
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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 30, 2019

ELI LILLY AND COMPANY
(Exact Name of Registrant as Specified in Charter)

Indiana
(State or Other Jurisdiction
of Incorporation)

001-06351
(Commission
File Number)

35-0470950
(I.R.S. Employer
Identification No.)

Lilly Corporate Center
Indianapolis, Indiana 46285
(Address of Principal Executive Offices, and Zip Code)

(317) 276-2000
Registrant's Telephone Number, Including Area Code

Not Applicable
(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 (*see* General Instruction A.2. below):

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

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

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.

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock (no par value)	LLY	New York Stock Exchange
1.000% Notes Due June 2, 2022	LLY22	New York Stock Exchange
7.125% Notes Due June 1, 2025	LLY25	New York Stock Exchange
1.625% Notes Due June 2, 2026	LLY26	New York Stock Exchange
2.125% Notes Due June 3, 2030	LLY30	New York Stock Exchange
6.77% Notes Due January 1, 2036	LLY36	New York Stock Exchange

Item 2.02. Results of Operations and Financial Condition

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

Attached as [Exhibit 99.1](#) and incorporated by reference into this Item 2.02 is a copy of the press release, dated July 30, 2019, announcing our results of operations for the second quarter and three-month period ended June 30, 2019, including, among other things, unaudited operating results for such period.

Item 9.01. Financial Statements and Exhibits

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press release dated July 30, 2019, together with related attachments.

SIGNATURES

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

ELI LILLY AND COMPANY
(Registrant)

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

Dated: July 30, 2019

EXHIBIT INDEX

Exhibit Number

99.1

Exhibit

[Press release dated July 30, 2019, together with related attachments](#)



July 30, 2019

Eli Lilly and Company

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Indianapolis, Indiana 46285
U.S.A.
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www.lilly.com

For Release: Immediately

Refer to: Mark Taylor; mark.taylor@lilly.com; (317) 276-5795 (Media)
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Lilly Reports Second-Quarter 2019 Financial Results, Raises 2019 EPS Guidance

- Revenue in the second quarter of 2019 grew 1 percent, driven by 6 percent volume growth. Key growth products launched since 2014, including Trulicity, Taltz, Jardiance, Verzenio, Olumiant, Basaglar, Emgality and Cyramza, contributed 13 percentage points of revenue growth and represented approximately 43 percent of total revenue.
- Second-quarter 2019 operating expenses rose 8 percent, reflecting increased investments in recently launched medicines and the late-stage pipeline.
- Second-quarter 2019 earnings per share (EPS) were \$1.44 on a reported basis, or \$1.50 on a non-GAAP basis.
- Notable pipeline events included Baqsimi approval in the U.S., new indications for Cyramza and Emgality, and positive data readouts for Verzenio and Trulicity.
- 2019 EPS guidance raised to be in the range of \$8.58 to \$8.68 on a reported basis and \$5.67 to \$5.77 on a non-GAAP basis.

Eli Lilly and Company (NYSE: LLY) today announced financial results for the second quarter of 2019.

\$ in millions, except per share data	Second Quarter		%
	2019	2018	Change
Revenue	\$ 5,636.7	\$ 5,585.0	1%
Net Income (Loss) – Reported	1,327.2	(259.9)	NM
Earnings (Loss) per share – Reported	1.44	(0.25)	NM
Net Income – Non-GAAP	1,388.0	1,431.2	(3)%
EPS – Non-GAAP	1.50	1.48	1%

Certain financial information for 2019 and 2018 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), include all revenue and expenses recognized during the periods, and reflect Elanco Animal Health (Elanco) as discontinued operations for all periods presented. Non-GAAP measures reflect adjustments for the items described in the reconciliation tables later in the release, and assume that the disposition of Elanco occurred at the beginning of all periods presented (including the benefit from the reduction in shares of common stock outstanding). The company's 2019 financial guidance is being provided on both a reported and a non-GAAP basis. The non-GAAP measures are presented to provide additional insights into the underlying trends in the company's business.

"Lilly's portfolio of newer medicines reached more patients in the second quarter, allowing the company to grow revenue despite headwinds, including the expiration of the U.S. patent for Cialis," said David A. Ricks, Lilly's chairman and CEO. "We are continuing to make significant investments in our business to ensure the success of our recent product launches. At the same time, we are expanding investment in our pipeline in order to develop new medicines that have the potential to more effectively treat patients that have diabetes, cancer, autoimmune disorders and other serious conditions."

