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 24, 2017

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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company o

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. o

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

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

Attached as Exhibit 99.1 and incorporated by reference into this Item 2.02 is a copy of the press release, dated October 24, 2017, announcing our results of operations for the third quarter and nine-month period ended September 30, 2017, including, among other things, unaudited operating results for such period.

#### Item 9.01. Financial Statements and Exhibits

Exhibit Number Description

99.1 Press release dated October 24, 2017 together with related attachments.

#### SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

# **ELI LILLY AND COMPANY** (Registrant)

By: <u>/s/ Donald A. Zakrowski</u> Name: Donald A. Zakrowski Title: Vice President, Finance and Chief Accounting Officer

Dated: October 24, 2017

#### EXHIBIT INDEX

Exhibit Number 99.1 Exhibit Press release dated October 24, 2017, together with related attachments.



October 24, 2017

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

For Release: Immediately

**Refer to:** Lauren Zierke; lauren\_zierke@lilly.com; (317) 277-6524 (Media) Philip Johnson; johnson\_philip\_l@lilly.com; (317) 655-6874 (Investors)

## Lilly Reports Third-Quarter Results, Announces Strategic Review of Elanco Animal Health

- Third-quarter 2017 revenue increased 9 percent, driven primarily by volume growth from new pharmaceutical products. Third-quarter 2017 earnings per share (EPS) were \$0.53 (reported) and \$1.05 (non-GAAP).
- Pharmaceutical revenue in the third quarter of 2017 grew 10 percent. New product revenue, composed of Trulicity, Basaglar, Taltz, Jardiance, Lartruvo, Cyramza, Olumiant and Portrazza, drove 14 percent volume growth and represented nearly 22 percent of total revenue.
- The company is reviewing strategic alternatives for Elanco Animal Health, including an initial public offering, merger, sale, or retention of the business, and will provide an update no later than the middle of 2018.
- Pipeline events included approval and launch of Verzenio in the U.S., an update regarding U.S. regulatory submission timing for baricitinib, and Phase 3 data for lasmiditan and Verzenio.
- The company has lowered 2017 reported EPS to be in the range of \$1.73 to \$1.83 to reflect charges associated with recently announced streamlining initiatives. The company has raised 2017 non-GAAP EPS to be in the range of \$4.15 to \$4.25 to reflect uptake trends for new pharmaceutical products.

Eli Lilly and Company (NYSE: LLY) today announced financial results for the third quarter of 2017.

\$ in millions, except per share data	<u>Third</u>	<u>Quar</u>	ter	<u>%</u>		
	<u>2017</u>		<u>2016</u>	<u>Change</u>		
Revenue	\$ 5,658.0	\$	5,191.7	9%		
Net Income – Reported	555.6		778.0	(29)%		
EPS – Reported	0.53		0.73	(27)%		
Net Income – Non-GAAP	1,106.7		931.0	19%		
EPS – Non-GAAP	1.05		0.88	19%		

Certain financial information for 2017 and 2016 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 2017 financial guidance is also being provided on both a reported and a non-GAAP basis. The non-GAAP measures are presented to provide additional insights into the underlying trends in the company's business.

"Lilly's focus on our key priorities led to strong performance in the third quarter, highlighted by revenue growth from our new pharmaceutical products. In addition, worldwide revenue from our diabetes products collectively grew 39 percent, and we continued to make improvements in our operating margins," said David A. Ricks, Lilly's chairman and CEO. "Our pipeline also continues to deliver. Including Verzenio, we've now launched nine medicines since 2014, and we are on a path to launch eleven more by 2023."

Ricks continued, "Today, we are also announcing a strategic review of our Elanco Animal Health business. Elanco has developed into a premier animal health company, and has been an important growth driver and source of revenue diversification for Lilly. Through acquisitions and organic growth, we've grown Elanco to a size and scale that now allows us to consider a variety of options to maximize future value."

## Key Events Over the Last Three Months

Commercial

• The company launched Olumiant<sup>®</sup> (baricitinib) in Japan for the treatment of rheumatoid arthritis (including the prevention of structural injury of joints) in patients with inadequate response to standard-of-care therapies. Olumiant is part of a collaboration with Incyte.

## Regulatory

- With respect to Verzenio<sup>TM</sup> (abemaciclib), a cyclin-dependent kinase (CDK) 4 & 6 inhibitor, the U.S. Food and Drug Administration (FDA):
  - Approved and the company launched Verzenio in combination with fulvestrant for the treatment of women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer with disease progression following endocrine therapy, and as monotherapy for the treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting.
  - Granted Priority Review designation for the New Drug Application based upon the positive interim results from a study of abemaciclib in combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer.
- After discussions with the FDA in late August, Lilly will resubmit the New Drug Application for baricitinib before the end of January 2018. The resubmission package will include new safety and efficacy data. Baricitinib, which is part of a collaboration between Lilly and Incyte, is a once-daily oral investigational medication for the treatment of patients with moderate-to-severe rheumatoid arthritis (RA). The companies anticipate the FDA will classify the application as a Class II resubmission, which will start a new six-month review cycle.
- Jardiance<sup>®</sup> (empagliflozin) was approved in China as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes. The Jardiance label includes data on the

reduction of risk of cardiovascular death in patients with type 2 diabetes and established cardiovascular disease. Jardiance is part of the company's alliance with Boehringer Ingelheim.

