

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): **July 26, 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 July 26, 2016, announcing our results of operations for the second quarter and six-month period ended June 30, 2016, including, among other things, unaudited financial statements for those periods, and providing updated financial expectations through the remainder of the decade.

Item 9.01. Financial Statements and Exhibits

<u>Exhibit Number</u>	<u>Description</u>
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99.1	Press release dated July 26, 2016 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: July 26, 2016

EXHIBIT INDEX

Exhibit Number

99.1

Exhibit

Press release dated July 26, 2016, together with related attachments.



July 26, 2016

Eli Lilly and Company

Lilly Corporate Center
Indianapolis, Indiana 46285
U.S.A.
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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 Second-Quarter 2016 Results, Provides Financial Expectations Through the Remainder of the Decade

- Revenue increased 9 percent, driven by 10 percent pharmaceutical volume growth coming primarily from recent product launches.
- Second-quarter 2016 earnings per share (EPS) were \$0.71 (reported), or \$0.86 (non-GAAP).
- The company confirms 2016 EPS to be in the range of \$2.68 to \$2.78 (reported) and \$3.50 to \$3.60 (non-GAAP).
- The company provides updated financial expectations through the remainder of the decade, including at least 5 percent average annual revenue growth driven by volume, along with an increase in gross margin as a percent of revenue, both on a constant currency basis. The company also plans to return to annual dividend increases for shareholders and reaffirmed its commitment to achieve an OPEX-to-revenue ratio of 50 percent or less in 2018.
- Significant pipeline progress continued with regulatory approval of Taltz in Japan, priority review granted for olaratumab in the U.S., a positive FDA Advisory Committee vote on Jardiance and an encouraging Phase 2 data read-out for abemaciclib.

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

\$ in millions, except per share data	Second Quarter		%
	2016	2015	Change
Revenue – Reported	\$ 5,404.8	\$ 4,978.7	9 %
Net Income – Reported	747.7	600.8	24 %
EPS – Reported	0.71	0.56	27 %
Net Income – non-GAAP	908.8	954.8	(5)%
EPS – non-GAAP	0.86	0.90	(4)%

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 is in the midst of one of the most productive periods of new product launches in our company's history, with new medicines making a substantial contribution to our revenue growth for the first half of the year," said John C. Lechleiter, Ph.D., Lilly's chairman, president and chief executive officer.

Lechleiter continued, "We've made great progress building an R&D engine that has the potential to launch 20 new products in 10 years beginning in 2014 and extending through 2023. Because of our confidence in our future growth prospects, we are providing updated financial expectations through the balance of the decade, including at least 5 percent average annual revenue growth driven by volume and an increase in gross margin as a percent of revenue. We are also returning to annual dividend increases for shareholders and reaffirming our commitment to achieve an OPEX-to-revenue ratio of 50 percent or less in 2018."

Key Events Over the Last Three Months

Commercial

- The company is launching Taltz[®] in Europe for the treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy.
- Elanco Animal Health launched Intepriety[™], a first-in-class, animal-use only, in-feed antibiotic

approved for the prevention of necrotic enteritis, an intestinal disease in poultry.

Regulatory

- The U.S. Food and Drug Administration (FDA) approved once-daily Jentadueto[®] XR (linagliptin and metformin hydrochloride extended-release) tablets as an adjunct to diet and exercise for the treatment of type 2 diabetes in adults. Jentadueto XR is part of the company's alliance with Boehringer Ingelheim.
- The company received approval of Cyramza[®] in Japan for the treatment of:
 - unresectable, advanced or recurrent colorectal cancer; and
 - unresectable, advanced or recurrent non-small cell lung cancer for patients who have received prior platinum therapy.
- The company received approval of Taltz in Japan for the treatment of patients with plaque psoriasis, psoriatic arthritis, pustular psoriasis and erythrodermic psoriasis after insufficient response to existing treatments.
- The FDA granted Priority Review for olaratumab in combination with doxorubicin, for the potential treatment of people with advanced soft tissue sarcoma not amenable to curative treatment with radiotherapy or surgery.
- An FDA Advisory Committee voted 12-11 that substantial evidence exists to establish that Jardiance[®] (empagliflozin) reduces cardiovascular (CV) death in adults with type 2 diabetes and established CV disease. Jardiance is marketed by Boehringer Ingelheim and Lilly.
- The FDA determined that the company met the requirements for pediatric exclusivity for Effient[®]. Based on this decision by the FDA, Lilly has gained an additional six months of U.S. market exclusivity for Effient.

