### SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

### FORM 8-K

Current Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): July 24, 2018

### ELI LILLY AND COMPANY

(Exact name of registrant as specified in its charter)

Indiana (State or Other Jurisdiction of Incorporation)

Lilly Corporate Center 001-06351
Indianapolis, Indiana (Commission (Address of Principal File Number)
Executive Offices)

**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))

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

The information in this Item 2.02, including Exhibit 99.1 attached, 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 <u>Exhibit 99.1</u> and incorporated by reference into this Item 2.02 is a copy of the press release, dated July 24, 2018, announcing our results of operations for the second quarter and three-month period ended June 30, 2018, including, among other things, unaudited operating results for those periods.

# Item 9.01. Financial Statements and Exhibits

Exhibit Number Description

99.1 Press release dated July 24, 2018

# **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. ZakrowskiName: Donald A. ZakrowskiTitle: Vice President, Finance and Chief Accounting Officer

Dated: July 24, 2018

# EXHIBIT INDEX

Exhibit Number Exhibit

99.1 <u>Press release dated July 24, 2018</u>



July 24, 2018

### **Eli Lilly and Company**

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For Release: Immediately

**Refer to:** Mark Taylor; mark.taylor@lilly.com; (317) 276-5795 (Media) Kevin Hern; hern\_kevin\_r@lilly.com; (317) 277-1838 (Investors)

# Lilly Delivers Strong Second-Quarter 2018 Results, Revises EPS Guidance

- Second-quarter 2018 revenue increased 9 percent, driven primarily by the increased demand for new pharmaceutical products, while operating expenses declined.
- Second-quarter 2018 earnings per share (EPS) were a loss of \$0.25 on an as-reported basis, primarily due to charges related to recent business development transactions. On a non-GAAP basis, second-quarter 2018 EPS increased to \$1.50.
- Pharmaceutical revenue in the second quarter of 2018 grew 10 percent. New pharmaceutical products, including Trulicity, Taltz, Cyramza, Basaglar, Jardiance, Lartruvo, Verzenio, and Olumiant, represented 28 percent of total revenue and drove 12 percent volume growth.
- Elanco Animal Health to be separated through initial public offering.
- Olumiant approved and launched in the U.S.; positive Phase 3 data readouts for tanezumab, Taltz, Trajenta, empagliflozin and galcanezumab, while lanabecestat discontinued.
- Acquired ARMO BioSciences and its immuno-oncology asset, pegilodecakin.
- 2018 EPS guidance range revised to \$3.19 to \$3.29 on a reported basis and \$5.40 to \$5.50 on a non-GAAP basis.

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

\$ in millions, except per share data	Second	<u>%</u>	
	<u>2018</u>	<u>2017</u>	<u>Change</u>
Revenue	\$ 6,355.2	\$ 5,824.3	9%
Net Income (Loss) – Reported	(259.9)	1,008.0	NM
Earnings (Loss) Per Share – Reported	(0.25)	0.95	NM
Net Income – Non-GAAP	1,546.7	1,177.4	31%
EPS – Non-GAAP	1.50	1.11	35%

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 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 results once more in the second quarter in terms of operational performance, pipeline advancements, and strategic objectives," said David A. Ricks, Lilly's chairman and CEO. "The increase in our worldwide revenue was fueled by volume growth of our new medicines, while we also maintained a keen focus on containing costs and improving productivity. Our pipeline continued to demonstrate our commitment to scientific innovation, highlighted by forward progress for key molecules, several positive late-stage data readouts and the addition of promising new assets through business development. In addition, the strategic decision to pursue an IPO for our Elanco animal

health business will maximize the after-tax value for Lilly shareholders and provide Lilly with even greater focus on our human pharmaceutical business."

"As it relates to U.S. drug pricing, the Administration has accelerated an important discussion, and Lilly is committed to working for greater affordability and access to our medicines," added Ricks. "We have not taken a list price increase on any of our medicines since the President's Blueprint was announced, as we remain focused on driving revenue growth through volume, not price. Our second-quarter 2018 results reflect this strategy, and the guidance we have provided for 2018 does not assume U.S. price increases for the remainder of the year. As the responses to the Blueprint are considered, we are hopeful that progress will be made on implementing proposals that lower the out-of-pocket cost of medicines for patients."

