
**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): October 26, 2021

ELI LILLY AND COMPANY

(Exact Name of Registrant as Specified in its 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
(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))
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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
0.500% Notes due 2033	LLY33	New York Stock Exchange
6.77% Notes due 2036	LLY36	New York Stock Exchange
1.625% Notes due 2043	LLY43	New York Stock Exchange
1.700% Notes due 2049	LLY49A	New York Stock Exchange
1.125% Notes due 2051	LLY51	New York Stock Exchange
1.375% Notes due 2061	LLY61	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 October 26, 2021, announcing the financial results of Eli Lilly and Company for the quarter ended September 30, 2021, including, among other things, unaudited financial results for that period.

Item 9.01. Financial Statements and Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Eli Lilly and Company, dated October 26, 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: October 26, 2021



October 26, 2021

Eli Lilly and Company

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**Lilly Reports Robust Third-Quarter 2021 Financial Results
as Pipeline Success Strengthens Future Growth Potential**

- Revenue in the third quarter of 2021 increased 18 percent, driven by volume growth of 17 percent. When excluding revenue from COVID-19 therapies, revenue growth was 11 percent in both third-quarter and year-to-date 2021.
- 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 58 percent of total revenue in the third quarter of 2021, excluding revenue from COVID-19 therapies. Revenue from Trulicity, Taltz, Verzenio and Emgality each grew by more than 30 percent versus prior year.
- Third-quarter 2021 earnings per share (EPS) decreased to \$1.22 on a reported basis and increased to \$1.94 on a non-GAAP basis, representing 38 percent growth versus prior year.
- Lilly announces today its U.S. submission of tirzepatide in type 2 diabetes using a priority review voucher and initiation of a rolling submission for donanemab to the FDA for accelerated approval in early Alzheimer's disease.
- Other notable recent pipeline events include U.S. approvals for new indications for both Verzenio and Jardiance, submission of Jardiance in the U.S. and Europe for heart failure with preserved ejection fraction (HFpEF) and positive Phase 3 readouts for lebrikizumab in atopic dermatitis.

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

"Lilly demonstrated strong performance again this quarter. Revenue attributable to our newer medicines grew more than 35 percent and represented nearly 60 percent of our core business, an important indicator of our long-term growth potential," said David A. Ricks, Lilly's chairman and CEO. "With numerous positive pipeline events this quarter, we have the potential to continue to expand the number of patients we serve through new indications for both Verzenio and Jardiance. We also progressed innovative, potential best-in-class treatment options in areas with high unmet need

through a regulatory submission for tirzepatide in diabetes, the initiation of a rolling submission for donanemab in early Alzheimer’s disease, the submission of Jardiance in HFpEF, and positive Phase 3 results for lebrikizumab in patients with atopic dermatitis.”

\$ in millions, except per share data	<u>Third Quarter</u>		<u>% Change</u>
	<u>2021</u>	<u>2020</u>	
Revenue	\$ 6,772.8	\$ 5,740.6	18%
Net Income – Reported	1,110.1	1,208.4	(8)%
EPS – Reported	1.22	1.33	(8)%
Net Income – Non-GAAP	1,763.7	1,289.2	37%
EPS – Non-GAAP	1.94	1.41	38%

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 company submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) and a Marketing Authorization Application to the European Medicines Agency for tirzepatide for the treatment of adults with type 2 diabetes. A Priority Review Voucher was applied to the NDA, leading to an anticipated review time of eight months from the date of submission according to current FDA priority review timelines. Several additional submissions are planned around the world before the end of 2021.
- The company initiated rolling submission for donanemab to the FDA for accelerated approval in early Alzheimer's disease.
- In October 2021, the company and Pfizer discontinued the global clinical development program for tanezumab, an investigational nerve growth factor inhibitor. This decision was made following receipt of a Complete Response Letter from the FDA for the tanezumab application in osteoarthritis (OA) and a negative opinion adopted by the European Medicines Agency's Committee for Medicinal Products for Human Use on the tanezumab Marketing Authorization Application in OA.
- The company announced that the FDA approved Verzenio[®] as the first and only CDK4/6 inhibitor for certain people with HR+ HER2- high risk early breast cancer.
- The company announced that the FDA approved a new indication for Erbitux[®] in combination with Braftovi[®] for the treatment of certain adult patients with metastatic colorectal cancer with a BRAF V600E mutation.
- The FDA expanded the Emergency Use Authorization for bamlanivimab and etesevimab administered together to include post-exposure prophylaxis in certain individuals for the prevention of SARS-CoV-2 infection.
- The FDA granted Breakthrough Therapy designation for Jardiance[®] as an investigational treatment for adults with HFpEF, the company and Boehringer Ingelheim announced. The companies submitted Jardiance for regulatory approval in this indication to the FDA and in Europe.