Clinical

- The company announced results from the Phase 2 study of abemaciclib, a cyclin-dependent kinase CDK 4 and CDK 6 inhibitor, in patients with hormone-receptor-positive, human epidermal growth factor receptor 2-negative metastatic breast cancer. The data showed single-agent activity in metastatic breast cancer patients for whom endocrine therapy was no longer a suitable treatment option.

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- The company and Incyte Corporation announced data from a pivotal long-term extension study, which demonstrated baricitinib was superior to placebo at inhibiting progressive radiographic joint damage in patients with rheumatoid arthritis.
 - The company and Boehringer Ingelheim announced clinical results on two jointly marketed medicines:
 - Results from a clinical trial demonstrated that Trajenta[®] (linagliptin) reduced blood sugar in adults with type 2 diabetes who are at risk for kidney impairment, with a renal safety profile similar to that seen in other trials.
 - New data showed Jardiance reduced the risk for new-onset or worsening kidney disease by 39 percent versus placebo when added to standard of care in adults with type 2 diabetes with established cardiovascular disease.

Business Development/Other

- The German Federal Supreme Court granted the appeal by the company in the case of *Lilly v. Actavis*, vacating the prior decision denying infringement. The German Supreme Court returned the case to the Court of Appeal (Dusseldorf) to reconsider infringement based on its judgment. The case concerns whether Lilly's vitamin regimen patent for Alimta[®] (pemetrexed disodium) would be infringed by a generic competitor that had stated an intention to market a dipotassium salt form of pemetrexed in Germany.
- Elanco Animal Health and EnBiotix, Inc. announced a collaboration to explore the application of EnBiotix's engineered phage technology in specific animal health targets, which could result in alternatives for traditional antibiotics in animals.

Second-Quarter Reported Results

In the second quarter of 2016, worldwide revenue was \$5.405 billion, an increase of 9 percent compared with the second quarter of 2015. The increase in revenue was driven by an 8 percent increase in volume, as realized prices and the impact of foreign exchange rates remained relatively flat, compared with the second quarter of 2015. The increase in worldwide volume was driven by new pharmaceutical products, including Trulicity[®] and Cyramza, as well as Humalog[®]. Revenue in the U.S.

increased 14 percent to \$2.890 billion, primarily driven by increased volume for several pharmaceutical products, including Trulicity and Humalog, and to a lesser extent, higher realized prices, primarily for Cialis[®] and Forteo[®], partially offset by lower realized prices for Humalog. Revenue outside the U.S. increased 3 percent to \$2.515 billion, driven by increased volume for several pharmaceutical products, primarily Cyramza, Trulicity and Humalog, partially offset by the loss of exclusivity for Cymbalta[®] in Europe in 2014.

Gross margin increased 5 percent to \$3.940 billion in the second quarter of 2016 compared with the second quarter of 2015. Gross margin as a percent of revenue was 72.9 percent, a decrease of 2.6 percentage points compared with the second 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, partially offset by 2015 inventory step-up costs related to the acquisition of Novartis Animal Health.

Operating expenses in the second quarter of 2016, defined as the sum of research and development and marketing, selling and administrative expenses, were \$2.959 billion, an increase of 5 percent compared with the second quarter of 2015. Research and development expenses increased 14 percent to \$1.336 billion, driven primarily by higher late-stage clinical development costs, including a \$100.0 million charge related to a development milestone for AZD3293, an oral beta secretase cleaving enzyme (BACE) inhibitor currently in development with AstraZeneca as a potential treatment for early Alzheimer's disease. Marketing, selling and administrative expenses decreased 1 percent to \$1.623 billion, primarily due to lower litigation expenses and reduced spending on late-life-cycle products, partially offset by expenses related to new products.

