

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): **April 30, 2019**

ELI LILLY AND COMPANY
(Exact name of registrant as specified in its charter)

Indiana
(State or Other Jurisdiction
of Incorporation)

Lilly Corporate Center
Indianapolis, Indiana
(Address of Principal
Executive Offices)

001-06351
(Commission
File Number)

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

46285
(Zip Code)

Registrant's telephone number, including area code: (317) 276-2000

No Change

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Emerging growth company

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

Item 2.02. Results of Operations and Financial Condition

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

Attached as Exhibit 99.1 and incorporated by reference into this Item 2.02 is a copy of the press release, dated April 30, 2019, announcing our results of operations for the first quarter and three-month period ended March 31, 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 April 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: April 30, 2019

EXHIBIT INDEX

Exhibit Number

99.1

Exhibit

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



April 30, 2019

Eli Lilly and Company

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For Release: Immediately

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Lilly Reports Solid First-Quarter 2019 Financial Results, Updates 2019 Guidance to Reflect Disposition of Elanco Animal Health

- Revenue in the first quarter of 2019 grew 3 percent, driven by 7 percent volume growth. Key growth products launched since 2014, including Trulicity, Taltz, Verzenio, Basaglar, Olumiant, Jardiance, Cyramza and Emgality represented approximately 39 percent of revenue and delivered strong volume growth.
- First-quarter 2019 operating expenses rose 12 percent, reflecting increased investments in recently launched medicines and the late-stage pipeline.
- Lilly successfully completed its previously announced disposition of the Elanco Animal Health business. Lilly's financial results on a GAAP basis reflect Elanco Animal Health as a discontinued operation for all periods presented.
- First-quarter 2019 earnings per share (EPS) grew to \$4.31 on a reported basis, or \$1.33 on a non-GAAP basis. First-quarter 2019 EPS on a reported basis includes the gain on sale associated with the disposition of Elanco Animal Health.
- Lilly completed the acquisition of Loxo Oncology, which broadens the scope of Lilly's oncology portfolio into precision medicines.
- 2019 EPS guidance updated to be in the range of \$8.57 to \$8.67 on a reported basis and \$5.60 to \$5.70 on a non-GAAP basis to reflect the disposition of the Elanco Animal Health business.

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

| \$ in millions, except per share data | <u>First Quarter</u> | | <u>%</u> |
|------------------------------------------|----------------------|-------------|---------------|
| | <u>2019</u> | <u>2018</u> | <u>Change</u> |
| Revenue | \$ 5,092.2 | \$ 4,963.8 | 3% |
| Net Income – Reported | 4,241.6 | 1,217.4 | NM |
| EPS – Reported | 4.31 | 1.16 | NM |
| Net Income – Non-GAAP | 1,236.7 | 1,289.9 | (4)% |
| EPS – Non-GAAP | 1.33 | 1.31 | 2% |

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 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 continued to execute well against our strategic priorities in the first quarter of 2019,” said David A. Ricks, Lilly's chairman and CEO. “We delivered volume-based revenue growth despite the loss of patent exclusivity for several products, increased our investments in new brands, and further funded our pipeline of potential new medicines. We also completed two transformative transactions in the first quarter, the disposition of our remaining ownership in Elanco Animal Health and the acquisition of Loxo Oncology, which adds a potential 2020 launch and strengthens our oncology pipeline of precision medicines for patients with difficult to treat cancers.”

Key Events Over the Last Three Months

Regulatory

- The U.S. Food and Drug Administration (FDA) granted Priority Review for the supplemental Biologics License Application (sBLA) for Emgality[®] for the preventive treatment of episodic cluster headache in adults.
- The company received notification that the U.S. FDA extended the review time by up to three months for nasal glucagon to allow for review of information requested late in the review cycle. The submission of the additional information constituted a Major Amendment.
- The company has been working with global regulatory agencies to facilitate the withdrawal from the market of Lartruvo[®] for the treatment of advanced soft tissue sarcoma. Lilly is establishing a program to ensure current patients will have access to Lartruvo with limited interruption after it is withdrawn from the market. The program will be established as allowed by local country regulations.