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- Jardiance was approved by the FDA to reduce the risk of cardiovascular death plus hospitalization for heart failure in adults with heart failure with reduced ejection fraction (HFrEF), the company and Boehringer Ingelheim announced.
 - The FDA approved an expanded label for the company's rapid-acting insulin, Lyumjev[®], indicated to improve glycemic control in adults with type 1 and type 2 diabetes, to include administration via continuous subcutaneous insulin infusion with an insulin pump.

Clinical

- The company announced plans to conduct TRAILBLAZER-ALZ 4, a Phase 3 head-to-head clinical trial comparing donanemab to aducanumab to assess superiority of brain amyloid plaque clearance in early symptomatic Alzheimer's disease. Enrollment is expected to begin this year.
- The company announced that in two Phase 3 trials lebrikizumab led to significant improvements at 16 weeks with at least 75 percent skin clearance in more than half of people with moderate-to-severe atopic dermatitis, and key secondary endpoints were achieved, including early onset in skin clearance and itch relief, improvement in interference of itch on sleep and quality of life.

Business Development/Other Developments

- The Office of the Assistant Secretary for Preparedness and Response, alongside the FDA, resumed the shipment and distribution of bamlanivimab and etesevimab administered together.
- The company announced an additional purchase by the U.S. government for its neutralizing antibody therapies authorized for emergency use as a treatment for COVID-19. As part of the agreement, the company will supply 388,000 doses of etesevimab to complement doses of bamlanivimab previously purchased by the U.S. government, with approximately 250,000 doses shipped in the third-quarter of 2021 and the remaining to be shipped in fourth-quarter 2021.

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- The company announced a Joint Procurement Agreement with the European Commission to supply up to 220,000 doses of bamlanivimab and etesevimab for the treatment of COVID-19. This agreement helps to provide access to these COVID-19 antibodies by enabling participating countries in the European Union and European Economic Area to purchase the products directly from Lilly, following national approval for emergency use, or marketing authorization at the EU level.
 - The company announced it will lower the list price of Insulin Lispro Injection in the U.S. by an additional 40 percent effective Jan. 1, 2022, bringing the list price down to 2008 levels.
 - The company issued its first sustainability bond, for 600.0 million euros in aggregate principal amount. The bond proceeds will be allocated toward environmental projects including pollution prevention, energy efficiency and renewable energy; as well as social projects to increase access to essential services and socioeconomic advancement and empowerment.
 - The company and Lycia Therapeutics, Inc. announced a multi-year research collaboration and licensing agreement focused on the discovery, development and commercialization of novel targeted therapeutics using Lycia's proprietary lysosomal targeting chimera protein degradation technology.

Third-Quarter Reported Results

In the third quarter of 2021, worldwide revenue was \$6.773 billion, an increase of 18 percent compared with the third quarter of 2020, driven by a 17 percent increase in volume and a 1 percent increase due to the favorable impact of foreign exchange rates, with net realized prices remaining essentially flat. 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 58 percent of total revenue for the third quarter of 2021, excluding COVID-19 therapies. The company recognized worldwide revenue of \$423.5 million for COVID-19 therapies during the quarter.

Revenue in the U.S. increased 26 percent, to \$3.990 billion, driven by a 22 percent increase in volume and a 4 percent increase due to higher realized prices. The company recognized U.S. revenue of \$392.9 million in the third quarter of 2021 for COVID-19 therapies. Excluding that revenue, revenue in the U.S. increased by 14 percent. The increase in U.S. volume was driven by certain key growth products, including Trulicity, Olumiant, Taltz, Jardiance, Verzenio, Retevmo and Emgality. Higher realized prices in the U.S. during the third quarter of 2021 were driven by lower utilization in the 340B segment, unfavorable changes to estimates for rebates and discounts for Trulicity in the third quarter of 2020, and modest list price increases, partially offset by increased rebates to maintain access for products across the business.

Revenue outside the U.S. increased 8 percent, to \$2.783 billion, driven by an 11 percent increase in volume and a 1 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 all key growth products.

