

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): **November 6, 2018**

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))

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 ☐

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. ☐

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 November 6, 2018, announcing our results of operations for the third quarter and three-month period ended September 30, 2018, including, among other things, unaudited operating results for such period.

Item 9.01. Financial Statements and Exhibits

<u>Exhibit Number</u>	<u>Description</u>
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99.1	Press release dated November 6, 2018
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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: November 6, 2018

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Exhibit</u>
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<u>99.1</u>	<u>Press release dated November 6, 2018</u>
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November 6, 2018

Eli Lilly and Company

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For Release: Immediately

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Kevin Hern; hern_kevin_r@lilly.com; (317) 277-1838 (Investors)

Lilly Delivers Solid Third-Quarter 2018 Results, Revises EPS Guidance

- *Third-quarter 2018 revenue increased 7 percent, driven primarily by increased demand for new medicines, while operating expenses increased 1 percent.*
- *Third-quarter 2018 earnings per share (EPS) grew to \$1.12 (reported), and \$1.39 (non-GAAP).*
- *Pharmaceutical revenue in the third quarter of 2018 grew 8 percent. New medicines, including Trulicity, Taltz, Basaglar, Cyramza, Jardiance, Verzenio, Lartruvo and Olumiant, represented 35 percent of pharma revenue and drove strong volume growth.*
- *Elanco Animal Health Incorporated became a publicly traded company via an initial public offering.*
- *Emgality approved and launched in the U.S.; positive Phase III data readouts for Ultra Rapid Lispro, empagliflozin and flortaucipir; and positive Phase II results for GIP/GLP-1.*
- *2018 EPS guidance range revised to \$3.04 to \$3.09 on a reported basis and \$5.55 to \$5.60 on a non-GAAP basis.*

Eli Lilly and Company (NYSE: LLY) today announced financial results for the third quarter of 2018.

\$ in millions, except per share data	<u>Third Quarter</u>		<u>%</u>
	<u>2018</u>	<u>2017</u>	<u>Change</u>
Revenue	\$ 6,061.9	\$ 5,658.0	7%
Net Income – Reported	1,149.5	555.6	NM
EPS – Reported	1.12	0.53	NM
Net Income – Non-GAAP	1,424.2	1,106.7	29%
EPS – Non-GAAP	1.39	1.05	32%

Certain financial information for 2018 and 2017 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 U.S. 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 2018 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. This press release does not constitute an offer of any securities for sale.

"Lilly delivered strong financial results in the third quarter. Revenue growth driven by greater use of our newest medicines, coupled with prudent expense management, led to strong EPS growth," said David A. Ricks, Lilly's chairman and CEO. "Our strategy is to focus on discovering and developing breakthrough medicines that can help doctors and patients who need new treatment options for serious diseases. We are pleased with our progress this quarter, achieving key development and regulatory milestones in pain and diabetes, while driving continued adoption of our new medicines around the world. Consistent with our revised guidance, we expect to finish 2018 by further delivering strong performance."

Key Events Over the Last Three Months

Regulatory

- The U.S. Food and Drug Administration (FDA) approved, and the company launched in the U.S., Emgality™ for the preventive treatment of migraine in adults. In addition, the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) issued a positive opinion for Emgality for the prophylaxis of migraine in adults who have at least four migraine days per month.
- Verzenio™ was approved in Europe for the treatment of women with hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative locally advanced or metastatic breast cancer in combination with an aromatase inhibitor or fulvestrant as initial endocrine-based therapy, or in women who have received prior endocrine therapy. Verzenio® was also approved in Japan, where it is indicated for HR+, HER2- unresectable or recurrent breast cancer.

Clinical

- The company announced that Trulicity® met the primary efficacy objective in the REWIND clinical trial, and significantly reduced major adverse cardiovascular events (MACE), a composite endpoint of cardiovascular (CV) death, non-fatal myocardial infarction (heart attack) or non-fatal stroke.
- The company announced that results from a Phase 2b clinical trial of its dual GIP and GLP-1 receptor agonist (GIP/GLP-1 RA, LY3298176) showed strong and clinically meaningful blood sugar reduction and weight loss in people with type 2 diabetes. Phase 3 studies for type 2 diabetes are expected to begin no later than early 2019 and to be completed in late 2021.
- The company and Boehringer Ingelheim announced that empagliflozin met the primary efficacy endpoint, defined as a change from baseline in A1C versus placebo after 26 weeks of treatment, for all doses investigated in a Phase III study in adults with type 1 diabetes.
- The company announced that readouts from two Phase 3 clinical trials demonstrated that Ultra Rapid Lispro (URLi) met the primary efficacy endpoint of non-inferior A1C reduction fro

m baseline compared to Humalog® and also demonstrated significantly improved post-meal glucose control in people with type 1 and type 2 diabetes. Based on these results, the company is planning to submit URLi to regulatory authorities in 2019.