## Clinical

- The company announced that lasmiditan, an investigational, oral, first-in-class molecule for the acute treatment of migraine, met its primary endpoint in a second Phase 3 study. At two hours following the first dose, a greater percentage of patients treated with lasmiditan were migraine pain-free compared to placebo. Lilly plans to submit a New Drug Application for lasmiditan to the FDA in the second half of 2018.
- The company and Incyte announced new safety and efficacy data from a Phase 2 study of baricitinib in people with moderate-to-severe atopic dermatitis (AD). The results showed that baricitinib in combination with a mid-potency topical corticosteroid (TCS) significantly improved the signs and symptoms of AD compared to TCS alone. Baricitinib is part of a collaboration with Incyte.
- The company announced that its Phase 3 study evaluating Verzenio as monotherapy in KRAS-mutated, advanced non-small lung cancer did not meet its primary endpoint of overall survival. However, an analysis of the secondary study endpoints of both progression-free survival and overall response rate showed evidence of monotherapy activity in the abemaciclib arm.

Business Development/Other Developments

- The company today announced that it is reviewing strategic alternatives for its Elanco Animal Health business, including an initial public offering, merger, sale, or retention of the business, and will provide an update no later than the middle of 2018.
- The Patent Trial and Appeal Board of the U.S. Patent and Trademark Office has ruled in the company's favor regarding patentability of the vitamin regimen for Alimta<sup>®</sup>. If the patent is ultimately upheld through all remaining challenges, Alimta would maintain U.S. exclusivity until May 2022, preventing marketing of generic products for as long as the patent remains in force.
- The company announced actions to streamline operations to more efficiently focus resources

on developing new medicines and to improve its cost structure. Global workforce reductions, including those from a U.S. voluntary early retirement program, are expected to impact approximately 3,500 positions. Annualized savings of approximately \$500 million will be about equally split to improve the company's cost structure and reinvest in the business, including product launches and clinical development for new indications and line extensions. Lilly confirmed these savings would improve upon its previous commitment and now expects to achieve an OPEX-to-revenue ratio of 49 percent or less in 2018.

- The company and CureVac AG announced a global immuno-oncology collaboration focused on the development and commercialization of up to five potential cancer vaccine products based on CureVac's proprietary RNActive<sup>®</sup> technology. This transaction is subject to clearance under the Hart-Scott-Rodino Antitrust Improvements Act and other customary closing conditions. Subject to the closing of this transaction and under the terms of the agreement, CureVac will receive an upfront payment of \$50 million and an equity investment of €45 million.
- Following the impact of Hurricane Maria, the company has accounted for all employees in Puerto Rico, and its manufacturing sites had minimal damage. The company's inventory strategy for products is designed to protect against this type of event, and Lilly sees no product supply risk or other significant financial impact at this time.
- The company announced plans to invest \$72 million in an insulin manufacturing project at one of its Indianapolis facilities. The investment will be used to replace an existing insulin vial filling line and allow Lilly to meet growing demand for its insulins -- including Humalog<sup>®</sup> (insulin lispro) and Humulin<sup>®</sup> (human insulin) -- while upgrading to state-of-the-art technology and preparing for its insulin pipeline. This new project is part of \$850 million in anticipated U.S. capital investments the company announced in March of this year.

## Third-Quarter Reported Results

In the third quarter of 2017, worldwide revenue was \$5.658 billion, an increase of 9 percent compared with the third quarter of 2016. The revenue increase was driven by a 7 percent increase due to volume and a 2 percent increase due to higher realized prices.

Revenue in the U.S. increased 9 percent, to \$3.104 billion, due to increased volume for new pharmaceutical products, including Trulicity<sup>®</sup>, Basaglar<sup>®</sup>, Taltz<sup>®</sup>, Jardiance and Lartruvo<sup>TM</sup>, as well as increased volume for companion animal products from the acquisition of Boehringer Ingelheim Vetmedica's U.S. feline, canine and rabies vaccine portfolio, and higher realized prices for several pharmaceutical products, primarily driven by Forteo<sup>®</sup>, Humalog and Cialis<sup>®</sup>. The increase in revenue was partially offset by decreased volume due to loss of exclusivity for Strattera<sup>®</sup> and Effient<sup>®</sup>, as well as decreased demand for Cialis and food animal products. Cymbalta<sup>®</sup> revenue declined by approximately \$145 million, as the third quarter of 2016 included an increase in revenue due to a reduction to the return reserve.

Revenue outside the U.S. increased 8 percent, to 2.554 billion, due to increased volume for several new pharmaceutical products, primarily driven by Trulicity and Cyramza<sup>®</sup>.