There were no acquired in-process research and development charges in the second quarter of 2016. In the second quarter of 2015, the company recognized acquired in-process research and development charges totaling \$80.0 million. These charges included a \$50.0 million payment to Hanmi Pharmaceutical Co., Ltd. (Hanmi), related to an exclusive license and collaboration agreement for

Hanmi's oral Bruton's tyrosine kinase (BTK) 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.

The company recognized asset impairment, restructuring and other special charges of \$58.0 million and \$72.4 million in the second quarters of 2016 and 2015, respectively, related to integration costs for Novartis Animal Health, severance costs and asset impairments.

Operating income in the second quarter of 2016 was \$923.3 million, an increase of 15 percent compared with the second quarter of 2015, driven by higher gross margin and lower acquired in-process research and development charges, partially offset by higher operating expenses.

Other income (expense) was income of \$21.2 million in the second quarter of 2016, compared with expense of \$123.3 million in the second quarter of 2015. Other expense during the second quarter of 2015 was driven by a net charge of \$152.7 million related to the repurchase of \$1.65 billion of debt.

The effective tax rate was 20.8 percent in the second quarter of 2016, compared with 11.6 percent in the second quarter of 2015. The increase in the effective tax rate for the second quarter of 2016 as compared with the second quarter of 2015 is primarily due to the tax impact of 2015 charges, including a net charge related to the repurchase of debt; asset impairment, restructuring and other special charges; and acquired in-process research and development charges.

In the second quarter of 2016, net income increased 24 percent to \$747.7 million, and earnings per share increased 27 percent to \$0.71, compared with \$600.8 million and \$0.56, respectively, in the second quarter of 2015. The increases in net income and earnings per share were driven by 2015 charges related to the repurchase of debt, as well as higher operating income, partially offset by higher income taxes. Earnings per share also benefited from a lower number of shares outstanding in the second quarter of 2016 compared with the second quarter of 2015.

Second-Quarter 2016 Non-GAAP Measures

On a non-GAAP basis, second-quarter 2016 gross margin increased 4 percent to \$4.106 billion. Gross margin as a percent of revenue was 76.0 percent, a decline of 3.2 percentage points compared with the second 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 \$25.8 million, or 2 percent, to \$1.150 billion in the second quarter of 2016, driven by higher operating expenses, largely offset by higher gross margin.

Other income (expense) was income of \$21.2 million in the second quarter of 2016, compared with income of \$29.4 million in the second quarter of 2015.

The effective tax rate was 22.4 percent in the second quarter of 2016, compared with 20.8 percent in the second quarter of 2015. The second-quarter 2016 effective tax rate reflects the benefit of certain U.S. tax provisions, including the R&D tax credit, reinstated for 2016, largely offset by the tax impact of an increased percentage of earnings in higher-tax jurisdictions. The second-quarter 2015 effective tax rate includes a net discrete tax benefit of approximately \$24 million and does not include the benefit of certain then-expired U.S. tax provisions, including the R&D tax credit.

Net income decreased 5 percent to \$908.8 million, and earnings per share decreased 4 percent to \$0.86 in the second quarter of 2016, compared with \$954.8 million and \$0.90, respectively, in the second quarter of 2015. The declines in net income and earnings per share were driven by lower operating income and a higher effective tax rate. Earnings per share benefited from a lower number of shares outstanding in the second quarter of 2016 compared with the second quarter of 2015.

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>Second Quarter</u>		<u>% Change</u>
	<u>2016</u>	<u>2015</u>	
Earnings per share (reported)	\$ 0.71	\$ 0.56	27%
Amortization of intangible assets	.11	.10	
Asset impairment, restructuring and other special charges	.04	.05	
Acquired in-process research and development	—	.05	
Net charge related to repurchase of debt	—	.09	
Novartis Animal Health inventory step-up	—	.05	
Earnings per share (non-GAAP)	<u>\$ 0.86</u>	<u>\$ 0.90</u>	(4)%

Numbers may not add due to rounding.

