

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 22, 2015**

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

On October 22, 2015 we issued a press release announcing our results of operations for the third quarter and nine month period ended September 30, 2015, 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 99.1.

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”). Our non-GAAP financial measures adjust our reported results to exclude the impact of significant acquisitions and divestitures, including amortization of intangible assets primarily associated with costs of marketed products acquired or licensed from third parties. We also exclude other items that are typically highly variable, difficult to predict, and of a size that could have a substantial impact on our reported operations for a period. We believe that these non-GAAP measures provide useful information to investors. Among other things, they may help investors evaluate our ongoing operations. They can assist in making meaningful period-over-period comparisons and in identifying operating trends that would otherwise be masked or distorted by the items subject to the adjustments. Management uses these non-GAAP measures internally to evaluate the performance of the business, including to allocate resources and to evaluate results relative to incentive compensation targets.

Investors should consider these non-GAAP measures in addition to, not as a substitute for or superior to, measures of financial performance prepared in accordance with GAAP. For the reasons described above for use of non-GAAP measures, our prospective earnings guidance is subject to adjustment for certain future matters, similar to those identified above, as to which prospective quantification generally is not feasible.

The information in this Item 2.02 and the press release attached as Exhibit 99.1 are considered furnished to the Commission and are not deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

Item 9.01. Financial Statements and Exhibits

<u>Exhibit Number</u>	<u>Description</u>
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99.1	Press release dated October 22, 2015 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: October 22, 2015

EXHIBIT INDEX

Exhibit Number

99.1

Exhibit

Press release dated October 22, 2015, together with related attachments.



October 22, 2015

Eli Lilly and Company

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For Release: Immediately

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Lilly Reports Third-Quarter 2015 Results, Revises 2015 Financial Guidance

- Revenue increased 2 percent with the inclusion of Novartis Animal Health and higher volume for several products, including Cyramza and Trulicity; these contributions were partially offset by the unfavorable effect of foreign exchange rates and the residual impact of the Cymbalta patent expiration.
- Third-quarter 2015 earnings per share were \$0.75 (reported), or \$0.89 (non-GAAP).
- Significant pipeline progress has continued with positive Jardiance cardiovascular outcomes data, two positive topline results for baricitinib and Breakthrough Therapy Designation for abemaciclib, as well as the acquisition of a promising Phase III intranasal glucagon and multiple oncology collaborations.
- 2015 EPS guidance has been revised to be in the range of \$2.40 to \$2.45 on a reported basis and \$3.40 to \$3.45 on a non-GAAP basis, reflecting solid underlying performance and net investment gains in the third quarter.

Eli Lilly and Company (NYSE: LLY) today announced financial results for the third quarter of 2015.

\$ in millions, except per share data	Third Quarter		% Change
	2015	2014	
Revenue – Reported	\$ 4,959.7	\$ 4,875.6	2 %
Net Income – Reported	799.7	500.6	60 %
EPS – Reported	0.75	0.47	60 %
Revenue – non-GAAP	4,959.7	5,151.0	(4)%
Net Income – non-GAAP	949.6	781.2	22 %
EPS – non-GAAP	0.89	0.73	22 %

Certain financial information for 2015 and 2014 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 period. Non-GAAP measures exclude the items described in the reconciliation tables later in the release. Non-GAAP measures in 2014 include the results of Novartis Animal Health as if the acquisition and the financing for the acquisition had occurred as of January 1, 2014. Non-GAAP financial measures for all periods presented also exclude amortization of intangibles primarily associated with costs of marketed products acquired or licensed from third parties. The company's 2015 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.

"We are pleased with our strong third-quarter results, which reflect the ongoing actions we are taking to grow revenue and increase productivity while we are replenishing and advancing our pipeline with an array of new, innovative therapies," said John C. Lechleiter, Ph.D., Lilly's chairman, president and chief executive officer. "Despite headwinds from foreign exchange rates, we are benefiting from recent launches as well as our acquisition of Novartis Animal Health earlier this year."

"This quarter, we had higher sales volume for several key products, including recently launched Cyramza and Trulicity. We also launched several new products in various global markets, including Synjardy in the U.S. for type 2 diabetes. Promising pipeline momentum continued with encouraging news for baricitinib and abemaciclib, while Jardiance reported positive cardiovascular outcomes. Finally, we continued to create new collaborations and pursue smaller-scale acquisitions to bolster our pipeline and our product portfolio."

Looking forward, Lechleiter noted that Lilly could have a regulatory submission and/or decision for multiple potential new medicines in the next 18 months -- reinforcing the company's confidence in its innovation-based strategy and in its ability to grow revenue and expand margins over the balance of this decade.