Gross margin increased 8 percent, to \$4.092 billion, in the third quarter of 2017 compared with the third quarter of 2016. Gross margin as a percent of revenue was 72.3 percent, a decrease of 0.7 percentage points compared with the third quarter of 2016. The decrease in gross margin percent was primarily due to the effect of foreign exchange rates on international inventories sold and negative product mix, partially offset by manufacturing efficiencies.

Operating expenses in the third quarter of 2017, defined as the sum of research and development and marketing, selling and administrative expenses, increased 3 percent to \$2.875 billion. Research and development expenses increased 7 percent, to \$1.319 billion, or 23.3 percent of revenue. This increase is primarily due to a \$50 million milestone payment related to lanabecestat as part of the company's

collaboration with AstraZeneca and, to a lesser extent, higher late-stage clinical development costs. Marketing, selling and administrative expenses decreased 1 percent, to \$1.556 billion, due to decreased expenses related to late life-cycle products, partially offset by increased expenses related to new pharmaceutical products. Operating expenses were 50.8 percent of revenue in the third quarter of 2017, a reduction of 3.2 percentage points compared with the third quarter of 2016.

In the third quarter of 2017, the company recognized acquired in-process research and development charges of \$205.0 million associated with a strategic collaboration with Nektar Therapeutics to co-develop NKTR-358, a novel immunological therapy that has potential to treat a number of autoimmune and other chronic inflammatory conditions, and a new collaboration with KeyBioscience focused on the development of Dual Amylin Calcitonin Receptor Agonists (DACRAs), a potential new class of treatments for metabolic disorders such as type 2 diabetes. There were no acquired in-process research and development charges in the third quarter of 2016.

In the third quarter of 2017, the company recognized asset impairment, restructuring and other special charges of \$406.5 million. The charges are partially associated with asset impairments related to lower projected revenue for  $Posilac^{(B)}$  (rbST). The company is exploring strategic options for Posilac, including seeking a buyer for the molecule and its Augusta manufacturing site. The charges are also associated with severance costs incurred as a result of actions taken to reduce the company's cost structure. Charges related to the U.S. voluntary early retirement program will be recognized in the fourth quarter of 2017. In the third quarter of 2016, the company recognized asset impairment, restructuring and other special charges of \$45.5 million, primarily related to integration and severance costs for Novartis Animal Health.

Operating income in the third quarter of 2017 was \$605.5 million, a decrease of \$338.0 million compared with the third quarter of 2016, primarily driven by asset impairment, restructuring and other special charges, and acquired in-process research and development, partially offset by higher gross margin.

Other income (expense) was expense of \$13.9 million in the third quarter of 2017, compared with income of \$27.2 million in the third quarter of 2016. The increase in other expense was driven by higher net gains on investments in the third quarter of 2016 as compared to 2017.

The effective tax rate was 6.1 percent in the third quarter of 2017, compared with 19.9 percent in the third quarter of 2016. The lower effective tax rate for the third quarter of 2017 is primarily due to the income tax benefit of acquired in-process research and development charges and asset impairment, restructuring, and other special charges.

In the third quarter of 2017, net income decreased 29 percent, to \$555.6 million, and earnings per share decreased 27 percent, to \$0.53, compared with \$778.0 million and \$0.73, respectively, in the third quarter of 2016. The decreases in net income and earnings per share were primarily driven by lower operating income.

#### Third-Quarter Non-GAAP Measures

On a non-GAAP basis, third-quarter 2017 gross margin increased 7 percent, to \$4.252 billion. Gross margin as a percent of revenue was 75.1 percent, a decrease of 1.3 percentage points compared with the third quarter of 2016. The decrease in gross margin percent was primarily due to the effect of foreign exchange rates on international inventories sold and negative product mix, partially offset by manufacturing efficiencies.

Operating expenses were 50.8 percent of revenue in the third quarter of 2017, a reduction of 3.1 percentage points compared with the third quarter of 2016.

Operating income increased \$211.7 million, or 18 percent, to \$1.378 billion in the third quarter of 2017, primarily due to higher gross margin partially offset by increased operating expenses.

The effective tax rate was 18.9 percent in the third quarter of 2017, compared with 22.0 percent in the third quarter of 2016. The lower effective tax rate for the third quarter of 2017 is primarily due to a net discrete tax benefit of approximately \$30 million.

In the third quarter of 2017, net income increased 19 percent, to \$1.107 billion, and earnings per share increased 19 percent, to \$1.05, compared with \$931.0 million and \$0.88, respectively, in the third quarter of 2016. The increases in net income and earnings per share were primarily driven by higher operating income.

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.

	Third Quarter								
		<u>2017</u>	, 	<u>2016</u>	<u>% Change</u>				
Earnings per share (reported)	\$	0.53	\$	0.73	(27)%				
Asset impairment, restructuring and other special charges		.29		.03					
Acquired in-process research and development		.13		_					
Amortization of intangible assets		.10		.11					
Earnings per share (non-GAAP)	\$	1.05	\$	0.88	19%				
Earnings per share (non Grace)		1.00	Ψ	0.00	1770				
Numbers may not add due to rounding.									

