UNITED STATES
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): August 3, 2021

ELI LILLY AND COMPANY

(Exact Name of Registrant as Specified in its Charter)

Indiana	**001-06351**	**35-0470950**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

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

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

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.):

☐ 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))

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

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. ☐

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 (the "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 filed 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 August 3, 2021, announcing the financial results of Eli Lilly and Company for the quarter ended June 30, 2021, including, among other things, unaudited financial results for that period.

Item 9.01. Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press Release of Eli Lilly and Company, dated August 3, 2021.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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
Date:	August 3, 2021

August 3, 2021

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Lilly Delivers Strong Second-Quarter 2021 Financial Results, Updates 2021 Financial Guidance

- *Revenue in the second quarter of 2021 increased 23 percent, driven by volume growth of 22 percent. Revenue growth was 12 percent when excluding effects of 2020 COVID-related stocking patterns, revenue from COVID-19 antibodies and recent business development.*
- *Year-to-date revenue grew 11 percent - excluding revenue from COVID-19 antibodies - with strong sequential growth from first quarter to second quarter 2021, suggesting continued recovery from the COVID-19 pandemic in line with company expectations.*
- *Revenue from all key products grew in the quarter and 2021 year-to-date. These key growth products, consisting of Trulicity, Taltz, Verzenio, Jardiance, Emgality, Olumiant, Tyvyt, Retevmo, and Cyramza, contributed 17 percentage points of revenue growth and represented approximately 54 percent of total revenue in the second quarter of 2021, excluding revenue from COVID-19 antibodies.*
- *Notable pipeline events included positive data readouts for tirzepatide for type 2 diabetes and Jardiance for adults, with or without diabetes, who live with heart failure with preserved ejection fraction (HFpEF). The company announced plans to submit donanemab for Alzheimer's disease and tirzepatide for type 2 diabetes to regulatory authorities by the end of 2021.*
- *Second-quarter 2021 operating expenses increased 18 percent, driven primarily by higher research and development investments for late-stage assets, as well as higher relative marketing and selling expenses due to pandemic-related spending reductions in 2020.*
- *Second-quarter 2021 earnings per share (EPS) decreased to $1.53 on a reported basis and increased to $1.87 on a non-GAAP basis.*
- *2021 EPS guidance updated to be in the range of $6.73 to $6.93 on a reported basis and remains in the range of $7.80 to $8.00 on a non-GAAP basis.*

Eli Lilly and Company (NYSE: LLY) today announced financial results for the second quarter of 2021.

"We delivered strong performance this quarter, with volume-driven growth across our core business and most major geographies. We accelerated use of our newest medicines around the world with solid sequential growth versus first-quarter 2021," said David A. Ricks, Lilly's chairman and CEO. "We had another robust period of pipeline milestones, as we announced plans to submit tirzepatide in type 2 diabetes and donanemab in Alzheimer's disease to regulatory authorities later this year, as well as positive results for Jardiance in patients with heart failure with preserved ejection fraction. We continue to increase investment in our future and look forward to several additional pipeline events in the second half of the year, along with the continued strengthening of our business."

$ in millions, except per share data	Second Quarter		%
	2021	2020	Change
Revenue	$ 6,740.1	$ 5,499.4	23%
Net Income – Reported	1,390.2	1,412.0	(2)%
EPS – Reported	1.53	1.55	(1)%
Net Income – Non-GAAP	1,703.3	1,323.0	29%
EPS – Non-GAAP	1.87	1.45	29%

Certain financial information for 2021 and 2020 is presented on both a reported and a non-GAAP basis. Some numbers in this press release may not add due to rounding. Reported results were prepared in accordance with U.S. generally accepted accounting principles (GAAP) and include all revenue and expenses recognized during the periods. Non-GAAP measures reflect adjustments for the items described in the reconciliation tables later in the release. Beginning in 2021, non-GAAP measures exclude gains and losses on investments in equity securities and 2020 amounts have been reclassified for comparability. The company's 2021 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.

Key Events Over the Last Three Months

Regulatory

- The FDA has broadened the Emergency Use Authorization (EUA) for baricitinib to allow for treatment with or without remdesivir. The EUA now provides for the use of baricitinib for the treatment of COVID-19 in hospitalized adults and pediatric patients two years of age or older requiring supplemental oxygen, non-invasive or invasive mechanical ventilation or extracorporeal membrane oxygenation (ECMO).
- The company announced donanemab received Breakthrough Therapy designation for treatment of Alzheimer's disease and its intention to submit a biologics license application (BLA) for donanemab under the accelerated approval pathway later this year based on data from TRAILBLAZER-ALZ.
- The company confirmed the tirzepatide SURPASS program has met global regulatory submission requirements for evaluating cardiovascular risk and its intention to submit the registration package to regulatory authorities by the end of 2021.
- The European Commission granted marketing authorization for Jardiance® as a treatment for adults with symptomatic chronic heart failure with reduced ejection fraction (systolic heart failure).
- The company and Incyte announced the FDA will not meet the Prescription Drug User Fee Act (PDUFA) action date for the supplemental new drug application (sNDA) for baricitinib for the treatment of adults with moderate to severe atopic dermatitis. The delay is related to the FDA's ongoing assessment of JAK inhibitors.
- In June 2021, the Office of the Assistant Secretary for Preparedness and Response halted shipment of bamlanivimab and etesevimab administered together in the U.S. This was due to the prevalence of the Gamma and Beta variants in the U.S. at that time and the fact that bamlanivimab and etesevimab administered together do not retain neutralization effects against those variants. The COVID-19 pandemic has involved, and may continue to involve, the spread of variants, including the Delta variant which is currently estimated to be the most dominant variant in the U.S. Preclinical data demonstrate that bamlanivimab and etesevimab

administered together retain neutralization activity against the variants currently in circulation in many countries, including Delta and Alpha.