Gross margin increased 21 percent, to \$5.342 billion, in the third quarter of 2021 compared with the third quarter of 2020. Gross margin as a percent of revenue was 78.9 percent, an increase of 2.0 percentage points compared to the third quarter of 2020. The increase in gross margin percent was primarily due to favorable product mix and favorable effect of foreign exchange rates on international inventories sold.

Total operating expenses in the third quarter of 2021, defined as the sum of research and development and marketing, selling, and administrative expenses, increased 8 percent to \$3.287 billion compared with the third quarter of 2020. Research and development expenses increased 17 percent to \$1.709 billion, or 25.2 percent of revenue, driven primarily by higher development expenses for late-stage assets. Research and development expenses for COVID-19 therapies were approximately \$50 million in the third quarter of 2021. Marketing, selling and administrative expenses increased 1 percent to \$1.578 billion.

In the third quarter of 2021, the company recognized acquired in-process research and development charges of \$174.0 million related to business development transactions with Protomer Technologies Inc., Kumquat Biosciences Inc., Lycia Therapeutics, Inc., and ProQR Therapeutics N.V. There were no acquired in-process research and development charges recognized in the third quarter of 2020.

There were no asset impairment, restructuring and other special charges recognized in the third quarter of 2021. In the third quarter of 2020, the company recognized asset impairment, restructuring and other special charges of \$101.4 million. These charges were primarily related to severance costs incurred related to restructuring.

Operating income in the third quarter of 2021 was \$1.881 billion, compared to \$1.278 billion in the third quarter of 2020. The increase in operating income was driven by higher revenue and, to a lesser extent, lower asset impairment, restructuring and other special charges, partially offset by higher research and development expenses and acquired in-process research and development charges. Operating margin, defined as operating income as a percent of revenue, was 27.8 percent.

Other income (expense) was expense of \$635.9 million in the third quarter of 2021, compared with income of \$158.9 million in the third quarter of 2020. The reduction in other income (expense) was primarily driven by a charge of \$405.2 million related to the repurchase of higher-cost debt and unfavorable mark-to-market adjustments on investments in equity securities in the third quarter of 2021 compared to favorable mark-to-market adjustments on investments in equity securities in the third quarter of 2020.

The effective tax rate was 10.9 percent in the third quarter of 2021, compared with 15.9 percent in the third quarter of 2020. The lower effective tax rate in the third quarter of 2021 compared to the same period in 2020 was primarily due to the income tax impact of the charge related to repurchase of

higher-cost debt and the unfavorable mark-to-market adjustments on investments in equity securities, partially offset by a lower net discrete tax benefit compared to the same period in 2020.

In the third quarter of 2021, net income and EPS were \$1.110 billion and \$1.22, respectively, compared with net income of \$1.208 billion and EPS of \$1.33 in the third quarter of 2020. Net income and EPS in the third quarter of 2021 decreased compared to the same period in 2020 as higher operating income and lower income tax expense were more than offset by a reduction in other income (expense) in 2021.

Third-Quarter Non-GAAP Measures

On a non-GAAP basis, third-quarter 2021 gross margin increased 18 percent, to \$5.351 billion compared with the third quarter of 2020. Gross margin as a percent of revenue was 79.0 percent, a decrease of 0.1 percentage points, driven by favorable product mix (excluding COVID-19 therapies) and favorable effect of foreign exchange rates on international inventories sold, more than offset by lower gross margin on COVID-19 therapies.

Operating income on a non-GAAP basis increased \$558.0 million, or 37 percent, to \$2.064 billion in the third quarter of 2021 compared with the third quarter of 2020, due to higher gross margin, partially offset by higher research and development expenses. Operating margin was 30.5 percent on a non-GAAP basis.

Other income (expense) was expense of \$7.3 million in the third quarter of 2021, compared with income of \$9.9 million in the third quarter of 2020.

The effective tax rate on a non-GAAP basis was 14.3 percent in the third quarter of 2021, compared with 15.0 percent in the third quarter of 2020. The lower effective tax rate in the third quarter of 2021 was driven by a mix of earnings in lower tax jurisdictions partially offset by a decrease in net discrete tax benefits compared to the same period in 2020.

On a non-GAAP basis, in the third quarter of 2021 net income increased 37 percent, to \$1.764 billion, while EPS increased 38 percent, to \$1.94, compared with \$1.289 billion and \$1.41, respectively, in the third quarter of 2020. The increases in net income and EPS were driven by higher operating income.