Clinical

- The company and Boehringer Ingelheim announced that the cardiovascular outcome trial of Tradjenta[®] met its primary endpoint of non-inferiority compared with glimepiride in time to first occurrence of cardiovascular death, non-fatal myocardial infarction or non-fatal stroke.
- The company announced that a Phase 3 study of Cyramza[®] met its primary endpoint of progression-free survival, demonstrating a statistically significant improvement in the time patients lived without their cancer growing or spreading after starting treatment. The Phase 3 trial evaluated Cyramza in combination with erlotinib, compared to placebo in combination with erlotinib, as a first-line treatment in patients with metastatic non-small cell lung cancer whose tumors have activating EGFR mutations.
- The company and Pfizer Inc. announced top-line results from a Phase 3 study evaluating tanezumab in patients with moderate-to-severe chronic low back pain. In the study, treatment with tanezumab 10 mg met the primary endpoint, demonstrating a statistically significant improvement in pain at 16 weeks compared to placebo. The tanezumab 5 mg arm

demonstrated a numerical improvement in pain, but did not reach statistical significance compared to placebo at the week 16 analysis.

- The company and Pfizer Inc. announced top-line results from a Phase 3 study comparing the long-term joint safety and 16-week efficacy of tanezumab relative to nonsteroidal anti-inflammatory drugs (NSAIDs) in patients with moderate-to-severe osteoarthritis (OA) of the hip or knee. The tanezumab 5 mg treatment arm met two of the three co-primary efficacy endpoints, demonstrating a statistically significant improvement in pain and physical function compared to NSAIDs at the 16-week analysis, while patients' overall assessment of their OA was not statistically different than NSAIDs. Patients who received tanezumab 2.5 mg did not experience a statistically significant improvement in pain, physical function or patients' overall assessment of their OA at 16 weeks compared to NSAIDs. In the safety analysis, there was a statistically significant higher rate of joint safety events in the tanezumab arms compared to NSAIDs at 80 weeks. The companies are analyzing these findings in the context of recent Phase 3 results and will assess potential next steps for tanezumab.
- The company announced that Taltz[®] met the primary and all major secondary endpoints in a Phase 3 study evaluating its safety and efficacy for the treatment of non-radiographic axial spondyloarthritis in patients who are biologic disease-modifying anti-rheumatic drug-naïve.

Business Development/Other Developments

- The company completed the previously announced disposition of Elanco Animal Health, and accepted shares of Lilly common stock in exchange for its remaining 80.2% interest in Elanco. As a result, Lilly recognized an approximate \$3.7 billion gain on the Elanco disposition in the first quarter of 2019.
- The company completed the acquisition of Loxo Oncology, Inc., broadening the scope of Lilly's oncology portfolio into precision medicines through the addition of a promising pipeline of investigational medicines, including LOXO-292, a first-in-class oral RET inhibitor that has been granted Breakthrough Therapy designation by the FDA for three indications, with an initial potential launch in 2020, and LOXO-305, an oral BTK inhibitor currently in

Phase 1/2. Additionally, Bayer Consumer Care AG exercised its election under the Bayer/Loxo agreement to convert its co-exclusive license to an exclusive license in the U.S. and Puerto Rico regarding the development and commercialization of the TRK inhibitors Vitrakvi[®] and LOXO-195. As a result, Lilly is eligible to receive milestones and royalties from Bayer on future sales of Vitrakvi and LOXO-195 both in the U.S. and in international markets.