Key Events Over the Last Three Months

Commercial

- The company launched Basaglar[®], a basal insulin product, in Japan, the UK, Germany and other European markets. Basaglar is part of the Boehringer Ingelheim and Eli Lilly and Company Diabetes Alliance.
- The company launched Trulicity[®] in Japan as a treatment for type 2 diabetes.

Regulatory

- The U.S. Food and Drug Administration (FDA) approved Synjardy[®] (empagliflozin and metformin hydrochloride) tablets and the product was launched in the U.S. for the treatment of adults with type 2 diabetes. Synjardy is part of the Boehringer Ingelheim and Eli Lilly and Company Diabetes Alliance.
- The FDA granted Breakthrough Therapy Designation to abemaciclib for patients with refractory hormone-receptor-positive advanced or metastatic breast cancer. Breakthrough Therapy Designation is designed to expedite the development and review of potential medicines that are intended to treat a serious condition, and preliminary clinical evidence indicates that the treatment may demonstrate substantial improvement over available therapy on a clinically significant endpoint.

Clinical

- The company and Boehringer Ingelheim announced positive results from a long-term clinical trial investigating cardiovascular (CV) outcomes for Jardiance[®] in adults with type 2 diabetes at high risk for CV events. Jardiance is the only diabetes medicine to have demonstrated a significant reduction in both cardiovascular risk and cardiovascular death in a dedicated outcomes trial.
- The company will terminate the Phase III trials of evacetrapib for the treatment of high-risk atherosclerotic cardiovascular disease due to insufficient efficacy.
- The company and Incyte Corporation announced positive top-line results for baricitinib, an investigational medicine for patients with moderately-to-severely active rheumatoid arthritis.
 - The third Phase III study evaluating safety and efficacy of baricitinib met its primary

objective of demonstrating non-inferiority of baricitinib monotherapy to methotrexate monotherapy based on ACR20 response rate after 24 weeks of treatment. Additionally, baricitinib was superior to methotrexate based on ACR20 response.

- The fourth Phase III study of baricitinib met its primary objective of demonstrating superiority compared to placebo after 12 weeks of treatment based on ACR20 response rate. Baricitinib was also superior to adalimumab in improving signs and symptoms of rheumatoid arthritis as measured by ACR20 response and improvement in the DAS28-hsCRP score after 12 weeks of treatment.

Business Development/Other

- The company announced external innovation agreements with:
 - AstraZeneca to expand their existing immuno-oncology collaboration exploring novel combination therapies for the treatment of patients with solid tumors. The company and AstraZeneca will evaluate the safety and efficacy of a range of additional combinations across the companies' complementary portfolios.
 - ImaginAb Inc. to conduct preclinical research studying potential novel T-cell-based immuno-oncology therapies.
 - Innovent Biologics, Inc. to expand their collaboration to support the development and potential commercialization of up to three anti-PD-1 based bispecific antibodies for cancer treatments over the next decade, both inside and outside of China.
- The company acquired worldwide rights from Locemia Solutions to a Phase III intranasal glucagon, a potential treatment for severe hypoglycemia in people with diabetes treated with insulin.
- Bristol-Myers Squibb transferred its Erbitux[®] commercialization rights to Lilly in North America.
- The company entered into a settlement agreement to resolve patent litigation with Sanofi regarding the company's insulin glargine product, Basaglar. As a part of the agreement, Lilly and its alliance partner, Boehringer Ingelheim, will have the ability to launch Basaglar in the U.S. on December 15, 2016. Under the terms of the agreement, Sanofi granted Lilly a royalty-

bearing license so Lilly can manufacture and sell Basaglar in the Kwikpen[®] device globally.

- The U.S. District Court for the Southern District of Indiana ruled that the Alimta[®] vitamin regimen patent would be infringed by the generic challengers' proposed products. The patent provides intellectual property protection for Alimta until May 2022.
- The Japan Patent Office issued a notice of closure in the trial regarding the validity of Lilly's vitamin regimen patent for Alimta. We expect a written decision upholding the patent validity in the coming weeks. This is the first of two decisions pending. If the patents are ultimately upheld through all challenges and appeals, they would provide intellectual property protection for Alimta in Japan until June 2021.
- The company plans to add 30,000 square feet and approximately 50 new jobs to its research and development presence at the Alexandria Center for Life Science in New York, New York. Upon completion in 2016, this space will include a translational immuno-oncology hub and a Lilly "portal," which will provide local academic scientists with opportunities for collaborative access to cutting-edge drug discovery capabilities.