Year-to-Date Results

For the first six months of 2016, worldwide revenue increased 7 percent to \$10.270 billion compared with \$9.623 billion in the same period in 2015. Reported net income and earnings per share were \$1.188 billion and \$1.12, respectively. Net income and earnings per share, on a non-GAAP basis, were \$1.791 billion and \$1.69, 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)	\$ 1.12	\$ 1.06	6%
Amortization of intangible assets	.22	.20	
Asset impairment, restructuring and other special charges	.16	.12	
Acquired in-process research and development	—	.20	
Venezuela charge	.19	—	
Net charge related to repurchase of debt	—	.09	
Novartis Animal Health inventory step-up	—	.09	
Earnings per share (non-GAAP)	<u><u>\$ 1.69</u></u>	<u><u>\$ 1.76</u></u>	(4)%

Numbers may not add due to rounding.

Select Revenue Highlights

<i>(Dollars in millions)</i>	Second Quarter			Year-to-Date		
	2016	2015	% Change	2016	2015	% Change
Established Pharmaceutical Products						
Humalog	\$ 701.9	\$ 654.3	7%	\$ 1,308.2	\$ 1,338.2	(2)%
Cialis	630.5	567.9	11%	1,207.2	1,106.2	9%
Alimta	607.1	664.3	(9)%	1,171.3	1,237.4	(5)%
Humulin®	332.3	316.4	5%	688.7	632.1	9%
Forteo	367.6	328.4	12%	686.3	621.4	10%
Cymbalta	236.5	274.1	(14)%	435.2	561.1	(22)%
Zyprexa®	210.7	253.7	(17)%	423.4	473.2	(11)%
Strattera®	224.6	191.8	17%	412.7	365.5	13%
Erbitux	180.6	134.6	34%	348.6	222.8	56%
Effient	135.1	128.8	5%	266.6	250.6	6%
New Pharmaceutical Products						
Trulicity	201.3	44.3	NM	344.9	62.6	NM
Cyramza	147.0	87.7	68%	278.0	155.2	79%
Jardiance ^(a)	40.1	11.1	NM	78.3	30.3	NM
Basaglar®	16.3	—	NM	27.2	—	NM
Taltz	19.3	—	NM	19.3	—	NM
Portrazza®	4.0	—	NM	5.7	—	NM
Animal Health	859.8	840.8	2%	1,614.4	1,590.5	1%
Total Revenue	5,404.8	4,978.7	9%	10,269.9	9,623.4	7%

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

Certain Established Pharmaceutical Products

Humalog

For the second quarter of 2016, worldwide Humalog revenues increased 7 percent compared with the second quarter of 2015 to \$701.9 million. Revenues in the U.S. increased 5 percent to \$420.0 million, driven by increased demand, partially offset by lower realized prices. Revenues outside the U.S. increased 11 percent to \$281.9 million, primarily driven by increased volume, partially offset by the unfavorable impact of foreign exchange rates.

Cialis

Cialis revenues for the second quarter of 2016 increased 11 percent compared with the second quarter of 2015 to \$630.5 million. U.S. revenues of Cialis were \$383.2 million, a 24 percent increase compared with the second quarter of 2015, driven primarily by higher realized prices and, to a lesser extent, increased volume. Revenues of Cialis outside the U.S. decreased 4 percent to \$247.3 million, driven by the unfavorable impact of foreign exchange rates and decreased volume.

Alimta

For the second quarter of 2016, Alimta generated revenues of \$607.1 million, a decline of 9 percent compared with the second quarter of 2015. U.S. revenues of Alimta decreased 12 percent to \$291.0 million, driven primarily by decreased demand due to competitive pressure. Revenues outside the U.S. decreased 5 percent to \$316.1 million, driven by decreased volume and lower realized prices, partially offset by the favorable impact of foreign exchange rates.