Key Events Over the Last Three Months

Regulatory

- The U.S. Food and Drug Administration (FDA) approved Cyramza[®] as a single agent for the treatment of patients with hepatocellular carcinoma (HCC) who have an alpha-fetoprotein (AFP) of ≥ 400 ng/mL and have been treated with sorafenib.
- The FDA approved Emgality[®] for the treatment of episodic cluster headache in adults.
- The FDA approved Baqsimi[™] (glucagon) nasal powder 3 mg for the treatment of severe hypoglycemia in people with diabetes ages four years and above.
- The FDA granted Fast Track designation to empagliflozin for the reduction of the risk of cardiovascular death and hospitalization for heart failure in people with chronic heart failure.
- Based on an assessment of the totality of subcutaneous tanezumab data and an initial discussion with the FDA during second-quarter 2019, the company and Pfizer have decided to pursue a U.S. regulatory submission for tanezumab in patients with moderate-to-severe osteoarthritis that is expected to be filed with the FDA by the first quarter of 2020, to be followed by potential regulatory filings in the EU and Japan. At this time, regulatory submissions are not planned for tanezumab in patients with moderate-to-severe chronic low back pain. The company and Pfizer intend to maintain an open dialogue with regulatory authorities on potential future regulatory pathways for tanezumab.

Clinical

- The company announced that Verzenio[®] demonstrated a statistically significant improvement in overall survival in a Phase 3 clinical trial evaluating Verzenio in combination with fulvestrant for the treatment of women with hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) advanced or metastatic breast cancer previously treated with endocrine therapy. The results were from a pre-planned interim analysis and are definitive. The company plans to submit these data to regulatory authorities and present the detailed data at an upcoming medical meeting later this year.
- The company announced that the clinical trial studying higher investigational doses (3.0 mg

and 4.5 mg) of Trulicity[®] met its primary efficacy endpoint of superiority, significantly reducing HbA1c from baseline in people with type 2 diabetes, compared to once-weekly Trulicity 1.5 mg after 36 weeks. The trial also met the secondary efficacy endpoint for superiority on weight reduction. The safety and tolerability profile of the investigational dulaglutide doses was consistent with the known profile of Trulicity 1.5 mg. The clinical trial will continue through 52 weeks to evaluate longer-term safety data and is expected to complete in late 2019. The company plans to submit to regulatory authorities by late 2019 and will share detailed results at a future date.

Business Development/Other Developments

- The company announced a license agreement to acquire the exclusive worldwide rights for CNTX-0290 from Centrexion Therapeutics Corporation. CNTX-0290 is a novel, small molecule somatostatin receptor type 4 agonist that is currently being studied in Phase 1 clinical testing as a potential non-opioid treatment for chronic pain conditions.

Second-Quarter Reported Results

In the second quarter of 2019, worldwide revenue was \$5.637 billion, an increase of 1 percent compared with the second quarter of 2018. The increase in revenue was driven by a 6 percent increase due to volume, partially offset by a 3 percent decrease due to lower realized prices, and a 2 percent decrease due to the unfavorable impact of foreign exchange rates.

Revenue in the U.S. was essentially flat at \$3.253 billion, as increased volume of 5 percent was almost entirely offset by lower realized prices. Increased U.S. volume for key growth products including Trulicity, Taltz[®], Jardiance[®], Verzenio[®], Basaglar[®], and Emgality, was largely offset by decreased volume for products that have lost exclusivity, including Cialis[®] and Adcirca[®], as well as the impact from the impending product withdrawal of Lartruvo. U.S. prices were negatively impacted by

increased coverage gap funding requirements in Medicare Part D, primarily driven by Trulicity and Humalog[®].

Revenue outside the U.S. increased 2 percent, to \$2.384 billion, driven by increased volume of 9 percent, which was primarily from key growth products, including Trulicity, Olumiant[®], Taltz, Jardiance, and Verzenio. The increase in revenue due to volume was largely offset by the unfavorable impact of foreign exchange rates and, to a lesser extent, lower realized prices.

Gross margin increased 4 percent, to \$4.512 billion, in the second quarter of 2019 compared with the second quarter of 2018. Gross margin as a percent of revenue was 80.0 percent, an increase of 2.1 percentage points compared with the second quarter of 2018.

The increase in gross margin percent

was primarily due to the favorable effect of foreign exchange rates on international inventories sold, lower intangibles amortization expense and greater manufacturing efficiencies, partially offset by unfavorable product mix and the impact of lower realized prices on revenue.

Operating expenses in the second quarter of 2019, defined as the sum of research and development and marketing, selling, and administrative expenses, increased 8 percent to \$2.989 billion compared with the second quarter of 2018. Research and development expenses increased 10 percent to \$1.402 billion, or 24.9 percent of revenue, driven by higher development expenses for late-stage assets. Marketing, selling, and administrative expenses increased 7 percent, to \$1.586 billion, primarily due to increased marketing expenses to support the recent U.S. launch of Emgality, as well as other key growth products.