# **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., the 2-mg dose of Olumiant® (baricitinib), a once-daily oral medication for the treatment of adults with moderately-to-severely active rheumatoid arthritis (RA) who have had an inadequate response to one or more tumor necrosis factor (TNF) inhibitor therapies.
- The FDA approved a label update for Taltz<sup>®</sup> (ixekizumab) injection 80 mg/mL to include data in psoriasis involving the genital area. The company also received a positive opinion from the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) regarding this label update for Taltz.
- The FDA granted approval for a new indication for Alimta<sup>®</sup> (pemetrexed for injection) in combination with carboplatin and Keytruda<sup>®</sup> (pembrolizumab) for the initial treatment of patients with metastatic nonsquamous non-small cell lung cancer (NSCLC), irrespective of PD-L1 expression status.
- The FDA approved a label update for Trulicity<sup>®</sup> to show the medicine's safety and efficacy in people with type 2 diabetes who have moderate to severe chronic kidney disease (CKD).

#### Clinical

- The company announced that galcanezumab-gnlm met its primary endpoint in a Phase 3 study of patients with episodic cluster headache, demonstrating statistically significant differences in the reduction of weekly cluster headache attacks compared to placebo across weeks one to three of the two-month, double-blind treatment period. The company also announced that a separate Phase 3 study of galcanezumab-gnlm for patients with chronic cluster headache did not meet its primary endpoint. Based on results from the episodic cluster headache trial, the company is working with regulatory agencies around the world to determine the best path forward.
- The company and Pfizer announced that a Phase 3 study of tanezumab in patients with osteoarthritis (OA) pain met all three co-primary endpoints. Tanezumab is part of an investigational class of pain medications known as nerve growth factor inhibitors and in addition to OA pain, is being evaluated for chronic low back pain and cancer pain (due to bone metastases).
- The company and Boehringer Ingelheim announced positive top-line results from a trial that evaluated the impact of treatment with Tradjenta<sup>®</sup> compared with placebo on cardiovascular safety on top of standard of care.
- The company and AstraZeneca announced the discontinuation of the global Phase 3 clinical trials of lanabecestat, an oral beta secretase cleaving enzyme (BACE) inhibitor, for the treatment of Alzheimer's disease. The decision was based on recommendations by an independent data monitoring committee, which concluded that both a trial in early Alzheimer's disease and a trial in mild Alzheimer's disease dementia were not likely to meet their primary endpoints upon completion and therefore should be stopped for futility.
- The company announced that a Phase 3 study of Taltz for the treatment of Ankylosing Spondylitis (AS), also known as radiographic axial spondyloarthritis (r-axSpA), met its primary and major secondary endpoints. The company plans to submit Taltz for U.S. regulatory approval in AS later this year.
- The company and Boehringer Ingelheim announced that two Phase 3 studies investigating the use of empagliflozin in combination with insulin therapy in adults with type 1 diabetes, met their primary endpoints.

### **Business Development/Other Developments**

• The company completed its strategic review of Elanco Animal Health, and will file a registration statement in the coming

weeks with the U.S. Securities and Exchange Commission (SEC) for a potential initial public offering (IPO) of a minority ownership stake in Elanco as a separate company. The offering is expected to represent an ownership stake of less than 20 percent. The number of shares to be offered and the price range for the offering have not yet been determined. The company expects to complete the IPO process during the second half of 2018.

- The company acquired ARMO BioSciences, an immuno-oncology company, and its lead product candidate pegilodecakin, which has demonstrated clinical benefit as a single agent, and in combination with both chemotherapy and checkpoint inhibitor therapy, across several tumor types.
- The company acquired AurKa Pharma, and its oncology compound AK-01, an Aurora kinase A inhibitor that is a potential first-in-class asset being studied in Phase 1 clinical trials in multiple types of solid tumors.
- The U.S. District Court for the Southern District of Indiana ruled in favor of Lilly that the Alimta vitamin regimen patent would be infringed by a competitor that had stated its intent to market alternative salt forms of pemetrexed prior to the patent's expiration in May 2022. In a separate decision, the District Court also ruled in favor of Lilly, denying another competitor's motion for summary judgment and granting Lilly's cross-motion for summary judgment. Both of these rulings have been appealed.
- The company completed its previously-announced \$5 billion share repurchase program and has authorized a new \$8 billion share repurchase program.

# Second-Quarter Reported Results

In the second quarter of 2018, worldwide revenue was \$6.355 billion, an increase of 9 percent compared with the second quarter of 2017. The revenue increase was driven by a 7 percent increase due to volume and a 2 percent increase due to the favorable impact of foreign exchange rates.