- The company and its wholly-owned subsidiary, Avid Radiopharmaceuticals, Inc., announced that a Phase 3 study of flortaucipir F 18, a Positron Emission Tomography (PET) imaging agent, met its two primary endpoints, defined as predicting brain tau pathology and predicting Alzheimer's disease diagnosis.

Business Development/Other Developments

- Elanco Animal Health Incorporated became a publicly traded company via an initial public offering (IPO). As of the closing of the IPO, Lilly owns approximately 80.2 percent of Elanco, and is actively working to divest its remaining position through a tax-efficient transaction within one year of the IPO. Elanco raised over \$4 billion in capital from the IPO and associated debt offering.
- The company announced a license agreement with Chugai Pharmaceutical Co., Ltd for OWL833, Chugai's oral non-peptidic GLP-1 receptor agonist. OWL833 is being studied for the treatment of type 2 diabetes. Under the terms of the agreement, Lilly will receive worldwide development and commercialization rights to OWL833. Chugai will receive an upfront payment of \$50 million and is eligible for milestone payments based on achievement of certain predetermined milestones. If the molecule is successfully commercialized, Chugai would also be eligible for royalty payments.
- The company announced a global licensing and research collaboration with Dicerna Pharmaceuticals focused on the discovery, development and commercialization of potential new medicines in the areas of cardio-metabolic disease, neurodegeneration and pain, utilizing Dicerna's RNA interference (RNAi) technology platform.
- The company acquired a Priority Review Voucher (PRV) from SIGA Technologies for \$80 million. The company intends to utilize this voucher to fast track a product application for an existing R&D project, although the specific project has not yet been determined. As a result of

this transaction, the company will record an acquired in-process research and development charge of \$80 million (pretax), or \$0.06 EPS (after tax), in the fourth quarter of 2018.

- The company announced a multi-year collaboration with NextCure, Inc. focused on the discovery and development of immuno-oncology cancer therapies. NextCure will apply its discovery platform to identify novel, functional immune-related targets and Lilly will develop antibodies to these targets.

Third-Quarter Reported Results

In the third quarter of 2018, worldwide revenue was \$6.062 billion, an increase of 7 percent compared with the third quarter of 2017. The increase in revenue was driven by a 12 percent increase due to volume, partially offset by a 4 percent decrease due to lower realized prices and a 1 percent decrease due to the unfavorable impact of foreign exchange rates.

Revenue in the U.S. increased 11 percent, to \$3.447 billion, driven primarily by increased volume for new pharmaceutical products, including Trulicity, Basaglar[®], Taltz[®], and Verzenio. The increase in revenue was partially offset by lower realized prices, primarily driven by Basaglar, Humalog and Taltz, as well as decreased volume for products that have lost exclusivity, including Cialis[®], Strattera[®] and Effient[®].

Revenue outside the U.S. increased 2 percent, to \$2.615 billion, driven by increased volume of 8 percent, which was primarily for new pharmaceutical products, including Trulicity, Olumiant[®] and Taltz. The increase in revenue was partially offset by lower realized prices for several pharmaceutical products, decreased volume for Cialis due to loss of exclusivity, as well as the unfavorable impact of foreign exchange rates.

Gross margin increased 11 percent, to 74.2 percent, in the third quarter of 2018 compared with the third quarter of 2017. Gross margin as a percent of revenue was 74.2 percent, an increase of 2.2 percentage points compared with the third quarter of 2017. The increase in gross margin percent

was primarily due to manufacturing efficiencies and, to a lesser extent, the effect of foreign exchange rates on international inventories sold and the favorable impact of product mix, partially offset by the negative impact of price on revenue.

Operating expenses in the third quarter of 2018, defined as the sum of research and development and marketing, selling, and administrative expenses, increased 1 percent to \$2.960 billion. Research and development expenses remained flat at \$1.343 billion, or 22.2 percent of revenue, as additional late-stage development expenditures were offset by lower development milestone payments compared to the third quarter of 2017. Marketing, selling, and administrative expenses increased 2 percent, to \$1.617 billion, primarily due to increased expenses related to new pharmaceutical product launches, partially offset by reduced expenses on late life-cycle products. Both research and development expenses and marketing, selling, and administrative expenses benefited from previously-announced actions taken to reduce the company's cost structure.