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>2021</u>	<u>Third Quarter 2020</u>	<u>% Change</u>
Earnings per share (reported)	\$ 1.22	\$ 1.33	(8)%
Charge related to repurchase of higher-cost debt	.35	—	
Net losses (gains) on investments in equity securities	.19	(.13)	
Acquired in-process research and development	.16	—	
Amortization of intangible assets	.12	.11	
Asset impairment, restructuring and other special charges	—	.11	
Partial reversal of COVID-19 antibodies inventory charge	(.11)	—	
Earnings per share (non-GAAP)	<u>\$ 1.94</u>	<u>\$ 1.41</u>	38%
<small>Numbers may not add due to rounding.</small>			

Year-to-Date Reported Results

For the first nine months of 2021, worldwide revenue increased 19 percent to \$20.319 billion, compared with \$17.100 billion in the same period in 2020. The increase in revenue was driven by a 19 percent increase in volume and a 2 percent increase due to the favorable impact of foreign exchange rates, partially offset by a 2 percent decrease due to lower realized prices. Excluding \$1.425 billion of revenue from COVID-19 therapies, worldwide revenue grew by 11 percent. For the first nine months of 2021, operating income was \$4.440 billion, an increase of 9 percent compared with \$4.066 billion in the same period of 2020. Reported net income and EPS for the first nine months of 2021 were \$3.856 billion and \$4.23, respectively, compared with \$4.077 billion and \$4.47, respectively, for the same

period of 2020. The decreases in net income and EPS in the first nine months of 2021 were driven by lower other income (expense), partially offset by higher operating income and lower income taxes.

Year-to-Date Non-GAAP Measures

For the first nine months of 2021, operating income was \$5.921 billion on a non-GAAP basis, an increase of 23 percent compared with \$4.809 billion in the same period of 2020. Net income and EPS, on a non-GAAP basis, were \$5.169 billion and \$5.67, respectively, compared with \$4.083 billion and \$4.48, 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.

	<u>2021</u>	<u>Year-to-Date</u> <u>2020</u>	<u>% Change</u>
Earnings per share (reported)	\$ 4.23	\$ 4.47	(5)%
Acquired in-process research and development	.45	.30	
Charge related to repurchase of higher-cost debt	.35	—	
Amortization of intangible assets	.34	.25	
COVID-19 antibodies inventory charges	.33	—	
Asset impairment, restructuring and other special charges	.19	.17	
Net gains on investments in equity securities	(.22)	(.71)	
Earnings per share (non-GAAP)	<u>\$ 5.67</u>	<u>\$ 4.48</u>	27%

Numbers may not add due to rounding.

Selected Revenue Highlights

Selected Revenue Highlights

(Dollars in millions)

Selected Products	Third Quarter			Year-to-Date		
	2021	2020	% Change	2021	2020	% Change
Trulicity	\$ 1,600.1	\$ 1,106.6	45%	\$ 4,588.2	\$ 3,565.7	29%
Humalog ^(a)	626.7	656.9	(5)%	1,851.3	1,907.8	(3)%
Alimta	457.0	578.0	(21)%	1,626.6	1,677.2	(3)%
Taltz	593.1	454.5	30%	1,565.4	1,293.2	21%
COVID-19 antibodies ^(b)	217.1	—	NM	1,176.2	—	NM
Jardiance ^(c)	390.4	310.8	26%	1,058.9	840.3	26%
Verzenio	335.5	234.4	43%	945.8	631.1	50%
Humulin ^(a)	286.7	305.9	(6)%	923.8	935.2	(1)%
Olumiant ^(d)	406.9	162.0	NM	809.1	446.7	81%
Cyramza	253.4	252.7	0%	762.5	748.4	2%
Basaglar ^(a)	192.8	248.2	(22)%	650.1	842.3	(23)%
Forteo ^(a)	200.9	266.9	(25)%	617.8	791.9	(22)%
Emgality	140.0	91.5	53%	415.7	252.9	64%
Tyvyt	125.6	84.4	49%	340.2	205.9	65%
Retevmo	33.6	11.6	NM	76.1	17.9	NM
Total Revenue	6,772.8	5,740.6	18%	20,318.5	17,099.8	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 (EUA)