Revenue in the U.S. increased 8 percent, to \$3.602 billion, driven primarily by increased volume for new pharmaceutical products, including Trulicity, Basaglar<sup>®</sup>, Taltz, and Verzenio<sup>TM</sup>, as well as an increase in U.S. collaboration revenue, partially offset by decreased volume for products that have lost exclusivity, including Effient<sup>®</sup> and Strattera<sup>®</sup>.

Revenue outside the U.S. increased 10 percent, to \$2.753 billion, largely due to increased volume for new pharmaceutical products, including Trulicity, Olumiant, and Taltz, as well as the favorable impact of foreign exchange rates. The increase in revenue was partially offset by decreased volume for Cialis<sup>®</sup>, as well as lower realized prices for several pharmaceutical products.

Gross margin increased 9 percent, to \$4.653 billion, in the second quarter of 2018 compared with the second quarter of 2017. Gross margin as a percent of revenue was 73.2 percent, an increase of 0.2 percentage points compared with the second quarter of 2017. The increase in gross margin percent

was primarily due to manufacturing efficiencies, largely offset by the effect of foreign exchange rates on international inventories sold and the timing of manufacturing production.

Operating expenses in the second quarter of 2018, defined as the sum of research and development and marketing, selling, and administrative expenses, decreased 1 percent to \$2.987 billion, reflecting previously-announced actions taken to reduce the company's cost structure. Research and development expenses increased 5 percent, to \$1.333 billion, or 21.0 percent of revenue. This increase was primarily due to additional late-stage development expenditures. Marketing, selling, and administrative expenses decreased 4 percent, to \$1.654 billion, due to decreased expenses related to late life-cycle products, partially offset by increased expenses related to new pharmaceutical products.

In the second quarter of 2018, the company recognized acquired in-process research and development charges of \$1.624 billion related to the acquisitions of ARMO BioSciences and AurKa Pharma, as well as a collaboration with Sigilon Therapeutics. There were no acquired in-process research and development charges in the second quarter of 2017.

In the second quarter of 2018, the company recognized asset impairment, restructuring, and other special charges of \$74.4 million. The charges were primarily associated with asset impairments and contractual commitments related to the suspension of commercial activities for Imrestor<sup>®</sup>, an animal health product, as well as expenses associated with the review of strategic alternatives for the Elanco animal health business. In the second quarter of 2017, the company recognized asset impairment, restructuring, and other special charges of \$50.0 million, primarily associated with integration costs and asset impairments related to the acquisition and integration of Novartis Animal Health.

Operating income (loss) in the second quarter of 2018 was a loss of \$33.2 million, compared to income of \$1.200 billion in the second quarter of 2017. The operating loss was primarily driven by the acquired in-process research and development charges described above.

Other income (expense) was income of \$38.0 million in the second quarter of 2018, compared with income of \$60.4 million in the second quarter of 2017.

During the second quarter of 2018, the company incurred \$264.7 million of tax expense, despite earning \$4.8 million of income before taxes, as a result of the non-deductible acquired in-process research and development charges totaling \$1.558 billion related to the acquisitions of ARMO BioSciences and AurKa Pharma. During the second quarter of 2017, the company's effective tax rate was 20.0 percent.

In the second quarter of 2018, net income (loss) and earnings (loss) per share were a loss of \$259.9 million and \$0.25, respectively, compared with income of \$1.008 billion and earnings per share of \$0.95 in the second quarter of 2017. These decreases in net income (loss) and earnings (loss) per share were primarily driven by the acquired in-process research and development charges described above.

### Second-Quarter Non-GAAP Measures

On a non-GAAP basis, second-quarter 2018 gross margin increased 9 percent, to \$4.838 billion. Gross margin as a percent of revenue was 76.1 percent, a decrease of 0.2 percentage points compared with the second quarter of 2017. The decrease in gross margin percent was primarily due to the effect of foreign exchange rates on international inventories sold and the timing of manufacturing production, largely offset by manufacturing efficiencies.

Reflecting the company's previously-announced actions to reduce its cost structure, operating expenses were 47.0 percent of revenue in the second quarter of 2018, a reduction of 4.5 percentage points compared with the second quarter of 2017.

Operating income increased \$408.2 million, or 28 percent, to \$1.852 billion in the second quarter of 2018, primarily due to higher revenue and lower operating expenses.