In the third quarter of 2018, the company recognized acquired in-process research and development charges of \$30.0 million related to a collaboration with Anima Biotech for the discovery and development of translation inhibitors for several target proteins. In the third quarter of 2017, the company recognized acquired in-process research and development charges of \$205.0 million associated with strategic collaborations with Nektar Therapeutics to co-develop NKTR-358 and with KeyBioscience focused on the development of Dual Amylin Calcitonin Receptor Agonists (DACRAs).

In the third quarter of 2018, the company recognized asset impairment, restructuring, and other special charges of \$83.3 million. The charges are primarily associated with asset impairment and restructuring charges related to the sale of the Posilac[®] (rbST) brand and the October 2, 2018 sale of the Augusta, Georgia manufacturing site. The charges also include expenses associated with the initial public offering and separation of the Elanco animal health business. In the third quarter of 2017, the company recognized asset impairment, restructuring and other special charges of \$406.5 million.

These charges were partially associated with asset impairments related to lower projected revenue for Posilac. The charges were also associated with severance costs incurred as a result of actions taken to reduce the company's cost structure.

Operating income in the third quarter of 2018 was \$1.426 billion, compared to \$541.7 million in the third quarter of 2017. The increase to operating income was driven by higher gross margin, lower asset impairment, restructuring, and other special charges, and, to a lesser extent, lower acquired in-process research and development charges.

Other income (expense) was expense of \$15.4 million in the third quarter of 2018, compared with income of \$49.9 million in the third quarter of 2017. The reduction in other income (expense) was driven by foreign exchange losses (primarily related to Argentina), higher net interest expense and mark-to-market adjustments on investment securities.

The effective tax rate was 18.5 percent in the third quarter of 2018, compared with 6.1 percent in the third quarter of 2017. The higher effective tax rate for the third quarter of 2018 is primarily due to a higher income tax benefit in the third quarter of 2017 for acquired in-process research and development charges, asset impairment, restructuring, and other special charges.

In the third quarter of 2018, net income and earnings per share were \$1.149 billion and \$1.12, respectively, compared with net income of \$555.6 million and earnings per share of \$0.53 in the third quarter of 2017. The increases in net income and earnings per share were primarily driven by higher operating income, partially offset by higher tax expense.

Third-Quarter Non-GAAP Measures

On a non-GAAP basis, third-quarter 2018 gross margin increased 10 percent, to \$4.651 billion. Gross margin as a percent of revenue was 76.7 percent, an increase of 1.9 percentage points compared with the third quarter of 2017. The increase in gross margin percent was primarily due to manufacturing efficiencies and, to a lesser extent, the effect of foreign exchange rates on international inventories sold and the favorable impact of product mix, partially offset by the negative impact of price on revenue.

Reflecting the company's previously-announced actions to reduce its cost structure, operating expenses were 48.8 percent of revenue in the third quarter of 2018, a reduction of 2.7 percentage points compared with the third quarter of 2017.

Operating income increased \$377.5 million, or 29 percent, to \$1.692 billion in the third quarter of 2018, primarily due to higher revenue.

The effective tax rate was 15.1 percent in the third quarter of 2018, compared with 18.9 percent in the third quarter of 2017. The lower effective tax rate for the third quarter of 2018 was primarily due to U.S. tax reform enacted in December 2017.

In the third quarter of 2018, net income increased 29 percent, to \$1.424 billion, and earnings per share increased 32 percent, to \$1.39, compared with \$1.107 billion and \$1.05, respectively, in the third quarter of 2017. 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.

	<u>2018</u>	<u>Third Quarter</u> <u>2017</u>	<u>% Change</u>
Earnings per share (reported)	\$ 1.12	\$ 0.53	NM
Amortization of intangible assets	.12	.10	
Asset impairment, restructuring and other special charges	.07	.29	
Income taxes(a)	.05	—	
Acquired in-process research and development	.02	.13	
Earnings per share (non-GAAP)	<u>\$ 1.39</u>	<u>\$ 1.05</u>	32%

Numbers may not add due to rounding.
(a) Relates to adjustments to the 2017 Toll Tax for U.S. tax reform proposed regulations and tax expenses associated with the separation of the Elanco animal health business.

Year-to-Date Results

For the first nine months of 2018, worldwide revenue increased 8 percent, to \$18.117 billion, compared with \$16.711 billion in the same period in 2017. Reported net income and earnings per share were \$2.107 billion and \$2.03, respectively, for the first nine months of 2018.

Year-to-Date Non-GAAP Measures

For the first nine months of 2018, net income and earnings per share, on a non-GAAP basis, were \$4.377 billion and \$4.22, 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.

