

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 25, 2016**

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

(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

The information in this Item 2.02, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (“Exchange Act”), or otherwise subject to the liabilities of that Section and shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended, or the Exchange Act, except as otherwise expressly stated in such filing.

Attached as Exhibit 99.1 and incorporated by reference into this Item 2.02 is a copy of the press release, dated October 25, 2016, announcing our results of operations for the third quarter and nine-month period ended September 30, 2016, including, among other things, unaudited financial statements for those periods.

Item 9.01. Financial Statements and Exhibits

| <u>Exhibit Number</u> | <u>Description</u> |
|-----------------------|--------------------|
|-----------------------|--------------------|

| | |
|------|---|
| 99.1 | Press release dated October 25, 2016 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/ Donald A. Zakrowski
Name: Donald A. Zakrowski
Title: Vice President, Finance and
Chief Accounting Officer

Dated: October 25, 2016

EXHIBIT INDEX

Exhibit Number

99.1

Exhibit

Press release dated October 25, 2016, together with related attachments.



October 25, 2016

Eli Lilly and Company

Lilly Corporate Center
Indianapolis, Indiana 46285
U.S.A.
+1.317.276.2000
www.lilly.com

For Release: Immediately

Refer to: Lauren Zierke; lauren_zierke@lilly.com; (317) 277-6524 (Media)
Philip Johnson; johnson_philip_l@lilly.com; (317) 655-6874 (Investors)

Lilly Reports Third-Quarter 2016 Results

- Revenue increased 5 percent, driven by 7 percent pharmaceutical volume growth coming primarily from recent product launches.
- Third-quarter 2016 earnings per share (EPS) were \$0.73 (reported), or \$0.88 (non-GAAP).
- The company now expects 2016 EPS to be in the range of \$2.66 to \$2.76 on a reported basis. On a non-GAAP basis, the company has reaffirmed 2016 EPS to be in the range of \$3.50 to \$3.60.
- Significant pipeline progress continued with FDA approval of Lartruvo and Fast Track designation for BACE inhibitor AZD3293, as well as positive opinions from Europe's CHMP for Lartruvo and Glyxambi.
- The company announced that John C. Lechleiter will retire as president and chief executive officer effective December 31, 2016. David A. Ricks will assume the role of president and chief executive officer on January 1, 2017.
- The company announced an agreement to acquire Boehringer Ingelheim Vetmedica, Inc.'s U.S. feline, canine and rabies vaccines portfolio, as well as a fully integrated manufacturing and research and development site.

Eli Lilly and Company (NYSE: LLY) today announced financial results for the third quarter of 2016.

| \$ in millions, except per share data | <u>Third Quarter</u> | | <u>%</u> |
|---------------------------------------|----------------------|-------------|---------------|
| | <u>2016</u> | <u>2015</u> | <u>Change</u> |
| Revenue | \$ 5,191.7 | \$ 4,959.7 | 5 % |
| Net Income – Reported | 778.0 | 799.7 | (3)% |
| EPS – Reported | 0.73 | 0.75 | (3)% |
| Net Income – Non-GAAP | 931.0 | 949.6 | (2)% |
| EPS – Non-GAAP | 0.88 | 0.89 | (1)% |

Certain financial information for 2016 and 2015 is 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 periods. Non-GAAP measures exclude the items described in the reconciliation tables later in the release. The company's 2016 financial guidance is also being provided on both a reported and a non-GAAP basis. The non-GAAP measures are presented to provide additional insights into the underlying trends in the company's business.

“Lilly's volume-driven growth in the third quarter was once again led by our portfolio of recently approved medicines including Trulicity, Cyramza, Taltz and Jardiance,” said John C. Lechleiter, Ph.D., Lilly's chairman, president and chief executive officer. “Our pipeline also continues to advance with a wide array of promising treatments for conditions from Alzheimer's disease to diabetes and cancer. Our focus on innovation and bringing important new medicines to the people who need them is leading Lilly into a new era of growth for the benefit of patients and shareholders alike.”

Key Events Over the Last Three Months

Regulatory

- The U.S. Food and Drug Administration (FDA) granted approval of LartruvoTM (olaratumab), in combination with doxorubicin, for the treatment of adults with soft tissue sarcoma with a histologic subtype for which an anthracycline-containing regimen is appropriate and which is not amenable to curative treatment with radiotherapy or surgery. Lartruvo's indication was approved under the Accelerated Approval process and is based on data from a Phase 2 trial. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.
- The company and AstraZeneca received FDA Fast Track designation for the development program in Alzheimer's disease for AZD3293, an oral beta secretase cleaving enzyme (BACE) inhibitor currently in Phase 3 clinical trials. The FDA's Fast Track program is designed to expedite the development and review of new therapies to treat serious conditions and address key unmet medical needs.
- The European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) issued positive opinions recommending:
 - Conditional marketing authorization for Lartruvo (olaratumab), in combination with doxorubicin, for the treatment of adults with advanced soft tissue sarcoma not amenable to curative treatment with radiotherapy or surgery and who have not been previously treated with doxorubicin.
 - Marketing authorization for Glyxambi[®], a single tablet combining Jardiance[®] (empagliflozin) and Trajenta[®] (linagliptin), for use in adults with type 2 diabetes. Glyxambi, Jardiance and Trajenta are part of the company's alliance with Boehringer Ingelheim.