The effective tax rate was 17.0 percent in the second quarter of 2018, compared with 21.7 percent in the second quarter of 2017. The lower effective tax rate for the second quarter of 2018 was primarily due to U.S. tax reform enacted in December 2017.

In the second quarter of 2018, net income increased 31 percent, to \$1.547 billion, and earnings per share increased 35 percent, to \$1.50, compared with \$1.177 billion and \$1.11, respectively, in the second 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.

			Seco	<u>ond Quarter</u>	
			<u>2017</u>	% Change	
Earnings (loss) per share (reported)	\$	(0.25)	\$	0.95	NM
Acquired in-process research and development		1.56		_	
Amortization of intangible assets		.12		.12	
Asset impairment, restructuring and other special charges		.06		.03	
Other, net		.01		.01	
Earnings per share (non-GAAP)	\$	1.50	\$	1.11	35%
Numbers may not add due to rounding.					

# Year-to-Date Results

For the first six months of 2018, worldwide revenue increased 9 percent, to \$12.055 billion, compared with \$11.053 billion in the same period in 2017. Reported net income and earnings per share were \$957.5 million and \$0.92, respectively.

### Year-to-Date Non-GAAP Measures

For the first six months of 2018, net income and earnings per share, on a non-GAAP basis, were \$2.953 billion and \$2.83, 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>	% Change		
Earnings per share (reported)	\$	0.92	\$	0.85	8%		
Acquired in-process research and development		1.55		.81			
Amortization of intangible assets		.24		.23			
Asset impairment, restructuring and other special charges		.13		.19			
Other, net		.01		.02			
Earnings per share (non-GAAP)	\$	2.83	\$	2.10	35%		
Numbers may not add due to rounding.	:						

# Selected Revenue Highlights

(Dollars in millions)	Second	Quarter	Year-to-Date				
Established Pharma Products	2018	2017	% Change	2018	2017	% Change	
Humalog®	\$ 769.8	\$ 678.4	13%	\$ 1,561.5	\$ 1,386.8	13%	
Alimta	555.9	532.9	4%	1,055.5	1,022.8	3%	
Cialis	538.7	627.3	(14)%	1,034.1	1,160.9	(11)%	
Forteo®	434.5	446.7	(3)%	747.8	794.2	(6)%	
Humulin®	346.0	357.8	(3)%	671.9	672.3	(0)%	
Cymbalta <sup>®</sup>	181.9	206.6	(12)%	351.5	381.2	(8)%	
Erbitux®	166.4	159.1	5%	316.1	313.5	1%	
Trajenta(a)	141.7	141.9	(0)%	282.8	254.9	11%	
Zyprexa®	128.0	140.8	(9)%	250.6	288.3	(13)%	
Strattera	114.2	186.6	(39)%	244.9	382.8	(36)%	
Select Products Launched Since 2014							
Trulicity	779.8	480.2	62%	1,458.1	853.1	71%	
Cyramza®	218.8	186.3	17%	402.4	357.6	13%	
Basaglar	201.8	86.6	133%	367.8	132.6	177%	
Taltz	220.1	138.7	59%	366.5	235.4	56%	
Jardiance(b)®	147.2	103.2	43%	298.2	177.1	68%	
Lartruvo <sup>TM</sup>	79.9	47.4	69%	144.3	89.5	61%	
Verzenio	57.7	_	NM	87.4	_	NM	
Olumiant	44.7	4.8	NM	76.9	6.6	NM	
Subtotal	1,750.0	1,047.3	67%	3,201.7	1,851.9	73%	
Animal Health	792.1	784.8	1%	1,553.4	1,554.2	(0)%	
Total Revenue	6,355.2	5,824.3	9%	12,055.2	11,052.6	9%	
(a) Trajenta includes Jentadueto® (b) Jardiance includes Glyxambi® and S	ynjardy®						

NM – not meaningful Numbers may not add due to rounding

#### **Selected Established Pharma Products**

# **Humalog**

For the second quarter of 2018, worldwide Humalog revenue increased 13 percent compared with the second quarter of 2017, to \$769.8 million. Revenue in the U.S. increased 19 percent, to \$464.5 million driven by higher realized prices due to changes in estimates to rebates and discounts and changes in payer segment mix, and, to a lesser extent, increased volume. Revenue outside the U.S. increased 6 percent, to \$305.2 million, driven by the favorable impact of foreign exchange rates and increased volume, partially offset by lower realized prices.