Third-Quarter Reported Results

In the third quarter of 2015, worldwide revenue was \$4.960 billion, an increase of 2 percent compared with the third quarter of 2014. The revenue growth included an increase of 12 percent due to increased volume, largely offset by decreases of 8 percent due to the unfavorable impact of foreign exchange rates and 2 percent due to lower prices. The 12 percent increase in volume was primarily due to the inclusion of revenue from Novartis Animal Health and increased volume for several products, including the U.S. Evista authorized generic, Cyramza[®] and Trulicity. These worldwide volume increases were partially offset by lower demand for Cymbalta[®] due to the U.S. patent expiration in December 2013. Revenue in the U.S. increased 14 percent to \$2.538 billion, due primarily to higher volume, partially offset by lower prices. The U.S. price decrease was driven by a lower price for the Evista authorized generic, which more than offset higher prices for other products. Revenue outside the U.S. decreased 9 percent to \$2.422 billion, driven by the unfavorable impact of foreign exchange

rates, partially offset by the inclusion of revenue from Novartis Animal Health and increased volumes for the majority of pharmaceutical products.

Gross margin increased 3 percent to \$3.723 billion in the third quarter of 2015, as the favorable impact of foreign exchange rates on cost of sales, including the impact on international inventories sold, the inclusion of Novartis Animal Health and increased contribution from recently launched products were largely offset by the unfavorable impact of foreign exchange rates on revenue. Gross margin as a percent of revenue was 75.1 percent, an increase of 1.1 percentage points compared with the third quarter of 2014. The increase in gross margin percent was primarily due to the favorable impact of foreign exchange rates on international inventories sold, partially offset by the inclusion of Novartis Animal Health.

Operating expenses in the third quarter of 2015, defined as the sum of research and development and marketing, selling and administrative expenses, were \$2.719 billion, a decline of 7 percent compared with the third quarter of 2014. Research and development expenses decreased 8 percent to \$1.143 billion, or 23.1 percent of revenue, driven primarily by a 2014 charge associated with the termination of tabalumab development, and to a lesser extent foreign exchange rates, partially offset by the inclusion of Novartis Animal Health. Marketing, selling and administrative expenses decreased 6 percent to \$1.576 billion, due to a 2014 charge associated with the Branded Prescription Drug Fee and foreign exchange rates, partially offset by the inclusion of Novartis Animal Health and expenses related to new product launches.

There were no acquired in-process research and development charges in the third quarter of 2015. In the third quarter of 2014, the company recognized acquired in-process research and development charges totaling \$95.0 million related to collaboration agreements with Immunocore Limited and AstraZeneca.

In the third quarter of 2015, the company recognized asset impairment, restructuring and other special charges of \$42.4 million. The charges primarily relate to integration costs for Novartis Animal Health and severance costs. In the third quarter of 2014, the company recognized asset impairment, restructuring and other special charges of \$36.3 million, primarily severance, associated with cost-containment efforts and costs related to the then pending acquisition of Novartis Animal Health.

Operating income in the third quarter of 2015 was \$961.3 million, an increase of 71 percent compared with the third quarter of 2014, driven by higher gross margin, lower operating expenses and lower acquired in-process research and development charges.

Other income (expense) was income of \$86.5 million in the third quarter of 2015, compared with income of \$93.5 million in the third quarter of 2014. Other income during the third quarter of 2015 was driven by net gains on investments. Other income during the third quarter of 2014 was driven primarily by net gains on investments and income from milestones earned.

The effective tax rate was 23.7 percent in the third quarter of 2015, compared with 23.6 percent in the third quarter of 2014. The 2015 effective tax rate reflects the impact of an increased percentage of forecasted earnings in higher taxed jurisdictions. The 2014 effective tax rate reflects the impact of a \$119.0 million nondeductible charge associated with the U.S. Branded Prescription Drug Fee. Neither period includes the benefit of certain expired U.S. tax provisions, including the R&D tax credit.

In the third quarter of 2015, net income and earnings per share both increased 60 percent to \$799.7 million, and \$0.75, respectively, compared with \$500.6 million and \$0.47, respectively, in the third quarter of 2014. The increases in net income and earnings per share were driven by higher operating income.

Third-Quarter 2015 Non-GAAP Measures

On a non-GAAP basis, worldwide revenue was \$4.960 billion in the third quarter of 2015, a decline of 4 percent compared with the third quarter of 2014. The revenue decline included decreases of 8

percent due to the unfavorable impact of foreign exchange rates and 2 percent due to lower prices, largely offset by an increase of 7 percent due to increased volume. The increase in volume was primarily due to the U.S. Evista authorized generic, as well as Cynamza and Trulicity, partially offset by lower demand for Cymbalta. U.S. revenue increased 11 percent to \$2.538 billion, due primarily to higher volume, partially offset by lower prices. The U.S. price decrease was driven by a lower price for the Evista authorized generic, which more than offset higher prices for other products. Revenue outside the U.S. decreased 15 percent to \$2.422 billion, driven by the unfavorable impact of foreign exchange rates, partially offset by increased volumes for the majority of pharmaceutical products.