^(c) Jardiance includes Glyxambi[®], Synjardy[®], and Trijardy[®] XR

^(d) Olumiant includes sales of baricitinib that were made pursuant to EUA

NM – not meaningful

Trulicity

Third-quarter 2021 worldwide Trulicity revenue was \$1.600 billion, an increase of 45 percent compared with the third quarter of 2020. U.S. revenue increased 52 percent, to \$1.201 billion, driven by increased demand and, to a lesser extent, higher realized prices due to segment mix, including lower utilization in the 340B program, unfavorable changes to estimates for rebates and discounts in the same period of 2020, and modest list price increases, which were partially offset by increased rebates to maintain access. Revenue outside the U.S. was \$398.8 million, an increase of 26 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 third quarter of 2021, worldwide Humalog revenue decreased 5 percent compared with the third quarter of 2020, to \$626.7 million. Revenue in the U.S. decreased 11 percent, to \$347.3 million, driven by lower realized prices. Revenue outside the U.S. increased 5 percent, to \$279.4 million, driven by the favorable impact of foreign exchange rates and increased volume, partially offset by lower realized prices.

Alimta

For the third quarter of 2021, worldwide Alimta revenue decreased 21 percent compared with the third quarter of 2020, to \$457.0 million. U.S. revenue increased 2 percent, to \$297.2 million, primarily driven by higher realized prices, partially offset by decreased demand and customer buying patterns. Revenue outside the U.S. decreased 44 percent to \$159.8 million, primarily driven by decreased volume due to entry of generic competition and, to a lesser extent, lower realized prices.

The company expects continued volume decline for Alimta as a result of the entry of generic competition due to the loss of patent exclusivity in Japan and major European markets. The company expects generic entrants in the U.S. beginning in the first quarter of 2022.

Taltz

For the third quarter of 2021, worldwide Taltz revenue increased 30 percent compared with the third quarter of 2020, to \$593.1 million. U.S. revenue increased 29 percent, to \$422.2 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 and unfavorable segment mix, partially offset by changes to estimates for rebates and discounts. Revenue outside the U.S. increased 33 percent, to \$170.9 million, primarily driven by increased volume, partially offset by lower realized prices.

Jardiance

The company's worldwide Jardiance revenue during the third quarter of 2021 was \$390.4 million, an increase of 26 percent compared with the third quarter of 2020. U.S. revenue increased 35 percent, to \$221.2 million, primarily driven by increased demand. Revenue outside the U.S. was \$169.2 million, an increase of 15 percent, driven by increased volume partially offset by the unfavorable impact of foreign exchange rates. Jardiance is part of the company's alliance with Boehringer Ingelheim. Lilly reports as revenue royalties received on net sales of Jardiance.

Verzenio

For the third quarter of 2021, worldwide Verzenio revenue increased 43 percent compared with the third quarter of 2020, to \$335.5 million. U.S. revenue was \$199.6 million, an increase of 26 percent, driven by increased demand, partially offset by lower realized prices. Revenue outside the U.S. was \$135.9 million, an increase of 80 percent, primarily driven by increased volume.

Humulin

For the third quarter of 2021, worldwide Humulin revenue decreased 6 percent compared with the third quarter of 2020, to \$286.7 million. U.S. revenue decreased 10 percent, to \$193.4 million, driven by lower realized prices and, to a lesser extent, decreased demand. Revenue outside the U.S. increased

2 percent, to \$93.4 million, due to higher realized prices and, to a lesser extent, the favorable impact of foreign exchange rates, largely offset by decreased volume.

Olumiant

For the third quarter of 2021, worldwide Olumiant revenue was \$406.9 million, an increase of \$244.9 million compared with the third quarter of 2020. U.S. revenue was \$194.0 million, representing growth of \$179.5 million compared with the third quarter of 2020, driven by utilization for the treatment of hospitalized patients with COVID-19 during the third quarter of 2021. Revenue outside the U.S. was \$212.9 million, an increase of 44 percent, driven by increased volume, partially offset by lower realized prices.

Cyramza

For the third quarter of 2021, worldwide Cyramza revenue remained essentially flat compared with the third quarter of 2020, at \$253.4 million. U.S. revenue was \$84.8 million, a decrease of 10 percent, primarily driven by decreased demand, partially offset by higher realized prices. Revenue outside the U.S. was \$168.6 million, an increase of 7 percent, driven by increased volume, partially offset by lower realized prices and the unfavorable impact of foreign exchange rates.