Clinical

- Following a pre-planned interim analysis, an independent Data Monitoring Committee recommended continuing a Phase 3 trial of abemaciclib without modification as the interim efficacy criteria were not met. The trial will continue into the first half of 2017. The trial

compares abemaciclib with fulvestrant versus placebo with fulvestrant in women with hormone-receptor-positive, human epidermal growth factor receptor 2-negative locally advanced or metastatic breast cancer.

- Taltz[®] met its primary endpoint of ACR20 response rate in a Phase 3 study investigating the treatment of psoriatic arthritis. Taltz showed improved signs and symptoms in adult patients who have previously been treated with a biologic disease-modifying antirheumatic drug. Lilly plans to submit to the FDA during the first half of 2017.
- Earlier this month, last patient visit was achieved in the Phase 3 trial evaluating solanezumab in patients with mild Alzheimer's disease. As a result, the company plans to issue a top-line press release before the end of the year.

Business Development/Other

- The company announced an agreement to acquire Boehringer Ingelheim Vetmedica, Inc.'s U.S. feline, canine and rabies vaccines portfolio, as well as a fully integrated manufacturing and research and development site, for approximately \$885 million, including the estimated cost of acquired inventory. The acquisition is anticipated to close by early 2017, subject to approval by the U.S. Federal Trade Commission and also subject to both antitrust approval of and the closing of a previously announced asset swap transaction between Boehringer Ingelheim and Sanofi SA.
- The U.S. Patent and Trademark Office determined that the method-of-use patents for Effient[®] are invalid. The patents would have provided intellectual property protection until 2023. The owners of the patent, Daiichi Sankyo and Ube, have appealed this ruling.
- The company announced that John C. Lechleiter will retire as president and chief executive officer from the company effective December 31, 2016. Lechleiter will continue on Lilly's board of directors until May 31, 2017, serving as non-executive chairman. David A. Ricks, currently senior vice president and president, Lilly Bio-Medicines, will assume the role of president and chief executive officer and join the board on January 1, 2017. He will become chairman of the board on June 1, 2017.

Third-Quarter Reported Results

In the third quarter of 2016, worldwide revenue was \$5.192 billion, an increase of 5 percent compared with the third quarter of 2015. The increase in revenue was driven by a 4 percent increase in volume and 1 percent favorable impact of foreign exchange rates, partially offset by 1 percent due to lower realized prices. The increase in worldwide volume was driven by new pharmaceutical products, including Trulicity[®], Cyramza[®], Taltz and Jardiance, as well as Humalog[®] and Erbitux[®] (due to the transfer of commercialization rights in North America to Lilly), partially offset by lower volumes for Zyprexa[®], animal health products, Alimta[®] and Cialis[®].

Revenue in the U.S. increased 12 percent to \$2.838 billion, driven by increased volume for several pharmaceutical products, including Trulicity, Humalog, Taltz and Jardiance, as well as Erbitux (due to the transfer of commercialization rights in North America to Lilly), partially offset by lower volumes for animal health products, Zyprexa and Cialis. Higher realized prices in the U.S., primarily for Cialis and Forteo[®], were largely offset by lower realized prices for Humalog. When the Cymbalta[®] patent expired at the end of 2013, the return reserve was increased to reflect expected product returns. As a result of lower-than-expected return volume, a reduction of approximately \$145 million in the Cymbalta return reserve increased U.S. revenue in the third quarter of 2016, favorably impacting both volume and price.

Revenue outside the U.S. decreased 3 percent to \$2.354 billion, as lower realized prices and volume, primarily from the losses of exclusivity for Cymbalta in Europe and Canada, Zyprexa in Japan and Alimta in several countries, more than offset increased volume for several recently launched pharmaceutical products, including Trulicity and Cyramza, and the favorable impact of foreign exchange rates, primarily the Japanese yen, partially offset by other foreign currencies.

Gross margin increased 2 percent to \$3.791 billion in the third quarter of 2016 compared with the third quarter of 2015. Gross margin as a percent of revenue was 73.0 percent, a decline of 2.1 percentage points compared with the third quarter of 2015. The decline in gross margin percent was

primarily due to a lower benefit from foreign exchange rates on international inventories sold and, to a lesser extent, the transfer of Erbitux[®] commercialization rights in North America.

Operating expenses in the third quarter of 2016, defined as the sum of research and development and marketing, selling and administrative expenses, were \$2.802 billion, an increase of 3 percent compared with the third quarter of 2015. Research and development expenses increased 8 percent to \$1.236 billion, driven primarily by higher late-stage clinical development costs. Marketing, selling and administrative expenses decreased 1 percent to \$1.565 billion, as reduced spending on late-life-cycle products was largely offset by expenses related to new products.

The company recognized asset impairment, restructuring and other special charges of \$45.5 million and \$42.4 million in the third quarters of 2016 and 2015, respectively, primarily related to integration and severance costs for Novartis Animal Health.

Operating income in the third quarter of 2016 was \$943.5 million, a decline of 2 percent compared with the third quarter of 2015, driven by higher research and development expenses, partially offset by higher gross margin.

