

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, 2020

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 2022	LLY22	New York Stock Exchange
7 1/8% Notes due 2025	LLY25	New York Stock Exchange
1.625% Notes due 2026	LLY26	New York Stock Exchange
2.125% Notes due 2030	LLY30	New York Stock Exchange
0.625% Notes due 2031	LLY31	New York Stock Exchange
6.77% Notes due 2036	LLY36	New York Stock Exchange
1.700% Notes due 2049	LLY49A	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 hereto as Exhibit 99.1 and incorporated by reference into this Item 2.02 is a copy of the press release, dated July 30, 2020 , announcing our results of operations for the quarter ended June 30, 2020 (the “Reported Period”), including, among other things, unaudited operating results for that period.

Item 9.01. Financial Statements and Exhibits

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press release dated July 30, 2020, together with related attachments
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

EXHIBIT INDEX

Exhibit Number

99.1

Exhibit

[Press release dated July 30, 2020, 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, 2020



July 30, 2020

Eli Lilly and Company

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For Release: Immediately

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Lilly Reports Second-Quarter Financial Results, Raises EPS Guidance

- *Revenue in the second quarter of 2020 declined 2 percent, comprised of volume growth of 6 percent, a 7 percent decrease in realized prices and a 1 percent unfavorable impact from foreign exchange rates.*
- *The estimated negative impact of the COVID-19 pandemic on Q2 2020 revenue included approximately \$250 million of decreased customer buying that largely offset product stocking that occurred in Q1 2020, as well as approximately \$250 million of lower revenue resulting from delayed new patient prescription trends.*
- *On a year-to-date basis, revenue in 2020 increased 6 percent, driven by 13 percent volume growth.*
- *Second-quarter 2020 operating expenses decreased 5 percent, driven by lower marketing expenses.*
- *Second-quarter 2020 earnings per share (EPS) increased to \$1.55 on a reported basis and to \$1.89 on a non-GAAP basis.*
- *Lilly continues to rapidly advance the development of potential therapeutics for the treatment of COVID-19, including antibody therapies and baricitinib.*
- *Positive phase 3 data for Verzenio highlights promising opportunity in early breast cancer treatment.*
- *Other notable recent events include FDA approvals for Retevmo, Lyumjev and Tauvid, new approved indications for Taltz and Cyramza, as well as positive phase 3 data for Jardiance, mirikizumab and Trulicity.*
- *2020 EPS guidance raised to be in the range of \$6.48 to \$6.68 on a reported basis and \$7.20 to \$7.40 on a non-GAAP basis.*

Eli Lilly and Company (NYSE: LLY) today announced financial results for the second quarter of 2020.

\$ in millions, except per share data	<u>Second Quarter</u>		<u>%</u>
	<u>2020</u>	<u>2019</u>	<u>Change</u>
Revenue	\$ 5,499.4	\$ 5,636.7	(2)%
Net Income – Reported	1,412.0	1,327.2	6%
EPS – Reported	1.55	1.44	8%
Net Income – Non-GAAP	1,721.2	1,388.0	24%
EPS – Non-GAAP	1.89	1.50	26%

Certain financial information for 2020 and 2019 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 during 2019. 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 2019 (including the benefit from the reduction in shares of common stock outstanding). The company’s 2020 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.

“In the second quarter, Lilly achieved several important R&D milestones, including three FDA approvals for new medicines, positive phase 3 results for several important clinical programs and continued progress in our quest to develop medicines for patients with COVID-19,” said David A. Ricks, Lilly’s chairman and CEO. “At the same time, the COVID-19 pandemic continues to strain healthcare systems around the world and has decreased new patient starts for some of Lilly’s

medicines. As anticipated, our second quarter financial results reflect the variability caused by the pandemic, but our year-to-date revenue performance, which includes 13 percent volume growth, demonstrates that our underlying business fundamentals remain strong. We expect growth in new prescription volume for our key growth products in the second half of 2020, and we remain confident in our outlook for the year.”

Key Events Over the Last Three Months

COVID-19

- The company completed dosing of a phase 1 study and initiated a phase 2 study of LY-CoV555, a potential antibody treatment designed to target COVID-19. LY-CoV555 is the first investigational medicine to emerge from the collaboration between Lilly and AbCellera Biologics to create antibody therapies for the potential prevention and treatment of COVID-19.
- The company entered into an agreement with Junshi Biosciences to co-develop therapeutic antibodies for the potential prevention and treatment of COVID-19, including LY-CoV016, the lead antibody from the collaboration. Dosing of a phase 1 study of LY-CoV016 in healthy volunteers has been completed and the antibody has demonstrated the safety and tolerability to proceed into further stages of clinical development.