In the second quarter of 2019, the company recognized acquired in-process research and development charges of \$25.0 million, related to the previously announced business development transaction with Avidity Biosciences, Inc. 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.

Operating income (loss) in the second quarter of 2019 was income of \$1.498 billion, compared to a loss of \$4.9 million in the second quarter of 2018. The increase in operating income was primarily driven by lower acquired in-process research and development charges.

Other income (expense) was expense of \$32.4 million in the second quarter of 2019, compared with income of \$46.6 million in the second quarter of 2018. The decrease in other income was primarily driven by higher net interest expense.

The effective tax rate was 9.5 percent in the second quarter of 2019, reflecting a net discrete tax benefit resulting from the resolution of certain global income tax audits. During the second quarter of 2018, the company incurred \$273.3 million of tax expense, despite earning \$41.7 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.

In the second quarter of 2019, net income and earnings per share were \$1.327 billion and \$1.44, respectively, compared with a net loss of \$259.9 million and loss per share of \$0.25 in the second quarter of 2018. The increases in net income and earnings per share in the second quarter of 2019 were primarily driven by lower acquired in-process research and development charges. Earnings per share in the second quarter of 2019 benefited compared to the second quarter of 2018 as a result of the Elanco exchange offer and share repurchases.

Second-Quarter Non-GAAP Measures

On a non-GAAP basis, second-quarter 2019 gross margin increased 2 percent, to \$4.563 billion compared with the second quarter of 2018. Gross margin as a percent of revenue was 81.0 percent, an increase of 1.2 percentage points. The increase in gross margin percent was primarily due to the favorable effect of foreign exchange rates on international inventories sold and greater manufacturing

efficiencies, partially offset by unfavorable product mix and the impact of lower realized prices on revenue.

Operating income on a non-GAAP basis decreased \$122.7 million, or 7 percent, to \$1.575 billion in the second quarter of 2019 compared with the second quarter of 2018, due to higher operating expenses, partially offset by higher gross margin.

The effective tax rate on a non-GAAP basis was 10.0 percent in the second quarter of 2019, compared with 16.7 percent in the second quarter of 2018. The lower effective tax rate for the second quarter of 2019 was primarily driven by a net discrete tax benefit resulting from the resolution of certain global income tax audits, as well as timing associated with the impact of U.S. tax reform.

On a non-GAAP basis, in the second quarter of 2019, net income decreased 3 percent, to \$1.388 billion, while earnings per share increased 1 percent, to \$1.50, compared with \$1.431 billion and \$1.48, respectively, in the second quarter of 2018. The decrease in net income was driven by lower operating income and, to a lesser extent, lower other income, partially offset by lower tax expense. Earnings per share increased due to a reduction in weighted average shares outstanding resulting from the company's share repurchase program. Non-GAAP weighted average shares outstanding for both periods have been reduced by the approximately 65 million shares retired in the Elanco exchange offer.

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>2019</u>	<u>Second Quarter</u> <u>2018</u>	<u>% Change</u>
Earnings (loss) per share (reported)	\$ 1.44	\$ (0.25)	NM
Discontinued operations	—	.03	
Earnings (loss) per share from continuing operations (reported)	1.44	(.22)	NM
Amortization of intangible assets	.04	.08	
Acquired in-process research and development	.02	1.61	
Impact of reduced shares outstanding for non-GAAP reporting ^(a)	—	.04	
Asset impairment, restructuring and other special charges	—	(.01)	
Other, net	—	(.02)	
Earnings per share (non-GAAP)	\$ 1.50	\$ 1.48	1%

Numbers may not add due to rounding.
^(a) Non-GAAP earnings per share assume that the disposition of Elanco occurred at the beginning of all periods presented and, therefore, exclude the approximately 65.0 million shares of Lilly common stock retired in the Elanco exchange offer.

Year-to-Date Reported Results

For the first six months of 2019, worldwide revenue increased 2 percent, to \$10.729 billion, compared with \$10.549 billion in the same period in 2018. Reported net income and earnings per share for the first six months of 2019 were \$5.569 billion and \$5.84, respectively, compared with \$957.5 million and \$0.92 in the same period of 2018. The increases in net income and earnings per share in the first six months of 2019 were driven primarily by the gain recognized on the disposition of Elanco Animal Health.