Other income (expense) was income of \$27.2 million in the third quarter of 2016, compared with income of \$86.5 million in the third quarter of 2015. The decline in other income was driven by lower net gains on investments in the third quarter of 2016 compared with 2015.

The effective tax rate was 19.9 percent in the third quarter of 2016, compared with 23.7 percent in the third quarter of 2015. The decline in the effective tax rate for the third quarter of 2016 is primarily due to the benefit of certain U.S. tax provisions, including the R&D tax credit, reinstated for 2016.

In the third quarter of 2016, net income and earnings per share decreased 3 percent to \$778.0 million, and \$0.73, respectively, compared with \$799.7 million and \$0.75, respectively, in the third quarter of

2015. The declines in net income and earnings per share were driven by lower other income and lower operating income, partially offset by a lower effective tax rate.

Third-Quarter 2016 Non-GAAP Measures

On a non-GAAP basis, third-quarter 2016 gross margin increased 3 percent to \$3.967 billion. Gross margin as a percent of revenue was 76.4 percent, a decline of 1.4 percentage points compared with the third quarter of 2015. The decline in gross margin percent was primarily due to a lower benefit from foreign exchange rates on international inventories sold.

Operating income decreased \$10.7 million, or 1 percent, to \$1.167 billion in the third quarter of 2016, as higher operating expenses were largely offset by higher gross margin.

The effective tax rate was 22.0 percent in the third quarter of 2016, compared with 24.9 percent in the third quarter of 2015. The decline in the effective tax rate for the third quarter of 2016 is primarily due to the benefit of certain U.S. tax provisions, including the R&D tax credit, reinstated for 2016.

Net income decreased 2 percent to \$931.0 million, and earnings per share decreased 1 percent to \$0.88 in the third quarter of 2016, compared with \$949.6 million and \$0.89, respectively, in the third quarter of 2015. The declines in net income and earnings per share were driven by lower other income and, to a lesser extent, lower operating income, partially offset by a lower effective tax rate.

For further detail of non-GAAP measures, see the reconciliation below as well as the Reconciliation of GAAP Reported to Selected Non-GAAP Adjusted Information table later in this press release.

| | <u>2016</u> | <u>Third Quarter</u> <u>2015</u> | <u>% Change</u> |
|---|-----------------------|-------------------------------------|-----------------|
| Earnings per share (reported) | \$ 0.73 | \$ 0.75 | (3)% |
| Amortization of intangible assets | .11 | .10 | |
| Asset impairment, restructuring and other special charges | .03 | .03 | |
| Novartis Animal Health inventory step-up | — | .01 | |
| Earnings per share (non-GAAP) | <u><u>\$ 0.88</u></u> | <u><u>\$ 0.89</u></u> | (1)% |

Numbers may not add due to rounding.

Year-to-Date Results

For the first nine months of 2016, worldwide revenue increased 6 percent to \$15.462 billion compared with \$14.583 billion in the same period in 2015. Reported net income and earnings per share were \$1.966 billion and \$1.85, respectively. Net income and earnings per share, on a non-GAAP basis, were \$2.722 billion and \$2.57, respectively.

For further detail, see the reconciliation below as well as the Reconciliation of GAAP Reported to Selected Non-GAAP Adjusted Information table later in this release.

| | <u>2016</u> | <u>Year-to-Date</u> <u>2015</u> | <u>% Change</u> |
|---|--------------------|------------------------------------|-----------------|
| Earnings per share (reported) | \$ 1.85 | \$ 1.81 | 2% |
| Amortization of intangible assets | .34 | .29 | |
| Asset impairment, restructuring and other special charges | .19 | .15 | |
| Venezuela charge | .19 | — | |
| Acquired in-process research and development | — | .20 | |
| Novartis Animal Health inventory step-up | — | .10 | |
| Net charge related to repurchase of debt | — | .09 | |
| Earnings per share (non-GAAP) | <u>2.57</u> | <u>2.65</u> | (3)% |

Numbers may not add due to rounding.

Select Revenue Highlights

| <i>(Dollars in millions)</i> | Third Quarter | | | Year-to-Date | | |
|--|----------------|----------------|-------------|-----------------|-----------------|-------------|
| | 2016 | 2015 | % Change | 2016 | 2015 | % Change |
| Established Pharmaceutical Products | | | | | | |
| Humalog | \$ 640.8 | \$ 705.0 | (9)% | \$ 1,949.0 | \$ 2,043.3 | (5)% |
| Cialis | 588.2 | 566.1 | 4% | 1,795.3 | 1,672.3 | 7% |
| Alimta | 570.4 | 628.5 | (9)% | 1,741.7 | 1,865.8 | (7)% |
| Forteo | 391.2 | 348.9 | 12% | 1,077.5 | 970.4 | 11% |
| Humulin® | 322.0 | 316.7 | 2% | 1,010.6 | 948.8 | 7% |
| Cymbalta | 313.5 | 242.9 | 29% | 748.7 | 804.0 | (7)% |
| Strattera® | 198.8 | 196.9 | 1% | 611.5 | 562.4 | 9% |
| Zyprexa | 148.9 | 237.9 | (37)% | 572.3 | 711.2 | (20)% |
| Erbitux | 184.6 | 85.9 | 115% | 533.3 | 308.8 | 73% |
| Effient | 127.7 | 132.1 | (3)% | 394.3 | 382.7 | 3% |
| New Pharmaceutical Products | | | | | | |
| Trulicity | 243.6 | 73.7 | NM | 588.5 | 136.2 | NM |
| Cyramza | 159.0 | 111.2 | 43% | 437.0 | 266.4 | 64% |
| Jardiance(a) | 47.5 | 15.4 | NM | 125.8 | 45.7 | NM |
| Taltz | 32.5 | — | NM | 51.9 | — | NM |
| Basaglar® | 19.4 | 3.8 | NM | 46.6 | 3.9 | NM |
| Portrazza® | 5.3 | — | NM | 11.0 | — | NM |
| Subtotal | 507.3 | 204.1 | NM | 1,260.8 | 452.2 | NM |
| Animal Health | 706.2 | 778.8 | (9)% | 2,320.5 | 2,369.3 | (2)% |
| Total Revenue | 5,191.7 | 4,959.7 | 5% | 15,461.6 | 14,583.1 | 6% |