Regulatory

- The U.S. Food and Drug Administration (FDA) approved Retevmo™, the first therapy specifically indicated for the treatment of adult patients with metastatic rearranged during transfection (RET) fusion-positive non-small cell lung cancer, and the treatment of adult and pediatric patients 12 years of age and older with advanced or metastatic RET-mutant medullary thyroid cancer who require systemic therapy, or advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate).
- The FDA approved Lyumjev™, a new rapid-acting insulin indicated to improve glycemic control in adults with type 1 and type 2 diabetes.
- The FDA approved a supplemental Biologics License Application (sBLA) for Taltz® for the treatment of active non-radiographic axial spondyloarthritis (nr-axSpA) in patients with objective signs of inflammation.
- The FDA approved Tauvid™, a radioactive diagnostic agent, for positron emission tomography imaging of the brain to estimate the density and distribution of aggregated tau

neurofibrillary tangles in adult patients with cognitive impairment who are being evaluated for Alzheimer's disease.

- The FDA approved Cyramza[®] in combination with erlotinib for the first-line treatment of people with metastatic non-small cell lung cancer with epidermal growth factor receptor exon 19 deletions or exon 21 mutations.

Clinical

- The company and Boehringer Ingelheim announced positive top-line results from a phase 3 study of Jardiance[®] in adults with heart failure with reduced ejection fraction, with and without diabetes. The study met its primary endpoint, demonstrating superiority with empagliflozin compared to placebo in reducing the risk for the composite of cardiovascular death or hospitalization due to heart failure, when added to standard of care.
- The company announced results from a pre-planned interim analysis of a phase 3 study of Verzenio[®] in combination with standard adjuvant endocrine therapy (ET). The study met the primary endpoint of invasive disease-free survival, significantly decreasing the risk of breast cancer recurrence or death compared to standard adjuvant ET alone.
- The company announced that mirikizumab met the primary and all key secondary endpoints in a phase 3 study comparing the efficacy and safety of mirikizumab to placebo and Cosentyx[®] in patients with moderate to severe plaque psoriasis.
- The company announced that higher investigational doses of Trulicity[®] meaningfully reduced A1C and body weight in people with type 2 diabetes. Data from a phase 3 study showed higher investigational doses of Trulicity (3 mg and 4.5 mg) were well-tolerated and led to A1C reductions up to 1.9 percent and weight reductions up to 10.4 pounds in people with type 2 diabetes.

Business Development/Other Developments

- The company announced its participation in, and \$100 million commitment to, the AMR Action Fund, a \$1 billion initiative from more than 20 biopharmaceutical companies to address

the urgent need for new antibiotics to combat antimicrobial resistance (AMR).

Second-Quarter Reported Results

In the second quarter of 2020, worldwide revenue was \$5.499 billion, a decrease of 2 percent compared with the second quarter of 2019, comprised of a 6 percent increase in volume, a 7 percent decrease due to lower realized prices, and a 1 percent decrease due to the unfavorable impact of foreign exchange rates. Key growth products launched since 2014, consisting of Trulicity, Tyvyt[®], Taltz, Verzenio, Emgality[®], Olumiant[®], Jardiance, Cyramza, Baqsimi[™], Basaglar[®], and Retevmo, contributed nearly 9 percentage points of revenue growth and represented approximately 54 percent of total revenue. The company estimates that the COVID-19 pandemic negatively impacted worldwide revenue in the second quarter of 2020, including approximately \$250 million of decreased customer buying that largely offset product stocking that occurred in the first quarter of 2020 and approximately \$250 million resulting from delayed new patient prescription trends.

Revenue in the U.S. decreased 3 percent, to \$3.145 billion, comprised of a 4 percent increase in volume and an 8 percent decrease due to lower realized prices. The decrease in realized prices in the U.S. was driven primarily by changes to estimates for rebates and discounts, mainly for diabetes products, reflecting both a favorable adjustment in the Medicaid segment in the second quarter of 2019 and an unfavorable adjustment in the commercial segment in the second quarter of 2020. The decrease in realized prices in the U.S. also reflects higher growth in lower net price segments across numerous products and increased rebates to gain and maintain broad commercial access across the portfolio. Increased U.S. volume for key growth products, including Trulicity, Taltz, Emgality, Verzenio, Baqsimi, Retevmo, Jardiance, Olumiant, Cyramza, and Basaglar was partially offset by lower volume for certain other products, including Tradjenta[®], Forteo[®] and Alimta[®]. The company estimates that the COVID-19 pandemic negatively impacted U.S. revenue in the second quarter of 2020, including approximately \$200 million of decreased customer buying that largely offset product stocking that occurred in the first quarter of 2020 and approximately \$150 million resulting from delayed new patient prescription trends.