	<u>Year-to-Date</u>		
	<u>2018</u>	<u>2017</u>	<u>% Change</u>
Earnings per share (reported)	\$ 2.03	\$ 1.37	48%
Acquired in-process research and development	1.57	.94	
Amortization of intangible assets	.36	.33	
Asset impairment, restructuring and other special charges	.20	.48	
Income taxes ^(a)	.05	—	
Other, net	.01	.02	
Earnings per share (non-GAAP)	\$ 4.22	\$ 3.14	34%

Numbers may not add due to rounding.
(a) Relates to adjustments to the 2017 Toll Tax for U.S. tax reform proposed regulations and tax expenses associated with the separation of the Elanco animal health business.

Selected Revenue Highlights

<i>(Dollars in millions)</i>						
Established Pharma Products	Third Quarter			Year-to-Date		
	2018	2017	% Change	2018	2017	% Change
Humalog	\$ 664.6	\$ 696.2	(5)%	\$ 2,226.1	\$ 2,083.0	7%
Alimta®	520.5	514.5	1%	1,576.0	1,537.3	3%
Cialis	467.1	564.9	(17)%	1,501.2	1,725.7	(13)%
Forteo®	390.8	441.7	(12)%	1,138.5	1,235.8	(8)%
Humulin®	322.1	300.5	7%	994.0	972.8	2%
Cymbalta®	172.0	183.2	(6)%	523.5	564.4	(7)%
Erbix®	159.5	163.5	(2)%	475.5	477.0	(0)%
Trajenta ^(a)	135.7	153.3	(12)%	418.5	408.2	3%
Zyprexa®	109.9	140.6	(22)%	360.4	428.9	(16)%
Strattera	98.7	137.1	(28)%	343.5	519.9	(34)%
Select Products Launched Since 2014						
Trulicity	816.2	527.7	55%	2,274.3	1,380.8	65%
Taltz	263.9	151.3	74%	630.4	386.7	63%
Cyramza®	198.4	196.0	1%	600.8	553.5	9%
Basaglar	201.2	145.7	38%	569.0	278.3	NM
Jardiance ^(b) ®	166.9	127.2	31%	465.1	304.3	53%
Lartruvo®	76.9	54.5	41%	221.2	144.0	54%
Verzenio	84.5	—	NM	171.9	—	NM
Olumiant	55.6	16.2	NM	132.5	22.8	NM
Subtotal	1,863.6	1,218.5	53%	5,065.3	3,070.4	65%
Animal Health	772.7	740.6	4%	2,326.0	2,294.8	1%
Total Revenue	6,061.9	5,658.0	7%	18,117.1	16,710.6	8%
^(a) Trajenta includes Jentadueto® ^(b) Jardiance includes Glyxambi® and Synjardy® NM – not meaningful Numbers may not add due to rounding						

Selected Established Pharma Products

Humalog

For the third quarter of 2018, worldwide Humalog revenue decreased 5 percent compared with the third quarter of 2017, to \$664.6 million. Revenue in the U.S. decreased 12 percent, to \$365.6 million, driven by lower realized prices primarily due to changes in segment mix and the impact of patient affordability programs, partially offset by increased volume. Revenue outside the U.S. increased 6 percent, to \$299.0 million, driven by increased volume, partially offset by lower realized prices and the unfavorable impact of foreign exchange rates.

Alimta

For the third quarter of 2018, Alimta generated worldwide revenue of \$520.5 million, which increased 1 percent compared with the third quarter of 2017. U.S. revenue increased 11 percent, to \$288.5 million, driven by increased demand and, to a lesser extent, higher realized prices. Revenue outside the U.S. decreased 9 percent to \$232.0 million, driven primarily by decreased volume due to competitive pressure and loss of exclusivity in several countries.

Cialis

For the third quarter of 2018, worldwide Cialis revenue decreased 17 percent to \$467.1 million. U.S. revenue was \$295.9 million in the third quarter, a 7 percent decrease compared with the third quarter of 2017, driven by decreased demand due to the entry of generic sildenafil, partially offset by higher realized prices. Cialis lost exclusivity, and generic tadalafil entered the U.S. market, in late September 2018. Revenue outside the U.S. decreased 30 percent to \$171.2 million, primarily driven by the loss of exclusivity in Europe.

Forteo

For the third quarter of 2018, worldwide revenue for Forteo was \$390.8 million, a 12 percent decrease compared with the third quarter of 2017. U.S. revenue decreased 22 percent, to \$182.5 million, primarily due to decreased demand and, to a lesser extent, lower realized prices. Revenue outside the

U.S. remained flat at \$208.3 million, driven by increased volume, offset by lower realized prices and the unfavorable impact of foreign exchange rates.