Basaglar

For the third quarter of 2021, worldwide Basaglar revenue was \$192.8 million, a decrease of 22 percent compared with the third quarter of 2020. U.S. revenue decreased 36 percent, to \$114.7 million, driven by continued competitive pressures that resulted in lower realized prices and, to a lesser extent, decreased demand. Due to competitive pressures, continued price decline and loss of market share over time is expected. Revenue outside the U.S. increased 12 percent, to \$78.1 million, driven by increased volume. 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 third quarter of 2021, worldwide Forteo revenue decreased 25 percent compared with the third quarter of 2020, to \$200.9 million. U.S. revenue decreased 24 percent, to \$109.6 million, driven by decreased demand and, to a lesser extent, lower realized prices. Revenue outside the U.S. decreased 25 percent to \$91.3 million, primarily driven by decreased volume.

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

Emgality

For the third quarter of 2021, Emgality generated worldwide revenue of \$140.0 million, an increase of 53 percent compared with the third quarter of 2020. U.S. revenue was \$99.9 million, an increase of 23 percent, driven by increased demand and higher realized prices. Revenue outside the U.S. was \$40.1 million, an increase of \$30.0 million compared with the third quarter of 2020, driven by increased demand.

Tyvvyt

For the third quarter of 2021, the company's Tyvvyt revenue in China was \$125.6 million, an increase of 49 percent compared with the third quarter of 2020, driven primarily by increased demand.

Tyvvyt is part of the company's alliance with Innovent. Lilly reports total sales of Tyvvyt 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 Tyvvyt sales made by Innovent.

Retevmo

For the third quarter of 2021, Retevmo generated U.S. revenue of \$29.2 million compared to revenue of \$22.5 million in the second quarter of 2021. Retevmo launched outside the U.S. during the second quarter of 2021 and generated revenue of \$4.4 million in the third quarter of 2021.

2021 Financial Guidance

The company has updated certain elements of its 2021 financial guidance on both a reported and non-GAAP basis. Earnings per share for 2021 are now expected to be in the range of \$6.38 to \$6.48 on a reported basis and \$7.95 to \$8.05 on a non-GAAP basis. The update to the company's 2021 financial guidance reflects adjustments shown in the reconciliation table below.

	2021 Expectations	% Change vs 2020
Earnings per share (reported)	\$6.38 to \$6.48	(6)% to (5)%
Amortization of intangible assets	.47	
Acquired IPR&D ^(a)	.45	
Charge related to repurchase of higher-cost debt	.35	
COVID-19 antibodies inventory charges	.33	
Asset impairment, restructuring and other special charges	.19	
Net gains on investments in equity securities	(.22)	
Earnings per share (non-GAAP)	\$7.95 to \$8.05	17% to 19%

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., Lycia Therapeutics Inc., ProQR Therapeutics N.V., MiNA Therapeutics Limited, and Asahi Kasei Pharma Corporation.

The company now anticipates 2021 revenue to be between \$27.2 billion and \$27.6 billion. This increase reflects additional revenue from COVID-19 antibodies and the underlying core business. Estimated revenue from COVID-19 antibodies is now expected to be approximately \$1.3 billion.

Other income (expense) for 2021 is now expected to be expense in the range of \$250 million to \$150 million on a reported basis and is still expected to be expense in the range of \$100 million to \$0 on a

non-GAAP basis. The company's updated reported guidance reflects the impact of the charge associated with the repurchase of higher-cost debt and unfavorable mark-to-market adjustments on investments in equity securities in the third quarter of 2021.

The 2021 effective tax rate is now expected to be approximately 11 percent on a reported basis, reflecting primarily the tax impacts of the charges related to repurchase of higher-cost debt and acquired IPR&D, as well as unfavorable mark-to-market adjustments on investments in equity securities in the third quarter of 2021. The 2021 effective tax rate 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	
	<u>Prior</u>	<u>Updated</u>
Revenue	\$26.8 to \$27.4 billion	\$27.2 to \$27.6 billion
Gross Margin % of Revenue (reported)	Approx. 75%	Unchanged
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)	\$375 to \$475 million	\$(250) to \$(150) million
Other Income/(Expense) (non-GAAP)	\$(100) million to \$0	Unchanged
Tax Rate (reported)	Approx. 12%	Approx. 11%
Tax Rate (non-GAAP)	Approx. 13%	Unchanged
Earnings per Share (reported)	\$6.73 to \$6.93	\$6.38 to \$6.48
Earnings per Share (non-GAAP)	\$7.80 to \$8.00	\$7.95 to \$8.05
Operating Margin (reported)	Approx. 24%	Unchanged
Operating Margin (non-GAAP)	Approx. 30%	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 third-quarter 2021 financial results conference call through a link on Lilly's website at www.lilly.com. The conference call will begin at 9 a.m. Eastern time 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.