Revenue outside the U.S. decreased 1 percent, to \$2.355 billion, comprised of a 7 percent increase in volume, a 7 percent decrease due to lower realized prices, and a 2 percent decrease due to the unfavorable impact of foreign exchange rates. The decrease in realized prices outside the U.S. was driven primarily by the inclusion of Tyvyt and Alimta in government reimbursement programs in China and bi-annual government mandated price decreases in Japan. The increase in volume outside the U.S. was driven primarily by the inclusion of Tyvyt and Alimta in government reimbursement programs in China, as well as volume gains for other key growth products, including Trulicity, Olumiant, Verzenio, Jardiance, Taltz, Cyramza, Emgality, Basaglar, and Baqsimi, partially offset by decreased volume for Cialis[®], Forteo, and Trajenta. The company estimates that the COVID-19 pandemic negatively impacted revenue outside the U.S. in the second quarter of 2020, including approximately \$100 million resulting from delayed new patient prescription trends and approximately \$50 million of decreased customer buying that largely offset product stocking that occurred in the first quarter of 2020.

Gross margin decreased 5 percent, to \$4.277 billion, in the second quarter of 2020 compared with the second quarter of 2019 and was unfavorably impacted by decreased customer buying patterns and patient prescription trends resulting from the COVID-19 pandemic. Gross margin as a percent of revenue was 77.8 percent, a decrease of 2.2 percentage points compared with the second quarter of 2019. The decrease in gross margin percent was primarily due to the impact of lower realized prices on revenue and higher intangibles amortization expense associated with the launch of Retevmo.

Total operating expenses in the second quarter of 2020, defined as the sum of research and development and marketing, selling, and administrative expenses, decreased 5 percent to \$2.839 billion compared with the second quarter of 2019. Research and development expenses decreased 1 percent to \$1.390 billion, or 25.3 percent of revenue, driven primarily by lower development expenses for late-stage assets and the pause in new clinical trial initiations and patient enrollment as a result of the

COVID-19 pandemic. Marketing, selling, and administrative expenses decreased 9 percent to \$1.449 billion, primarily due to lower marketing expenses.

In the second quarter of 2020, the company recognized acquired in-process research and development charges of \$241.8 million related to the acquisition of a pre-clinical stage company as well as the previously announced business development transactions with AbCellera Biologics, Evox Therapeutics, and Junshi Biosciences. In the second quarter of 2019, the company recognized an acquired in-process research and development charge of \$25.0 million related to the business development transaction with Avidity Biosciences.

Operating income in the second quarter of 2020 was \$1.197 billion, compared to \$1.498 billion in the second quarter of 2019. The decrease in operating income was primarily driven by lower gross margin and higher acquired in-process research and development charges, partially offset by lower marketing, selling, and administrative expenses.

Other income was \$446.9 million in the second quarter of 2020, compared with other expense of \$32.4 million in the second quarter of 2019. The increase in other income was driven primarily by favorable mark-to-market adjustments on investment securities, including equity positions the company holds in Asian biopharmaceutical companies as well as two U.S.-based companies that had successful initial public offerings in the second quarter of 2020.

The effective tax rate was 14.1 percent in the second quarter of 2020, compared with 9.5 percent in the second quarter of 2019. The higher effective tax rate in the second quarter of 2020 was driven by a mix of earnings in higher tax jurisdictions, a lower net discrete tax benefit compared to the same period in 2019, and nondeductible acquired in-process research and development charges.

In the second quarter of 2020, net income and earnings per share were \$1.412 billion and \$1.55, respectively, compared with net income of \$1.327 billion and earnings per share of \$1.44 in the

second quarter of 2019. The increase in net income and earnings per share in the second quarter of 2020 was primarily driven by higher other income, partially offset by lower operating income and, to a lesser extent, higher income tax expense.

Second-Quarter Non-GAAP Measures

On a non-GAAP basis, second-quarter 2020 gross margin decreased 4 percent, to \$4.380 billion compared with the second quarter of 2019 and was unfavorably impacted by decreased customer buying patterns and patient prescription trends resulting from the COVID-19 pandemic. Gross margin as a percent of revenue was 79.6 percent, a decrease of 1.4 percentage points. The decrease in gross margin percent was primarily due to the impact of lower realized prices on revenue.

Operating income on a non-GAAP basis decreased \$33.5 million, or 2 percent, to \$1.541 billion in the second quarter of 2020 compared with the second quarter of 2019, due to lower gross margin, partially offset by lower marketing, selling, and administrative expenses.