Year-to-Date Non-GAAP Measures

For the first six months of 2019, net income and earnings per share, on a non-GAAP basis, were \$2.625 billion and \$2.83, respectively, compared with \$2.721 billion and \$2.79 in the same period of 2018.

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>2019</u>	<u>Year-to-Date</u> <u>2018</u>	<u>% Change</u>
Earnings per share (reported)	\$ 5.84	\$ 0.92	NM
Discontinued operations	(3.86)	(.02)	
Earnings per share from continuing operations (reported)	1.98	0.90	NM
Asset impairment, restructuring and other special charges	.44	.03	
Lartruvo charges	.14	—	
Acquired in-process research and development	.14	1.65	
Amortization of intangible assets	.08	.17	
Impact of reduced shares outstanding for non-GAAP reporting(a)	.05	.06	
Other, net	—	(.02)	
Earnings per share (non-GAAP)	\$ 2.83	\$ 2.79	1%

Numbers may not add due to rounding.
(a) Non-GAAP earnings per share assume that the disposition of Elanco occurred at the beginning of all periods presented and, therefore, exclude the approximately 65.0 million shares of Lilly common stock retired in the Elanco exchange offer.

Selected Revenue Highlights

<i>(Dollars in millions)</i>	Second Quarter			Year-to-Date		
	2019	2018	% Change	2019	2018	% Change
Selected Products						
Trulicity	\$ 1,028.5	\$ 779.8	32%	\$ 1,908.3	\$ 1,458.1	31%
Humalog ^(a)	677.6	769.8	(12)%	1,408.4	1,561.5	(10)%
Alimta [®]	577.8	555.9	4%	1,076.9	1,055.5	2%
Forteo [®]	360.8	434.5	(17)%	673.7	747.8	(10)%
Humulin [®]	322.6	346.0	(7)%	620.3	671.9	(8)%
Taltz	353.8	220.1	61%	606.3	366.5	65%
Basaglar	290.7	201.8	44%	542.1	367.8	47%
Cialis	200.2	538.7	(63)%	508.4	1,034.1	(51)%
Cyramza	241.8	218.8	11%	440.0	402.4	9%
Jardiance ^(b)	231.9	147.2	58%	435.5	298.2	46%
Verzenio	133.9	57.7	NM	243.3	87.4	NM
Olumiant	102.4	44.7	NM	184.5	76.9	NM
Emgality	34.3	—	NM	48.5	—	NM
Total Revenue	5,636.7	5,585.0	1%	10,728.9	10,548.8	2%

(a) Humalog includes Insulin Lispro
(b) Jardiance includes Glyxambi[®] and Synjardy[®]
NM – not meaningful; Numbers may not add due to rounding

Trulicity

Second-quarter 2019 worldwide Trulicity revenue was \$1.029 billion, an increase of 32 percent compared with the second quarter of 2018. U.S. revenue increased 29 percent, to \$792.1 million, driven by increased demand, partially offset by lower realized prices due to higher contracted rebates, increased coverage gap funding requirements in Medicare Part D, and changes in segment mix. Revenue outside the U.S. was \$236.4 million, an increase of 41 percent, driven by increased volume, partially offset by the unfavorable impact of foreign exchange rates and, to a lesser extent, lower realized prices.

Humalog

For the second quarter of 2019, worldwide Humalog revenue decreased 12 percent compared with the second quarter of 2018, to \$677.6 million. Revenue in the U.S. decreased 15 percent, to \$396.1 million, driven by lower realized prices due to higher contracted rebates, increased coverage gap funding requirements in Medicare Part D, and the impact of patient affordability programs, and, to a lesser extent, decreased demand. Revenue outside the U.S. decreased 8 percent, to \$281.5 million, driven primarily by the unfavorable impact of foreign exchange rates and, to a lesser extent, decreased volume.

Alimta

For the second quarter of 2019, worldwide Alimta revenue increased 4 percent compared with the second quarter of 2018, to \$577.8 million. U.S. revenue increased 21 percent, to \$341.7 million, primarily driven by increased demand and, to a lesser extent, the impact of buying patterns. Revenue outside the U.S. decreased 14 percent to \$236.1 million, driven by decreased volume resulting from the entry of generic pemetrexed in Germany and, to a lesser extent, the unfavorable impact of foreign exchange rates.

Forteo

For the second quarter of 2019, worldwide Forteo revenue decreased 17 percent compared with the second quarter of 2018, to \$360.8 million. U.S. revenue decreased 23 percent, to \$172.8 million, driven by decreased demand and, to a lesser extent, lower realized prices. Revenue outside the U.S. decreased 10 percent to \$188.0 million, driven by the unfavorable impact of foreign exchange rates and decreased volume.