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Alimta[®] (pemetrexed disodium, Lilly)
Basaglar[®] (insulin glargine injection, Lilly)
Braftovi[®] (encorafenib, Pfizer)
Cialis[®] (tadalafil, Lilly)
Cynamza[®] (ramucirumab, Lilly)
Emgality[®] (galcanezumab-gnlm, Lilly)
Erbitux[®] (cetuximab, Lilly)
Forteo[®] (teriparatide of recombinant DNA origin injection, Lilly)
Glyxambi[®] (empagliflozin/linagliptin, Boehringer Ingelheim)
Humalog[®] (insulin lispro injection of recombinant DNA origin, Lilly)
Humulin[®] (human insulin of recombinant DNA origin, Lilly)
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)

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

Eli Lilly and Company Employment Information

	<u>September 30, 2021</u>	<u>December 31, 2020</u>
Worldwide Employees	34,914	34,960

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2021	2020	% Chg.	2021	2020	% Chg.
Revenue	\$ 6,772.8	\$ 5,740.6	18%	\$ 20,318.5	\$ 17,099.8	19%
Cost of sales	1,430.8	1,326.4	8%	5,262.6	3,763.5	40%
Research and development	1,708.9	1,465.4	17%	5,066.5	4,247.7	19%
Marketing, selling and administrative	1,577.9	1,569.1	1%	4,839.6	4,567.3	6%
Acquired in-process research and development	174.0	—	NM	498.3	294.1	69%
Asset impairment, restructuring and other special charges	—	101.4	(100)%	211.6	161.3	31%
Operating income	1,881.2	1,278.3	47%	4,439.9	4,065.9	9%
Net interest income (expense)	(76.6)	(83.8)		(240.4)	(243.2)	
Net other income (expense)	(559.3)	242.7		116.1	938.1	
Other income (expense)	(635.9)	158.9	NM	(124.3)	694.9	NM
Income before income taxes	1,245.3	1,437.2	(13)%	4,315.6	4,760.8	(9)%
Income tax expense	135.2	228.8	(41)%	460.0	683.9	(33)%
Net income	\$ <u>1,110.1</u>	\$ <u>1,208.4</u>	(8)%	\$ <u>3,855.6</u>	\$ <u>4,076.9</u>	(5)%
Earnings per share - diluted	\$ <u>1.22</u>	\$ <u>1.33</u>	(8)%	\$ <u>4.23</u>	\$ <u>4.47</u>	(5)%
Dividends paid per share	\$.85	.74		\$ 2.55	\$ 2.22	
Weighted-average shares outstanding (thousands) - diluted	910,751	911,423		911,656	911,868	

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 September 30, 2021			Three Months Ended September 30, 2020		
	GAAP Reported	Adjustments ^(b)	Non-GAAP Adjusted ^(a)	GAAP Reported	Adjustments ^(c)	Non-GAAP Adjusted ^(a)
Cost of sales	\$ 1,430.8	\$ (9.0)	\$ 1,421.8	\$ 1,326.4	\$ (126.5)	\$ 1,199.9
Acquired in-process research and development	174.0	(174.0)	—	—	—	—
Asset impairment, restructuring and other special charges	—	—	—	101.4	(101.4)	—
Other income (expense)	(635.9)	628.6	(7.3)	158.9	(149.0)	9.9
Income tax expense	135.2	158.0	293.2	228.8	(1.9)	226.9
Net income	1,110.1	653.6	1,763.7	1,208.4	80.8	1,289.2
Earnings per share - diluted	1.22	0.72	1.94	1.33	0.09	1.41

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 September 30, 2021, include the following:

(Dollars in millions, except per share data)	Amortization ⁽ⁱ⁾	IPR&D ⁽ⁱⁱ⁾	Equity investments ⁽ⁱⁱⁱ⁾	Repurchase of Debt ^(iv)	Other specified items ^(v)	Total
Cost of sales	\$ (137.1)	\$ —	\$ —	\$ —	\$ 128.1	(9.0)
Acquired in-process research and development	—	(174.0)	—	—	—	(174.0)
Other income (expense)	—	—	223.4	405.2	—	628.6
Income tax expense	28.8	24.5	46.5	85.1	(26.9)	158.0
Net income	108.3	149.5	176.9	320.1	(101.2)	653.6
Earnings per share - diluted	0.12	0.16	0.19	0.35	(0.11)	0.72

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 Protomer Technologies Inc., Kumquat Biosciences Inc., Lycia Therapeutics, Inc., and ProQR Therapeutics N.V.
- iii. Exclude gains and losses on investments in equity securities.
- iv. Exclude charge related to the repurchase of higher-cost debt.
- v. Exclude partial reversal of COVID-19 antibodies inventory charge.