#### Alimta

For the second quarter of 2018, Alimta generated worldwide revenue of \$555.9 million, which increased 4 percent compared with the second quarter of 2017. U.S. Alimta revenue increased 3 percent, to \$281.3 million, driven by increased demand and customer buying patterns. Alimta revenue outside the U.S. increased 6 percent, to \$274.6 million, driven by the favorable impact of foreign exchange rates and higher realized prices, partially offset by decreased volume driven by competitive pressure and loss of exclusivity in several countries.

#### Cialis

For the second quarter of 2018, worldwide Cialis revenue decreased 14 percent to \$538.7 million. U.S. Cialis revenue was \$345.7 million in the second quarter, a 9 percent decrease compared with the second quarter of 2017, driven by decreased demand due to the entry of generic sildenafil, partially offset by higher realized prices. The company now expects the entry of generic tadalafil in the U.S. in late September 2018. Cialis revenue outside the U.S. decreased 22 percent to \$193.0 million, driven by the loss of exclusivity in Europe and, to a lesser extent, lower realized prices, partially offset by the favorable impact of foreign exchange rates.

#### Forteo

For the second quarter of 2018, worldwide revenue for Forteo was \$434.5 million, a 3 percent decrease compared with the second quarter of 2017. U.S. revenue decreased 10 percent, to \$224.5 million, primarily due to decreased demand and lower realized prices. Revenue outside the U.S. increased 7 percent, to \$210.0 million, driven by the favorable impact of foreign exchange rates and, to a lesser extent, increased volume, partially offset by lower realized prices.

# **Humulin**

For the second quarter of 2018, worldwide Humulin revenue decreased 3 percent compared with the second quarter of 2017, to \$346.0 million. U.S. revenue increased 5 percent, to \$238.8 million, driven by higher realized prices. Revenue outside the U.S. decreased 18 percent, to \$107.2 million, driven by decreased volume, primarily in China, partially offset by the favorable impact of foreign exchange rates.

#### **Select Products Launched Since 2014**

# **Trulicity**

Second-quarter 2018 worldwide Trulicity revenue was \$779.8 million, an increase of 62 percent compared with the second quarter of 2017. U.S. revenue increased 61 percent, to \$612.4 million, primarily driven by higher demand as a result of increased share of market for Trulicity and growth in the GLP-1 class. Revenue outside the U.S. was \$167.4 million, an increase of 69 percent, primarily driven by increased volume and, to a lesser extent, the favorable impact of foreign exchange rates, partially offset by lower realized prices.

### **Cyramza**

For the second quarter of 2018, worldwide Cyramza revenue was \$218.8 million, an increase of 17 percent compared with the second quarter of 2017. U.S. revenue was \$75.4 million, an increase of 10 percent, driven primarily by increased volume. Revenue outside the U.S. was \$143.3 million, an

increase of 22 percent, driven by increased volume, and, to a lesser extent, the favorable impact of foreign exchange rates.

# **Basaglar**

For the second quarter of 2018, Basaglar generated worldwide revenue of \$201.8 million. U.S. revenue was \$156.5 million, an increase of \$29.8 million compared with the first quarter of 2018, driven by increased demand. Revenue outside the U.S. was \$45.3 million, an increase of \$6.0 million compared with the first quarter of 2018. 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.

# **Taltz**

For the second quarter of 2018, worldwide Taltz revenue was \$220.1 million, an increase of 59 percent compared with the second quarter of 2017. U.S. revenue was \$173.6 million, an increase of 39 percent, driven by higher demand, partially offset by lower realized prices. Revenue outside the U.S. was \$46.5 million, an increase of \$32.2 million, driven by increased volume from new launches.

### **Jardiance**

The company's worldwide Jardiance revenue during the second quarter of 2018 was \$147.2 million, an increase of 43 percent compared with the second quarter of 2017. U.S. revenue increased 28 percent, to \$85.6 million, driven by increased demand, partially offset by lower realized prices due to changes in estimates to rebates and discounts. Revenue outside the U.S. was \$61.6 million, an increase of 70 percent, primarily driven by increased volume and, to a lesser extent, the favorable impact of foreign exchange rates. 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 second quarter of 2018, Lartruvo generated worldwide revenue of \$79.9 million. U.S. revenue was \$51.3 million, an increase of \$8.3 million compared with the first quarter of 2018. Revenue outside the U.S. was \$28.6 million, an increase of \$7.2 million compared with the first quarter of 2018.