- The company announced it will introduce Insulin Lispro, a lower-priced version of Humalog[®], in the United States, providing people with diabetes an insulin option that will have a list price 50 percent lower than the current Humalog list price.
- The company and ImmuNext, Inc. announced a global licensing and research collaboration focused on the study of a preclinical novel target that could lead to potential new medicines for autoimmune diseases by regulating immune cell metabolism.
- The company and Avidity Biosciences, Inc. announced a global licensing and research collaboration focused on the discovery, development and commercialization of potential new medicines in immunology and other select indications.
- The company announced an agreement to sell the rights in China for two legacy antibiotic medicines, Ceclor[®] and Vancocin[®], as well as a manufacturing facility in Suzhou, China that produces Ceclor, to Eddingpharm, a China-based specialty pharmaceutical company.
- The company and Incyte Corporation announced that Incyte has elected to no longer co-fund the development of baricitinib. As a result, Lilly will solely fund all future development of baricitinib and pay a lower royalty rate to Incyte on future sales.
- The U.S. Court of Appeals for the Federal Circuit ruled in the company's favor regarding patentability of the vitamin regimen for Alimta[®]. The decision upholds an October 2017 decision by the Patent Trial and Appeal Board of the U.S. Patent and Trademark Office.

First-Quarter Reported Results

In the first quarter of 2019, worldwide revenue was \$5.092 billion, an increase of 3 percent compared with the first quarter of 2018. The increase in revenue was driven by a 7 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. increased 3 percent, to \$2.891 billion, driven by increased volume of 6 percent, partially offset by lower realized prices. U.S. volume growth was driven by key growth products, primarily Trulicity[®], Taltz, Verzenio[®], and Basaglar[®], partially offset by significant volume declines for products that have lost exclusivity, including Cialis[®] and Strattera[®].

Revenue outside the U.S. increased 2 percent, to \$2.201 billion, driven by increased volume of 9 percent, which was primarily from key growth products, including Trulicity, Olumiant[®], and Taltz. The increase in revenue was partially offset by the unfavorable impact of foreign exchange rates and, to a lesser extent, lower realized prices.

Gross margin increased 4 percent, to \$3.953 billion, in the first quarter of 2019 compared with the first quarter of 2018. Gross margin as a percent of revenue was 77.6 percent, an increase of 1.1 percentage points compared with the first quarter of 2018. The increase in gross margin percent

was primarily due to the favorable effect of foreign exchange rates on international inventories sold, partially offset by the timing of planned manufacturing production schedules, decreased volume for post-patent products, unfavorable product mix, the negative impact of price on revenue, and charges resulting from the suspension of promotion of Lartruvo.

Operating expenses in the first quarter of 2019, defined as the sum of research and development and marketing, selling, and administrative expenses, increased 12 percent to \$2.748 billion compared with the first quarter of 2018. Research and development expenses increased 11 percent to \$1.231 billion, or 24.2 percent of revenue, driven by higher development expenses for late-stage assets. Marketing, selling, and administrative expenses increased 13 percent, to \$1.517 billion, primarily due to increased marketing expenses related to recent product launches.

In the first quarter of 2019, the company recognized acquired in-process research and development charges of \$136.9 million, related to the previously announced business development transactions with AC Immune SA and ImmuNext, Inc. There were no acquired in-process research and development charges in the first quarter of 2018.

In the first quarter of 2019, the company recognized asset impairment, restructuring, and other special charges of \$423.9 million. The charges were primarily associated with accelerated vesting of Loxo Oncology employee equity awards as part of the closing of the \$8.0 billion acquisition of Loxo Oncology. In the first quarter of 2018, the company recognized asset impairment, restructuring and other special charges of \$56.8 million, primarily associated with asset impairment and restructuring charges related to the decision to end Posilac[®] (rbST) production at the Augusta, Georgia manufacturing site.

Operating income in the first quarter of 2019 was \$645.1 million, compared to \$1.296 billion in the first quarter of 2018. The decrease in operating income was driven by higher asset impairment, restructuring, and other special charges, higher operating expense and higher acquired in-process research and development charges, partially offset by higher gross margin.

Other income (expense) was income of \$86.0 million in the first quarter of 2019, compared with income of \$69.5 million in the first quarter of 2018. The increase in other income was primarily

driven by higher mark-to-market adjustments on investment securities, partially offset by higher net interest expense.