## Year-to-Date Reported Results

For the first nine months of 2017, worldwide revenue increased 8 percent, to \$16.711 billion, compared with \$15.462 billion in the same period in 2016. Reported net income and earnings per share were \$1.453 billion and \$1.37, respectively.

## Year-to-Date Non-GAAP Measures

For the first nine months of 2017, net income and earnings per share, on a non-GAAP basis, were \$3.324 billion and \$3.14, respectively.

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.

		N.	Year-to-Date	
	<u>2017</u>		<u>2016</u>	<u>% Change</u>
Earnings per share (reported)	\$ 1.37	\$	1.85	(26)%
Acquired in-process research and development	.94		_	
Asset impairment, restructuring and other special charges	.48		.19	
Amortization of intangible assets	.33		.34	
Inventory step up costs associated with the acquisition of Boehringer Ingelheim Vetmedica's U.S. feline, canine and rabies vaccine portfolio	.02		_	
Venezuela charge	—		.19	
Earnings per share (non-GAAP)	\$ 3.14	\$	2.57	22%
Numbers may not add due to rounding.				

# Select Revenue Highlights

Dollars in millions)	Th	ird Qu	arter	Year-to-Date						
Established Pharmaceutical Products	2017		2016	% Change		2017	2016	% Change		
Humalog	\$ 696	5.2 \$	640.8	9%	\$	2,083.0	\$ 1,949.0	7%		
Cialis	564	.9	588.2	(4)%		1,725.7	1,795.3	(4)%		
Alimta	514	.5	570.4	(10)%		1,537.3	1,741.7	(12)%		
Forteo	44]	.7	391.2	13%		1,235.8	1,077.5	15%		
Humulin	300	.5	322.0	(7)%		972.8	1,010.6	(4)%		
Cymbalta	183	.2	313.5	(42)%		564.4	748.7	(25)%		
Strattera	137	'.1	198.8	(31)%		519.9	611.5	(15)%		
Erbitux®	163	.5	184.6	(11)%		477.0	533.3	(11)%		
Zyprexa®	14(	.6	148.9	(6)%		428.9	572.3	(25)%		
Effient	55	.9	127.7	(56)%		326.6	394.3	(17)%		
New Pharmaceutical Products	S									
Trulicity	527	.7	243.6	117%		1,380.8	588.5	135%		
Cyramza	196	0.0	159.0	23%		553.5	437.0	27%		
Taltz	151	.3	32.5	365%		386.7	51.9	646%		
Jardiance(a)	127	.2	47.5	168%		304.3	125.8	142%		
Basaglar	145	5.7	19.4	650%		278.3	46.6	497%		
Lartruvo	54	.5		NM		144.0		NM		
Olumiant	16	5.2		NM		22.8		NM		
Portrazza®	2	.3	5.3	(57)%		8.2	11.0	(26)%		
Subtotal	1,220	.9	507.3	141%		3,078.6	1,260.8	144%		
Animal Health	740	0.6	706.2	5%		2,294.8	2,320.5	(1)%		
		5.0	5,191.7	9%		16,710.6	15,461.6	8%		

## **Selected Established Pharmaceutical Products**

## <u>Humalog</u>

For the third quarter of 2017, worldwide Humalog revenue increased 9 percent compared with the third quarter of 2016, to \$696.2 million. Revenue in the U.S. increased 10 percent, to \$414.9 million, driven by higher realized prices due to changes in estimates to rebates and discounts and, to a lesser extent, increased volume. Revenue outside the U.S. increased 7 percent, to \$281.3 million, driven by increased volume, higher realized prices and, to a lesser extent, the favorable impact of foreign exchange rates.

## Cialis

For the third quarter of 2017, worldwide Cialis revenue decreased 4 percent to \$564.9 million. U.S. Cialis revenue was \$319.6 million in the third quarter, an 8 percent decrease compared with the third quarter of 2016, driven by decreased demand partially offset by higher realized prices. Cialis revenue outside the U.S. increased 2 percent to \$245.3 million, driven by higher realized prices and, to a lesser extent, the favorable impact of foreign exchange rates, partially offset by decreased volume.

## <u>Alimta</u>

For the third quarter of 2017, Alimta generated worldwide revenue of \$514.5 million, which decreased 10 percent compared with the third quarter of 2016. U.S. Alimta revenue decreased 6 percent, to \$260.3 million, driven by decreased demand due to competitive pressure. Alimta revenue outside the U.S. decreased 13 percent, to \$254.2 million, driven by competitive pressure, lower realized prices, and loss of exclusivity in several countries.

#### Forteo

For the third quarter of 2017, worldwide revenue for Forteo was \$441.7 million, a 13 percent increase compared with the third quarter of 2016. U.S. revenue increased 13 percent, to \$234.1 million, driven by higher realized prices. Revenue outside the U.S. increased 13 percent, to \$207.6 million, driven by increased volume.