Humulin

For the third quarter of 2018, worldwide Humulin revenue increased 7 percent compared with the third quarter of 2017, to \$322.1 million. U.S. revenue increased 7 percent, to \$216.9 million, driven by increased volume. Revenue outside the U.S. increased 8 percent, to \$105.1 million, primarily due to buying patterns in China, partially offset by the unfavorable impact of foreign exchange rates.

Select Products Launched Since 2014

Trulicity

Third-quarter 2018 worldwide Trulicity revenue was \$816.2 million, an increase of 55 percent compared with the third quarter of 2017. U.S. revenue increased 56 percent, to \$645.9 million, driven by higher demand. Revenue outside the U.S. was \$170.3 million, an increase of 48 percent, primarily driven by increased volume.

Taltz

For the third quarter of 2018, worldwide Taltz revenue was \$263.9 million, an increase of 74 percent compared with the third quarter of 2017. U.S. revenue was \$210.6 million, an increase of 60 percent, driven by higher demand, partially offset by lower realized prices. Revenue outside the U.S. was \$53.3 million, an increase of \$33.3 million, driven by increased volume from new launches.

Cyramza

For the third quarter of 2018, worldwide Cyramza revenue was \$198.4 million, an increase of 1 percent compared with the third quarter of 2017. U.S. revenue was \$67.0 million, a decrease of 4 percent, driven by lower realized prices. Revenue outside the U.S. was \$131.4 million, an increase of 4 percent, driven by increased volume, partially offset by lower realized prices.

Basaglar

For the third quarter of 2018, Basaglar generated worldwide revenue of \$201.2 million, an increase of 38 percent compared with the third quarter of 2017. U.S. revenue was \$157.3 million, an increase of 37 percent, driven by increased demand, partially offset by lower realized prices due to increased volume in Medicare Part D and, to a lesser extent, changes to estimates for rebates and discounts. Revenue outside the U.S. was \$43.9 million, an increase of 44 percent, primarily driven by increased demand. Basaglar is part of the company's alliance with Boehringer Ingelheim, and Lilly reports total sales as revenue, with payments made to Boehringer Ingelheim for its portion of the gross margin reported as cost of sales.

Jardiance

The company's worldwide Jardiance revenue during the third quarter of 2018 was \$166.9 million, an increase of 31 percent compared with the third quarter of 2017. U.S. revenue increased 24 percent, to \$104.2 million, driven by increased demand. Revenue outside the U.S. was \$62.7 million, an increase of 45 percent, primarily driven by increased volume. Jardiance is part of the company's alliance with Boehringer Ingelheim, and Lilly reports as revenue a portion of Jardiance's gross margin.

Lartruvo

For the third quarter of 2018, Lartruvo generated worldwide revenue of \$76.9 million, an increase of 41 percent compared with third quarter of 2017. U.S. revenue increased 12 percent, to \$47.4 million, driven by increased demand. Revenue outside the U.S. was \$29.5 million, an increase of \$17.5 million, driven by increased volume from new launches.

Verzenio

For the third quarter of 2018, Verzenio, a treatment for women with HR+, HER2- advanced breast cancer, generated U.S. revenue of \$84.5 million, an increase of \$26.7 million compared with the second quarter of 2018.

Olumiant

For the third quarter of 2018, Olumiant generated worldwide revenue of \$55.6 million. U.S. revenue was \$0.8 million. Revenue outside the U.S. was \$54.8 million, an increase of \$11.9 million compared with the second quarter of 2018, reflecting uptake of new launches in Europe.

Animal Health

In the third quarter of 2018, worldwide animal health revenue totaled \$772.7 million, an increase of 4 percent compared with the third quarter of 2017, driven by higher prices and higher volume, partially offset by the negative impact of foreign exchange rates. In terms of animal health product categories, higher sales of companion animal disease prevention, ruminants and swine, and companion animal therapeutics products were partially offset by lower sales of products that are being exited. For specific animal health product performance, refer to today's Elanco Animal Health Incorporated press release.

2018 Financial Guidance

The company has revised certain elements of its 2018 financial guidance on a reported basis and on a non-GAAP basis. On a reported basis, earnings per share for 2018 are now expected to be in the range of \$3.04 to \$3.09. On a non-GAAP basis, earnings per share are now expected to be in the range of \$5.55 to \$5.60.