The effective tax rate was 23.3 percent in the first quarter of 2019, compared with 14.5 percent in the first quarter of 2018. The higher effective tax rate is primarily due to the non-deductibility of the accelerated vesting of Loxo Oncology employee equity awards as part of the closing of the acquisition of Loxo Oncology, as well as tax expenses associated with the suspension of promotion of Lartruvo.

Net income from discontinued operations was \$3.681 billion in the first quarter of 2019, compared with \$50.2 million in the first quarter of 2018. The increase in income from discontinued operations was driven by the gain recognized on the disposition of Elanco Animal Health.

In the first quarter of 2019, net income and earnings per share were \$4.242 billion and \$4.31, respectively, compared with net income of \$1.217 billion and earnings per share of \$1.16 in the first quarter of 2018. The increases in net income and earnings per share in the first quarter of 2019 were driven by the gain recognized on the disposition of Elanco Animal Health, partially offset by lower operating income.

First-Quarter Non-GAAP Measures

On a non-GAAP basis, first-quarter 2019 gross margin increased 5 percent, to \$4.082 billion compared with the first quarter of 2018. Gross margin as a percent of revenue was 80.2 percent, an increase of 1.6 percentage points. The increase in gross margin percent was primarily due to the favorable effect of foreign exchange rates on international inventories sold, partially offset by the timing of planned manufacturing shutdowns, decreased volume for post-patent products, unfavorable product mix and the negative impact of price on revenue.

Operating income decreased \$122.1 million, or 8 percent, to \$1.334 billion in the first quarter of 2019 compared with the first quarter of 2018, due to higher operating expenses, partially offset by higher gross margin.

The effective tax rate was 12.9 percent in the first quarter of 2019, compared with 15.5 percent in the first quarter of 2018. The lower effective tax rate for the first quarter of 2019 was primarily driven by timing associated with the impact of U.S. tax reform.

In the first quarter of 2019, net income decreased 4 percent, to \$1.237 billion, while earnings per share increased 2 percent, to \$1.33, compared with \$1.290 billion and \$1.31, respectively, in the first quarter of 2018. The decrease in net income was primarily driven by lower operating income. Earnings per share increased due to a reduction in weighted average shares outstanding resulting from the company's regular, ongoing 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>First Quarter</u> <u>2018</u> | <u>% Change</u> |
|-----------------------------------------------------------------|----------------|-------------------------------------|-----------------|
| Earnings per share (reported) | \$ 4.31 | \$ 1.16 | NM |
| Discontinued operations | (3.74) | (.05) | |
| Earnings per share from continuing operations (reported) | .57 | 1.11 | (42)% |
| Asset impairment, restructuring and other special charges | .44 | .04 | |
| Lartruvo charges | .13 | — | |
| Acquired in-process research and development | .12 | — | |
| Amortization of intangible assets | .04 | .08 | |
| Impact of reduced shares outstanding for non-GAAP reporting(a) | .03 | .08 | |
| Earnings per share (non-GAAP) | \$ 1.33 | \$ 1.31 | 2% |

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> Selected Products | First Quarter | | % Change |
|----------------------------------------------------------|---------------|----------|----------|
| | 2019 | 2018 | |
| Trulicity | \$ 879.7 | \$ 678.3 | 30% |
| Humalog | 730.8 | 791.7 | (8)% |
| Alimta | 499.2 | 499.6 | (0)% |
| Forteo® | 312.9 | 313.2 | (0)% |
| Cialis | 308.2 | 495.4 | (38)% |
| Humulin® | 297.7 | 325.9 | (9)% |
| Taltz | 252.5 | 146.5 | 72% |
| Basaglar | 251.4 | 166.0 | 51% |
| Jardiance®(a) | 203.6 | 151.0 | 35% |
| Cyramza | 198.3 | 183.6 | 8% |
| Verzenio | 109.4 | 29.7 | NM |
| Olumiant | 82.1 | 32.2 | NM |
| Emgality | 14.2 | — | NM |
| Total Revenue | 5,092.2 | 4,963.8 | 3% |