## <u>Humulin</u>

For the third quarter of 2017, worldwide Humulin revenue decreased 7 percent compared with the third quarter of 2016, to \$300.5 million. U.S. revenue increased 4 percent, to \$203.0 million, driven by increased volume, partially offset by lower realized prices. Revenue outside the U.S. decreased 23 percent, to \$97.5 million, driven by decreased volume, primarily due to buying patterns in China.

#### **Selected New Pharmaceutical Products**

#### Trulicity

Third-quarter 2017 worldwide Trulicity revenue was \$527.7 million, an increase of 117 percent compared with the third quarter of 2016. U.S. revenue increased 119 percent, to \$412.9 million, driven by increased share of market for Trulicity and growth in the GLP-1 class. Revenue outside the U.S. was \$114.8 million, an increase of 109 percent, primarily driven by uptake in Europe and Japan.

## <u>Cyramza</u>

For the third quarter of 2017, worldwide Cyramza revenue was \$196.0 million, an increase of 23 percent compared with the third quarter of 2016. U.S. revenue was \$69.5 million, an increase of 4 percent, driven by increased volume. Revenue outside the U.S. was \$126.5 million, an increase of 38 percent, primarily due to strong volume growth in Japan, partially offset by the unfavorable impact of foreign exchange rates and lower realized prices.

## <u>Taltz</u>

For the third quarter of 2017, Taltz generated worldwide revenue of \$151.3 million. U.S. revenue was \$131.3 million, an increase of \$6.9 million compared with the second quarter of 2017.

## Jardiance

The company's worldwide Jardiance revenue during the third quarter of 2017 was \$127.2 million, an increase of 168 percent compared with the third quarter of 2016. U.S. revenue increased 154 percent,

to \$83.8 million, driven by increased share of market for Jardiance and growth in the SGLT2 class. Revenue outside the U.S. was \$43.4 million, an increase of \$28.8 million compared with the third quarter of 2016, primarily driven by increased volume in several countries. Jardiance is part of the company's alliance with Boehringer Ingelheim, and Lilly reports as revenue a portion of Jardiance's gross margin.

## <u>Basaglar</u>

For the third quarter of 2017, Basaglar generated worldwide revenue of \$145.7 million. U.S. revenue was \$115.2 million, an increase of \$55.7 million compared with the second quarter of 2017, reflecting strong launch uptake. Basaglar is part of the company's alliance with Boehringer Ingelheim, and Lilly reports as revenue total sales, with payments made to Boehringer Ingelheim for its portion of the gross margin reported as cost of sales.

#### <u>Lartruvo</u>

For the third quarter of 2017, Lartruvo, a treatment in combination with doxorubicin for a subset of adult patients with advanced soft tissue sarcoma, generated worldwide revenue of \$54.5 million. U.S. revenue was \$42.4 million, an increase of \$2.7 million compared with the second quarter of 2017.

#### <u>Olumiant</u>

For the third quarter of 2017, Olumiant, a treatment for moderate-to-severe rheumatoid arthritis, generated worldwide revenue of \$16.2 million, an increase of \$11.5 million compared with the second quarter of 2017, reflecting strong launch uptake in Germany.

## **Animal Health**

In the third quarter of 2017, worldwide animal health revenue totaled \$740.6 million, an increase of 5 percent compared with the third quarter of 2016. Worldwide food animal revenue decreased 6 percent, to \$488.4 million, driven by market access and competitive pressures in U.S. cattle. Worldwide

companion animal revenue increased 35 percent, to \$252.2 million, driven by the inclusion of \$61.2 million in revenue from the acquisition of Boehringer Ingelheim Vetmedica's U.S. feline, canine and rabies vaccine portfolio, and wholesaler buying patterns in the U.S. in the third quarter of 2016. The increase in revenue was partially offset by competitive pressure and lower realized prices. The company expects these pressures to continue for the balance of 2017.

Elanco has now completed the full integration of two large acquisitions in Novartis Animal Health and Vetmedica's vaccines portfolio, and most recently announced actions to explore strategic options for Posilac (rbST) and consolidate manufacturing operations. It expects the acquisitions to provide the foundation for a return to top-line growth. Elanco remains focused on its three core priorities of delivering innovative products and services to its customers, strengthening performance in high-growth segments, and driving future margin expansion through its long-term productivity agenda.

#### 2017 Financial Guidance

The company has revised certain elements of its 2017 financial guidance on a reported basis and on a non-GAAP basis. Earnings per share for 2017 are being decreased to be in the range of \$1.73 to \$1.83 on a reported basis to reflect charges associated with recently announced streamlining initiatives. Earnings per share for 2017 are being increased to be in the range of \$4.15 to \$4.25 on a non-GAAP basis to reflect uptake trends for new pharmaceutical products.