(a) Jardiance includes Glyxambi and Synjardy®
 NM – not meaningful

Selected Established Pharmaceutical Products

Humalog

For the third quarter of 2016, Humalog revenues decreased 9 percent compared with the third quarter of 2015 to \$640.8 million. Revenues in the U.S. decreased 14 percent to \$378.8 million, driven by lower realized prices, partially offset by increased demand. The decrease in realized prices for the third quarter of 2016 also included changes in estimates for rebates and discounts. Revenues outside the U.S. decreased 1 percent to \$262.0 million, as the unfavorable impact of foreign exchange rates was largely offset by higher realized prices.

Cialis

Cialis revenues for the third quarter of 2016 increased 4 percent compared with the third quarter of 2015 to \$588.2 million. U.S. revenues of Cialis were \$348.5 million, an 11 percent increase compared with the third quarter of 2015, driven by higher realized prices, partially offset by lower demand. Revenues of Cialis outside the U.S. decreased 5 percent to \$239.7 million, driven by decreased volume and the unfavorable impact of foreign exchange rates, partially offset by higher realized prices.

Alimta

For the third quarter of 2016, Alimta generated revenues of \$570.4 million, a decline of 9 percent compared with the third quarter of 2015. U.S. revenues of Alimta decreased 7 percent to \$277.0 million, driven primarily by decreased demand due to competitive pressure. Revenues outside the U.S. decreased 12 percent to \$293.4 million, driven primarily by the loss of exclusivity in several countries, partially offset by the favorable impact of foreign exchange rates.

Forteo

Third-quarter 2016 revenues of Forteo were \$391.2 million, a 12 percent increase compared with the third quarter of 2015. U.S. revenues of Forteo increased 29 percent to \$206.7 million, driven by higher

realized prices. Revenues outside the U.S. decreased 2 percent to \$184.5 million, driven by lower realized prices, partially offset by the favorable impact of foreign exchange rates.

Humulin

Humulin revenues for the third quarter of 2016 increased 2 percent compared with the third quarter of 2015 to \$322.0 million. U.S. revenues increased 5 percent to \$195.6 million, driven by increased demand, partially offset by lower realized prices. Revenues outside the U.S. decreased 4 percent to \$126.4 million, driven by the unfavorable impact of foreign exchange rates and lower realized prices, partially offset by increased volume.

New Pharmaceutical Products

Trulicity

Third-quarter 2016 revenues of Trulicity were \$243.6 million. U.S. revenues of Trulicity were \$188.7 million, driven by growth in the GLP-1 market and increased share of market for Trulicity. Revenues of Trulicity outside the U.S. were \$54.9 million.

Cyramza

For the third quarter of 2016, Cyramza revenues were \$159.0 million, an increase of 43 percent compared with the third quarter of 2015. U.S. revenues were \$67.0 million, a decrease of 12 percent, due to competitive pressure primarily in the non-small cell lung cancer indication. Revenues outside the U.S. were \$92.0 million, primarily due to strong uptake for the gastric cancer indication in Japan.

Jardiance

The company's revenues for Jardiance during the third quarter of 2016 were \$47.5 million. U.S. revenues were \$32.9 million, driven by growth in the SGLT2 class and increased share of market for Jardiance. Revenues outside the U.S. were \$14.6 million. Jardiance is part of the company's alliance with Boehringer Ingelheim, and Lilly reports as revenue a portion of Jardiance's gross margin.

Taltz

For the third quarter of 2016, Taltz, a treatment for moderate-to-severe plaque psoriasis, generated revenues of \$32.5 million. Taltz launched in the U.S. in April 2016 and began launching in Europe in July 2016.

Basaglar

For the third quarter of 2016, Basaglar, a treatment to control high blood sugar in adults and children with type 1 diabetes and adults with type 2 diabetes, generated revenues of \$19.4 million, driven by early uptake in Japan and various European countries. Basaglar is part of the company's alliance with Boehringer Ingelheim.

Portrazza

For the third quarter of 2016, Portrazza, a first-line treatment for metastatic squamous non-small cell lung cancer, generated revenues of \$5.3 million.