Clinical

- The company announced positive top-line results from the SURPASS-4 Phase 3 clinical trial of tirzepatide in adults with type 2 diabetes, evaluating A1C and body weight reductions from baseline. The trial compared tirzepatide to insulin glargine in adults with type 2 diabetes and increased cardiovascular risk. Additionally, results from previously announced SURPASS trials were presented at the American Diabetes Association Scientific Sessions.
- The company and Boehringer Ingelheim announced positive top-line data from the EMPEROR-Preserved Phase 3 trial in which Jardiance significantly reduced the risk of the composite of cardiovascular death or hospitalization for heart failure in adults, with or without diabetes, who live with heart failure with preserved ejection fraction (HFpEF).
- The company and Pfizer Inc. announced top-line results of a Phase 3 study evaluating subcutaneous administration of tanezumab in adults with moderate to severe cancer pain due to bone metastases or multiple myeloma. Study A4091061 (NCT02609828) met its primary endpoint of demonstrating a statistically significant improvement in daily average pain intensity at eight weeks for tanezumab compared to placebo in patients receiving background opioid therapy. Preliminary safety data showed that during the 24-week treatment period, the adverse event profile of tanezumab 20 mg was generally consistent with the adverse events expected in patients with cancer pain due to bone metastasis and the known safety profile of tanezumab. There were two adjudicated composite joint safety outcomes, both pathological fractures, which occurred near the site of the bone metastases in tanezumab-treated patients.

Business Development/Other Developments

- The company and MiNA Therapeutics Limited announced a global research collaboration to develop novel drug candidates using MiNA's proprietary small activating RNA (saRNA) technology platform.

- The company announced the acquisition of Protomer Technologies Inc., whose proprietary peptide- and protein-engineering platform is used to identify and synthesize molecules that can sense glucose or other endogenous modulators of protein activity.
- Loxo Oncology at Lilly and Kumquat Biosciences Inc. announced an exclusive collaboration focused on the discovery, development and commercialization of potential novel small molecules that stimulate tumor-specific immune responses.
- The company announced the authorization of the repurchase of up to an additional $5 billion of the company's common stock.

Second-Quarter Reported Results

In the second quarter of 2021, worldwide revenue was $6.740 billion, an increase of 23 percent compared with the second quarter of 2020, driven by a 22 percent increase in volume and a 3 percent increase due to the favorable impact of foreign exchange rates, partially offset by a 2 percent decrease due to lower realized prices. Key growth products, consisting of Trulicity®, Taltz®, Verzenio®, Jardiance, Emgality®, Olumiant®, Tyvyt®, Retevmo® and Cyramza®, contributed 17 percentage points of revenue growth and represented approximately 54 percent of total revenue for the second quarter of 2021, excluding revenue from COVID-19 antibodies. The company recognized worldwide revenue of $148.9 million in the second quarter of 2021 for its COVID-19 antibodies. The company estimates that the COVID-19 pandemic negatively impacted worldwide revenue in the second quarter of 2020, causing approximately $250 million of decreased customer buying that largely offset product stocking that occurred in the first quarter of 2020. During the second quarter of 2021, the company recognized $170.0 million of revenue associated with the sale of its rights to Cialis® in China.

Excluding $148.9 million of revenue in the second quarter of 2021 from COVID-19 antibodies, $170.0 million of revenue from the company's sale of its rights to Cialis in China, and the estimated negative impact of approximately $250 million of revenue in the second quarter of 2020 associated with decreased customer buying patterns, worldwide revenue in the second quarter of 2021 grew by 12 percent.

Revenue in the U.S. increased 18 percent, to $3.704 billion, driven by an 18 percent increase in volume, partially offset by a 1 percent decrease due to lower realized prices. The company recognized U.S. revenue of $83.4 million in the second quarter of 2021 for COVID-19 antibodies. Excluding revenue from sales of COVID-19 antibodies and the approximately $200 million negative impact of customer buying patterns in the second quarter of 2020 resulting from the COVID-19 pandemic, revenue in the U.S. increased by 8 percent. The increase in U.S. volume was driven by certain key growth products, including Trulicity, Taltz, Verzenio, Jardiance, Retevmo and Emgality. Segment mix was not a major driver of U.S. price performance in the second quarter of 2021, as increased utilization in more highly-rebated government segments was offset by lower utilization in the 340B segment, primarily for the diabetes portfolio.