(a) Jardiance includes Glyxambi® and Synjardy®
NM – not meaningful
Numbers may not add due to rounding

Selected Products

Trulicity

First-quarter 2019 worldwide Trulicity revenue was \$879.7 million, an increase of 30 percent compared with the first quarter of 2018. U.S. revenue increased 26 percent, to \$665.6 million, driven by increased demand, partially offset by lower realized prices and changes in estimates to rebates and discounts. Revenue outside the U.S. was \$214.1 million, an increase of 43 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 first quarter of 2019, worldwide Humalog revenue decreased 8 percent compared with the first quarter of 2018, to \$730.8 million. Revenue in the U.S. decreased 11 percent, to \$448.6 million, driven by decreased demand and, to a lesser extent, lower realized prices primarily due to the impact of patient affordability programs. Revenue outside the U.S. decreased 2 percent, to \$282.2 million, driven primarily by the unfavorable impact of foreign exchange rates, largely offset by increased volume.

Alimta

For the first quarter of 2019, Alimta generated worldwide revenue of \$499.2 million, which was unchanged compared with the first quarter of 2018. U.S. revenue increased 15 percent, to \$281.8 million, primarily driven by increased demand. Revenue outside the U.S. decreased 15 percent to \$217.4 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 and lower realized prices.

Forteo

For the first quarter of 2019, worldwide revenue for Forteo was \$312.9 million, which was unchanged compared with the first quarter of 2018. U.S. revenue increased 3 percent, to \$125.9 million, primarily due to higher realized prices, partially offset by decreased demand. Revenue outside the U.S. decreased 2 percent to \$187.0 million, primarily driven by the unfavorable impact of foreign exchange rates, partially offset by increased volume.

Cialis

For the first quarter of 2019, worldwide Cialis revenue decreased 38 percent compared with the first quarter of 2018, to \$308.2 million. U.S. revenue was \$143.2 million in the first quarter, a 54 percent

decrease compared with the first quarter of 2018, driven by decreased demand due to generic competition, partially offset by higher realized prices. Revenue outside the U.S. decreased 9 percent to \$164.9 million, primarily driven by the unfavorable impact of foreign exchange rates.

Humulin

For the first quarter of 2019, worldwide Humulin revenue decreased 9 percent compared with the first quarter of 2018, to \$297.7 million. U.S. revenue decreased 9 percent, to \$201.3 million, driven by lower realized prices due to changes in estimates to rebates and discounts and, to a lesser extent, decreased volume. Revenue outside the U.S. decreased 8 percent, to \$96.4 million, primarily due to the unfavorable impact of foreign exchange rates.

Taltz

For the first quarter of 2019, worldwide Taltz revenue was \$252.5 million, an increase of 72 percent compared with the first quarter of 2018. U.S. revenue was \$180.8 million, an increase of 63 percent, driven by increased demand, partially offset by lower realized prices. Revenue outside the U.S. was \$71.7 million, an increase of \$36.4 million, driven by increased volume from recent launches, partially offset by the unfavorable impact of foreign exchange rates.

Basaglar

For the first quarter of 2019, Basaglar generated worldwide revenue of \$251.4 million, an increase of 51 percent compared with the first quarter of 2018. U.S. revenue was \$198.2 million, an increase of 56 percent, driven primarily by increased demand and, to a lesser extent, higher realized prices and changes in estimates to rebates and discounts. Revenue outside the U.S. was \$53.2 million, an increase of 35 percent, primarily driven by increased volume, partially offset by lower realized prices and 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.

Jardiance

The company's worldwide Jardiance revenue during the first quarter of 2019 was \$203.6 million, an increase of 35 percent compared with the first quarter of 2018. U.S. revenue increased 32 percent, to \$125.2 million, driven by increased demand. Revenue outside the U.S. was \$78.4 million, an increase of 40 percent, primarily 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.