Humulin

For the second quarter of 2019, worldwide Humulin revenue decreased 7 percent compared with the second quarter of 2018, to \$322.6 million. U.S. revenue decreased 8 percent, to \$220.1 million, driven by lower realized prices due to higher contracted rebates, changes in segment mix, and increased coverage gap funding in Medicare Part D, partially offset by increased demand. Revenue outside the U.S. decreased 4 percent, to \$102.6 million, due to the unfavorable impact of foreign exchange rates and, to a lesser extent, lower realized prices, partially offset by increased volume.

Taltz

For the second quarter of 2019, worldwide Taltz revenue was \$353.8 million, an increase of 61 percent compared with the second quarter of 2018. U.S. revenue was \$268.1 million, an increase of 54 percent, driven by increased demand. Revenue outside the U.S. was \$85.7 million, an increase of 84 percent, primarily driven by increased volume from recent launches, partially offset by the unfavorable impact of foreign exchange rates.

Basaglar

For the second quarter of 2019, Basaglar generated worldwide revenue of \$290.7 million, an increase of 44 percent compared with the second quarter of 2018. U.S. revenue was \$232.2 million, an increase of 48 percent, driven by higher realized prices and increased demand. Revenue outside the U.S. was \$58.6 million, an increase of 29 percent, driven by increased volume, partially offset by the unfavorable impact of foreign exchange rates. Basaglar is part of the company's alliance with Boehringer Ingelheim, and Lilly reports total sales of Basaglar as revenue, with payments made to Boehringer Ingelheim for its portion of the gross margin reported as cost of sales.

Cialis

For the second quarter of 2019, worldwide Cialis revenue decreased 63 percent compared with the second quarter of 2018, to \$200.2 million. U.S. revenue was \$35.1 million in the second quarter, a 90

percent decrease compared with the second quarter of 2018, driven by decreased demand due to generic competition. Revenue outside the U.S. decreased 14 percent to \$165.1 million, driven by decreased demand due to generic competition, the unfavorable impact of foreign exchange rates and, to a lesser extent, lower realized prices.

Cyramza

For the second quarter of 2019, worldwide Cyramza revenue was \$241.8 million, an increase of 11 percent compared with the second quarter of 2018. U.S. revenue was \$89.8 million, an increase of 19 percent, primarily driven by increased demand. Revenue outside the U.S. was \$152.0 million, an increase of 6 percent, driven by increased volume, partially offset by the unfavorable impact of foreign exchange rates.

Jardiance

The company's worldwide Jardiance revenue during the second quarter of 2019 was \$231.9 million, an increase of 58 percent compared with the second quarter of 2018. U.S. revenue increased 67 percent, to \$142.6 million, driven by increased demand. Revenue outside the U.S. was \$89.3 million, an increase of 45 percent, driven by increased volume, partially offset by the unfavorable 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.

Verzenio

For the second quarter of 2019, Verzenio generated worldwide revenue of \$133.9 million, an increase of \$24.5 million compared with the first quarter of 2019. U.S. revenue was \$105.2 million, an increase of \$11.7 million compared with the first quarter of 2019, primarily driven by increased demand. Revenue outside the U.S. was \$28.7 million, an increase of \$12.7 million compared with the first quarter of 2019.

Olumiant

For the second quarter of 2019, Olumiant generated worldwide revenue of \$102.4 million. U.S. revenue was \$10.7 million. Revenue outside the U.S. was \$91.7 million, an increase of \$48.7 million compared with the second quarter of 2018, driven by increased demand, partially offset by the unfavorable impact of foreign exchange rates.

Emgality

For the second quarter of 2019, Emgality generated worldwide revenue of \$34.3 million, an increase of \$20.1 million compared with the first quarter of 2019. U.S. revenue was \$33.8 million, an increase of \$21.7 million compared with the first quarter of 2019. Emgality launched in certain international markets in the first quarter of 2019 and generated revenue outside of the U.S. of \$0.5 million in the second quarter of 2019.

2019 Financial Guidance

The company has updated certain elements of its 2019 financial guidance. On a reported basis, earnings per share for 2019 are now expected to be in the range of \$8.58 to \$8.68. On a non-GAAP basis, earnings per share are now expected to be in the range of \$5.67 to \$5.77.

Following the disposition of the company's remaining ownership in Elanco Animal Health, Elanco's financial results were no longer included in Lilly's financial results beginning March 12, 2019. On a reported basis, the 2019 financial guidance outlined below includes the financial results of the Elanco business from January 1, 2019 to March 11, 2019 as discontinued operations, including the gain on the disposition of Elanco. The company's 2019 non-GAAP financial guidance excludes the discontinued operations results for Elanco.

