.4	1,209.4	1%	4,901.5	6,138.9	(20)%
Income taxes	271.2	240.5	13%	1,117.5	1,225.4	(9)%
Net income	\$ 945.2	\$ 968.9	(2)%	\$ 3,784.0	\$ 4,913.5	(23)%
Earnings per share – diluted	\$ 0.85	\$ 0.87	(2)%	\$ 3.39	\$ 4.41	(23)%
Dividends paid per share	\$ 0.49	\$ 0.49	NM	\$ 1.96	\$ 1.96	NM
Weighted-average shares outstanding (thousands) – diluted	1,113,880	1,115,883		1,117,294	1,113,967	

- (a) The fourth-quarter 2012 financial statements have been adjusted to eliminate asset impairments, restructuring and other special charges totaling \$204.0 million (pretax), or \$0.11 per share (after-tax), primarily related to an intangible asset impairment for liprotamase and restructuring to reduce the company's cost structure and global workforce. The full-year 2012 financial statements have been adjusted to eliminate asset impairments, restructuring and other special charges of \$281.1 million (pretax), or \$0.16 per share (after-tax), primarily related to an intangible asset impairment for liprotamase, restructuring to reduce the company's cost structure and global workforce, the asset impairment of a product delivery device platform, and the withdrawal of Xigris. Additionally, the full-year 2012 financial

statements have been adjusted for income of \$787.8 million (pretax), or \$0.43 per share (after-tax) related to the early payment of the exenatide revenue-sharing obligation.

- (b) The fourth-quarter 2011 financial statements have been adjusted to eliminate asset impairments, restructuring and other special charges totaling \$167.6 million (pretax), or \$0.10 per share (after-tax), primarily related to a special charge for the withdrawal of Xigris and restructuring to reduce the company's cost structure and global workforce. The full-year 2011 financial statements have been adjusted to eliminate asset impairments, restructuring, and other special charges of \$401.4 million (pretax), or \$0.29 per share (after-tax), primarily related to severance costs and a special charge for the withdrawal of Xigris. Additionally, the full-year 2011 financial statements have been adjusted for an acquired in-process research and development charge of \$388.0 million (pretax), or \$0.23 per share (after-tax), associated with the Boehringer Ingelheim diabetes collaboration. (Numbers do not add due to rounding.)