#### Verzenio

For the second quarter of 2018, Verzenio, a treatment for women with HR+, HER2- advanced breast cancer, generated U.S. revenue of \$57.7 million, an increase of \$28.0 million compared with the first quarter of 2018.

### **Olumiant**

For the second quarter of 2018, Olumiant generated worldwide revenue of \$44.7 million. U.S. revenue was \$1.7 million due to initial wholesaler stocking. Olumiant was launched in the U.S. in June 2018. Revenue outside the U.S. was \$42.9 million, an increase of \$10.7 million compared with the first quarter of 2018, reflecting uptake of new launches in Europe.

#### **Animal Health**

In the second quarter of 2018, worldwide animal health revenue totaled \$792.1 million, an increase of 1 percent compared with the second quarter of 2017. Worldwide food animal revenue increased 4 percent, to \$491.7 million, primarily driven by the favorable impact of foreign exchange rates, increased volume, and higher realized prices. Worldwide companion animal revenue decreased 4 percent, to \$300.5 million, primarily driven by decreased volume, partially offset by higher realized prices, and, to a lesser extent, the favorable impact of foreign exchange rates.

# 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 \$3.19 to \$3.29, due to higher acquired in-process research and development charges associated with the acquisition of ARMO BioSciences, partially offset by higher revenue. On a non-GAAP basis, earnings per share are now expected to be in the range of \$5.40 to \$5.50, reflecting company expectations of higher revenue and higher gross margin percent.

	2018	
	Expectations	% Change from 2017
Earnings per share (reported)	\$3.19 to \$3.29	NM
Amortization of intangible assets	.43	
Asset impairment, restructuring and other special charges	.19	
Acquired in-process research and development	1.58	
Other, net	.01	
Earnings per share (non-GAAP)	\$5.40 to \$5.50	26% to 29%
Numbers may not add due to rounding		

The company now anticipates 2018 revenue between \$24.0 billion and \$24.5 billion. The increase from prior guidance is due to strong performance across the pharmaceutical portfolio, particularly in diabetes, as well as higher collaboration revenue, partially offset by the impact of foreign exchange rates. Revenue growth is still expected to be driven by new products including Trulicity, Taltz, Basaglar, Jardiance, Verzenio, Cyramza, Olumiant and Lartruvo.

Gross margin percentage is now expected to be approximately 73.5 percent on a reported basis, and approximately 76 percent on a non-GAAP basis.

The 2018 effective tax rate is now expected to be approximately 22.5 percent on a reported basis, due to higher non-deductible inprocess research and development charges associated with the acquisitions of ARMO BioSciences and AurKa Pharma. On a non-GAAP basis, the effective tax rate is still expected to be approximately 17 percent. 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>	Revised					
Revenue	\$23.7 to \$24.2 billion	\$24.0 to \$24.5 billion					
Gross Margin % of Revenue (reported)	Approx. 73%	Approx. 73.5%					
Gross Margin % of Revenue (non-GAAP)	Approx. 75%	Approx. 76%					
Marketing, Selling & Administrative	\$6.2 to \$6.5 billion	Unchanged					
Research & Development	\$5.2 to \$5.4 billion	Unchanged					
Other Income/(Expense)	\$75 to \$200 million	Unchanged					
Tax Rate (reported)	Approx. 17%	Approx. 22.5%					
Tax Rate (non-GAAP)	Approx. 17%	Unchanged					
Earnings per share (reported)	\$4.52 to \$4.62	\$3.19 to \$3.29					
Earnings per share (non-GAAP)	\$5.10 to \$5.20	\$5.40 to \$5.50					
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 second-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 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. 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; and the impact of exchange rates and global macroeconomic conditions. With respect to the potential initial public offering of the Elanco animal health business, there are significant risks and uncertainties relating to the potential IPO of Elanco. There can be no guarantees that the IPO will be consummated on the timeline anticipated or at all or that Lilly will achieve the anticipated benefits of the IPO. Lilly's ability to consummate and achieve the anticipated benefits of the potential IPO may be materially affected by such factors as changes to the business, results of operation or financial condition of Elanco or Lilly; changes in the animal health or pharmaceutical industries; adverse market or macroeconomic conditions; and other factors outside Lilly's control that could affect the advisability, pricing and timing of the potential Elanco IPO. 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 ex

pressly disclaims any obligation to publicly release any revisions to forward-looking statements to reflect events after the date of this release.