Revenue outside the U.S. increased 29 percent, to $3.036 billion, driven by a 26 percent increase in volume and a 6 percent increase due to the favorable impact of foreign exchange rates, partially offset by a 4 percent decrease due to lower realized prices. The increase in volume outside the U.S. was primarily driven by increased volume for certain key growth products, including Trulicity, Olumiant, Verzenio, Taltz, Jardiance, Emgality and Tyvyt®, as well as the company's sale of its rights to Cialis in China and $65.7 million of revenue from sales of COVID-19 antibodies. Excluding revenue from sales of COVID-19 antibodies, the sale of the company's rights to Cialis in China and the approximately $50 million negative impact of customer buying patterns in the second quarter of 2020 resulting from the COVID-19 pandemic, revenue outside the U.S. increased by 16 percent.

Gross margin increased 12 percent, to $4.787 billion, in the second quarter of 2021 compared with the second quarter of 2020. Gross margin as a percent of revenue was 71.0 percent, a decrease of 6.8 percentage points compared with the second quarter of 2020. The decrease in gross margin percent was primarily due to an excess inventory charge of $423.0 million recognized in the second quarter of 2021 related to COVID-19 antibodies. As part of Lilly's response to the COVID-19 pandemic, and at the request of U.S. and international governments, Lilly invested in large-scale manufacturing of

COVID-19 antibodies at risk, in order to ensure rapid access to patients around the world. As the COVID-19 pandemic has continued to evolve during the second quarter of 2021, Lilly incurred excess inventory charges primarily due to the combination of changes to current and forecasted demand from U.S. and international governments and near-term expiry dates of COVID-19 antibodies.

Total operating expenses in the second quarter of 2021, defined as the sum of research and development and marketing, selling, and administrative expenses, increased 18 percent to $3.359 billion compared with the second quarter of 2020. Research and development expenses increased 20 percent to $1.673 billion, or 24.8 percent of revenue, driven primarily by higher development expenses for late-stage assets. Research and development expenses for COVID-19 therapies were approximately $85 million in the second quarter of 2021. Marketing, selling, and administrative expenses increased 16 percent to $1.686 billion, driven primarily by lower marketing and selling expenses in the second quarter of 2020 due to pandemic-related spending reductions.

In the second quarter of 2021, the company recognized acquired in-process research and development charges of $25.0 million related to a business development transaction with MiNA Therapeutics Limited. 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 business development transactions with AbCellera Biologics Inc., Evox Therapeutics Limited, and Junshi Biosciences Co., Ltd.

Operating income in the second quarter of 2021 was $1.403 billion, compared to $1.197 billion in the second quarter of 2020. The increase in operating income was driven by higher gross margin and lower acquired in-process research and development charges, partially offset by higher operating expenses. Operating margin, defined as operating income as a percent of revenue, was 20.8 percent.

Other income was $190.5 million in the second quarter of 2021, compared with other income of $446.9 million in the second quarter of 2020. The decrease in other income was driven primarily by

lower net gains on investments in equity securities, partially offset by income from patent settlements in Europe for Alimta® in the second quarter of 2021.

The effective tax rate was 12.8 percent in the second quarter of 2021, compared with 14.1 percent in the second quarter of 2020. The lower effective tax rate in the second quarter of 2021 was primarily due to the income tax impact of the excess inventory charge related to COVID-19 antibodies and lower income tax expense related to lower net gains on investment securities compared to the same period in 2020, partially offset by a lower net discrete tax benefit compared to the same period in 2020 and a nondeductible acquired in-process research and development charge in the second quarter of 2020.

In the second quarter of 2021, net income and earnings per share were $1.390 billion and $1.53, respectively, compared with net income of $1.412 billion and earnings per share of $1.55 in the second quarter of 2020. The decrease in net income and earnings per share in the second quarter of 2021 was driven by lower other income, largely offset by higher operating income and lower income tax expense.

Second-Quarter Non-GAAP Measures

On a non-GAAP basis, second-quarter 2021 gross margin increased 22 percent, to $5.342 billion compared with the second quarter of 2020. Gross margin as a percent of revenue was 79.3 percent, a decrease of 0.3 percentage points. The decrease in gross margin percent was primarily driven by sales of COVID-19 antibodies and the unfavorable effect of foreign exchange rates on international inventories sold, partially offset by favorable product mix.

Operating income on a non-GAAP basis increased $442.2 million, or 29 percent, to $1.984 billion in the second quarter of 2021 compared with the second quarter of 2020, due to higher gross margin, partially offset by higher operating expenses. Operating margin was 29.4 percent on a non-GAAP basis.

Other income was $5.0 million in the second quarter of 2021, compared with other expense of $57.1 million in the second quarter of 2020. The increase in other income was driven primarily by income from patent settlements in Europe for Alimta in the second quarter of 2021.

The effective tax rate on a non-GAAP basis was 14.4 percent in the second quarter of 2021, compared with 10.9 percent in the second quarter of 2020. The effective tax rates for both periods were reduced by net discrete tax benefits, with a lower net discrete tax benefit reflected in the second quarter of 2021.