	2017 Expectations	% Change from 2016
Earnings per share (reported)	\$1.73 to \$1.83	(33)% to (29)%
Asset impairment, restructuring and other special charges, including the estimated participation of the U.S. voluntary early retirement program, global severance, facility closures and Novartis Animal Health integration costs	.99	
Acquired in-process research and development charges related to the acquisition of CoLucid Pharmaceuticals and the collaborations with Nektar Therapeutics, KeyBioscience and CureVac	.97	
Amortization of intangible assets (1)	.44	
Inventory step-up costs associated with the acquisition of Boehringer Ingelheim Vetmedica's U.S. feline, canine and rabies vaccines portfolio (1)	.03	
Earnings per share (non-GAAP)	\$4.15 to \$4.25	
(1) Subject to acquisition accounting adjustments		=
Numbers may not add due to rounding		

The company now anticipates 2017 revenue between \$22.4 billion and \$22.7 billion, primarily due to uptake trends for new pharmaceutical products and, to a lesser extent, to the positive impact of the Euro. Excluding the impact of foreign exchange rates, the company expects revenue growth from new pharmaceutical products including Trulicity, Taltz, Basaglar, Cyramza, Jardiance and Lartruvo, as well as a number of established pharmaceutical products including Trajenta<sup>®</sup>, Forteo and Humalog.

Gross margin percentage is still expected to be approximately 72.5 percent on a reported basis and approximately 76.0 percent on a non-GAAP basis.

Marketing, selling and administrative expenses are still expected to be in the range of \$6.4 billion to \$6.6 billion. Research and development expenses are now expected to be in the range of \$5.1 billion to \$5.2 billion.

The 2017 tax rate is now expected to be approximately 20.0 percent on a reported basis and approximately 21.0 percent on a non-GAAP basis.

The following table summarizes the company's 2017 financial guidance:

	2017 Guidance								
	Prior	Revised							
Revenue	\$22.0 to \$22.5 billion	\$22.4 to \$22.7 billion							
Gross Margin % of Revenue (reported)	Approx. 72.5%	Unchanged							
Gross Margin % of Revenue (non-GAAP)	Approx. 76.0%	Unchanged							
Marketing, Selling & Administrative	\$6.4 to \$6.6 billion	Unchanged							
Research & Development	\$5.0 to \$5.2 billion	\$5.1 to \$5.2 billion							
Other Income/(Expense)	\$0 to \$100 million	Unchanged							
Tax Rate (reported)	Approx. 23.5%	Approx. 20.0%							
Tax Rate (non-GAAP)	Approx. 22.0%	Approx. 21.0%							
Earnings per Share (reported)	\$2.51 to \$2.61	\$1.73 to \$1.83							
Earnings per Share (non-GAAP)	\$4.10 to \$4.20	\$4.15 to \$4.25							
Capital Expenditures	Approx. \$1.1 billion	Unchanged							
Non-GAAP adjustments are consistent with the earnings per share table above.									

## Webcast of Conference Call

As previously announced, investors and the general public can access a live webcast of the third-quarter 2017 financial results conference call through a link on Lilly's website at www.lilly.com. The conference call will be held today from 9 a.m. to 10:30 a.m. Eastern time (ET) 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 voluntarism. 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 receive the necessary clinical and manufacturing regulatory approvals or that they will prove to be commercially successful. With respect to the review of and any potential initial public offering, merger, sale, or retention of the Elanco animal health business, there can be no guarantee that the company will realize the expected benefits of the review or other strategic efforts or that the review or other strategic efforts will be completed on the anticipated timeline, if at all. 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 Securities and Exchange Commission (SEC); acquisitions and business development transactions and related integration costs; the impact of exchange rates and global macroeconomic conditions: and the impact of any strategic alternatives the company decides to pursue for it animal health products business. 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-O and 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.

# # #

Alimta<sup>®</sup> (pemetrexed disodium, Lilly) Basaglar<sup>®</sup> (insulin glargine injection, Lilly) Cialis<sup>®</sup> (tadalafil, Lilly)

Cymbalta® (duloxetine hydrochloride, Lilly) Cyramza<sup>®</sup> (ramucirumab, Lilly) Effient<sup>®</sup> (prasugrel, Lilly) Erbitux<sup>®</sup> (cetuximab, Lilly) Forteo® (teriparatide of recombinant DNA origin injection, Lilly) Glyxambi<sup>®</sup> (empagliflozin/linagliptin, Boehringer Ingelheim) Humalog® (insulin lispro injection of recombinant DNA origin, Lilly) Humulin® (human insulin of recombinant DNA origin, Lilly) Jardiance® (empagliflozin, Boehringer Ingelheim) Lartruvo<sup>TM</sup> (olaratumab, Lilly) Olumiant<sup>®</sup> (baricitinib, Lilly) Portrazza® (necitumumab, Lilly) Posilac<sup>®</sup> (recombinant bovine somatotropin, Lilly) Strattera® (atomoxetine hydrochloride, Lilly) Synjardy® (empagliflozin/metformin, Boehringer Ingelheim) Taltz<sup>®</sup> (ixekizumab, Lilly) Trajenta® (linagliptin, Boehringer Ingelheim) Trulicity® (dulaglutide, Lilly) Verzenio<sup>TM</sup> (abemaciclib, Lilly) Zyprexa® (olanzapine, Lilly)