Gross margin remained relatively flat at \$3.861 billion in the third quarter of 2015, as the favorable impact of foreign exchange rates on cost of sales, including the impact on international inventories sold, and increased contribution from recently launched products were offset by the unfavorable impact of foreign exchange rates on revenue. Gross margin as a percent of revenue was 77.8 percent, an increase of 3.0 percentage points compared with the third quarter of 2014. The increase in gross margin percent was due to the favorable impact of foreign exchange rates on international inventories sold.

Operating expenses in the third quarter of 2015 were \$2.683 billion, a decline of 7 percent compared with the third quarter of 2014. Research and development expenses decreased 10 percent to \$1.143 billion, or 23.0 percent of revenue, driven primarily by a 2014 charge associated with the termination of tabalumab development, and to a lesser extent the favorable impact of foreign exchange rates. Marketing, selling and administrative expenses decreased 5 percent to \$1.540 billion, due to the favorable impact of foreign exchange rates, partially offset by expenses related to new product launches.

Other income (expense) was income of \$86.5 million in the third quarter of 2015, compared with income of \$59.3 million in the third quarter of 2014.

The effective tax rate increased 1.6 percentage points compared to the third quarter of 2014 to 24.9 percent, due to an increased percentage of forecasted earnings in higher taxed jurisdictions.

Net income and earnings per share both increased 22 percent to \$949.6 million and \$0.89 respectively, compared with \$781.2 million and \$0.73, respectively, in the third quarter of 2014. The increases in net income and earnings per share were driven by higher operating income.

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>Third Quarter</u>		<u>% Change</u>
	<u>2015</u>	<u>2014</u>	
Earnings per share (reported)	\$ 0.75	\$ 0.47	60%
Novartis Animal Health 2014 results	—	(.01)	
Novartis Animal Health inventory step-up	.01	—	
Amortization of intangible assets	.10	.08	
Branded Prescription Drug Fee	—	.11	
Acquired in-process research and development	—	.06	
Asset impairment, restructuring and other special charges	.03	.02	
Earnings per share (non-GAAP)	\$ 0.89	\$ 0.73	22%
Numbers may not add due to rounding.			

Year-to-Date Results

For the first nine months of 2015, worldwide revenue increased 1 percent compared to the same period in 2014 to \$14.583 billion. Reported net income and earnings per share were \$1.930 billion and \$1.81, respectively. Net income and earnings per share, on a non-GAAP basis, were \$2.828 billion and \$2.65, 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>Year-to-date</u>		
	<u>2015</u>	<u>2014</u>	<u>% Change</u>
Earnings per share (reported)	\$ 1.81	\$ 1.82	(1)%
Novartis Animal Health 2014 results	—	(.06)	
Novartis Animal Health inventory step-up	.10	—	
Amortization of intangible assets	.29	.24	
Branded Prescription Drug Fee	—	.11	
Acquired in-process research and development	.20	.06	
Asset impairment, restructuring and other special charges	.15	.04	
Net charge related to repurchase of debt	.09	—	
Earnings per share (non-GAAP)	\$ 2.65	\$ 2.21	20%

Numbers may not add due to rounding.

Select Revenue Highlights

(Dollars in millions)	Third Quarter			Year-to-Date		
	2015	2014	% Change	2015	2014	% Change
Humalog®	\$ 705.0	\$ 706.1	0%	\$ 2,043.3	\$ 2,056.1	(1)%
Alimta	628.5	723.4	(13)%	1,865.8	2,067.0	(10)%
Cialis®	566.1	568.4	0%	1,672.3	1,668.6	0%
Forteo®	348.9	332.2	5%	970.4	941.2	3%
Humulin®	316.7	335.9	(6)%	948.8	1,004.5	(6)%
Cymbalta	242.9	368.0	(34)%	804.0	1,247.5	(36)%
Zyprexa®	237.9	257.4	(8)%	711.2	784.2	(9)%
Strattera®	196.9	191.9	3%	562.4	543.7	3%
Effient®	132.1	131.5	0%	382.7	384.4	0%
Cyramza	111.2	28.4	NM	266.4	42.0	NM
Trajenta®(a)	92.7	78.9	17%	255.0	246.1	4%
Evista	58.0	89.5	(35)%	184.5	347.8	(47)%
Trulicity	73.7	—	NM	136.2	—	NM
Animal Health	778.8	584.7	33%	2,369.3	1,713.3	38%
Total Revenue	4,959.7	4,875.6	2%	14,583.1	14,494.3	1%

(a)Trajenta revenue includes Jentadueto®
 NM – not meaningful

Humalog

For the third quarter of 2015, worldwide Humalog sales remained flat at \$705.0 million compared with the third quarter of 2014. Sales in the U.S. increased 6 percent to \$440.9 million, driven by higher prices and, to a lesser extent, increased demand. Sales outside the U.S. decreased 9 percent to \$264.1 million, driven by the unfavorable impact of foreign exchange rates, partially offset by increased volume.