The effective tax rate on a non-GAAP basis was 13.4 percent in the second quarter of 2020, compared with 10.0 percent in the second quarter of 2019. The higher effective tax rate for the second quarter of 2020 was driven by a mix of earnings in higher tax jurisdictions and a lower net discrete tax benefit compared to the same period in 2019.

On a non-GAAP basis, in the second quarter of 2020 net income increased 24 percent, to \$1.721 billion, while earnings per share increased 26 percent, to \$1.89, compared with \$1.388 billion and \$1.50, respectively, in the second quarter of 2019. The increase in net income and earnings per share was driven primarily by higher other income, partially offset by higher income tax expense.

For further detail on 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>Second Quarter</u>		<u>% Change</u>
	<u>2020</u>	<u>2019</u>	
Earnings per share (reported)	\$ 1.55	\$ 1.44	8%
Acquired in-process research and development	.25	.02	
Amortization of intangible assets	.09	.04	
Earnings per share (non-GAAP)	\$ 1.89	\$ 1.50	26%

Numbers may not add due to rounding.

Year-to-Date Reported Results

For the first six months of 2020, worldwide revenue increased 6 percent to \$11.359 billion, compared with \$10.729 billion in the same period in 2019. The increase in revenue was driven by a 13 percent increase in volume, partially offset by a 7 percent decrease due to lower realized prices. The company estimates that the COVID-19 pandemic negatively impacted revenue in the first six months of 2020 by approximately \$250 million due to lower patient prescription trends, while increased customer buying in the first quarter of 2020 was essentially offset by decreased customer buying in the second quarter of 2020. For the first six months of 2020, operating income was \$2.788 billion, an increase of 30 percent compared to the same period of 2019. Reported net income and earnings per share for the first six months of 2020 were \$2.869 billion and \$3.15, respectively, compared with \$5.569 billion and \$5.84 in the same period of 2019. The decreases in net income and earnings per share in the first six months of 2020 were driven primarily by the approximate \$3.7 billion gain recognized on the disposition of Elanco in 2019, partially offset by higher operating income and higher other income for the first six months of 2020.

Year-to-Date Non-GAAP Measures

For the first six months of 2020, operating income was \$3.303 billion on a non-GAAP basis, an increase of 14 percent compared to the same period of 2019. Net income and earnings per share, on a non-GAAP basis, were \$3.320 billion and \$3.64, respectively, compared with \$2.625 billion and \$2.83 in the same period of 2019.

For further detail on 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>2020</u>	<u>Year-to-Date</u> <u>2019</u>	<u>% Change</u>
Earnings per share (reported)	\$ 3.15	\$ 5.84	(46)%
Discontinued operations	—	(3.86)	
Earnings per share from continuing operations (reported)	3.15	1.98	59%
Acquired in-process research and development	.30	.14	
Amortization of intangible assets	.14	.08	
Asset impairment, restructuring and other special charges	.06	.44	
Lartruvo [®] charges	—	.14	
Impact of reduced shares outstanding for non-GAAP reporting ^(a)	—	.05	
Earnings per share (non-GAAP)	\$ 3.64	\$ 2.83	29%

Numbers may not add due to rounding.
(a) Non-GAAP earnings per share assume that the disposition of Elanco occurred at the beginning of 2019 and, therefore, exclude the approximately 65.0 million shares of Lilly common stock retired in the Elanco exchange offer.

Selected Revenue Highlights

Selected Revenue Highlights

<i>(Dollars in millions)</i>						
Selected Products	Second Quarter			Year-to-Date		
	2020	2019	% Change	2020	2019	% Change
Trulicity	\$ 1,229.8	\$ 1,028.5	20%	\$ 2,459.1	\$ 1,908.3	29%
Humalog ^{®(a)}	555.1	677.6	(18)%	1,250.8	1,408.4	(11)%
Alimta	539.1	577.8	(7)%	1,099.2	1,076.9	2%
Taltz	395.2	353.8	12%	838.7	606.3	38%
Humulin [®]	313.6	322.6	(3)%	629.3	620.3	1%
Basaglar	290.4	290.7	(0)%	594.1	542.1	10%
Jardiance ^{®(b)}	262.0	231.9	13%	529.5	435.5	22%
Forteo	252.7	360.8	(30)%	525.0	673.7	(22)%
Cyramza	256.7	241.8	6%	495.7	440.0	13%
Verzenio	208.6	133.9	56%	396.7	243.3	63%
Olumiant	145.0	102.4	42%	284.7	184.5	54%
Emgality	87.4	34.3	NM	161.5	48.5	NM
Tyvyt	64.1	40.1	60%	121.5	50.0	NM
Baqsimi	13.6	—	NM	31.4	—	NM
Retevmo	6.3	—	NM	6.3	—	NM
Total Revenue	5,499.4	5,636.7	(2)%	11,359.2	10,728.9	6%