# # #

Alimta® (pemetrexed disodium, Lilly)

Basaglar® (insulin glargine injection, Lilly)

Cialis® (tadalafil, Lilly)

Cymbalta® (duloxetine hydrochloride, Lilly)

Cyramza® (ramucirumab, Lilly)

Effient® (prasugrel, 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)

Imrestor® (pegbovigrastim injection, Lilly)

Jardiance® (empagliflozin, Boehringer Ingelheim)

Jentadueto® (linagliptin/metformin HCl, Boehringer Ingelheim)

Keytruda® (pembrolizumab, Merck)

Lartruvo<sup>TM</sup> (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<sup>TM</sup> (abemaciclib, Lilly)

Zyprexa® (olanzapine, Lilly)

Eli Lilly and Company Employment Information

June 30, 2018

Worldwide Employees

38.160

December 31, 2017

40,655

Eli Lilly and Company
Operating Results (Unaudited) – REPORTED
(Dollars in millions, except per share data)

	Three Months Ended June 30,					Si		nths Ended ne 30,	
	 2018		2017	% Chg.		2018		2017	% Chg.
Revenue	\$ 6,355.2	\$	5,824.3	9%	\$	12,055.2	\$	11,052.6	9 %
Cost of sales	1,702.7		1,571.7	8%		3,274.0		2,919.6	12 %
Research and development	1,333.1		1,272.1	5%		2,510.0		2,530.4	(1)%
Marketing, selling and administrative	1,653.7		1,730.4	(4)%		3,153.7		3,298.1	(4)%
Acquired in-process research and development	1,624.5		_	NM		1,624.5		857.6	89 %
Asset impairment, restructuring and other special charges	 74.4	_	50.0	49%		152.7		263.9	(42)%
Operating income (loss)	(33.2)		1,200.1	NM		1,340.3		1,183.0	13 %
Net interest income (expense)	(22.1)		(16.7)			(37.8)		(30.7)	
Net other income (expense)	60.1		77.1			143.3		169.4	
Other income (expense)	 38.0	_	60.4	(37)%	_	105.5	_	138.7	(24)%
Income before income taxes	4.8		1,260.5	(100)%		1,445.8		1,321.7	9 %
Income taxes	 264.7	_	252.5	5%		488.3		424.5	15 %
Net income (loss)	\$ (259.9)	\$_	1,008.0	NM	\$	957.5	\$	897.2	7 %
Earnings (loss) per share	\$ (0.25)	\$_	0.95	NM	\$	0.92	\$	0.85	8 %
Dividends paid per share	\$ 0.5625	\$	0.52	8%	\$	1.125	\$	1.04	8 %
Weighted-average shares outstanding (thousands)  NM – not meaningful	 1,030,210		1,057,110		3 *	1,041,561		1,057,543	1.

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 six months ended June 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 June 30, 2018							Three Months Ended June 30, 2017				
	GAAP Reported	Non-GAAI Adjustments(c) Adjusted(a)		_	_	GAAP Reported	Adjustments(d)		Non-GAAP Adjusted <sup>(a)</sup>			
Cost of sales	\$ 1,702.7	\$	(185.4)	\$	1,517.3	\$	1,571.7	\$	(192.4)	\$	1,379.3	
Operating expenses(b)	2,986.8		(1.3)		2,985.5		3,002.5		(1.8)		3,000.8	
Acquired in-process research and development	1,624.5		(1,624.5)		_		_		_		_	
Asset impairment, restructuring and other special charges	74.4		(74.4)		_		50.0		(50.0)		_	
Other income (expense)	38.0		(25.8)		12.2		60.4		_		60.4	
Income taxes	264.7		53.3		317.9		252.5		74.7		327.2	
Net income (loss)	(259.9)		1,806.6		1,546.7		1,008.0		169.5		1,177.4	
Earnings (loss) per share	(0.25)		1.75		1.50		0.95		0.16		1.11	

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 June 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 June 30, 2018, include the following:

(Dollars in millions, except per share data)	Amortization(i)	IPR&D(ii)	Other specified items(iii)	Total Adjustments
Cost of sales	\$ (151.6) \$	<u> </u>	33.8) \$	(185.4)
Operating expenses	(1.3)	_	_	(1.3)
Acquired in-process research and development	_	(1,624.5)	_	(1,624.5)
Asset impairment, restructuring and other special charges	_	_	(74.4)	(74.4)
Other income (expense)	_	_	(25.8)	(25.8)
Income taxes	30.0	14.0	9.2	53.3
Net income	123.0	1,610.5	73.2	1,806.6
Earnings per share	0.12	1.56	0.07	1.75