Animal Health

In the third quarter of 2016, animal health revenues totaled \$706.2 million, a decline of 9 percent compared with the third quarter of 2015. U.S. animal health revenues decreased 14 percent to \$338.6 million, primarily due to wholesaler buying patterns for companion animal products and decreased revenues for food animal products due to market access pressures. Animal health revenues outside the U.S. decreased 5 percent to \$367.6 million, negatively impacted by food animal products, primarily due to macroeconomic conditions in Latin America.

2016 Financial Guidance

The company has revised certain elements of its 2016 financial guidance. Full-year 2016 earnings per share are now expected to be in the range of \$2.66 to \$2.76 on a reported basis. On a non-GAAP basis, full-year 2016 earnings per share are still expected to be in the range of \$3.50 to \$3.60.

| | 2016 Expectations |
|---|-------------------------|
| Earnings per share (reported) | \$2.66 to \$2.76 |
| Amortization of intangible assets | .42 |
| Asset impairment, restructuring and other special charges, including Novartis Animal Health integration costs and closure of an animal health manufacturing facility in Ireland | .23 |
| Venezuela charge | .19 |
| Earnings per share (non-GAAP) | \$3.50 to \$3.60 |
| Numbers may not add due to rounding. | |

The company now expects 2016 revenue of between \$20.8 billion and \$21.2 billion. Excluding the impact of foreign exchange rates, the company expects revenue growth from a number of established products including Trajenta, Cialis, Forteo, Strattera, Erbitux and animal health products, as well as higher revenues from new products including Cyramza, Jardiance, Trulicity, Portrazza, Basaglar and Taltz. The company expects this revenue growth to be partially offset by lower revenue from Alimta as a result of increased competitive pressures.

Gross margin percentage is still expected to be approximately 73 percent on a reported basis, and 76 percent on a non-GAAP basis.

Marketing, selling and administrative expenses are now expected to be in the range of \$6.2 billion to \$6.4 billion. Research and development expenses are still expected to be in the range of \$4.9 billion to \$5.1 billion.

Other income (expense) is now expected to be in a range between \$150 million and \$100 million of expense on a reported basis. On a non-GAAP basis, other income (expense) is now expected to be in a range between \$50 and \$100 million of income.

The 2016 tax rate is still expected to be approximately 21 percent.

Capital expenditures are now expected to be approximately \$1.0 billion.

The following table summarizes the company's 2016 financial guidance:

| | 2016 Guidance | |
|--------------------------------------|------------------------------------|------------------------------------|
| | <u>Prior</u> | <u>Revised</u> |
| Revenue | \$20.6 to \$21.1 billion | \$20.8 to \$21.2 billion |
| Gross Margin % of Revenue (reported) | Approx. 73% | Unchanged |
| Gross Margin % of Revenue (non-GAAP) | Approx. 76% | Unchanged |
| Marketing, Selling & Administrative | \$6.1 to \$6.3 billion | \$6.2 to \$6.4 billion |
| Research & Development | \$4.9 to \$5.1 billion | Unchanged |
| Other Income/(Expense) (reported) | \$(200 million) to \$(125 million) | \$(150 million) to \$(100 million) |
| Other Income/(Expense) (non-GAAP) | \$0 to \$75 million | \$50 million to \$100 million |
| Tax Rate | Approx. 21.0% | Unchanged |
| Earnings per share (reported) | \$2.68 to \$2.78 | \$2.66 to \$2.76 |
| Earnings per share (non-GAAP) | \$3.50 to \$3.60 | Unchanged |
| Capital Expenditures | Approx. \$1.1 billion | Approx. \$1.0 billion |

Non-GAAP adjustments are consistent with the earnings per share table above.

Webcast of Conference Call

As previously announced, investors and the general public can access a live webcast of the third-quarter 2016 financial results conference call through a link on Lilly's website at <https://investor.lilly.com/events.cfm>. The conference call will begin at 9:00 a.m. Eastern Time (ET) on Tuesday, October 25, 2016, and will be available for replay via the website.

Lilly is a global healthcare leader that unites caring with discovery to make life better for people around the world. We were founded more than a century ago by a man committed to creating high-quality medicines that meet real needs, and today we remain true to that mission in all our work. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism. To learn more about Lilly, please visit us at www.lilly.com and <http://newsroom.lilly.com/social-channels>. F-LLY