	2019	
	Expectations	% Change from 2018
Earnings per share (reported)	\$8.58 to \$8.68	NM
Discontinued operations	(3.93)	
Earnings per share from continuing operations (reported)	\$4.65 to \$4.75	52% to 56%
Asset impairment, restructuring and other special charges	.44	
Amortization of intangible assets	.18	
Lartuvo charges	.14	
Acquired in-process research and development	.18	
Impact of reduced shares outstanding for non-GAAP reporting	.08	
Earnings per share (non-GAAP)	\$5.67 to \$5.77	4% to 6%
Numbers may not add due to rounding		

The company still anticipates 2019 revenue between \$22.0 billion and \$22.5 billion. Revenue growth is expected to be driven by volume from key growth products including Trulicity, Taltz, Basaglar,

Jardiance, Verzenio, Cyramza and Olumiant. Revenue growth is also expected to benefit from the recent launch of Emgality and could benefit from the potential approval and launch of other medicines in 2019. Revenue growth is expected to be partially offset by lower revenue for Cialis and other products that have lost patent exclusivity. Revenue growth is also expected to be partially offset by the negative impact of foreign exchange rates, continued low- to mid-single digit realized price declines in the U.S. driven primarily by rebates and legislated increases to Medicare Part D cost sharing, patient affordability programs, price declines in some international markets and the impact of the impending product withdrawal of Lartruvo.

Gross margin as a percent of revenue rate is still expected to be approximately 79.0 percent on a reported basis and approximately 80.0 percent on a non-GAAP basis.

Marketing, selling and administrative expenses are now expected to be in the range of \$5.9 billion to \$6.1 billion. Research and development expenses are still expected to be in the range of \$5.5 billion to \$5.7 billion.

Other income (expense) is now expected to be expense between \$0 million and \$150 million.

The 2019 effective tax rate is now expected to be in the range of 14 percent to 15 percent on a reported basis and 13 percent to 14 percent on a non-GAAP basis.

The following table summarizes the company's 2019 financial guidance:

	2019 Guidance	
	<u>Prior</u>	<u>Updated</u>
Revenue	\$22.0 to \$22.5 billion	Unchanged
Gross Margin % of Revenue (reported)	Approx. 79.0%	Unchanged
Gross Margin % of Revenue (non-GAAP)	Approx. 80.0%	Unchanged
Marketing, Selling & Administrative	\$5.7 to \$6.0 billion	\$5.9 to \$6.1 billion
Research & Development	\$5.5 to \$5.7 billion	Unchanged
Other Income/(Expense)	\$(250) to \$(100) million	\$(150) to \$0 million
Tax Rate (reported)	15.0% to 16.0%	14.0% to 15.0%
Tax Rate (non-GAAP)	14.0% to 15.0%	13.0% to 14.0%
Earnings per share (reported)	\$8.57 to \$8.67	\$8.58 to \$8.68
Earnings per share (non-GAAP)	\$5.60 to \$5.70	\$5.67 to \$5.77
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 2019 financial results conference call through a link on Lilly's website at www.lilly.com. The conference call will begin at 9:00 a.m. Eastern time (ET) today 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. 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 and our pipeline; 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 past, current or future products; unauthorized disclosure, misappropriation, or compromise of trade secrets or other confidential data stored in the company’s information systems, networks and facilities, or those of third parties with which the company shares its data; changes in tax law and regulations, including the impact of U.S. 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; information technology system inadequacies or operating failures; reliance on third-party relationships and outsourcing arrangement; and global macroeconomic conditions. For additional information about the factors that could cause actual results to differ materially from forward-looking statements, please see the company’s latest Form 10-K and 10-Q 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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Adcirca® (tadalafil, Lilly)
Alimta® (pemetrexed disodium, Lilly)
Baqsimi™ (glucagon, Lilly)
Basaglar® (insulin glargine injection, Lilly)
Cialis® (tadalafil, Lilly)
Cyramza® (ramucirumab, Lilly)
Emgality® (galcanezumab-gnlm, 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)
Lartruvo® (olaratumab, Lilly)

Olumiant® (baricitinib, Lilly)
Posilac® (recombinant bovine somatotropin, Lilly)
Synjardy® (empagliflozin/metformin, Boehringer Ingelheim)
Taltz® (ixekizumab, Lilly)
Trulicity® (dulaglutide, Lilly)
Verzenio® (abemaciclib, Lilly)

Eli Lilly and Company Employment Information

	<u>June 30, 2019</u>	<u>December 31, 2018</u>
Worldwide Employees	33,815	38,680*

*Employment information as of December 31, 2018 includes employees of Elanco Animal Health