^(a) Humalog includes Insulin Lispro
^(b) Jardiance includes Glyxambi[®], Synjardy[®], and Trijardy[®] XR
 NM – not meaningful

Trulicity

Second-quarter 2020 worldwide Trulicity revenue was \$1.230 billion, an increase of 20 percent compared with the second quarter of 2019. U.S. revenue increased 20 percent, to \$952.5 million, driven by increased demand, partially offset by lower realized prices. Trulicity's lower realized prices in the U.S. were primarily due to higher contracted rebates and changes in segment mix, partially offset by higher list prices. Revenue outside the U.S. was \$277.2 million, an increase of 17 percent, driven by

increased volume, partially offset by the unfavorable impact of foreign exchange rates and lower realized prices.

Humalog

For the second quarter of 2020, worldwide Humalog revenue decreased 18 percent compared with the second quarter of 2019, to \$555.1 million. Revenue in the U.S. decreased 29 percent, to \$281.7 million, driven primarily by lower realized prices due to changes in estimates for rebates and discounts, reflecting both a favorable Medicaid adjustment in the second quarter of 2019 and an unfavorable Managed Care adjustment in the second quarter of 2020. Revenue outside the U.S. decreased 3 percent, to \$273.3 million, driven primarily by the unfavorable impact of foreign exchange rates.

Alimta

For the second quarter of 2020, worldwide Alimta revenue decreased 7 percent compared with the second quarter of 2019, to \$539.1 million. U.S. revenue decreased 7 percent, to \$317.2 million, primarily driven by decreased demand, partially offset by higher realized prices. Revenue outside the U.S. decreased 6 percent to \$221.9 million, primarily driven by lower realized prices, partially offset by increased volume.

Taltz

For the second quarter of 2020, worldwide Taltz revenue increased 12 percent compared with the second quarter of 2019, to \$395.2 million. U.S. revenue increased 8 percent, to \$289.2 million, driven by increased demand, partially offset by lower realized prices. Revenue outside the U.S. increased 24 percent, to \$106.0 million, driven by increased volume, partially offset by lower realized prices.

Humulin

For the second quarter of 2020, worldwide Humulin revenue decreased 3 percent compared with the second quarter of 2019, to \$313.6 million. U.S. revenue decreased 3 percent, to \$214.3 million, driven by lower realized prices due to changes in segment mix and, to a lesser extent, lower demand. Revenue

outside the U.S. decreased 3 percent, to \$99.3 million, due to the unfavorable impact of foreign exchange rates, partially offset by higher realized prices.

Basaglar

For the second quarter of 2020, worldwide Basaglar revenue was \$290.4 million and was flat compared with the second quarter of 2019. U.S. revenue decreased 1 percent, to \$229.7 million, driven by lower realized prices, partially offset by increased demand. Revenue outside the U.S. increased 4 percent, to \$60.7 million, 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. Lilly reports as cost of sales payments made to Boehringer Ingelheim for royalties and for its portion of the gross margin in 2020 and 2019, respectively.

Jardiance

The company's worldwide Jardiance revenue during the second quarter of 2020 was \$262.0 million, an increase of 13 percent compared with the second quarter of 2019. U.S. revenue increased 2 percent, to \$145.1 million, driven by increased demand. Revenue outside the U.S. was \$116.9 million, an increase of 31 percent, driven by increased volume. Jardiance is part of the company's alliance with Boehringer Ingelheim. Lilly reports as revenue royalties received on net sales of Jardiance and its portion of Jardiance's gross margin in 2020 and 2019, respectively.

Forteo

For the second quarter of 2020, worldwide Forteo revenue decreased 30 percent compared with the second quarter of 2019, to \$252.7 million. U.S. revenue decreased 31 percent, to \$119.6 million, driven by lower demand and lower realized prices primarily due to the unfavorable impact of higher contracted rates. Revenue outside the U.S. decreased 29 percent to \$133.0 million, primarily driven by decreased volume and lower realized prices.

The company expects further volume declines for Forteo as a result of competitive dynamics in the U.S. and the entry of generic and biosimilar competition following the loss of patent exclusivity in the third quarter of 2019 in the U.S., Japan and major European markets.

Cyramza

For the second quarter of 2020, worldwide Cyramza revenue was \$256.7 million, an increase of 6 percent compared with the second quarter of 2019. U.S. revenue was \$94.1 million, an increase of 5 percent, primarily driven by higher realized prices and increased demand. Revenue outside the U.S. was \$162.7 million, an increase of 7 percent, driven by increased volume, partially offset by lower realized prices.