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," "anticipate," and similar expressions are intended to identify forward-looking statements. Actual results may differ materially from these forward-looking statements due to various factors. There are significant risks and uncertainties in pharmaceutical research and development. There can be no guarantees that pipeline products will succeed in clinical testing, will receive the necessary clinical and manufacturing regulatory approvals, or will prove to be commercially successful. The company's results may also be affected by such factors as the timing of anticipated regulatory approvals and launches of new products; market uptake of recently launched products; competitive developments affecting current products; the expiration of intellectual property protection for certain of the company's products; the company's ability to protect and enforce patents and other intellectual property; the impact of governmental actions regarding pricing, importation, and reimbursement for pharmaceuticals, including U.S. health care reform; regulatory compliance problems or government investigations; regulatory actions regarding currently marketed products; unexpected safety or efficacy concerns associated with the company's products; issues with product supply stemming from manufacturing difficulties or disruptions; regulatory changes or other developments; changes in patent law or regulations related to data-package exclusivity; litigation involving current or future products; the extent to which third-party indemnification obligations relating to product liability litigation and similar matters will be performed; unauthorized disclosure of trade secrets or other confidential data stored in the company's information systems and networks; changes in tax law and regulations; changes in inflation, interest rates, and foreign currency exchange rates; asset impairments and restructuring charges; changes in accounting standards promulgated by the Financial Accounting Standards Board and the U.S. Securities and Exchange Commission (SEC); acquisitions and business development transactions and related integration considerations; and the impact of exchange rates and global macroeconomic conditions, including the effect of the pending exit of the United Kingdom from the European Union. 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-K filed with the SEC. 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® (pemetrexed disodium, Lilly)
Basaglar® (insulin glargine injection, Lilly)
Cialis® (tadalafil, Lilly)
Cymbalta® (duloxetine hydrochloride, Lilly)
Cycramza® (ramucirumab, Lilly)
Effient® (prasugrel, Lilly)
Erbix® (cetuximab, Lilly)
Forteo® (teriparatide of recombinant DNA origin injection, Lilly)
Glyxambi® (empagliflozin/linagliptin, Boehringer Ingelheim)
Humalog® (insulin lispro injection of recombinant DNA origin, Lilly)
Humulin® (human insulin of recombinant DNA origin, Lilly)
Jardiance® (empagliflozin, Boehringer Ingelheim)
Lartruvo™ (olaratumab, Lilly)
Portrazza® (necitumumab, Lilly)
Synjardy® (empagliflozin/metformin, Boehringer Ingelheim)
Taltz® (ixekizumab, Lilly)
Trajenta® (linagliptin, Boehringer Ingelheim)
Trulicity® (dulaglutide, Lilly)
Zyprexa® (olanzapine, Lilly)

Eli Lilly and Company Employment Information

| | <u>September 30, 2016</u> | <u>December 31, 2015</u> |
|---------------------|---------------------------|--------------------------|
| Worldwide Employees | 42,400 | 41,275 |

Eli Lilly and Company

Operating Results (Unaudited) – REPORTED

(Dollars in millions, except per share data)

| | Three Months Ended September 30, | | | Nine Months Ended September 30, | | |
|--|-------------------------------------|-----------------|--------|------------------------------------|-------------------|--------|
| | 2016 | 2015 | % Chg. | 2016 | 2015 | % Chg. |
| Revenue | \$ 5,191.7 | \$ 4,959.7 | 5% | \$ 15,461.6 | \$ 14,583.1 | 6% |
| Cost of sales | 1,400.9 | 1,236.9 | 13% | 4,188.9 | 3,648.0 | 15% |
| Research and development | 1,236.4 | 1,143.4 | 8% | 3,793.3 | 3,352.2 | 13% |
| Marketing, selling and administrative | 1,565.4 | 1,575.7 | (1)% | 4,661.9 | 4,734.6 | (2)% |
| Acquired in-process research and development | — | — | NM | — | 336.0 | (100)% |
| Asset impairment, restructuring and other special charges | 45.5 | 42.4 | 7% | 234.9 | 222.8 | 5% |
| Operating income | 943.5 | 961.3 | (2)% | 2,582.6 | 2,289.5 | 13% |
| Net interest income (expense) | (18.1) | (18.1) | | (57.0) | (53.8) | |
| Net other income (expense) | 45.3 | 104.6 | | (43.6) | 109.7 | |
| Other income (expense) | 27.2 | 86.5 | (69)% | (100.6) | 55.9 | NM |
| Income before income taxes | 970.7 | 1,047.8 | (7)% | 2,482.0 | 2,345.4 | 6% |
| Income taxes | 192.7 | 248.1 | (22)% | 516.2 | 415.4 | 24% |
| Net income | \$ <u>778.0</u> | \$ <u>799.7</u> | (3)% | \$ <u>1,965.8</u> | \$ <u>1,930.0</u> | 2% |
| Earnings per share – diluted | \$ <u>0.73</u> | \$ <u>0.75</u> | (3)% | \$ <u>1.85</u> | \$ <u>1.81</u> | 2% |
| Dividends paid per share | \$ 0.51 | \$ 0.50 | 2% | \$ 1.53 | \$ 1.50 | 2% |
| Weighted-average shares outstanding (thousands) – diluted | 1,060,786 | 1,065,159 | | 1,061,065 | 1,065,961 | |

NM – not meaningful

Eli Lilly and Company

Reconciliation of GAAP Reported to Selected Non-GAAP Adjusted Information (Unaudited)(a)