On a non-GAAP basis, in the second quarter of 2021 net income increased 29 percent, to $1.703 billion, while earnings per share increased 29 percent, to $1.87, compared with $1.323 billion and $1.45, respectively, in the second quarter of 2020. The increase in net income and earnings per share was primarily driven by higher operating 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.

	Second Quarter		
	2021	2020	% Change
Earnings per share (reported)	**$ 1.53**	**$ 1.55**	**(1)%**
COVID-19 antibodies excess inventory charges	.37	—	
Amortization of intangible assets	.12	.09	
Acquired in-process research and development	.02	.25	
Net gains on investments in equity securities	(.16)	(.44)	
Earnings per share (non-GAAP)	**$ 1.87**	**$ 1.45**	**29%**

Numbers may not add due to rounding.

Year-to-Date Reported Results

For the first six months of 2021, worldwide revenue increased 19 percent to $13.546 billion, compared with $11.359 billion in the same period in 2020. The increase in revenue was driven by a 20 percent increase in volume and a 3 percent increase due to the favorable impact of foreign exchange rates, partially offset by a 3 percent decrease due to lower realized prices. Excluding $959.1 million of revenue from COVID-19 antibodies and $170.0 million of revenue from the company's sale of its rights to Cialis in China, worldwide revenue grew by 9 percent. For the first six months of 2021, operating income was $2.559 billion, a decrease of 8 percent compared to the same period of 2020. Reported net income and earnings per share for the first six months of 2021 were $2.746 billion and $3.01, respectively, compared with $2.869 billion and $3.15, respectively, for the same period of 2020. The decreases in net income and earnings per share in the first six months of 2021 were driven primarily by lower operating income.

Year-to-Date Non-GAAP Measures

For the first six months of 2021, operating income was $3.857 billion on a non-GAAP basis, an increase of 17 percent compared to the same period of 2020. Net income and earnings per share, on a non-GAAP basis, were $3.405 billion and $3.74, respectively, compared with $2.794 billion and $3.07, respectively, for the same period of 2020.

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.

	Year-to-Date		
	2021	2020	% Change
Earnings per share (reported)	**$ 3.01**	**$ 3.15**	**(4)%**
COVID-19 antibodies excess inventory charges	.44	—	
Acquired in-process research and development	.28	.30	
Amortization of intangible assets	.22	.14	
Asset impairment, restructuring and other special charges	.19	.06	
Net gains on investments in equity securities	(.41)	(.58)	
Earnings per share (non-GAAP)	**$ 3.74**	**$ 3.07**	**22%**

Numbers may not add due to rounding.

Selected Revenue Highlights

Selected Revenue Highlights

(Dollars in millions)	Second Quarter			Year-to-Date		
Selected Products	2021	2020	% Change	2021	2020	% Change
Trulicity	$ 1,535.6	$ 1,229.8	25%	$ 2,988.1	$ 2,459.1	22%
Humalog®[(a)]	607.6	555.1	9%	1,224.6	1,250.8	(2)%
Alimta	610.6	539.1	13%	1,169.6	1,099.2	6%
Taltz	569.1	395.2	44%	972.4	838.7	16%
COVID-19 antibodies[(b)]	148.9	—	NM	959.1	—	NM
Jardiance[(c)]	356.5	262.0	36%	668.5	529.5	26%
Humulin®	315.3	313.6	1%	637.0	629.3	1%
Verzenio	341.3	208.6	64%	610.3	396.7	54%
Cyramza	268.7	256.7	5%	509.2	495.7	3%
Basaglar	210.7	290.4	(27)%	457.3	594.1	(23)%
Forteo®	218.4	252.7	(14)%	416.9	525.0	(21)%
Olumiant	208.4	145.0	44%	402.2	284.7	41%
Emgality	156.3	87.4	79%	275.7	161.5	71%
Tyvyt	105.0	64.1	64%	214.6	121.5	77%
Retevmo	25.7	6.3	NM	42.5	6.3	NM
Total Revenue	6,740.1	5,499.4	23%	13,545.7	11,359.2	19%

[(a)] Humalog includes Insulin Lispro
[(b)] COVID-19 antibodies include sales for bamlanivimab administered alone as well as sales for bamlanivimab and etesevimab administered together and were made pursuant to Emergency Use Authorizations
[(c)] Jardiance includes Glyxambi®, Synjardy®, and Trijardy® XR
NM – not meaningful

Impact of COVID-19 on Second-Quarter 2020 Revenue

The company estimates that the COVID-19 pandemic negatively impacted worldwide revenue in the second quarter of 2020, including decreased customer buying patterns of approximately $200 million in the U.S. and approximately $50 million outside the U.S. that largely offset product stocking that occurred in the first quarter of 2020. The company believes that this decrease in U.S. revenue in the second quarter of 2020 primarily impacted its portfolio of diabetes medicines, with estimated decreases of approximately $70 million to $80 million for insulin products and approximately $30 million to $40 million for Trulicity. The company also estimates that U.S. revenue for Taltz in the second quarter of 2020 was negatively impacted by approximately $20 million to $25 million.