	2018 Expectations	% Change from 2017
Earnings per share (reported)	\$3.04 to \$3.09	NM
Acquired in-process research and development	1.80	
Amortization of intangible assets	.43	
Asset impairment, restructuring and other special charges	.22	
Income taxes ^(a)	.05	
Other, net	.01	
Earnings per share (non-GAAP)	\$5.55 to \$5.60	30% to 31%
Numbers may not add due to rounding		
^(a) Relates to adjustments to the 2017 Toll Tax for U.S. tax reform proposed regulations and tax expenses associated with the separation of the Elanco animal health business.		

The company now anticipates 2018 revenue between \$24.3 billion and \$24.5 billion. The increase in the low end of the revenue range from prior guidance is due to strong performance across the pharmaceutical portfolio, particularly in diabetes. Revenue growth is still expected to be driven by new products including Trulicity, Taltz, Basaglar, Jardiance, Verzenio, Cyramza, Olumiant and Lartruvo.

Marketing, selling and administrative expenses are now expected to be in the range of \$6.3 billion to \$6.5 billion.

The 2018 effective tax rate is still expected to be approximately 22.5 percent on a reported basis and is now expected to be approximately 16 percent on a non-GAAP basis, reflecting recently issued guidance on elements of U.S. tax reform. The 2018 effective tax rate benefits from a lower corporate income tax rate, partially offset by the changes to certain business exclusions, deductions, credits and international tax provisions. The 2018 effective tax rate is subject to change based upon changes in the company's interpretations of the tax laws, along with subsequent regulations, interpretations, guidance, and accounting policy elections that the company continues to evaluate.

The following table summarizes the company's 2018 financial guidance:

	2018 Guidance	
	<u>Prior</u>	<u>Revised</u>
Revenue	\$24.0 to \$24.5 billion	\$24.3 to \$24.5 billion
Gross Margin % of Revenue (reported)	Approx. 73.5%	Unchanged
Gross Margin % of Revenue (non-GAAP)	Approx. 76%	Unchanged
Marketing, Selling & Administrative	\$6.2 to \$6.5 billion	\$6.3 to \$6.5 billion
Research & Development	\$5.2 to \$5.4 billion	Unchanged
Other Income/(Expense)	\$75 to \$200 million	Unchanged
Tax Rate (reported)	Approx. 22.5%	Unchanged
Tax Rate (non-GAAP)	Approx. 17%	Approx. 16%
Earnings per share (reported)	\$3.19 to \$3.29	\$3.04 to \$3.09
Earnings per share (non-GAAP)	\$5.40 to \$5.50	\$5.55 to \$5.60
Capital Expenditures	Approx. \$1.2 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 2018 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 create medicines that make life better for people around the world. We were founded more than a century ago by a man committed to creating high-quality medicines that meet real needs, and today we remain true to that mission in all our work. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism. To learn more about Lilly, please visit us at www.lilly.com and <http://newsroom.lilly.com/social-channels>. F-LLY

This press release contains management's current intentions and expectations for the future, all of which are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. The words "estimate", "project", "intend", "expect", "believe", "target", "anticipate" and similar expressions are intended to identify forward-looking statements. Actual results may differ materially due to various factors. There are significant risks and uncertainties in pharmaceutical research and development. There can be no guarantees that pipeline products will 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, including the impact of tax reform legislation enacted in December 2017 and related guidance; 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 uncertainties and risks related to timing and potential value to both Elanco and Lilly of the planned separation of the Elanco animal health business, including business, industry, and market risks, as well as risks involving realizing the anticipated tax-free nature of the separation. 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)
Cylamza® (ramucirumab, Lilly)
Effient® (prasugrel, Lilly)
Emgality™ (galcanezumab-gnlm, Lilly)
Erbitux® (cetuximab, Lilly)
Forteo® (teriparatide of recombinant DNA origin injection, Lilly)
Glyxambi® (empagliflozin/linagliptin, Boehringer Ingelheim)
Humalog® (insulin lispro injection of recombinant DNA origin, Lilly)
Humulin® (human insulin of recombinant DNA origin, Lilly)
Jardiance® (empagliflozin, Boehringer Ingelheim)
Jentadueto® (linagliptin/metformin HCl, Boehringer Ingelheim)
Lartruvo® (olaratumab, Lilly)
Olumiant® (baricitinib, Lilly)
Posilac® (recombinant bovine somatotropin, Lilly)
Strattera® (atomoxetine hydrochloride, Lilly)
Synjardy® (empagliflozin/metformin, Boehringer Ingelheim)
Taltz® (ixekizumab, Lilly)
Trajenta® (linagliptin, Boehringer Ingelheim)
Trulicity® (dulaglutide, Lilly)
Verzenio®, Verzenio™ (abemaciclib, Lilly)
Zyprexa® (olanzapine, Lilly)