Verzenio

For the second quarter of 2020, worldwide Verzenio revenue increased 56 percent compared with the second quarter of 2019, to \$208.6 million. U.S. revenue was \$141.7 million, an increase of 35 percent, primarily driven by increased demand and, to a lesser extent, higher realized prices. Revenue outside the U.S. was \$66.9 million, an increase of \$38.3 million compared with the second quarter of 2019.

Olumiant

For the second quarter of 2020, Olumiant generated worldwide revenue of \$145.0 million. U.S. revenue was \$13.2 million. Revenue outside the U.S. was \$131.8 million, an increase of 44 percent compared with the second quarter of 2019, driven by increased volume.

Emgality

For the second quarter of 2020, Emgality generated worldwide revenue of \$87.4 million, an increase of \$13.4 million compared with the first quarter of 2020. U.S. revenue was \$80.6 million, an increase of \$13.2 million compared with the first quarter of 2020, primarily driven by increased demand and,

to a lesser extent, higher realized prices due to changes to estimates in rebates and discounts. Revenue outside of the U.S. was \$6.8 million in the second quarter of 2020.

Tyvyt

The company's Tyvyt revenue during the second quarter of 2020 was \$64.1 million, an increase of \$6.7 million compared with the first quarter of 2020. Tyvyt is part of the company's alliance with Innovent Biologics, Inc. in China. Lilly reports total sales of Tyvyt made by Lilly as revenue, with payments made to Innovent for its portion of the gross margin reported as cost of sales. Lilly also reports as revenue a portion of the gross margin for Tyvyt sales made by Innovent.

Baqsimi

For the second quarter of 2020, Baqsimi generated worldwide revenue of \$13.6 million, a decrease of 4.2 million compared with the first quarter of 2020. U.S revenue was \$11.1 million, while revenue outside the U.S. was \$2.6 million.

Retevmo

For the second quarter of 2020, Retevmo generated U.S. revenue of \$6.3 million. Retevmo was approved by the FDA and launched in the U.S. during the second quarter of 2020.

2020 Financial Guidance

The company has updated certain elements of its 2020 financial guidance to reflect management's current expectations for underlying business performance.

There is uncertainty in the company's 2020 financial guidance surrounding the extent and duration of the impact of the COVID-19 pandemic. Key management assumptions related to the COVID-19 pandemic that support the company's 2020 guidance include:

- Healthcare activity, including non-COVID-19 related patient visits with their physicians, will align more closely with historical levels in the second half of 2020;
- New-to-brand prescription trends will improve in the U.S. in the second half of 2020, exceeding pre-pandemic levels by the fourth quarter of 2020 for most brands;
- Increased utilization of patient affordability programs and changes in segment mix due to higher U.S. unemployment will have a modestly negative impact U.S. pricing;
- Promotional spend will constitute a mix of in-person customer interactions, direct-to-consumer advertising and investments in digital promotion;
- Clinical trial enrollment in existing studies, as well as initiation of new clinical trials, will resume in the second half of 2020; and
- Investment in COVID-19 related research, testing and support will continue throughout 2020.

The company now expects earnings per share for 2020 to be in the range of \$6.48 to \$6.68 on a reported basis and \$7.20 to \$7.40 on a non-GAAP basis, reflecting expectations of lower marketing, selling and administrative expenses, higher other income and a lower effective tax rate.

	2020 Expectations	% Change from 2019
Earnings per share (reported)^(a)	\$6.48 to \$6.68	31% to 35%
Amortization of intangible assets	.36	
Acquired IPR&D ^(b)	.30	
Asset impairment, restructuring and other special charges	.06	
Earnings per share (non-GAAP)	\$7.20 to \$7.40	19% to 23%
Numbers may not add due to rounding		
^(a) Reported earnings per share percent change from 2019 calculated based on change from 2019 earnings per share from continuing operations.		
^(b) Includes costs related to both a business development transaction with a pre-clinical stage company as well as business development transactions with Sitryx, AbCellera Biologics Inc., Evox Therapeutics, and Junshi Biosciences.		

The company still anticipates 2020 revenue between \$23.7 billion and \$24.2 billion. Revenue growth is still expected to be driven by volume from key growth products including Trulicity, Taltz, Basaglar, Jardiance, Verzenio, Cyramza, Olumiant, Emgality, Baqsimi, Tyvyt, and Retevmo. Revenue growth is expected to be partially offset by lower revenue for products that have lost patent exclusivity. Revenue growth is also expected to be partially offset by a mid-single digit net price decline in the U.S. (driven primarily by rebates and legislated increases to Medicare Part D cost sharing, and patient affordability programs), as well as net price declines in China, Japan and Europe.