Trulicity

Second-quarter 2021 worldwide Trulicity revenue was $1.536 billion, an increase of 25 percent compared with the second quarter of 2020. U.S. revenue increased 20 percent, to $1.148 billion, 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, partially offset by modest list price increases. Revenue outside the U.S. was $388.0 million, an increase of 40 percent, driven by increased volume and, to a lesser extent, the favorable impact of foreign exchange rates, partially offset by lower realized prices.

Humalog

For the second quarter of 2021, worldwide Humalog revenue increased 9 percent compared with the second quarter of 2020, to $607.6 million. Revenue in the U.S. increased 17 percent, to $329.1 million, driven by increased demand and higher realized prices due to changes to estimates in rebates and discounts. Revenue outside the U.S. increased 2 percent, to $278.6 million, driven by the favorable impact of foreign exchange rates, partially offset by decreased volume and, to a lesser extent, lower realized prices.

Alimta

For the second quarter of 2021, worldwide Alimta revenue increased 13 percent compared with the second quarter of 2020, to $610.6 million. U.S. revenue increased 11 percent, to $353.5 million, primarily driven by higher volume as a result of customer buying patterns and, to a lesser extent, higher realized prices. Revenue outside the U.S. increased 16 percent to $257.1 million, primarily driven by increased volume and, to a lesser extent, the favorable impact of foreign exchange rates, partially offset by lower realized prices.

The company expects volume declines in the second half of 2021 for Alimta as a result of the anticipated entry of generic competition due to the loss of patent exclusivity in Japan and major European markets.

Taltz

For the second quarter of 2021, worldwide Taltz revenue increased 44 percent compared with the second quarter of 2020, to $569.1 million. U.S. revenue increased 38 percent, to $399.8 million, primarily driven by increased demand, partially offset by lower realized prices. The lower realized prices were driven by increased rebates to gain commercial access. The revenue increase was favorably impacted by inventory destocking in the second quarter of 2020. Revenue outside the U.S. increased 60 percent, to $169.3 million, driven by increased volume and, to a lesser extent, the favorable impact of foreign exchange rates.

Jardiance

The company’s worldwide Jardiance revenue during the second quarter of 2021 was $356.5 million, an increase of 36 percent compared with the second quarter of 2020. U.S. revenue increased 34 percent, to $194.4 million, primarily driven by increased demand. Revenue outside the U.S. was $162.1 million, an increase of 39 percent, driven by increased volume and, to a lesser extent, the favorable impact of

foreign exchange rates. Jardiance is part of the company’s alliance with Boehringer Ingelheim. Lilly reports as revenue royalties received on net sales of Jardiance.

Humulin

For the second quarter of 2021, worldwide Humulin revenue increased 1 percent compared with the second quarter of 2020, to $315.3 million. U.S. revenue increased 3 percent, to $221.1 million, driven by increased volume, partially offset by lower realized prices. Revenue outside the U.S. decreased 5 percent, to $94.3 million, due to decreased volume, partially offset by the favorable impact of foreign exchange rates and higher realized prices.

Verzenio

For the second quarter of 2021, worldwide Verzenio revenue increased 64 percent compared with the second quarter of 2020, to $341.3 million. U.S. revenue was $209.7 million, an increase of 48 percent, driven by increased demand and, to a lesser extent, higher realized prices. Revenue outside the U.S. was $131.6 million, an increase of 97 percent, primarily driven by increased volume.

Cyramza

For the second quarter of 2021, worldwide Cyramza revenue was $268.7 million, an increase of 5 percent compared with the second quarter of 2020. U.S. revenue was $101.4 million, an increase of 8 percent, primarily driven by increased volume. Revenue outside the U.S. was $167.3 million, an increase of 3 percent, primarily driven by increased volume.

Basaglar

For the second quarter of 2021, worldwide Basaglar revenue was $210.7 million, a decrease of 27 percent compared with the second quarter of 2020. U.S. revenue decreased 42 percent, to $133.4 million, driven by continued competitive pressures that resulted in lower realized prices and, to a lesser extent, decreased demand. Due to competitive pressures, some price decline and loss of market share over time is expected. Revenue outside the U.S. increased 27 percent, to $77.3 million, driven by

increased volume and, to a lesser extent, the favorable 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.

Forteo

For the second quarter of 2021, worldwide Forteo revenue decreased 14 percent compared with the second quarter of 2020, to $218.4 million. U.S. revenue increased 3 percent, to $122.8 million, driven by higher realized prices, largely offset by decreased demand. Revenue outside the U.S. decreased 28 percent to $95.6 million, primarily driven by decreased volume.

The company expects further volume declines for Forteo as a result of the anticipated entry of generic and biosimilar competition due to the loss of patent exclusivity in the U.S., Japan and major European markets.

Olumiant

For the second quarter of 2021, worldwide Olumiant revenue increased 44 percent compared with second quarter of 2020, to $208.4 million. U.S. revenue was $17.8 million. Revenue outside the U.S. was $190.6 million, an increase of 45 percent, driven by increased volume and, to a lesser extent, the favorable impact of foreign exchange rates, partially offset by lower realized prices.