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

	Three Months Ended			Six Months Ended		
	June 30,			June 30,		
	2019	2018	% Chg.	2019	2018	% Chg.
Revenue	\$ 5,636.7	\$ 5,585.0	1%	\$ 10,728.9	\$ 10,548.8	2%
Cost of sales	1,124.9	1,234.3	(9)%	2,263.6	2,398.9	(6)%
Research and development	1,402.2	1,271.0	10%	2,632.7	2,378.5	11%
Marketing, selling and administrative	1,586.3	1,485.6	7%	3,103.4	2,824.3	10%
Acquired in-process research and development	25.0	1,624.5	(98)%	161.9	1,624.5	(90)%
Asset impairment, restructuring and other special charges	—	(25.5)	(100)%	423.9	31.3	NM
Operating income (loss)	1,498.3	(4.9)	NM	2,143.4	1,291.3	66%
Net interest income (expense)	(91.5)	(22.1)		(147.4)	(37.8)	
Net other income (expense)	59.1	68.7		201.0	153.9	
Other income (expense)	(32.4)	46.6	NM	53.6	116.1	(54)%
Income before income taxes	1,465.9	41.7	NM	2,197.0	1,407.4	56%
Income tax expense	138.7	273.3	(49)%	308.7	471.8	(35)%
Net income (loss) from continuing operations	1,327.2	(231.6)	NM	1,888.3	935.6	NM
Net income (loss) from discontinued operations	—	(28.3)	(100)%	3,680.5	21.9	NM
Net income (loss)	\$ <u>1,327.2</u>	\$ <u>(259.9)</u>	NM	\$ <u>5,568.8</u>	\$ <u>957.5</u>	NM
Earnings (loss) from continuing operations - diluted	1.44	(0.22)	NM	1.98	0.90	NM
Earnings (loss) from discontinued operations - diluted	—	(0.03)		3.86	0.02	
Earnings (loss) per share - diluted	\$ <u>1.44</u>	\$ <u>(0.25)</u>	NM	\$ <u>5.84</u>	\$ <u>0.92</u>	NM
Dividends paid per share	\$ 0.645	\$ 0.5625	15%	\$ 1.29	\$ 1.125	15%
Weighted-average shares outstanding (thousands) - diluted	924,630	1,030,210		954,156	1,041,561	

NM – not meaningful

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, 2019			Three Months Ended June 30, 2018		
	GAAP Reported	Adjustments ^(b)	Non-GAAP Adjusted ^(a)	GAAP Reported	Adjustments ^(c)	Non-GAAP Adjusted ^(a)
Cost of sales	\$ 1,124.9	\$ (51.6)	\$ 1,073.3	\$ 1,234.3	\$ (103.5)	\$ 1,130.8
Acquired in-process research and development	25.0	(25.0)	—	1,624.5	(1,624.5)	—
Asset impairment, restructuring and other special charges	—	—	—	(25.5)	25.5	—
Other income (expense)	(32.4)	—	(32.4)	46.6	(25.8)	20.9
Income tax expense	138.7	15.8	154.5	273.3	14.0	287.3
Net income (loss) from continuing operations	1,327.2	60.8	1,388.0	(231.6)	1,662.8	1,431.2
Net income (loss) from discontinued operations	—	—	—	(28.3)	28.3	—
Net income (loss)	1,327.2	60.8	1,388.0	(259.9)	1,691.1	1,431.2
Earnings (loss) per share - diluted	1.44	0.07	1.50	(0.25)	1.73	1.48
Weighted-average shares outstanding (thousands) - diluted	924,630	—	924,630	1,030,210	(61,898)	968,312

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 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) Adjustments to certain GAAP reported measures for the three months ended June 30, 2019, include the following:

(Dollars in millions, except per share data)	Amortization (i)	IPR&D(ii)	Total adjustments
Cost of sales	\$ (51.6)	\$ —	(51.6)
Acquired in-process research and development	—	(25.0)	(25.0)
Income taxes	10.6	5.2	15.8
Net income	41.0	19.8	60.8
Earnings per share - diluted	0.04	0.02	0.07

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 with Avidity Biosciences, Inc.