(c) Adjustments to certain GAAP reported measures for the three months ended September 30, 2020, include the following:

(Dollars in millions, except per share data)	Amortization ⁽ⁱ⁾	Equity investments ⁽ⁱⁱ⁾	Other specified items ⁽ⁱⁱⁱ⁾	Total
Cost of sales	\$ (126.5)	\$ —	\$ —	(126.5)
Asset impairment, restructuring and other special charges	—	—	(101.4)	(101.4)
Other income (expense)	—	(149.0)	—	(149.0)
Income tax expense	26.3	(31.3)	3.1	(1.9)
Net income	100.2	(117.7)	98.3	80.8
Earnings per share - diluted	0.11	(0.13)	0.11	0.09

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 gains and losses on investments in equity securities.
- iii. Exclude primarily severance costs incurred related to restructuring.

Eli Lilly and Company

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

	Nine Months Ended September 30, 2021			Nine Months Ended September 30, 2020		
	GAAP Reported	Adjustments ^(b)	Non-GAAP Adjusted ^(a)	GAAP Reported	Adjustments ^(c)	Non-GAAP Adjusted ^(a)
Cost of sales	\$ 5,262.6	\$ (771.4)	\$ 4,491.2	\$ 3,763.5	\$ (287.9)	\$ 3,475.6
Acquired in-process research and development	498.3	(498.3)	—	294.1	(294.1)	—
Asset impairment, restructuring and other special charges	211.6	(211.6)	—	161.3	(161.3)	—
Other income (expense)	(124.3)	156.6	32.3	694.9	(814.7)	(119.8)
Income tax expense	460.0	324.6	784.6	683.9	(77.8)	606.1
Net income	3,855.6	1,313.3	5,168.9	4,076.9	6.4	4,083.3
Earnings per share - diluted	4.23	1.44	5.67	4.47	0.01	4.48

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 nine months ended September 30, 2021, include the following:

(Dollars in millions, except per share data)	Amortization ⁽ⁱ⁾	IPR&D ⁽ⁱⁱ⁾	Equity investments ⁽ⁱⁱⁱ⁾	Repurchase of Debt ^(iv)	Other specified items ^(v)	Total
Cost of sales	\$ (395.0)	\$ —	\$ —	\$ —	\$ (376.4)	(771.4)
Acquired in-process research and development	—	(498.3)	—	—	—	(498.3)
Asset impairment, restructuring and other special charges	—	—	—	—	(211.6)	(211.6)
Other income (expense)	—	—	(248.5)	405.2	—	156.6
Income tax expense	81.8	92.6	(48.9)	85.1	114.0	324.6
Net income	313.2	405.7	(199.6)	320.1	474.0	1,313.3
Earnings per share – diluted	0.34	0.45	(0.22)	0.35	0.52	1.44

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., Protomer Technologies Inc., Kumquat Biosciences Inc., Merus N.V., Lycia Therapeutics, Inc., ProQR Therapeutics N.V, MiNA Therapeutics Limited and Asahi Kasei Pharma Corporation.
- iii. Exclude gains and losses on investments in equity securities.
- iv. Excludes charge related to the repurchase of higher-cost debt.
- v. Excludes primarily the net inventory charge 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 nine months ended September 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	\$ (283.7)	\$ —	\$ —	\$ (4.2)	(287.9)
Acquired in-process research and development	—	(294.1)	—	—	(294.1)
Asset impairment, restructuring and other special charges	—	—	—	(161.3)	(161.3)
Other income (expense)	—	—	(814.7)	—	(814.7)
Income tax expense	58.9	25.0	(171.1)	9.4	(77.8)
Net income	224.8	269.1	(643.6)	156.1	6.4
Earnings per share - diluted	0.25	0.30	(0.71)	0.17	0.01

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 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. Exclude primarily severance costs incurred related to restructuring, as well as acquisition and integration costs as part of the closing of the acquisition of Dermira, Inc.