Alimta

For the third quarter of 2015, Alimta generated sales of \$628.5 million, a decline of 13 percent compared with the third quarter of 2014. U.S. sales of Alimta decreased 7 percent to \$296.7 million, driven by decreased volume due to increased competitive pressures and customer buying patterns. Sales outside the U.S. decreased 18 percent to \$331.8 million, driven by the unfavorable impact of foreign exchange rates and, to a lesser extent, lower prices, partially offset by increased volume.

Cialis

Cialis sales for the third quarter of 2015 remained flat at \$566.1 million compared with the third quarter of 2014. U.S. sales of Cialis were \$313.3 million, a 25 percent increase compared with the third quarter of 2014, driven by higher prices and, to a lesser extent, increased volume. Sales of Cialis outside the U.S. decreased 21 percent to \$252.8 million, driven by the unfavorable impact of foreign exchange rates.

Forteo

Third-quarter 2015 sales of Forteo were \$348.9 million, a 5 percent increase compared with the third quarter of 2014. U.S. sales of Forteo increased 26 percent to \$160.1 million, driven by higher prices and increased volume. Sales outside the U.S. decreased 8 percent to \$188.8 million, due to the unfavorable impact of foreign exchange rates, partially offset by increased volume.

Humulin

Worldwide Humulin sales of \$316.7 million for the third quarter of 2015 decreased 6 percent compared with the third quarter of 2014. U.S. sales increased 12 percent to \$185.5 million, driven by higher prices. Sales outside the U.S. decreased 23 percent to \$131.2 million, driven by decreased volume, primarily due to the loss of a government contract in Brazil, and the unfavorable impact of foreign exchange rates.

Cymbalta

For the third quarter of 2015, Cymbalta generated \$242.9 million of sales, a decline of 34 percent compared with the third quarter of 2014. Sales of Cymbalta outside the U.S. were \$218.3 million, a decline of 27 percent, driven by the unfavorable impact of foreign exchange rates and the loss of exclusivity in Europe in 2014.

Zyprexa

In the third quarter of 2015, Zyprexa sales totaled \$237.9 million, a decline of 8 percent compared with the third quarter of 2014. Zyprexa sales outside the U.S. decreased 20 percent to \$191.0 million, due primarily to the unfavorable impact of foreign exchange rates.

Strattera

During the third quarter of 2015, Strattera generated \$196.9 million of sales, an increase of 3 percent compared with the third quarter of 2014. U.S. sales increased 7 percent to \$128.8 million, driven by higher prices. Sales outside the U.S. decreased 4 percent to \$68.1 million, driven by the unfavorable impact of foreign exchange rates, largely offset by increased volume.

Effient

Effient sales remained flat at \$132.1 million in the third quarter of 2015 compared with the third quarter of 2014. U.S. Effient sales increased 7 percent to \$106.3 million, due to higher prices, partially offset by decreased demand. Sales outside the U.S. decreased 19 percent to \$25.8 million, driven primarily by the unfavorable impact of foreign exchange rates.

Evista

Evista sales for the third quarter of 2015 were \$58.0 million, a decline of 35 percent compared with the third quarter of 2014. U.S. sales of Evista were \$15.5 million as sales of the authorized generic led to increased volume and lower prices. Sales outside the U.S. decreased 22 percent to \$42.5 million, driven primarily by the unfavorable impact of foreign exchange rates.

Animal Health

In the third quarter of 2015, worldwide animal health sales totaled \$778.8 million, an increase of 33 percent compared with the third quarter of 2014. U.S. animal health sales increased 25 percent to \$392.6 million, and animal health sales outside the U.S. increased 42 percent to \$386.2 million. The increases were primarily driven by the inclusion of revenue from Novartis Animal Health.

Including the sales of Novartis Animal Health in 2014, worldwide animal health sales decreased 9 percent, U.S. sales increased 1 percent, and sales outside the U.S. decreased 18 percent. The increase in U.S. sales was driven by increased volume in food animal products, partially offset by decreased volume in companion animal products. The decline in sales outside the U.S. was driven by the unfavorable impact of foreign exchange rates and to a lesser extent decreased volume, primarily in companion animal products, partially offset by higher prices. Including the sales of Novartis Animal Health in 2014 and excluding the unfavorable impact of foreign exchange rates, worldwide animal health sales decreased 2 percent.

2015 Financial Guidance

The company has revised certain elements of its 2015 financial guidance on a reported basis and on a non-GAAP basis. Full-year 2015 earnings per share are now expected to be in the range of \$2.40 to \$2.45 on a reported basis. On a non-GAAP basis, full-year 2015 earnings per share are now expected to be in the range of \$3.40 to \$3.45.