Emgality

For the second quarter of 2021, Emgality generated worldwide revenue of $156.3 million, an increase of 79 percent compared with the second quarter of 2020. U.S. revenue was $112.1 million, an increase of 39 percent driven by higher realized prices and, to a lesser extent, increased demand. Revenue outside of the U.S. was $44.2 million.

Tyvyt

For the second quarter of 2021, the company's Tyvyt revenue in China was $105.0 million, an increase of 64 percent compared with the second quarter of 2020.

Tyvyt is part of the company’s alliance with Innovent. 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.

Retevmo

For the second quarter of 2021, Retevmo generated U.S. revenue of $22.5 million compared to revenue of $16.8 million in the first quarter of 2021. Retevmo was approved by the FDA and launched in the U.S. during the second quarter of 2020. Retevmo launched outside the U.S. and generated revenue of $3.2 million in the second quarter of 2021.

2021 Financial Guidance

The company has updated certain elements of its 2021 financial guidance on a reported basis. Earnings per share for 2021 are now expected to be in the range of $6.73 to $6.93 on a reported basis and remain in the range of $7.80 to $8.00 on a non-GAAP basis. The update to the company's 2021 financial guidance on a reported basis reflects adjustments shown in the reconciliation table below.

	2021 Expectations	% Change vs 2020
Earnings per share (reported)	**$6.73 to $6.93**	**(1)% to 2%**
Amortization of intangible assets	.47	
COVID-19 antibodies excess inventory charges	.44	
Acquired IPR&D[(a)]	.38	
Asset impairment, restructuring and other special charges	.19	
Net gains on investments in equity securities	(.41)	
Earnings per share (non-GAAP)	**$7.80 to $8.00**	**15% to 18%**

Numbers may not add due to rounding

(a) includes costs related to business development transactions with Rigel Pharmaceuticals, Inc., Precision Biosciences, Inc., Protomer Technologies Inc., Kumquat Biosciences Inc., Merus N.V., MiNA Therapeutics Limited, and Asahi Kasei Pharma Corporation.

The company now anticipates 2021 revenue to be between $26.8 billion and $27.4 billion. This modest change reflects an increase of $200 million in estimated revenue from products in the company's core business, reflecting strong performance and, to a lesser extent, the favorable impact of foreign exchange rates, and a reduction in estimated revenue from COVID-19 therapies, which is now expected to be in the range of $1.0 billion to $1.1 billion.

Gross margin as a percent of revenue for 2021 is now expected to be approximately 75 percent on a reported basis and is still expected to be approximately 79 percent on a non-GAAP basis. The

reduction in reported guidance reflects the impact of the excess inventory charges related to COVID-19 antibodies.

Marketing, selling and administrative expenses for 2021 are unchanged and remain in the range of $6.2 billion to $6.4 billion. Research and development expenses for 2021 are unchanged and remain in the range of $6.9 billion to $7.1 billion.

Operating margin for 2021 is now expected to be approximately 24 percent on a reported basis, reflecting primarily the impact of the excess inventory charges related to COVID-19 antibodies, and approximately 30 percent on a non-GAAP basis.

Other income (expense) for 2021 is now expected to be income in the range of $375 million to $475 million on a reported basis and expense in the range of $100 million to $0 on a non-GAAP basis. These estimates reflect the patent settlements in Europe for Alimta. The company's updated reported guidance also reflects the impact of net gains on investments in equity securities in the second quarter of 2021.

The 2021 effective tax rate is now expected to be approximately 12 percent on a reported basis, reflecting primarily the tax impact of the excess inventory charges related to COVID-19 antibodies, and is still expected to be approximately 13 percent on a non-GAAP basis.

The following table summarizes the company's 2021 financial guidance:

	2021 Guidance	
	Prior	Updated
Revenue	$26.6 to $27.6 billion	$26.8 to $27.4 billion
Gross Margin % of Revenue (reported)	Approx. 77%	Approx. 75%
Gross Margin % of Revenue (non-GAAP)	Approx. 79%	Unchanged
Marketing, Selling & Administrative	$6.2 to $6.4 billion	Unchanged
Research & Development	$6.9 to $7.1 billion	Unchanged
Other Income/(Expense) (reported)	$150 to $250 million	$375 to $475 million
Other Income/(Expense) (non-GAAP)	$(200) to $(100) million	$(100) million to $0
Tax Rate (reported)	Approx. 13%	Approx. 12%
Tax Rate (non-GAAP)	Approx. 13%	Unchanged
Earnings per Share (reported)	$7.03 to $7.23	$6.73 to $6.93
Earnings per Share (non-GAAP)	$7.80 to $8.00	Unchanged
Operating Margin (reported)	Approx. 26%	Approx. 24%
Operating Margin (non-GAAP)	Approx. 31%	Approx. 30%