Eli Lilly and Company Employment Information

Worldwide Employees

<u>September 30, 2017</u> 41,225

December 31, 2016 41,975

# Eli Lilly and Company

# Operating Results (Unaudited) - REPORTED

(Dollars in millions, except per share data)

				onths Ended nber 30,		Nine Months Ended September 30,			
		2017		2016	% Chg.	2017	1	2016	% Chg.
Revenue	\$	5,658.0	\$	5,191.7	9%	\$ 16,710.6	\$	15,461.6	8%
Cost of sales		1,566.1		1,400.9	12%	4,445.4		4,188.9	6%
Research and development		1,319.4		1,236.4	7%	3,808.6		3,793.3	0%
Marketing, selling and administrative		1,555.5		1,565.4	(1)%	4,807.6		4,661.9	3%
Acquired in-process research and development		205.0		_	NM	1,062.6		_	NM
Asset impairment, restructuring and other special charges	. <u> </u>	406.5		45.5	NM	 670.4		234.9	NM
Operating income		605.5		943.5	(36)%	1,916.0		2,582.6	(26)%
Net interest income (expense)		(16.8)		(18.1)		(47.5)		(57.0)	
Net other income (expense)		2.9		45.3		44.8		(43.6)	
Other income (expense)		(13.9)		27.2	NM	 (2.7)		(100.6)	(97)%
Income before income taxes		591.6		970.7	(39)%	1,913.3		2,482.0	(23)%
Income taxes		36.0	_	192.7	(81)%	 460.5		516.2	(11)%
Net income	\$	555.6	\$	778.0	(29)%	\$ 1,452.8	\$	1,965.8	(26)%
Earnings per share – diluted	\$	0.53	\$	0.73	(27)%	\$ 1.37	\$	1.85	(26)%
Dividends paid per share	\$	0.52	\$	0.51	2%	\$ 1.56	\$	1.53	2%
Weighted-average shares outstanding (thousands) – diluted NM – not meaningful		1,056,025		1,060,786		1,056,972		1,061,065	

#### Eli Lilly and Company

Reconciliation of GAAP Reported to Selected Non-GAAP Adjusted Information (Unaudited) (Dollars in millions, except per share data)

		Three Months Ended September 30, 2017						Three Months Ended September 30, 2016						
	-	GAAP Reported	Adjustments(c)		Non-GAAP Adjusted <sup>(a)</sup>		_	GAAP Reported		Adjustments(d)		n-GAAP justed <sup>(a)</sup>		
Cost of sales	\$	1,566.1	\$	(160.0)	\$	1,406.1	\$	1,400.9	\$	(175.8)	\$	1,225.1		
Operating expenses(b)		2,874.9		(1.3)		2,873.5		2,801.8		(1.9)		2,799.9		
Acquired in-process research and development		205.0		(205.0)		_		_		_		_		
Asset impairment, restructuring and other special charges		406.5		(406.5)		_		45.5		(45.5)		_		
Income taxes		36.0		221.9		257.8		192.7		70.1		262.9		
Net income		555.6		550.9		1,106.7		778.0		153.2		931.0		
Earnings per share – diluted		0.53		0.52		1.05		0.73		0.14		0.88		

Numbers may not add due to rounding.

The table above reflects only line items with non-GAAP adjustments.

(a) The company uses non-GAAP financial measures that differ from financial statements reported in conformity with U.S. generally accepted accounting principles (GAAP). The company's non-GAAP measures adjust reported results to exclude amortization of intangibles and items that are typically highly variable, difficult to predict, and/or of a size that could have a substantial impact on the company's reported operations for a period. The company believes that these non-GAAP measures provide useful information to investors. Among other things, they may help investors evaluate the company's ongoing operations. They can assist in making meaningful period-over-period comparisons and in identifying operating trends that would otherwise be masked or distorted by the items subject to the adjustments. Management uses these non-GAAP measures internally to evaluate the performance of the business, including to allocate resources and to evaluate results relative to incentive compensation targets. Investors should consider these non-GAAP measures in addition to, not as a substitute for or superior to, measures of financial performance prepared in accordance with GAAP.

- (b) Operating expenses include research and development and marketing, selling and administrative expenses.
- (c) Adjustments to certain GAAP reported measures for the three months ended September 30, 2017, include the following:

(Dollars in millions, except per share data)	Am	ortization(i)	IPR&D(ii)	Inventory step- up <sup>(iii)</sup>	Other specified items(iv)	Total Adjustments
Cost of sales	\$	(154.5)	\$ —	\$ (5.5)	\$\$	6 (160.0)
Operating expenses Acquired in-process research and development		(1.3)	(205.0)	—	_	(1.3) (205.0)
Asset impairment, restructuring and other special charges		_	_	_	(406.5)	(406.5)
Income taxes		46.8	71.8	1.9	101.4	221.9
Net income		109.0	133.3	3.6	305.1	550.9
Earnings per share – diluted		0.10	0.13	0.00	0.29	0.52

Numbers may not add due to rounding.

The table above reflects only line items with non-GAAP adjustments.