	2015 Expectations
Earnings per share (reported)	\$2.40 to \$2.45
Amortization of intangible assets including the impact of the transfer of Erbitux rights	.39
Acquired in-process research and development charges	.20
Net charge related to repurchase of debt	.09
Asset impairment, restructuring, integration and inventory step-up costs, primarily related to the acquisition of Novartis Animal Health	.31
Earnings per share (non-GAAP)	\$3.40 to \$3.45

Amortization and inventory step-up costs associated with the acquisition of Novartis Animal Health and the transfer of Erbitux commercialization rights are subject to final acquisition accounting adjustments. The company's 2015 financial guidance, on a reported basis, does not include the potential impact of the recent acquisition of worldwide rights to an intranasal glucagon from Locemia Solutions. Numbers may not add due to rounding.

The company still expects 2015 revenue of between \$19.7 billion and \$20.0 billion.

The company still expects gross margin as a percent of revenue will be approximately 74.5 percent on a reported basis. On a non-GAAP basis, gross margin as a percent of revenue is still expected to be approximately 78.0 percent, reflecting the exclusion of inventory step-up costs associated with the acquisition of Novartis Animal Health as well as amortization of intangibles.

Marketing, selling and administrative expenses on a reported basis are now expected to be in the range of \$6.4 billion to \$6.6 billion. On a non-GAAP basis, marketing, selling and administrative expenses are now expected to be in the range of \$6.3 billion to \$6.5 billion. Research and development expenses are now expected to be in the range of \$4.6 billion to \$4.8 billion.

Other income (expense) is now expected to be in a range between \$50 million and \$75 million of income on a reported basis, reflecting net gains on investments realized to date, partially offset by the net charge related to the repurchase of debt. On a non-GAAP basis, other income (expense) is now expected to be in a range between \$200 million and \$225 million of income, reflecting net gains on investments realized to date.

The 2015 tax rate is now expected to be approximately 16.5 percent on a reported basis and 21.5 percent on a non-GAAP basis, reflecting the impact of an increased percentage of forecasted earnings in higher taxed jurisdictions. Both rates assume a full-year 2015 benefit of the R&D tax credit and other tax provisions up for extension. If these items are not extended, the non-GAAP 2015 tax rate would be approximately 1.5 percentage points higher.

Capital expenditures are now expected to be approximately \$1.1 billion.

The company's 2015 financial guidance, on a reported basis, does not include the potential impact of the recent acquisition of worldwide rights to an intranasal glucagon from Locemia Solutions.

The following table summarizes the company's 2015 financial guidance:

	2015 Guidance	
	Prior	Revised
Revenue	\$19.7 to \$20.0 billion	\$19.7 to \$20.0 billion
Gross Margin % of Revenue (reported)	Approx. 74.5%	Approx. 74.5%
Gross Margin % of Revenue (non-GAAP)	Approx. 78.0%	Approx. 78.0%
Marketing, Selling & Admin (reported)	\$6.4 to \$6.7 billion	\$6.4 to \$6.6 billion
Marketing, Selling & Admin (non-GAAP)	\$6.3 to \$6.6 billion	\$6.3 to \$6.5 billion
Research & Development	\$4.7 to \$4.9 billion	\$4.6 to \$4.8 billion
Other Income/(Expense) (reported)	(\$50 million) to \$0	\$50 to \$75 million
Other Income/(Expense) (non-GAAP)	\$100 to \$150 million	\$200 to \$225 million
Tax Rate (reported)	Approx. 14.5%	Approx. 16.5%
Tax Rate (non-GAAP)	Approx. 21.0%	Approx. 21.5%
Earnings per share (reported)	\$2.20 to \$2.30	\$2.40 to \$2.45
Earnings per share (non-GAAP)	\$3.20 to \$3.30	\$3.40 to \$3.45
Capital Expenditures	Approx. \$1.3 billion	Approx. \$1.1 billion
The company's 2015 financial guidance is subject to final accounting adjustments for the acquisition of Novartis Animal Health and the transfer of Erbitux commercialization rights.		

Webcast of Conference Call

As previously announced, investors and the general public can access a live webcast of the third-quarter 2015 financial results conference call through a link on Lilly's website at www.lilly.com. The conference call will begin at 9:00 a.m. Eastern Daylight Time (EDT) 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,” 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. 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. 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)
Erbitux® (cetuximab, Bristol-Myers Squibb Company)

Evista® (raloxifene hydrochloride, 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)
Jentadueto® (linagliptin/metformin, Boehringer Ingelheim)
Sentinel® (lufenuron and milbemycin oxime, Virbac)
Strattera® (atomoxetine hydrochloride, Lilly)
Synjardy® (empagliflozin/metformin, Boehringer Ingelheim)
Trajenta® (linagliptin, Boehringer Ingelheim)
Trulicity® (dulaglutide, Lilly)
Zyprexa® (olanzapine, Lilly)

Eli Lilly and Company Employment Information

	<u>September 30, 2015</u>	<u>December 31, 2014</u>
Worldwide Employees	41,265*	39,135

*Employment totals reflect additions from the acquisition of Novartis Animal Health on January 1, 2015.