Cyramza

For the first quarter of 2019, worldwide Cyramza revenue was \$198.3 million, an increase of 8 percent compared with the first quarter of 2018. U.S. revenue was \$75.1 million, an increase of 10 percent, driven primarily by increased demand. Revenue outside the U.S. was \$123.2 million, an increase of 7 percent, driven by increased volume, partially offset by the unfavorable impact of foreign exchange rates and lower realized prices.

Verzenio

For the first quarter of 2019, Verzenio generated worldwide revenue of \$109.4 million, an increase of \$26.4 million compared with the fourth quarter of 2018. U.S. revenue was \$93.5 million, an increase of \$17.0 million compared with the fourth quarter of 2018, driven by increased demand and, to a lesser extent, higher realized prices. Revenue outside the U.S. was \$15.9 million, an increase of \$9.4 million compared with the fourth quarter of 2018.

Olumiant

For the first quarter of 2019, Olumiant generated worldwide revenue of \$82.1 million. U.S. revenue was \$6.4 million. Revenue outside the U.S. was \$75.7 million, an increase of \$43.5 million compared with the first quarter of 2018, reflecting uptake of new launches in Europe.

Emgality.

For the first quarter of 2019, Emgality generated worldwide revenue of \$14.2 million, an increase of \$9.3 million compared with the fourth quarter of 2018. U.S. revenue was \$12.2 million, an increase of \$7.2 million compared with the fourth quarter of 2018. Emgality was launched in certain international markets in the first quarter of 2019 and generated revenue outside of the U.S. of \$2.1 million.

2019 Financial Guidance

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.

The company has updated certain elements of its 2019 financial guidance on a reported basis and on a non-GAAP basis to reflect the disposition of Elanco and provide current expectations for the company's human pharmaceutical business. On a reported basis, earnings per share for 2019 are now expected to be in the range of \$8.57 to \$8.67. On a non-GAAP basis, earnings per share are now expected to be in the range of \$5.60 to \$5.70.

| | 2019 Expectations | % Change from 2018 |
|-----------------------------------------------------------------|------------------------------|---------------------------|
| Earnings per share (reported) | \$8.57 to \$8.67 | NM |
| Discontinued operations | (3.93) | |
| Earnings per share from continuing operations (reported) | \$4.64 to \$4.74 | 52% to 55% |
| Asset impairment, restructuring and other special charges | .44 | |
| Amortization of intangible assets | .17 | |
| Lartruvo charges | .14 | |
| Acquired in-process research and development | .14 | |
| Impact of reduced shares outstanding for non-GAAP reporting | .07 | |
| Earnings per share (non-GAAP) | \$5.60 to \$5.70 | 3% to 5% |
| Numbers may not add due to rounding | | |

The company 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 patient affordability programs, rebates and legislated increases to Medicare Part D cost sharing, price declines in some international markets and the impact of the planned Lartruvo withdrawal.

Gross margin as a percent of revenue rate is 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 expected to be in the range of \$5.7 billion to \$6.0 billion. Research and development expenses are expected to be in the range of \$5.5 billion to \$5.7 billion.

Other income (expense) is expected to be expense between \$100 million and \$250 million.

The 2019 effective tax rate is expected to be in the range of 15 percent to 16 percent on a reported basis and 14 percent to 15 percent on a non-GAAP basis.

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

| | 2019 Guidance | |
|------------------------------------------------------------------------------|----------------------------|-----------------------------------------------------|
| | <u>Prior</u> | <u>Updated to Reflect Disposition of Elanco</u> |
| Revenue | \$25.1 to \$25.6 billion | \$22.0 to \$22.5 billion |
| Gross Margin % of Revenue (reported) | Approx. 75.0% | Approx. 79.0% |
| Gross Margin % of Revenue (non-GAAP) | Approx. 76.5% | Approx. 80.0% |
| Marketing, Selling & Administrative | \$6.4 to \$6.7 billion | \$5.7 to \$6.0 billion |
| Research & Development | \$5.8 to \$6.0 billion | \$5.5 to \$5.7 billion |
| Other Income/(Expense) | \$(325) to \$(175) million | \$(250) to \$(100) million |
| Tax Rate (reported) | Approx. 16.5% | 15.0% to 16.0% |
| Tax Rate (non-GAAP) | Approx. 15.0% | 14.0% to 15.0% |
| Earnings per share (reported) | \$4.57 to \$4.67 | \$8.57 to \$8.67 |
| Earnings per share (non-GAAP) | \$5.55 to \$5.65 | \$5.60 to \$5.70 |
| 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 first-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; 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 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; and the impact of exchange rates and global macroeconomic conditions. For additional information about the factors that could cause actual results to differ materially from forward-looking statements, please see the company’s latest Form 10-K filed with the SEC. You should not place undue reliance on forward-looking statements, which speak only as of the date of this release. Except as is required by law, the company expressly disclaims any obligation to publicly release any revisions to forward-looking statements to reflect events after the date of this release.