(Dollars in millions, except per share data)

| | Three Months Ended September 30, 2016 | | | Three Months Ended September 30, 2015 | | |
|---|--|----------------|----------------------|--|----------------|----------------------|
| | GAAP Reported | Adjustments(c) | Non-GAAP Adjusted | GAAP Reported | Adjustments(d) | Non-GAAP Adjusted |
| Revenue | \$ 5,191.7 | \$ — | \$ 5,191.7 | \$ 4,959.7 | \$ — | \$ 4,959.7 |
| Cost of sales | 1,400.9 | (175.8) | 1,225.1 | 1,236.9 | (137.9) | 1,099.0 |
| Operating expenses(b) | 2,801.8 | (1.9) | 2,799.9 | 2,719.1 | (35.8) | 2,683.3 |
| Acquired in-process research and development | — | — | — | — | — | — |
| Asset impairment, restructuring and other special charges | 45.5 | (45.5) | — | 42.4 | (42.4) | — |
| Other income (expense) | 27.2 | — | 27.2 | 86.5 | — | 86.5 |
| Income taxes | 192.7 | 70.1 | 262.9 | 248.1 | 66.2 | 314.3 |
| Net income | \$ 778.0 | \$ 153.2 | \$ 931.0 | \$ 799.7 | \$ 149.8 | \$ 949.6 |
| Earnings per share – diluted | \$ 0.73 | \$ 0.14 | \$ 0.88 | \$ 0.75 | \$ 0.14 | \$ 0.89 |

Numbers may not add due to rounding.

- (a) The company uses non-GAAP financial measures that differ from financial statements reported in conformity with U.S. generally accepted accounting principles (GAAP). The company's non-GAAP measures adjust reported results to exclude amortization of intangibles and items that are typically highly variable, difficult to predict, and/or of a size that could have a substantial impact on the company's reported operations for a period. The company believes that these non-GAAP measures provide useful information to investors. Among other things, they may help investors evaluate the company's 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.

- (b) Operating expenses include research and development and marketing, selling and administrative expenses.
- (c) Adjustments to certain GAAP reported measures for the three months ended September 30, 2016, include the following:

| (Dollars in millions, except per share data) | Amortization ⁽ⁱ⁾ | Other specified items ⁽ⁱⁱ⁾ | Total Adjustments |
|---|-----------------------------|---------------------------------------|--------------------------|
| Revenue | \$ — | \$ — | \$ — |
| Cost of sales | (175.8) | — | (175.8) |
| Operating expenses | (1.9) | — | (1.9) |
| Acquired in-process research and development | — | — | — |
| Asset impairment, restructuring and other special charges | — | (45.5) | (45.5) |
| Other income (expense) | — | — | — |
| Income taxes | 56.4 | 13.7 | 70.1 |
| Net income | \$ 121.3 | \$ 31.9 | \$ 153.2 |
| Earnings per share – diluted | \$ 0.11 | \$ 0.03 | \$ 0.14 |

Numbers may not add due to rounding.

- i. Exclude amortization of intangibles primarily associated with costs of marketed products acquired or licensed from third parties.
- ii. Exclude charges associated with integration and severance costs for Novartis Animal Health.

(d) Adjustments to certain GAAP reported measures for the three months ended September 30, 2015, include the following:

| (Dollars in millions, except per share data) | Amortization ⁽ⁱ⁾ | Inventory step-up ⁽ⁱⁱ⁾ | Other specified items ⁽ⁱⁱⁱ⁾ | Total Adjustments |
|---|-----------------------------|-----------------------------------|--|--------------------------|
| Revenue | \$ — | \$ — | \$ — | \$ — |
| Cost of sales | (116.7) | (21.2) | — | (137.9) |
| Operating expenses | (35.8) | — | — | (35.8) |
| Acquired in-process research and development | — | — | — | — |
| Asset impairment, restructuring and other special charges | — | — | (42.4) | (42.4) |
| Other income (expense) | — | — | — | — |
| Income taxes | 51.0 | 6.0 | 9.3 | 66.2 |
| Net income | \$ 101.6 | \$ 15.1 | \$ 33.1 | \$ 149.8 |
| Earnings per share – diluted | \$ 0.10 | \$ 0.01 | \$ 0.03 | \$ 0.14 |

Numbers may not add due to rounding.

- i. Exclude amortization of intangibles primarily associated with costs of marketed products acquired or licensed from third parties.
- ii. Exclude inventory step-up costs associated with the acquisition of Novartis Animal Health.
- iii. Exclude costs associated with restructuring to reduce the company's cost structure, asset impairments, and integration costs associated with the acquisition of Novartis Animal Health.

Eli Lilly and Company

Reconciliation of GAAP Reported to Selected Non-GAAP Adjusted Information (Unaudited)(a)

(Dollars in millions, except per share data)

| | Nine Months Ended September 30, 2016 | | | Nine Months Ended September 30, 2015 | | |
|--|---|----------------|----------------------|---|----------------|----------------------|
| | GAAP Reported | Adjustments(c) | Non-GAAP Adjusted | GAAP Reported | Adjustments(d) | Non-GAAP Adjusted |
| Total revenue | \$ 15,461.6 | \$ — | \$ 15,461.6 | \$ 14,583.1 | \$ — | \$ 14,583.1 |
| Cost of sales | 4,188.9 | (513.0) | 3,675.9 | 3,648.0 | (502.8) | 3,145.2 |
| Operating expenses(b) | 8,455.2 | (5.8) | 8,449.4 | 8,086.8 | (107.4) | 7,979.4 |
| Acquired in-process research and development | — | — | — | 336.0 | (336.0) | — |
| Asset impairment, restructuring and other special charges | 234.9 | (234.9) | — | 222.8 | (222.8) | — |
| Other income (expense) | (100.6) | 203.9 | 103.3 | 55.9 | 152.7 | 208.6 |
| Income taxes | 516.2 | 201.2 | 717.4 | 415.4 | 423.5 | 839.0 |
| Net income | \$ 1,965.8 | 756.5 | \$ 2,722.2 | \$ 1,930.0 | 898.1 | \$ 2,828.1 |
| Earnings per share – diluted | \$ 1.85 | 0.71 | \$ 2.57 | \$ 1.81 | 0.84 | \$ 2.65 |

Numbers may not add due to rounding.