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,		
	2015	2014	% Chg.	2015	2014	% Chg.
Revenue	\$ 4,959.7	\$ 4,875.6	2%	\$ 14,583.1	\$ 14,494.3	1%
Cost of sales	1,236.9	1,267.0	(2)%	3,648.0	3,679.4	(1)%
Research and development	1,143.4	1,243.2	(8)%	3,352.2	3,547.9	(6)%
Marketing, selling and administrative	1,575.7	1,672.1	(6)%	4,734.6	4,820.9	(2)%
Acquired in-process research and development	—	95.0	NM	336.0	95.0	NM
Asset impairment, restructuring and other special charges	42.4	36.3	17%	222.8	67.7	NM
Operating income	961.3	562.0	71%	2,289.5	2,283.4	0%
Net interest income (expense)	(18.1)	(9.3)		(53.8)	(14.6)	
Net other income (expense)	104.6	102.8		109.7	217.9	
Other income (expense)	86.5	93.5	(7)%	55.9	203.3	(73)%
Income before income taxes	1,047.8	655.5	60%	2,345.4	2,486.7	(6)%
Income taxes	248.1	154.9	60%	415.4	524.7	(21)%
Net income	\$ 799.7	\$ 500.6	60%	\$ 1,930.0	\$ 1,962.0	(2)%
Earnings per share – diluted	\$ 0.75	\$ 0.47	60%	\$ 1.81	\$ 1.82	(1)%
Dividends paid per share	\$ 0.50	\$ 0.49	2%	\$ 1.50	\$ 1.47	2%
Weighted-average shares outstanding (thousands) – diluted	1,065,159	1,074,386		1,065,961	1,075,740	

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, 2015			Three Months Ended September 30, 2014		
	GAAP Reported	Adjustments(c)	Non-GAAP Adjusted	GAAP Reported	Adjustments(d)	Non-GAAP Adjusted
Revenue	\$ 4,959.7	\$ —	\$ 4,959.7	\$ 4,875.6	\$ 275.4	\$ 5,151.0
Cost of sales	1,236.9	(137.9)	1,099.0	1,267.0	32.6	1,299.7
Operating expenses(b)	2,719.1	(35.8)	2,683.3	2,915.3	(23.2)	2,892.0
Acquired in-process research and development	—	—	—	95.0	(95.0)	—
Asset impairment, restructuring and other special charges	42.4	(42.4)	—	36.3	(36.3)	—
Other income (expense)	86.5	—	86.5	93.5	(34.1)	59.3
Income taxes	248.1	66.2	314.3	154.9	82.4	237.4
Net income	\$ 799.7	\$ 149.8	\$ 949.6	\$ 500.6	\$ 280.7	\$ 781.2
Earnings per share – diluted	\$ 0.75	\$ 0.14	\$ 0.89	\$ 0.47	\$ 0.26	\$ 0.73

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 items that are typically highly variable, difficult to predict, and of a size that could have a substantial impact on the company's reported operations for a period. Non-GAAP adjusted amounts for 2014 assume the Novartis Animal Health acquisition was completed on January 1, 2014. Beginning in 2015, non-GAAP financial measures for periods presented also exclude amortization of intangibles primarily associated with costs of marketed products acquired or licensed from third parties. 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, 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.

(d) Adjustments to certain GAAP reported measures for the three months ended September 30, 2014, include the following:

(Dollars in millions, except per share data)	IPR&D ⁽ⁱ⁾	Novartis Animal Health ⁽ⁱⁱ⁾	Legacy Amortization ⁽ⁱⁱⁱ⁾	Branded Prescription Drug Fee ^(iv)	Other specified items ^(v)	Total Adjustments
Revenue	\$ —	\$ 275.4	\$ —	\$ —	\$ —	\$ 275.4
Cost of sales	—	130.7	(98.1)	—	—	32.6
Operating expenses	—	132.3	(36.5)	(119.0)	—	(23.2)
Acquired in-process research and development	(95.0)	—	—	—	—	(95.0)
Asset impairment, restructuring and other special charges	—	—	—	—	(36.3)	(36.3)
Other income (expense)	—	(34.1)	—	—	—	(34.1)
Income taxes	33.2	(8.0)	46.1	—	11.1	82.4
Net income	\$ 61.8	\$ (13.8)	\$ 88.5	\$ 119.0	\$ 25.2	\$ 280.7
Earnings per share – diluted	\$ 0.06	\$ (0.01)	\$ 0.08	\$ 0.11	\$ 0.02	\$ 0.26

Numbers may not add due to rounding.