Humulin

Worldwide Humulin revenues for the second quarter of 2016 increased 5 percent compared with the second quarter of 2015 to \$332.3 million. U.S. revenues increased 9 percent to \$204.3 million, driven by increased volume. Revenues outside the U.S. remained relatively flat at \$128.0 million.

Forteo

Second-quarter 2016 revenues of Forteo were \$367.6 million, a 12 percent increase compared with the second quarter of 2015. U.S. revenues of Forteo increased 29 percent to \$186.4 million, driven by higher realized prices. Revenues outside the U.S. decreased 1 percent to \$181.2 million, driven by lower realized prices, largely offset by increased volume and the favorable impact of foreign exchange rates.

New Pharmaceutical Products

Trulicity

Second-quarter 2016 revenues of Trulicity were \$201.3 million. U.S. revenues of Trulicity were \$161.4 million, driven by growth in the GLP-1 market and increased share of market for Trulicity. Revenues of Trulicity outside the U.S. were \$39.9 million.

Cyramza

For the second quarter of 2016, Cyramza revenues were \$147.0 million. U.S. revenues were \$67.9 million, a decrease of 4 percent compared with the second quarter of 2015, due to competitive pressure in the non-small cell lung cancer indication. Revenues outside the U.S. were \$79.1 million, primarily due to strong uptake for the gastric cancer indication in Japan.

Jardiance

The company's revenues for Jardiance during the second quarter of 2016 were \$40.1 million. U.S. revenues were \$26.0 million, driven by growth in the SGLT2 class and increased share of market for Jardiance. Revenues outside the U.S. were \$14.1 million. Jardiance is part of the company's alliance with Boehringer Ingelheim, and Lilly reports as revenue a portion of Jardiance's gross margin.

Basaglar

Second-quarter 2016 revenues of Basaglar, which has launched in multiple countries outside the U.S., were \$16.3 million, driven by early uptake in Japan and various European countries.

Taltz

For the second quarter of 2016, Taltz revenues were \$19.3 million. Taltz launched in the U.S. in April 2016.

Portrazza

For the second quarter of 2016, Portrazza revenues were \$4.0 million. Portrazza launched in the U.S. in December 2015 and began launching in Europe in April 2016.

Animal Health

In the second quarter of 2016, worldwide animal health revenues totaled \$859.8 million, an increase of 2 percent compared with the second quarter of 2015. U.S. animal health revenues increased 8 percent to \$444.5 million, due to wholesaler buying patterns and uptake of new companion animal products, partially offset by decreased revenues for food animal products. Animal health revenues outside the U.S. decreased 3 percent to \$415.3 million, primarily due to the unfavorable impact of foreign exchange rates. Excluding the unfavorable impact of foreign exchange rates, worldwide animal health revenues increased 4 percent.

2016 Financial Guidance

The company confirmed its 2016 financial guidance on a reported basis and on a non-GAAP basis, consistent with the explanations provided in the company's first-quarter 2016 earnings press release.

Full-year 2016 earnings per share are still expected to be in the range of \$2.68 to \$2.78 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)	\$2.68 to \$2.78
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	.21
Venezuela charge	.19
Earnings per share (non-GAAP)	\$3.50 to \$3.60

Numbers may not add due to rounding.

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

	<u>2016 Guidance</u>
Revenue	\$20.6 to \$21.1 billion
Gross Margin % of Revenue (reported)	Approx. 73%
Gross Margin % of Revenue (non-GAAP)	Approx. 76%
Marketing, Selling & Administrative	\$6.1 to \$6.3 billion
Research & Development	\$4.9 to \$5.1 billion
Other Income/(Expense) (reported)	\$(200 million) to \$(125 million)
Other Income/(Expense) (non-GAAP)	\$0 to \$75 million
Tax Rate	Approx. 21.0%
Earnings per share (reported)	\$2.68 to \$2.78
Earnings per share (non-GAAP)	\$3.50 to \$3.60
Capital Expenditures	Approx. \$1.1 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 second-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 Daylight Time (EDT) on Tuesday, July 26, 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 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)
Cyramza® (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)
Integrity™ (avilamycin, Lilly)