Eli Lilly and Company Employment Information

	<u>September 30, 2018</u>	<u>December 31, 2017</u>
Worldwide Employees	38,585	40,655

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,		
	2018	2017	% Chg.	2018	2017	% Chg.
Revenue	\$ 6,061.9	\$ 5,658.0	7%	\$ 18,117.1	\$ 16,710.6	8 %
Cost of sales	1,562.3	1,586.3	(2)%	4,836.3	4,505.9	7 %
Research and development	1,343.3	1,340.0	0%	3,853.3	3,870.4	(0)%
Marketing, selling and administrative	1,616.6	1,578.5	2%	4,770.3	4,876.6	(2)%
Acquired in-process research and development	30.0	205.0	(85)%	1,654.5	1,062.6	56 %
Asset impairment, restructuring and other special charges	83.3	406.5	(80)%	236.0	670.4	(65)%
Operating income	1,426.4	541.7	NM	2,766.7	1,724.7	60 %
Net interest income (expense)	(37.3)	(16.8)		(75.1)	(47.5)	
Net other income (expense)	21.9	66.7		165.2	236.1	
Other income (expense)	(15.4)	49.9	NM	90.1	188.6	(52)%
Income before income taxes	1,411.0	591.6	NM	2,856.8	1,913.3	49 %
Income taxes	261.5	36.0	NM	749.8	460.5	63 %
Net income	\$ 1,149.5	\$ 555.6	NM	\$ 2,107.0	\$ 1,452.8	45 %
Earnings per share - diluted	\$ 1.12	\$ 0.53	NM	\$ 2.03	\$ 1.37	48 %
Dividends paid per share	\$ 0.5625	\$ 0.52	8%	\$ 1.6875	\$ 1.56	8 %
Weighted-average shares outstanding (thousands) - diluted	1,026,298	1,056,025		1,037,759	1,056,972	

NM – not meaningful

Beginning in 2018, pension and postretirement benefit cost components other than service costs are presented in other income (expense). As a result, comparable amounts for the three and nine months ended September 30, 2017 have been reclassified to conform with this new presentation.

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, 2018			Three Months Ended September 30, 2017		
	GAAP Reported	Adjustments(c)	Non-GAAP Adjusted(a)	GAAP Reported	Adjustments(d)	Non-GAAP Adjusted(a)
Cost of sales	\$ 1,562.3	\$ (151.3)	\$ 1,411.0	\$ 1,586.3	\$ (160.0)	\$ 1,426.3
Operating expenses(b)	2,959.9	(1.1)	2,958.8	2,918.5	(1.3)	2,917.1
Acquired in-process research and development	30.0	(30.0)	—	205.0	(205.0)	—
Asset impairment, restructuring and other special charges	83.3	(83.3)	—	406.5	(406.5)	—
Income taxes	261.5	(9.1)	252.5	36.0	221.9	257.8
Net income	1,149.5	274.7	1,424.2	555.6	550.9	1,106.7
Earnings per share - diluted	1.12	0.27	1.39	0.53	0.52	1.05

Numbers may not add due to rounding.

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

Beginning in 2018, pension and postretirement benefit cost components other than service costs are presented in other income (expense). As a result, comparable amounts for the three months ended September 30, 2017 have been reclassified to conform with this new presentation.

- (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, 2018, include the following:

(Dollars in millions, except per share data)	Amortization ⁽ⁱ⁾	IPR&D ⁽ⁱⁱ⁾	Other specified items ⁽ⁱⁱⁱ⁾	Income taxes ^(iv)	Total Adjustments
Cost of sales	\$ (152.3)	\$ —	\$ 1.0	\$ —	(151.3)
Operating expenses	(1.1)	—	—	—	(1.1)
Acquired in-process research and development	—	(30.0)	—	—	(30.0)
Asset impairment, restructuring and other special charges	—	—	(83.3)	—	(83.3)
Income taxes	29.9	6.3	10.2	(55.5)	(9.1)
Net income	123.5	23.7	72.1	55.5	274.7
Earnings per share - diluted	0.12	0.02	0.07	0.05	0.27

Numbers may not add due to rounding.