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 2021 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. The following include some but not all of the factors that could cause actual results or events to differ materially from those anticipated, including the impact of the evolving COVID-19 pandemic and the global response thereto; uncertainties related to the company's efforts to develop potential treatments for COVID-19; the significant costs and uncertainties in the pharmaceutical research and development process, including with respect to the timing and process of obtaining regulatory approvals; the impact of acquisitions and business development transactions and related integration costs; the expiration of intellectual property protection for certain of the company's products and competition from generic and/or biosimilar products; the company's ability to protect and enforce patents and other intellectual property; changes in patent law or regulations related to data package exclusivity; competitive developments affecting current products and the company's pipeline; market uptake of recently launched products; information technology system inadequacies, breaches, or operating failures; unauthorized access, disclosure, misappropriation, or compromise of confidential information or other data stored in the company's IT systems, networks, and facilities, or those of third parties with whom the company shares its data; unexpected safety or efficacy concerns associated with the company's products; litigation, investigations, or other similar proceedings involving past, current, or future products or commercial activities as the company is largely self-insured; issues with product supply and regulatory approvals stemming from manufacturing difficulties or disruptions, including as a result of regulatory actions related to our facilities; reliance on third-party relationships and outsourcing arrangements; regulatory changes or other developments; regulatory actions regarding currently marketed products; continued pricing pressures and the impact of actions of governmental and private payers affecting pricing of, reimbursement for, and access to pharmaceuticals; devaluations in foreign currency exchange rates or changes in interest rates, and inflation; changes in tax law, tax rates, or events that differ from the company's assumptions related to tax positions; asset impairments and restructuring charges; the impact of global macroeconomic conditions and trade disruptions or disputes; changes in accounting and reporting standards promulgated by the Financial Accounting Standards Board and the Securities and Exchange Commission (SEC); and regulatory compliance problems or government investigations. 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.

# # #

Alimta® (pemetrexed disodium, Lilly)
Basaglar® (insulin glargine injection, Lilly)
Cialis® (tadalafil, Lilly)
Cyramza® (ramucirumab, Lilly)
Emgality® (galcanezumab-gnlm, Lilly)
Forteo® (teriparatide of recombinant DNA origin injection, Lilly)
Glyxambi® (empagliflozin/linagliptin, Boehringer Ingelheim)
Humalog® (insulin lispro injection of recombinant DNA origin, Lilly)
Humulin® (human insulin of recombinant DNA origin, Lilly)
Jardiance® (empagliflozin, Boehringer Ingelheim)
Olumiant® (baricitinib, Lilly)
QBREXZA® (glycopyrronium cloth, Dermira)
Retevmo® (selpercatinib, Lilly)
Synjardy® (empagliflozin/metformin, Boehringer Ingelheim)
Taltz® (ixekizumab, Lilly)
Trijardy® XR (empagliflozin/linagliptin/metformin hydrochloride extended release tablets, Boehringer Ingelheim)
Trulicity® (dulaglutide, Lilly)
Tyvyt® (sintilimab injection, Lilly)
Verzenio® (abemaciclib, Lilly)

Eli Lilly and Company Employment Information

	June 30, 2021	December 31, 2020
Worldwide Employees	34,657	34,960

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

	Three Months Ended June 30,			Six Months Ended June 30,		
	2021	2020	% Chg.	2021	2020	% Chg.
Revenue	$ 6,740.1	$ 5,499.4	23%	$ 13,545.7	$ 11,359.2	19%
Cost of sales	1,953.2	1,222.0	60%	3,831.8	2,437.1	57%
Research and development	1,672.8	1,390.2	20%	3,357.6	2,782.3	21%
Marketing, selling and administrative	1,685.7	1,448.6	16%	3,261.7	2,998.2	9%
Acquired in-process research and development	25.0	241.8	(90)%	324.3	294.1	10%
Asset impairment, restructuring and other special charges	—	—	NM	211.6	59.9	NM
Operating income	1,403.4	1,196.8	17%	2,558.7	2,787.6	(8)%
Net interest income (expense)	(81.5)	(81.2)		(163.8)	(159.4)	
Net other income (expense)	272.0	528.1		675.4	695.4	
Other income (expense)	190.5	446.9	(57)%	511.6	536.0	(5)%
Income before income taxes	1,593.9	1,643.7	(3)%	3,070.3	3,323.6	(8)%
Income tax expense	203.7	231.7	(12)%	324.8	455.1	(29)%
Net income	$ 1,390.2	$ 1,412.0	(2)%	$ 2,745.5	$ 2,868.5	(4)%
Earnings per share - diluted	$ 1.53	$ 1.55	(1)%	$ 3.01	$ 3.15	(4)%
Dividends paid per share	$ .85	.74		$ 1.70	$ 1.48	
Weighted-average shares outstanding (thousands) - diluted	910,384	910,890		911,623	911,605	

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, 2021			Three Months Ended June 30, 2020		
	GAAP Reported	Adjustments[(b)]	Non-GAAP Adjusted[(a)]	GAAP Reported	Adjustments[(c)]	Non-GAAP Adjusted[(a)]
Cost of sales	**$ 1,953.2**	$ (555.2)	$ 1,398.0	**$ 1,222.0**	$ (102.8)	$ 1,119.2
Acquired in-process research and development	**25.0**	(25.0)	—	**241.8**	(241.8)	—
Other income (expense)	**190.5**	(185.5)	5.0	**446.9**	(504.0)	(57.1)
Income tax expense	**203.7**	81.6	285.3	**231.7**	(70.4)	161.3
Net income	**1,390.2**	313.1	1,703.3	**1,412.0**	(89.0)	1,323.0
Earnings per share - diluted	**1.53**	0.34	1.87	**1.55**	(0.10)	1.45