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Alimta® (pemetrexed disodium, Lilly)
Basaglar® (insulin glargine injection, Lilly)
Ceclor® (cefaclor, 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)

Strattera® (atomoxetine hydrochloride, Lilly)
Synjardy® (empagliflozin/metformin, Boehringer Ingelheim)
Taltz® (ixekizumab, Lilly)
Trajenta® (linagliptin, Boehringer Ingelheim)
Trulicity® (dulaglutide, Lilly)
Vancocin® (vancomycin, Lilly)
Verzenio® Verzenios™ (abemaciclib, Lilly)
Vitrakvi® (larotrectinib, Bayer)

Eli Lilly and Company Employment Information

| | <u>March 31, 2019</u> | <u>December 31, 2018</u> |
|---------------------|-----------------------|--------------------------|
| Worldwide Employees | 33,610* | 38,680 |

*Employment information as of March 31, 2019 excludes employees of Elanco Animal Health

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

| | Three Months Ended | | |
|-----------------------------------------------------------|--------------------|------------|--------|
| | March 31, | | % Chg. |
| | 2019 | 2018 | |
| Revenue | \$ 5,092.2 | \$ 4,963.8 | 3% |
| Cost of sales | 1,138.7 | 1,164.6 | (2)% |
| Research and development | 1,230.5 | 1,107.5 | 11% |
| Marketing, selling and administrative | 1,517.1 | 1,338.7 | 13% |
| Acquired in-process research and development | 136.9 | — | NM |
| Asset impairment, restructuring and other special charges | 423.9 | 56.8 | NM |
| Operating income | 645.1 | 1,296.2 | (50)% |
| Net interest income (expense) | (55.9) | (15.7) | |
| Net other income (expense) | 141.9 | 85.2 | |
| Other income (expense) | 86.0 | 69.5 | 24% |
| Income before income taxes | 731.1 | 1,365.7 | (46)% |
| Income tax expense | 170.0 | 198.5 | (14)% |
| Net income from continuing operations | 561.1 | 1,167.2 | (51)% |
| Net income from discontinued operations | 3,680.5 | 50.2 | NM |
| Net income | \$ 4,241.6 | \$ 1,217.4 | NM |
| Earnings from continuing operations - basic | 0.57 | 1.11 | (42)% |
| Earnings from discontinued operations - basic | 3.76 | 0.05 | |
| Earnings per share - basic | \$ 4.33 | \$ 1.16 | NM |
| Earnings from continuing operations - diluted | 0.57 | 1.11 | (42)% |
| Earnings from discontinued operations - diluted | 3.74 | 0.05 | |
| Earnings per share - diluted | \$ 4.31 | \$ 1.16 | NM |
| Dividends paid per share | \$ 0.645 | \$ 0.5625 | 15% |
| Weighted-average shares outstanding (thousands) - diluted | 984,001 | 1,049,839 | |