Jardiance® (empagliflozin, Boehringer Ingelheim)
Jentadueto® XR (linagliptin/metformin, Boehringer Ingelheim)
Portrazza® (necitumumab, Lilly)
Synjardy® (empagliflozin/metformin, Boehringer Ingelheim)
Taltz® (ixekizumab, Lilly)
Trajenta® (linagliptin, Boehringer Ingelheim)
Trulicity® (dulaglutide, Lilly)

Eli Lilly and Company Employment Information

	<u>June 30, 2016</u>	<u>December 31, 2015</u>
Worldwide Employees	41,900	41,275

Eli Lilly and Company

Operating Results (Unaudited) – REPORTED

(Dollars in millions, except per share data)

	Three Months Ended			Six Months Ended		
	June 30,			June 30,		
	2016	2015	% Chg.	2016	2015	% Chg.
Revenue	\$ 5,404.8	\$ 4,978.7	9%	\$ 10,269.9	\$ 9,623.4	7%
Cost of sales	1,465.0	1,218.4	20%	2,788.0	2,411.1	16%
Research and development	1,335.9	1,169.5	14%	2,556.9	2,208.8	16%
Marketing, selling and administrative	1,622.6	1,635.4	(1)%	3,096.5	3,158.9	(2)%
Acquired in-process research and development	—	80.0	(100)%	—	336.0	(100)%
Asset impairment, restructuring and other special charges	58.0	72.4	(20)%	189.4	180.4	5%
Operating income	923.3	803.0	15%	1,639.1	1,328.2	23%
Net interest income (expense)	(19.7)	(16.2)		(38.9)	(35.7)	
Net other income (expense)	40.9	(107.1)		(88.9)	5.1	
Other income (expense)	21.2	(123.3)	NM	(127.8)	(30.6)	NM
Income before income taxes	944.5	679.7	39%	1,511.3	1,297.6	16%
Income taxes	196.8	78.9	NM	323.5	167.3	93%
Net income	\$ 747.7	\$ 600.8	24%	\$ 1,187.8	\$ 1,130.3	5%
Earnings per share – diluted	\$ 0.71	\$ 0.56	27%	\$ 1.12	\$ 1.06	6%
Dividends paid per share	\$ 0.51	\$ 0.50	2%	\$ 1.02	\$ 1.00	2%
Weighted-average shares outstanding (thousands) – diluted	1,060,083	1,065,584		1,061,023	1,066,335	

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 June 30, 2016			Three Months Ended June 30, 2015		
	GAAP Reported	Adjustments(c)	Non-GAAP Adjusted	GAAP Reported	Adjustments(d)	Non-GAAP Adjusted
Revenue	\$ 5,404.8	\$ —	\$ 5,404.8	\$ 4,978.7	\$ —	\$ 4,978.7
Cost of sales	1,465.0	(166.6)	1,298.4	1,218.4	(184.5)	1,033.9
Operating expenses(b)	2,958.5	(2.0)	2,956.5	2,804.9	(35.8)	2,769.1
Acquired in-process research and development	—	—	—	80.0	(80.0)	—
Asset impairment, restructuring and other special charges	58.0	(58.0)	—	72.4	(72.4)	—
Other income (expense)	21.2	—	21.2	(123.3)	152.7	29.4
Income taxes	196.8	65.6	262.3	78.9	171.3	250.3
Net income	\$ 747.7	\$ 161.1	\$ 908.8	\$ 600.8	\$ 354.1	\$ 954.8
Earnings per share – diluted	\$ 0.71	\$ 0.15	\$ 0.86	\$ 0.56	\$ 0.33	\$ 0.90

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 June 30, 2016, include the following:

(Dollars in millions, except per share data)	Amortization ⁽ⁱ⁾	Other specified items ⁽ⁱⁱ⁾	Total Adjustments
Revenue	\$ —	\$ —	\$ —
Cost of sales	(166.6)	—	(166.6)
Operating expenses	(2.0)	—	(2.0)
Acquired in-process research and development	—	—	—
Asset impairment, restructuring and other special charges	—	(58.0)	(58.0)
Other income (expense)	—	—	—
Income taxes	52.7	12.8	65.6
Net income	\$ 115.8	\$ 45.2	\$ 161.1
Earnings per share – diluted	\$ 0.11	\$ 0.04	\$ 0.15

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 primarily associated with integration and severance costs for Novartis Animal Health.