- i. 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 \$95.0 million of payments related to collaboration agreements with Immunocore Limited and AstraZeneca.
- ii. Inclusion of the results of Novartis Animal Health as if the acquisition and the financing for the acquisition had occurred as of January 1, 2014. Amounts reflect GAAP reported measures of Novartis Animal Health, adjusted as follows:
 1. Exclude results associated with the Sentinel[®] canine parasiticide franchise in the U.S., which was divested following the closing of the acquisition
 2. Exclude amortization of intangibles
 3. Exclude integration and inventory step-up costs
 4. Other miscellaneous adjustments.
- iii. Exclude legacy amortization of intangibles primarily associated with costs of marketed products acquired or licensed from third parties.
- iv. Exclude charge created by the IRS final regulations in regard to its administration of the U.S. Branded Prescription Drug Fee. In addition to accounting for the fee that was imposed and paid in 2014, the company accrued for the fee imposed and paid in 2015.
- v. Exclude costs primarily associated with restructuring to reduce the company's cost structure.

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, 2015			Nine Months Ended September 30, 2014		
	GAAP Reported	Adjustments(c)	Non-GAAP Adjusted	GAAP Reported	Adjustments(d)	Non-GAAP Adjusted
Total revenue	\$ 14,583.1	\$ —	\$ 14,583.1	\$ 14,494.3	\$ 802.8	\$ 15,297.1
Cost of sales	3,648.0	(502.8)	3,145.2	3,679.4	90.5	3,770.0
Operating expenses(b)	8,086.8	(107.4)	7,979.4	8,368.8	219.5	8,588.2
Acquired in-process research and development	336.0	(336.0)	—	95.0	(95.0)	—
Asset impairment, restructuring and other special charges	222.8	(222.8)	—	67.7	(67.7)	—
Other income (expense)	55.9	152.7	208.6	203.3	(89.8)	113.4
Income taxes	415.4	423.5	839.0	524.7	150.4	675.2
Net income	\$ 1,930.0	898.1	\$ 2,828.1	\$ 1,962.0	415.1	\$ 2,377.1
Earnings per share – diluted	\$ 1.81	0.84	\$ 2.65	\$ 1.82	0.39	\$ 2.21

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 items that are typically highly variable, difficult to predict, and of a size that could have a substantial impact on the company's reported operations for a period. Non-GAAP adjusted amounts for 2014 assume the Novartis Animal Health acquisition was completed on January 1, 2014. Beginning in 2015, non-GAAP financial measures for periods presented also exclude amortization of intangibles primarily associated with costs of marketed products acquired or licensed from third parties. 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, 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 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 Pharma 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.
- 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.

(d) Adjustments to certain GAAP reported measures for the nine months ended September 30, 2014, include the following:

(Dollars in millions, except per share data)	IPR&D ⁽ⁱ⁾	Novartis Animal Health ⁽ⁱⁱ⁾	Legacy Amortization ⁽ⁱⁱⁱ⁾	Branded Prescription Drug Fee ^(iv)	Other specified items ^(v)	Total Adjustments
Revenue	\$ —	\$ 802.8	\$ —	\$ —	\$ —	\$ 802.8
Cost of sales	—	376.8	(286.3)	—	—	90.5
Operating expenses	—	447.7	(109.2)	(119.0)	—	219.5
Acquired in-process research and development	(95.0)	—	—	—	—	(95.0)
Asset impairment, restructuring and other special charges	—	—	—	—	(67.7)	(67.7)
Other income (expense)	—	(89.8)	—	—	—	(89.8)
Income taxes	33.2	(38.7)	135.4	—	20.5	150.4
Net income	\$ 61.8	\$ (72.9)	\$ 260.0	\$ 119.0	\$ 47.2	\$ 415.1
Earnings per share – diluted	\$ 0.06	\$ (0.06)	\$ 0.24	\$ 0.11	\$ 0.04	\$ 0.39

Numbers may not add due to rounding.

- i. 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 \$95.0 million of payments related to collaboration agreements with Immunocore Limited and AstraZeneca.
- ii. Inclusion of the results of Novartis Animal Health as if the acquisition and the financing for the acquisition had occurred as of January 1, 2014. Amounts reflect GAAP reported measures of Novartis Animal Health, adjusted as follows:
 1. Exclude results associated with the Sentinel® canine parasiticide franchise in the U.S., which was divested following the closing of the acquisition
 2. Exclude amortization of intangibles
 3. Exclude integration and inventory step-up costs
 4. Other miscellaneous adjustments.
- iii. Exclude legacy amortization of intangibles primarily associated with costs of marketed products acquired or licensed from third parties.
- iv. Exclude charge created by the IRS final regulations in regard to its administration of the U.S. Branded Prescription Drug Fee. In addition to accounting for the fee that was imposed and paid in 2014, the company accrued for the fee imposed and paid in 2015.
- v. Exclude costs primarily associated with restructuring to reduce the company's cost structure.