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 March 31, 2019 | | | Three Months Ended March 31, 2018 | | |
|-----------------------------------------------------------|--------------------------------------|----------------|-------------------------|--------------------------------------|----------------|-------------------------|
| | GAAP Reported | Adjustments(b) | Non-GAAP Adjusted(a) | GAAP Reported | Adjustments(c) | Non-GAAP Adjusted(a) |
| Cost of sales | \$ 1,138.7 | \$ (128.2) | \$ 1,010.5 | \$ 1,164.6 | \$ (103.2) | \$ 1,061.4 |
| Acquired in-process research and development | 136.9 | (136.9) | — | — | — | — |
| Asset impairment, restructuring and other special charges | 423.9 | (423.9) | — | 56.8 | (56.8) | — |
| Income tax expense | 170.0 | 13.4 | 183.4 | 198.5 | 37.3 | 235.8 |
| Net income from continuing operations | 561.1 | 675.6 | 1,236.7 | 1,167.2 | 122.7 | 1,289.9 |
| Net income from discontinued operations | 3,680.5 | (3,680.5) | — | 50.2 | (50.2) | — |
| Net Income | 4,241.6 | (3,004.9) | 1,236.7 | 1,217.4 | 72.5 | 1,289.9 |
| Earnings per share | 4.31 | (2.98) | 1.33 | 1.16 | 0.15 | 1.31 |
| Weighted-average shares outstanding (thousands) - diluted | 984,001 | 54,167 | 929,834 | 1,049,839 | 65,001 | 984,838 |

Numbers may not add due to rounding.

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

- (a) The company uses non-GAAP financial measures that differ from financial statements reported in conformity with U.S. generally accepted accounting principles (GAAP). The company's non-GAAP measures adjust reported results to exclude amortization of intangibles and items that are typically highly variable, difficult to predict, and/or of a size that could have a substantial impact on the company's reported operations for a period. The company believes that these non-GAAP measures provide useful information to investors. Among other things, they may help investors evaluate the company's ongoing operations. They can assist in making meaningful period-over-period comparisons and in identifying operating trends that would otherwise be masked or distorted by the items

subject to the adjustments. Management uses these non-GAAP measures internally to evaluate the performance of the business, including to allocate resources and to evaluate results relative to incentive compensation targets. Investors should consider these non-GAAP measures in addition to, not as a substitute for or superior to, measures of financial performance prepared in accordance with GAAP.

(b) Adjustments to certain GAAP reported measures for the three months ended March 31, 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 | \$ (43.6) | \$ — | \$ — | \$ — | \$ (84.6) | \$ — | (128.2) |
| Acquired in-process research and development | — | (136.9) | — | — | — | — | (136.9) |
| Asset impairment, restructuring and other special charges | — | — | (411.8) | — | (12.1) | — | (423.9) |
| Income taxes | 8.9 | 28.7 | 4.2 | — | (28.5) | — | 13.4 |
| Net income | 34.7 | 108.1 | 407.6 | — | 125.2 | (3,680.5) | (3,004.9) |
| Earnings per share - diluted | 0.04 | 0.12 | 0.44 | 0.03 | 0.13 | (3.74) | (2.98) |

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 and ImmuNext, 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 three months ended March 31, 2018, include the following:

| (Dollars in millions, except per share data) | Amortization ⁽ⁱ⁾ | Other specified items ⁽ⁱⁱ⁾ | Reduced shares outstanding ⁽ⁱⁱⁱ⁾ | Discontinued operations ^(iv) | Total adjustments |
|-----------------------------------------------------------|-----------------------------|---------------------------------------|---------------------------------------------|-----------------------------------------|--------------------------|
| Cost of sales | \$ (103.2) | \$ — | \$ — | | \$ (103.2) |
| Asset impairment, restructuring and other special charges | — | (56.8) | — | | (56.8) |
| Income taxes | 21.3 | 16.0 | — | | 37.3 |
| Net income | 81.9 | 40.8 | — | (50.2) | 72.5 |
| Earnings per share | 0.08 | 0.04 | 0.08 | (0.05) | 0.15 |

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 asset impairment and restructuring charges related to the decision to end Posilac (rbST) production at the Augusta, Georgia manufacturing site.
- iii. 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.
- iv. Exclude discontinued operations of Elanco Animal Health business.