(a) The company uses non-GAAP financial measures that differ from financial statements reported in conformity with U.S. generally accepted accounting principles (GAAP). The company's non-GAAP measures adjust reported results to exclude amortization of intangibles and items that are typically highly variable, difficult to predict, and/or of a size that could have a substantial impact on the company's reported operations for a period. The company believes that these non-GAAP measures provide useful information to investors. Among other things, they may help investors evaluate the company's 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.

- (b) Operating expenses include research and development and marketing, selling and administrative expenses.
- (c) Adjustments to certain GAAP reported measures for the nine months ended September 30, 2016, include the following:

| (Dollars in millions, except per share data) | Amortization ⁽ⁱ⁾ | Venezuela ⁽ⁱⁱ⁾ | Other specified items ⁽ⁱⁱⁱ⁾ | Total Adjustments |
|---|-----------------------------|---------------------------|--|--------------------------|
| Revenue | \$ — | \$ — | \$ — | \$ — |
| Cost of sales | (513.0) | — | — | (513.0) |
| Operating expenses | (5.8) | — | — | (5.8) |
| Acquired in-process research and development | — | — | — | — |
| Asset impairment, restructuring and other special charges | — | — | (234.9) | (234.9) |
| Other income (expense) | — | 203.9 | — | 203.9 |
| Income taxes | 163.2 | — | 38.0 | 201.2 |
| Net income | \$ 355.6 | \$ 203.9 | \$ 196.9 | \$ 756.5 |
| Earnings per share – diluted | \$ 0.34 | \$ 0.19 | \$ 0.19 | \$ 0.71 |

Numbers may not add due to rounding.

- i. Exclude amortization of intangibles primarily associated with costs of marketed products acquired or licensed from third parties.
- ii. Exclude charge related to the impact of the Venezuelan financial crisis, including the significant deterioration of the bolívar.
- iii. Exclude charges associated with asset impairments related to the closure of an animal health manufacturing facility in Ireland and integration and severance costs for Novartis Animal Health.

(d) Adjustments to certain GAAP reported measures for the nine months ended September 30, 2015, include the following:

| (Dollars in millions, except per share data) | Amortization ⁽ⁱ⁾ | | IPR&D ⁽ⁱⁱ⁾ | | Inventory step-up ⁽ⁱⁱⁱ⁾ | | Repurchase of debt ^(iv) | | Other specified items ^(v) | | Total Adjustments | |
|---|-----------------------------|---------|-----------------------|---------|------------------------------------|---------|------------------------------------|-------|--------------------------------------|---------|-------------------|---------|
| Revenue | \$ | — | \$ | — | \$ | — | \$ | — | \$ | — | \$ | — |
| Cost of sales | | (349.8) | | — | | (153.0) | | — | | — | | (502.8) |
| Operating expenses | | (107.4) | | — | | — | | — | | — | | (107.4) |
| Acquired in-process research and development | | — | | (336.0) | | — | | — | | — | | (336.0) |
| Asset impairment, restructuring and other special charges | | — | | — | | — | | — | | (222.8) | | (222.8) |
| Other income (expense) | | — | | — | | — | | 152.7 | | — | | 152.7 |
| Income taxes | | 150.8 | | 117.6 | | 43.6 | | 53.5 | | 58.0 | | 423.5 |
| Net income | \$ | 306.3 | \$ | 218.4 | \$ | 109.4 | \$ | 99.3 | \$ | 164.7 | \$ | 898.1 |
| Earnings per share – diluted | \$ | 0.29 | \$ | 0.20 | \$ | 0.10 | \$ | 0.09 | \$ | 0.15 | \$ | 0.84 |

Numbers may not add due to rounding.

- i. Exclude amortization of intangibles primarily associated with costs of marketed products acquired or licensed from third parties.
- ii. Exclude costs associated with upfront payments for acquired in-process research and development projects acquired in a transaction other than a business combination. These costs included a \$200.0 million payment to Pfizer following the FDA decision allowing the resumption of the Phase 3 clinical program for tanezumab, a \$56.0 million charge associated with a collaboration with Innovent to develop potential oncology therapies, a \$50.0 million payment to Hanmi related to an exclusive license and collaboration agreement for Hanmi's oral Bruton's tyrosine kinase inhibitor for the treatment of autoimmune and other diseases, and a \$30.0 million payment to BioNTech AG related to a research collaboration to discover novel cancer immunotherapies.
- iii. Exclude inventory step-up costs associated with the acquisition of Novartis Animal Health.
- iv. Exclude a net charge associated with the repurchase of \$1.65 billion of debt.
- v. Exclude costs associated with restructuring to reduce the company's cost structure, asset impairments, and integration costs associated with the acquisition of Novartis Animal Health.