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

- Exclude amortization of intangibles primarily associated with costs of marketed products acquired or licensed from third parties.
- 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 were related to business development activity for the collaboration with Anima Biotech for the discovery and development of translation inhibitors for several target proteins.
- Exclude charges primarily associated with asset impairment and restructuring charges related to the asset impairment and restructuring charges related to the sale of the Posilac (rbST) brand and the October 2, 2018 sale of the Augusta, Georgia manufacturing site. The charges also include expenses associated with the initial public offering and separation of the Elanco animal health business.
- Relates to adjustments to the 2017 Toll Tax for U.S. tax reform proposed regulations and tax expenses associated with the separation of the Elanco animal health business.

(d) Adjustments to certain GAAP reported measures for the three months ended September 30, 2017, include the following:

(Dollars in millions, except per share data)	Amortization(i)	IPR&D(ii)	Other specified items(iii)	Total Adjustments
Cost of sales	\$ (154.5)	\$ —	\$ (5.5)	\$ (160.0)
Operating expenses	(1.3)	—	—	(1.3)
Acquired in-process research and development	—	(205.0)	—	(205.0)
Asset impairment, restructuring and other special charges	—	—	(406.5)	(406.5)
Income taxes	46.8	71.8	103.3	221.9
Net income	109.0	133.3	308.7	550.9
Earnings per share – diluted	0.10	0.13	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 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.

Eli Lilly and Company

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

(Dollars in millions, except per share data)

	Nine Months Ended September 30, 2018			Nine Months Ended September 30, 2017		
	GAAP Reported	Adjustments(c)	Non-GAAP Adjusted(a)	GAAP Reported	Adjustments(d)	Non-GAAP Adjusted(a)
Cost of sales	\$ 4,836.3	\$ (487.8)	\$ 4,348.5	\$ 4,505.9	\$ (537.1)	\$ 3,968.8
Operating expenses(b)	8,623.6	(3.7)	8,619.9	8,747.0	(4.9)	8,742.1
Acquired in-process research and development	1,654.5	(1,654.5)	—	1,062.6	(1,062.6)	—
Asset impairment, restructuring and other special charges	236.0	(236.0)	—	670.4	(670.4)	—
Other income (expense)	90.1	(25.8)	64.3	188.6	—	188.6
Income taxes	749.8	86.2	836.0	460.5	404.2	864.6
Net income	2,107.0	2,270.0	4,377.0	1,452.8	1,870.8	3,323.7
Earnings per share – diluted	2.03	2.19	4.22	1.37	1.77	3.14

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, 2018, include the following:

(Dollars in millions, except per share data)	Amortization ⁽ⁱ⁾	IPR&D ⁽ⁱⁱ⁾	Other specified items ⁽ⁱⁱⁱ⁾	Income taxes ^(iv)	Total Adjustments
Cost of sales	\$ (455.0)	\$ —	\$ (32.8)	\$ —	\$ (487.8)
Operating expenses	(3.7)	—	—	—	(3.7)
Acquired in-process research and development	—	(1,654.5)	—	—	(1,654.5)
Asset impairment, restructuring and other special charges	—	—	(236.0)	—	(236.0)
Other income (expense)	—	—	(25.8)	—	(25.8)
Income taxes	89.8	20.3	31.5	(55.5)	86.2
Net income	368.9	1,634.1	211.4	55.5	2,270.0
Earnings per share – diluted	0.36	1.57	0.21	0.05	2.19

Numbers may not add due to rounding.

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

- Exclude amortization of intangibles primarily associated with costs of marketed products acquired or licensed from third parties.
- 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 were related to business development activity, primarily driven by the acquisitions of ARMO BioSciences (\$1.476B) and AurKa Pharma (\$81.8M), as well as collaborations with Sigilon Therapeutics (\$66.9M) and Anima Biotech (\$30.0M).
- Exclude charges primarily associated with asset impairment and restructuring charges related to expenses associated with the sale of the Posilac® (rbST) brand and Augusta, Georgia manufacturing site, the review of strategic alternatives for, including expenses associated with the initial public offering and separation of, the Elanco animal health business, as well as charges related to the suspension of commercial activities for Imrestor.
- Relates to adjustments to the 2017 Toll Tax for U.S. tax reform proposed regulations and tax expenses associated with the separation of the Elanco animal health business.

(d) Adjustments to certain GAAP reported measures for the nine months ended September 30, 2017, include the following:

(Dollars in millions, except per share data)	Amortization(i)	IPR&D(ii)	Other specified items(iii)	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	174.9	404.2
Net income	352.6	990.8	527.4	1,870.8
Earnings per share – diluted	0.33	0.94	0.50	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 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, asset impairments related to the acquisition and integration of Novartis Animal Health, as well as inventory step-up costs associated with the acquisition of Boehringer Ingelheim Vetmedica's U.S. feline, canine and rabies vaccine portfolio.