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 were related to business development activity, primarily driven by the acquisitions of ARMO BioSciences (\$1.476B) and AurKa Pharma (\$81.8M), as well as a collaboration with Sigilon Therapeutics (\$66.9M).
- iii. Exclude charges primarily associated with asset impairment and restructuring charges related to the suspension of commercial activities for Imrestor, as well as expenses associated with the review of strategic alternatives for the Elanco Animal Health business.

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

(Dollars in millions, except per share data)	A	.mortization(i)	Other specified items(ii)	Total Adjustments
Cost of sales	\$	(176.3)	\$ (16.1) \$	(192.4)
Operating expenses		(1.8)	_	(1.8)
Asset impairment, restructuring and other special charges		_	(50.0)	(50.0)
Income taxes		55.4	19.3	74.7
Net income		122.7	46.8	169.5
Earnings per share – diluted		0.12	0.04	0.16

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 primarily associated with integration costs and 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.

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

Six Months Ended Six Months Ended June 30, 2018 June 30, 2017 **GAAP** Non-GAAP **GAAP** Non-GAAP Reported Adjustments(c) Adjusted(a) Reported Adjustments(d) Adjusted(a) Cost of sales 3,274.0 (336.5)2,937.5 2,919.6 \$ (377.1)\$ 2,542.5 Operating expenses(b) 5,663.7 (2.6)5,661.1 5,828.5 (3.6)5,825.0 Acquired in-process research and development 1,624.5 (1,624.5)857.6 (857.6)Asset impairment, restructuring and other special charges 152.7 (152.7)263.9 (263.9)Other income (expense) 105.5 (25.8)79.7 138.7 138.7 Income taxes 488.3 95.2 583.5 424.5 182.3 606.8 Net income 957.5 1,995.3 2,952.8 897.2 1,319.9 2,217.0 0.85 Earnings per share – diluted 0.92 1.92 2.83 1.25 2.10

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

Numbers may not add due to rounding.

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

- (b) Operating expenses include research and development and marketing, selling and administrative expenses.
- (c) Adjustments to certain GAAP reported measures for the six months ended June 30, 2018, include the following:

(Dollars in millions, except per share data)	Am	ortization <sup>(i)</sup>	IPR&D(ii)	Other specified items(iii)	Total Adjustments
Cost of sales	\$	(302.7) \$	_ 5	\$ (33.8) \$	(336.5)
Operating expenses		(2.6)	_	_	(2.6)
Acquired in-process research and development		_	(1,624.5)	_	(1,624.5)
Asset impairment, restructuring and other special charges		_	_	(152.7)	(152.7)
Other income (expense)		_	_	(25.8)	(25.8)
Income taxes		59.9	14.0	21.3	95.2
Net income		245.5	1,610.5	139.4	1,995.3
Earnings per share – diluted		0.24	1.55	0.13	1.92

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 were related to business development activity, primarily driven by the acquisitions of ARMO BioSciences(\$1.476B) and AurKa Pharma (\$81.8M), as well as a collaboration with Sigilon Therapeutics (\$66.9M).
- iii. Exclude charges primarily associated with asset impairment and restructuring charges related to the review of strategic alternatives for the Elanco Animal Health business, expenses associated with the decision to end Posilac® (rbST) production at the Augusta, Georgia manufacturing site, as well as charges related to the suspension of commercial activities for Imrestor.

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

(Dollars in millions, except per share data)	A	Amortization(i)	IPR&D(ii)	Other specified items(iii)	Total Adjustments
Cost of sales	\$	(350.6) \$	— \$	(26.5) \$	(377.1)
Operating expenses		(3.6)	_	_	(3.6)
Acquired in-process research and development		_	(857.6)	_	(857.6)
Asset impairment, restructuring and other special charges		_	_	(263.9)	(263.9)
Income taxes		110.6	_	71.7	182.3
Net income		243.5	857.6	218.7	1,319.9
Earnings per share – diluted		0.23	0.81	0.21	1.25

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.
- iii. Exclude charges related to severance costs incurred as a result of actions taken to reduce the company's cost structure, as well as integration costs and 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.