Gross margin as a percent of revenue is now expected to be approximately 78 percent on a reported basis and approximately 80 percent on a non-GAAP basis, reflecting changes in the geographic mix of product sales and lower realized prices on revenue.

Marketing, selling and administrative expenses are now expected to be in the range of \$6.0 billion to \$6.2 billion, reflecting savings from reduced travel, meetings, and promotional activities. Research and development expenses are still expected to be in the range of \$5.6 billion to \$5.9 billion.

Operating margin percentage, defined as operating income as a percent of revenue, is still expected to be 28 percent on a reported basis and 31 percent on a non-GAAP basis.

Other income (expense) is now expected to be in the range of \$350 to \$500 million of income, reflecting mark-to-market gains on investment securities in the second quarter of 2020.

The 2020 effective tax rate is now expected to be approximately 14 percent on both a reported basis and a non-GAAP basis, reflecting net discrete tax benefits recognized in the first six months of 2020.

The following table summarizes the company's 2020 financial guidance:

	2020 Guidance	
	<u>Prior</u>	<u>Updated</u>
Revenue	\$23.7 to \$24.2 billion	Unchanged
Gross Margin % of Revenue (reported)	Approx. 79%	Approx. 78%
Gross Margin % of Revenue (non-GAAP)	Approx. 81%	Approx. 80%
Marketing, Selling & Administrative	\$6.2 to \$6.4 billion	\$6.0 to \$6.2 billion
Research & Development	\$5.6 to \$5.9 billion	Unchanged
Other Income/(Expense)	\$(150) to \$0 million	\$350 to \$500 million
Tax Rate	Approx. 15%	Approx. 14%
Earnings per share (reported)	\$6.20 to \$6.40	\$6.48 to \$6.68
Earnings per share (non-GAAP)	\$6.70 to \$6.90	\$7.20 to \$7.40
Operating Income % of Revenue (reported)	28%	Unchanged
Operating Income % of Revenue (non-GAAP)	31%	Unchanged
Non-GAAP guidance reflects adjustments presented in 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 2020 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 the company's 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 actions of governmental and private payers affecting the pricing of, reimbursement for, and access to pharmaceuticals; 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; the impact of the evolving COVID-19 pandemic, and the global response thereto; reliance on third-party relationships and outsourcing arrangements; 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 subsequent Forms 8-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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Alimta® (pemetrexed disodium, Lilly)
Baqsimi™ (glucagon, Lilly)
Basaglar® (insulin glargine injection, Lilly)
Cialis® (tadalafil, Lilly)
Cymbalta® (duloxetine, 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)
Lyumjev™ (insulin lispro-aabc injection, Lilly)
Olumiant® (baricitinib, Lilly)
QBREXZA® (Glycopyrronium cloth, Dermira)
Retevmo™ (selpercatinib, Lilly)
Synjardy® (empagliflozin/metformin, Boehringer Ingelheim)
Taltz® (ixekizumab, Lilly)
Tauvid™ (flortaucipir F 18 injection, Lilly)
Trajenta® (linagliptin, Boehringer Ingelheim)
Trijardy™ XR (empagliflozin/linagliptin/metformin hydrochloride extended release tablets, Boehringer Ingelheim)
Trulicity® (dulaglutide, Lilly)
Tyvyt® (sintilimab injection, Lilly)
Verzenio® (abemaciclib, Lilly)

Third party trademarks used herein are trademarks of their respective owners.

Eli Lilly and Company Employment Information

	<u>June 30, 2020</u>	<u>December 31, 2019</u>
Worldwide Employees	34,720	33,755

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,		
	2020	2019	% Chg.	2020	2019	% Chg.
Revenue	\$ 5,499.4	\$ 5,636.7	(2)%	\$ 11,359.2	\$ 10,728.9	6%
Cost of sales	1,222.0	1,124.9	9%	2,437.1	2,263.6	8%
Research and development	1,390.2	1,402.2	(1)%	2,782.3	2,632.7	6%
Marketing, selling and administrative	1,448.6	1,586.3	(9)%	2,998.2	3,103.4	(3)%
Acquired in-process research and development	241.8	25.0	NM	294.1	161.9	82%
Asset impairment, restructuring and other special charges	—	—	NM	59.9	423.9	(86)%
Operating income	1,196.8	1,498.3	(20)%	2,787.6	2,143.4	30%
Net interest income (expense)	(81.2)	(91.5)		(159.4)	(147.4)	
Net other income (expense)	528.1	59.1		695.4	201.0	
Other income (expense)	446.9	(32.4)	NM	536.0	53.6	NM
Income before income taxes	1,643.7	1,465.9	12%	3,323.6	2,197.0	51%
Income tax expense	231.7	138.7	67%	455.1	308.7	47%
Net income from continuing operations	1,412.0	1,327.2	6%	2,868.5	1,888.3	52%
Net income from discontinued operations	—	—	NM	—	3,680.5	NM
Net income	\$ <u>1,412.0</u>	\$ <u>1,327.2</u>	6%	\$ <u>2,868.5</u>	\$ <u>5,568.8</u>	(48)%
Earnings from continuing operations - diluted	1.55	1.44	8%	3.15	1.98	59%
Earnings from discontinued operations - diluted	—	—	NM	—	3.86	NM
Earnings per share - diluted	\$ <u>1.55</u>	\$ <u>1.44</u>	8%	\$ <u>3.15</u>	\$ <u>5.84</u>	(46)%
Dividends paid per share	\$ 0.740	\$ 0.645	15%	\$ 1.480	\$ 1.290	15%
Weighted-average shares outstanding (thousands) - diluted	910,890	924,630		911,605	954,156	