(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⁾	Reduced shares outstanding ^(iv)	Discontinued operations ^(v)	Total adjustments
Cost of sales	\$ (103.5)	\$ —	\$ —	\$ —	\$ —	(103.5)
Acquired in-process research and development	—	(1,624.5)	—	—	—	(1,624.5)
Asset impairment, restructuring and other special charges	—	—	25.5	—	—	25.5
Other income (expense)	—	—	(25.8)	—	—	(25.8)
Income taxes	21.4	14.0	(21.4)	—	—	14.0
Net income	82.1	1,610.5	(29.8)	—	28.3	1,691.1
Earnings per share - diluted	0.08	1.61	(0.03)	0.04	0.03	1.73

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 income associated with other investment income, as well as a reduction in estimated severance liabilities.
- iv. Non-GAAP earnings per share assume that the disposition of Elanco occurred at the beginning of all periods presented and therefore include the benefit from the reduction in shares of common stock outstanding.
- v. Exclude discontinued operations of Elanco Animal Health business.

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 June 30, 2019			Six Months Ended June 30, 2018		
	GAAP Reported	Adjustments ^(b)	Non-GAAP Adjusted ^(a)	GAAP Reported	Adjustments ^(c)	Non-GAAP Adjusted ^(a)
Cost of sales	\$ 2,263.6	\$ (179.8)	\$ 2,083.8	\$ 2,398.9	\$ (206.7)	\$ 2,192.2
Acquired in-process research and development	161.9	(161.9)	—	1,624.5	(1,624.5)	—
Asset impairment, restructuring and other special charges	423.9	(423.9)	—	31.3	(31.3)	—
Other income (expense)	53.6	—	53.6	116.1	(25.8)	90.4
Income taxes	308.7	29.2	337.9	471.8	51.3	523.1
Net income from continuing operations	1,888.3	736.4	2,624.7	935.6	1,785.5	2,721.1
Net income from discontinued operations	3,680.5	(3,680.5)	—	21.9	(21.9)	—
Net income	5,568.8	(2,944.1)	2,624.7	957.5	1,763.6	2,721.1
Earnings per share - diluted	5.84	(3.01)	2.83	0.92	1.87	2.79
Weighted-average shares outstanding (thousands) - diluted	954,156	(27,083)	927,073	1,041,561	(65,001)	976,560

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 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) Adjustments to certain GAAP reported measures for the six months ended June 30, 2019, include the following:

(Dollars in millions, except per share data)	Amortization ⁽ⁱ⁾	IPR&D ⁽ⁱⁱ⁾	Other specified items ⁽ⁱⁱⁱ⁾	Reduced shares outstanding ^(iv)	Lartruvo charges ^(v)	Discontinued operations ^(vi)	Total adjustments
Cost of sales	\$ (95.2)	\$ —	\$ —	\$ —	\$ (84.6)	\$ —	(179.8)
Acquired in-process research and development	—	(161.9)	—	—	—	—	(161.9)
Asset impairment, restructuring and other special charges	—	—	(411.8)	—	(12.1)	—	(423.9)
Income taxes	19.5	34.0	4.2	—	(28.5)	—	29.2
Net income	75.7	127.9	407.6	—	125.2	(3,680.5)	(2,944.1)
Earnings per share – diluted	0.08	0.14	0.44	0.05	0.14	(3.86)	(3.01)

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 with AC Immune SA, ImmuNext, Inc. and Avidity Biosciences, Inc.
- iii. Exclude charges primarily associated with the accelerated vesting of Loxo Oncology employee equity awards as part of the closing of the acquisition of Loxo Oncology.
- iv. Non-GAAP earnings per share assume that the disposition of Elanco occurred at the beginning of all periods presented and therefore include the benefit from the reduction in shares of common stock outstanding.
- v. Exclude charges related to the suspension of promotion of Lartruvo.
- vi. Exclude discontinued operations of the Elanco Animal Health business.

(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)	Amortization(i)	IPR&D(ii)	Other specified items(iii)	Reduced shares outstanding(iv)	Discontinued operations(v)	Total adjustments
Cost of sales	\$ (206.7)	\$ —	\$ —	\$ —	\$ —	(206.7)
Acquired in-process research and development	—	(1,624.5)	—	—	—	(1,624.5)
Asset impairment, restructuring and other special charges	—	—	(31.3)	—	—	(31.3)
Other income (expense)	—	—	(25.8)	—	—	(25.8)
Income taxes	42.7	14.0	(5.4)	—	—	51.3
Net income	164.0	1,610.5	11.0	—	(21.9)	1,763.6
Earnings per share - diluted	0.17	1.65	0.01	0.06	(0.02)	1.87

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 decision to end Posilac® (rbST) production at the Augusta, Georgia manufacturing site, other investment income, and income from a reduction in estimated severance liabilities.
- iv. Non-GAAP earnings per share assume that the disposition of Elanco occurred at the beginning of all periods presented and therefore include the benefit from the reduction in shares of common stock outstanding.
- v. Exclude discontinued operations of the Elanco Animal Health Business.