(d) Adjustments to certain GAAP reported measures for the three months ended June 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	(116.1)	—	(68.4)	—	—	(184.5)
Operating expenses	(35.8)	—	—	—	—	(35.8)
Acquired in-process research and development	—	(80.0)	—	—	—	(80.0)
Asset impairment, restructuring and other special charges	—	—	—	—	(72.4)	(72.4)
Other income (expense)	—	—	—	152.7	—	152.7
Income taxes	49.5	28.0	19.5	53.5	20.8	171.3
Net income	\$ 102.4	\$ 52.0	\$ 48.9	\$ 99.3	\$ 51.6	354.1
Earnings per share – diluted	\$ 0.10	\$ 0.05	\$ 0.05	\$ 0.09	\$ 0.05	0.33

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 \$50.0 million payment to Hanmi related to an exclusive license and collaboration agreement for Hanmi's oral BTK 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.

Eli Lilly and Company

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

(Dollars in millions, except per share data)

	Six Months Ended June 30, 2016			Six Months Ended June 30, 2015		
	GAAP Reported	Adjustments(c)	Non-GAAP Adjusted	GAAP Reported	Adjustments(d)	Non-GAAP Adjusted
Total revenue	\$ 10,269.9	\$ —	\$ 10,269.9	\$ 9,623.4	\$ —	\$ 9,623.4
Cost of sales	2,788.0	(337.2)	2,450.8	2,411.1	(364.9)	2,046.2
Operating expenses(b)	5,653.4	(3.9)	5,649.5	5,367.7	(71.6)	5,296.1
Acquired in-process research and development	—	—	—	336.0	(336.0)	—
Asset impairment, restructuring and other special charges	189.4	(189.4)	—	180.4	(180.4)	—
Other income (expense)	(127.8)	203.9	76.1	(30.6)	152.7	122.1
Income taxes	323.5	131.1	454.6	167.3	357.4	524.7
Net income	\$ 1,187.8	603.3	\$ 1,791.1	\$ 1,130.3	748.3	\$ 1,878.5
Earnings per share – diluted	\$ 1.12	0.57	\$ 1.69	\$ 1.06	0.70	\$ 1.76

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 six months ended June 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	(337.2)	—	—	(337.2)
Operating expenses	(3.9)	—	—	(3.9)
Acquired in-process research and development	—	—	—	—
Asset impairment, restructuring and other special charges	—	—	(189.4)	(189.4)
Other income (expense)	—	203.9	—	203.9
Income taxes	106.8	—	24.3	131.1
Net income	\$ 234.3	\$ 203.9	\$ 165.1	\$ 603.3
Earnings per share – diluted	\$ 0.22	\$ 0.19	\$ 0.16	\$ 0.57

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 six months ended June 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		(233.0)		—		(131.9)		—		—		(364.9)
Operating expenses		(71.6)		—		—		—		—		(71.6)
Acquired in-process research and development		—		(336.0)		—		—		—		(336.0)
Asset impairment, restructuring and other special charges		—		—		—		—		(180.4)		(180.4)
Other income (expense)		—		—		—		152.7		—		152.7
Income taxes		99.9		117.6		37.6		53.5		48.8		357.4
Net income	\$	204.7	\$	218.4	\$	94.3	\$	99.3	\$	131.6	\$	748.3
Earnings per share – diluted	\$	0.20	\$	0.20	\$	0.09	\$	0.09	\$	0.12	\$	0.70

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 III 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 BTK 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.