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, 2020			Three Months Ended June 30, 2019		
	GAAP Reported	Adjustments ^(b)	Non-GAAP Adjusted ^(a)	GAAP Reported	Adjustments ^(c)	Non-GAAP Adjusted ^(a)
Cost of sales	\$ 1,222.0	\$ (102.8)	\$ 1,119.2	\$ 1,124.9	\$ (51.6)	\$ 1,073.3
Acquired in-process research and development	241.8	(241.8)	—	25.0	(25.0)	—
Income tax expense	231.7	35.4	267.1	138.7	15.8	154.5
Net income	1,412.0	309.2	1,721.2	1,327.2	60.8	1,388.0
Earnings per share - diluted	1.55	0.34	1.89	1.44	0.07	1.50

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, 2020, include the following:

(Dollars in millions, except per share data)	Amortization ⁽ⁱ⁾	IPR&D ⁽ⁱⁱ⁾	Total
Cost of sales	\$ (102.8)	\$ —	\$ (102.8)
Acquired in-process research and development	—	(241.8)	(241.8)
Income taxes	21.3	14.1	35.4
Net income	81.5	227.7	309.2
Earnings per share - diluted	0.09	0.25	0.34

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 both a business development transaction with a pre-clinical stage company as well as business development transactions with AbCellera Biologics Inc., Evox Therapeutics, and Junshi Biosciences.

(c) 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
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 the business development transaction with Avidity Biosciences, Inc.

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, 2020			Six Months Ended June 30, 2019		
	GAAP Reported	Adjustments ^(b)	Non-GAAP Adjusted ^(a)	GAAP Reported	Adjustments ^(c)	Non-GAAP Adjusted ^(a)
Cost of sales	\$ 2,437.1	\$ (161.4)	\$ 2,275.7	\$ 2,263.6	\$ (179.8)	\$ 2,083.8
Acquired in-process research and development	294.1	(294.1)	—	161.9	(161.9)	—
Asset impairment, restructuring and other special charges	59.9	(59.9)	—	423.9	(423.9)	—
Income tax expense	455.1	63.9	519.0	308.7	29.2	337.9
Net income from continuing operations	2,868.5	451.5	3,320.0	1,888.3	736.4	2,624.7
Net income from discontinued operations	—	—	—	3,680.5	(3,680.5)	—
Net income	2,868.5	451.5	3,320.0	5,568.8	(2,944.1)	2,624.7
Earnings per share - diluted	3.15	0.49	3.64	5.84	(3.01)	2.83
Weighted-average shares outstanding (thousands) - diluted	911,605	—	911,605	954,156	(27,083)	927,073

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, 2020, include the following:

(Dollars in millions, except per share data)	Amortization ⁽ⁱ⁾	IPR&D ⁽ⁱⁱ⁾	Other specified items ⁽ⁱⁱⁱ⁾	Total
Cost of sales	\$ (157.2)	\$ —	\$ (4.2)	\$ (161.4)
Acquired in-process research and development	—	(294.1)	—	(294.1)
Asset impairment, restructuring and other special charges	—	—	(59.9)	(59.9)
Income taxes	32.6	25.1	6.2	63.9
Net income	124.6	269.0	57.9	451.5
Earnings per share – diluted	0.14	0.30	0.06	0.49

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 payments for acquired in-process research and development projects acquired in a transaction other than a business combination. These costs were related to both a business development transaction with a pre-clinical stage company as well as business development transactions with Sitryx, AbCellera Biologics Inc., Evox Therapeutics, and Junshi Biosciences.
- iii. Asset impairment, restructuring and other special charges exclude primarily acquisition and integration costs as part of the closing of the acquisition of Dermira.

(c) 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
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, primarily driven by the acquisition of 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 Elanco.