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 other 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 also 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, 2021, include the following:

(Dollars in millions, except per share data)	Amortization[(i)]	IPR&D[(ii)]	Equity investments[(iii)]	Other specified items[(iv)]	**Total**
Cost of sales	$ (132.2)	$ —	$ —	$ (423.0)	**$ (555.2)**
Acquired in-process research and development	—	(25.0)	—	—	**(25.0)**
Other income (expense)	—	—	(185.5)	—	**(185.5)**
Income tax expense	27.0	5.3	(39.6)	88.8	**81.6**
Net income	105.2	19.7	(145.9)	334.2	**313.1**
Earnings per share - diluted	0.12	0.02	(0.16)	0.37	**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 a business development transaction with MiNA Therapeutics Limited.

iii. Exclude gains and losses on investments in equity securities.

iv. Exclude a charge resulting from excess inventory related to COVID-19 antibodies.

(c) 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)]	Equity investments[(iii)]	**Total**
Cost of sales	$ (102.8)	$ —	$ —	**$ (102.8)**
Acquired in-process research and development	—	(241.8)	—	**(241.8)**
Other income (expense)	—	—	(504.0)	**(504.0)**
Income tax expense	21.3	14.1	(105.8)	**(70.4)**
Net income	81.5	227.7	(398.2)	**(89.0)**
Earnings per share - diluted	0.09	0.25	(0.44)	**(0.10)**

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

iii. Exclude gains and losses on investments in equity securities.

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, 2021			Six Months Ended June 30, 2020		
	GAAP Reported	Adjustments[(b)]	Non-GAAP Adjusted[(a)]	GAAP Reported	Adjustments[(c)]	Non-GAAP Adjusted[(a)]
Cost of sales	**$ 3,831.8**	$ (762.4)	$ 3,069.4	**$ 2,437.1**	$ (161.4)	**$** 2,275.7
Acquired in-process research and development	**324.3**	(324.3)	—	**294.1**	(294.1)	—
Asset impairment, restructuring and other special charges	**211.6**	(211.6)	—	**59.9**	(59.9)	—
Other income (expense)	**511.6**	(472.0)	39.6	**536.0**	(665.7)	(129.7)
Income tax expense	**324.8**	166.6	491.4	**455.1**	(75.9)	379.2
Net income	**2,745.5**	659.7	3,405.2	**2,868.5**	(74.4)	2,794.1
Earnings per share - diluted	**3.01**	0.73	3.74	**3.15**	(0.08)	3.07

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 other 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 also 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, 2021, include the following:

(Dollars in millions, except per share data)	Amortization[(i)]	IPR&D[(ii)]	Equity investments[(iii)]	Other specified items[(iv)]	Total
Cost of sales	$ (257.9)	$ —	$ —	$ (504.5)	**$ (762.4)**
Acquired in-process research and development	—	(324.3)	—	—	**(324.3)**
Asset impairment, restructuring and other special charges	—	—	—	(211.6)	**(211.6)**
Other income (expense)	—	—	(472.0)	—	**(472.0)**
Income tax expense	53.0	68.1	(95.4)	140.9	**166.6**
Net income	204.9	256.2	(376.6)	575.2	**659.7**
Earnings per share – diluted	0.22	0.28	(0.41)	0.63	**0.73**

Numbers may not add due to rounding.

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

i. Exclude amortization of intangibles primarily associated with costs of marketed products acquired or licensed from third parties.

ii. Exclude costs associated with upfront payments for acquired in-process research and development projects acquired in a transaction other than a business combination. These costs were related to business development transactions with Rigel Pharmaceuticals, Inc., Precision Biosciences, Inc., Merus N.V., Asahi Kasei Pharma Corporation, and MiNA Therapeutics Limited.

iii. Exclude gains and losses on investments in equity securities.

iv. Exclude primarily charges resulting from excess inventory related to COVID-19 antibodies, an intangible asset impairment resulting from the sale of the rights to QBREXZA, and acquisition and integration costs recognized as part of the closing of the acquisition of Prevail Therapeutics Inc.

(c) 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]	Equity investments[iii]	Other specified items[iv]	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)**
Other income (expense)	—	—	(665.7)	—	**(665.7)**
Income tax expense	32.6	25.1	(139.8)	6.2	**(75.9)**
Net income	124.6	269.0	(525.9)	57.9	**(74.4)**
Earnings per share - diluted	0.14	0.30	(0.58)	0.06	**(0.08)**

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 Sitryx Therapeutics Limited, AbCellera Biologics Inc., Evox Therapeutics Limited, and Junshi Biosciences Co., Ltd.

iii. Exclude gains and losses on investments in equity securities.

iv. Asset impairment, restructuring and other special charges exclude primarily acquisition and integration costs as part of the closing of the acquisition of Dermira, Inc.