- 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 are related to collaborations with Nektar Therapeutics and with KeyBioscience.
- iii. Exclude inventory step-up costs associated with the acquisition of Boehringer Ingelheim Vetmedica's U.S. feline, canine and rabies vaccine portfolio.
- iv. Exclude charges primarily associated with asset impairments related to lower projected revenue for Posilac (rbST) and severance costs incurred as a result of actions taken to reduce the company's cost structure.

#### (d) Adjustments to certain GAAP reported measures for the three months ended September 30, 2016, include the following:

(Dollars in millions, except per share data)	Am	ortization <sup>(i)</sup>	Other specified items(ii)	Total Adjustments
Cost of sales	\$	(175.8) \$	— \$	(175.8)
Operating expenses		(1.9)	_	(1.9)
Asset impairment, restructuring and other special charges		_	(45.5)	(45.5)
Income taxes		56.4	13.7	70.1
Net income		121.3	31.9	153.2
Earnings per share – diluted		0.11	0.03	0.14

Numbers may not add due to rounding.

The table above reflects only line items with non-GAAP adjustments.

i. Exclude amortization of intangibles primarily associated with costs of marketed products acquired or licensed from third parties.

ii. Exclude charges associated with integration and severance costs for Novartis Animal Health.

#### Eli Lilly and Company

Reconciliation of GAAP Reported to Selected Non-GAAP Adjusted Information (Unaudited) (Dollars in millions, except per share data)

				e Months Ende tember 30, 201			Nine Months Ended September 30, 2016							
		GAAP Reported	Adju	Adjustments(c)		Non-GAAP Adjusted(a)		GAAP Reported	Adjustments(d)		Non-GAAP Adjusted(a)			
Cost of sales	\$	4,445.4	\$	(537.1)	\$	3,908.3	\$	4,188.9	\$	(513.0)	\$	3,675.9		
Operating expenses(b)		8,616.2		(4.9)		8,611.3		8,455.2		(5.8)		8,449.4		
Acquired in-process research and development		1,062.6		(1,062.6)		_		_		_		_		
Asset impairment, restructuring and other special charges		670.4		(670.4)		_		234.9		(234.9)		_		
Other income (expense)		(2.7)		_		(2.7)		(100.6)		203.9		103.3		
Income taxes		460.5		404.2		864.6		516.2		201.2		717.4		
Net income		1,452.8		1,870.8		3,323.7		1,965.8		756.5		2,722.2		
Earnings per share – diluted		1.37		1.77		3.14		1.85		0.71		2.57		

Numbers may not add due to rounding.

The table above reflects only line items with non-GAAP adjustments.

(a) The company uses non-GAAP financial measures that differ from financial statements reported in conformity with U.S. generally accepted accounting principles (GAAP). The company's non-GAAP measures adjust reported results to exclude amortization of intangibles and items that are typically highly variable, difficult to predict, and/or of a size that could have a substantial impact on the company's reported operations for a period. The company believes that these non-GAAP measures provide useful information to investors. Among other things, they may help investors evaluate the company's ongoing operations. They can assist in making meaningful period-over-period comparisons and in identifying operating trends that would otherwise be masked or distorted by the items subject to the adjustments. Management uses these non-GAAP measures internally to evaluate the performance of the business, including to allocate resources and to evaluate results relative to incentive compensation targets. Investors should consider these non-GAAP measures in addition to, not as a substitute for or superior to, measures of financial performance prepared in accordance with GAAP.

- (b) Operating expenses include research and development and marketing, selling and administrative expenses.
- (c) Adjustments to certain GAAP reported measures for the nine months ended September 30, 2017, include the following:

(Dollars in millions, except per share data)	1	Amortization(i)	IPR&D(ii)	Inventory step- up <sup>(iii)</sup>	Other specified items(iv)	Total Adjustments
Cost of sales	\$	(505.1) \$	_	\$ (32.0)	\$ —	\$ (537.1)
Operating expenses		(4.9)	—	_	_	(4.9)
Acquired in-process research and development		_	(1,062.6)	_	_	(1,062.6)
Asset impairment, restructuring and other special charges		_	_	_	(670.4)	(670.4)
Income taxes		157.5	71.8	11.2	163.7	404.2
Net income		352.6	990.8	20.8	506.6	1,870.8
Earnings per share – diluted		0.33	0.94	0.02	0.48	1.77

Numbers may not add due to rounding.

The table above reflects only line items with non-GAAP adjustments.

- 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 are related to the acquisition of CoLucid Pharmaceuticals and to collaborations with Nektar Therapeutics and with KeyBioscience.
- iii. Exclude inventory step-up costs associated with the acquisition of Boehringer Ingelheim Vetmedica's U.S. feline, canine and rabies vaccine portfolio.
- iv. Exclude charges related to severance costs incurred as a result of actions taken to reduce the company's cost structure, asset impairments related to lower projected revenue for Posilac (rbST), and integration costs and asset impairments related to the acquisition and integration of Novartis Animal Health.

(d) Adjustments to certain GAAP reported measures for the nine months ended September 30, 2016, include the following:

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

Numbers may not add due to rounding.

The table above reflects only line items with non-GAAP adjustments.

- 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.