
**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): February 2, 2023

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
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 February 2, 2023, announcing the financial results of Eli Lilly and Company for the quarter and year ended December 31, 2022.

Item 9.01. Financial Statements and Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Eli Lilly and Company, dated February 2, 2023.
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: Senior Vice President, Finance, and
Chief Accounting Officer
Date: February 2, 2023



Feb. 2, 2023

For Release: Immediately

Refer to: Jordan Bishop; jordan.bishop@lilly.com; (317) 473-5712 (Media)

Joe Fletcher; jfletcher@lilly.com; (317) 296-2884 (Investors)

Lilly Reports Fourth-Quarter 2022 Financial Results, Core Business Growth and Pipeline Advancements Support Strong Long-Term Outlook

- *Revenue in Q4 2022 decreased 9%. Excluding COVID-19 antibodies, revenue in Q4 2022 increased 5%, or 10% on a constant currency basis, driven by volume growth of key growth products, partially offset by lower Alimta revenue. Excluding COVID-19 antibodies, total worldwide volume in Q4 2022 increased 13%.*
- *Pipeline advancements included FDA approval of Jaypirca for mantle cell lymphoma under the accelerated approval pathway and FDA and EMA acceptance of regulatory submissions for Jardiance for adults with chronic kidney disease. Additionally, the company initiated a rolling submission in the U.S. for tirzepatide in obesity and the FDA granted Fast Track designation for tirzepatide in obstructive sleep apnea.*
- *Key growth products - consisting of Verzenio, Mounjaro, Jardiance, Taltz, Trulicity, Retevmo, Emgality, Cyramza, Tyvyt and Olumiant - grew 21% and represented 70% of revenue in Q4 2022.*
- *Q4 2022 EPS increased 13% to \$2.14 on a reported basis and decreased 4% to \$2.09 on a non-GAAP basis, both inclusive of \$0.23 of acquired IPR&D and development milestone charges.*
- *2023 EPS guidance updated to be in the range of \$7.90 to \$8.10 on a reported basis and \$8.35 to \$8.55 on a non-GAAP basis.*

INDIANAPOLIS, Feb. 2, 2023 - Eli Lilly and Company (NYSE: LLY) today announced its financial results for the fourth quarter of 2022.

"2023 is an inflection point for Lilly - a chance to expand our impact on patients and growth potential as an R&D-driven biopharma company," said David A. Ricks, Lilly's chair and CEO. "Over the course of this critical year, we hope to launch as many as four new medicines for challenging diseases, while advancing our next generation of molecules currently in Phase 3."

Eli Lilly and Company | Lilly Corporate Center | Indianapolis, Indiana 46285 | U.S.A.

Anat Ashkenazi, Lilly's executive vice president and chief financial officer added: "As we closed out 2022, Lilly demonstrated strong growth and achieved meaningful pipeline progress that included the launch for Mounjaro in type 2 diabetes. We expect to capitalize on this momentum and deliver mid-teen revenue growth for our core business in 2023 while remaining committed to investing in innovation, late-stage opportunities, manufacturing capacity, and our people."

Lilly shared numerous updates recently on key regulatory, clinical, business development and other events, including:

- The U.S. Food and Drug Administration (FDA) approval of Jaypirca™ (pirtobrutinib) for adults with relapsed or refractory mantle cell lymphoma after at least two lines of systemic therapy, including a BTK inhibitor, under the accelerated approval pathway;
- FDA issuance of a complete response letter for the accelerated approval submission of donanemab for early Alzheimer's disease;
- FDA and European Medicines Agency acceptance of regulatory submissions for Jardiance® for adults with chronic kidney disease based on results from the EMPA-KIDNEY Phase 3 trial;
- The initiation of a rolling submission in the U.S. for tirzepatide in obesity and FDA Fast Track designation for tirzepatide in obstructive sleep apnea;
- The announcement that Jardiance is the first SGLT2 inhibitor to show statistically significant reduction in blood sugar levels in children and adolescents with type 2 diabetes;
- Positive donanemab data from the first Phase 3 active comparator study in early Alzheimer's disease, TRAILBLAZER-ALZ 4;
- Plans to invest an additional \$450 million and create at least 100 new jobs to expand manufacturing capacity at the company's Research Triangle Park facility;
- The acquisition of Akouos, Inc., which expands Lilly's efforts in genetic medicines to include Akouos's potential first-in-class adeno-associated viral gene therapies;
- The fifth consecutive 15% annual increase in Lilly's quarterly dividend, doubling since 2018;
- A collaboration with EVA Pharma to establish local manufacturing capabilities to supply low-cost insulin to at least 1 million people by 2030, mostly in Africa; and

- An initiative with Direct Relief to expand cold chain capacity in Africa, Latin America, the Caribbean and Southeast Asia.

For additional information on these and other important public announcements, visit the news section of Lilly's website.

Financial Results

\$ in millions, except per share data	<u>Fourth Quarter</u>		<u>%</u>
	<u>2022</u>	<u>2021</u>	<u>Change</u>
Revenue	\$7,301.8	\$7,999.9	(9)%
Net Income – Reported	1,937.7	1,726.1	12%
EPS – Reported	2.14	1.90	13%
Net Income – Non-GAAP	1,893.1	1,970.5	(4)%
EPS – Non-GAAP	2.09	2.17	(4)%

A discussion of the non-GAAP financial measures is included under "Reconciliation of GAAP Reported to Selected Non-GAAP Adjusted Information (Unaudited)."

Fourth-Quarter Reported Results

In Q4 2022, worldwide revenue was \$7.30 billion, a decrease of 9% compared with Q4 2021, driven by a 4% decrease from the unfavorable impact of foreign exchange rates, a 3% decrease due to lower realized prices, and a 2% decrease in volume.

Excluding COVID-19 antibodies, revenue in Q4 2022 increased 5% and total worldwide volume increased 13%. Key growth products, consisting of Verzenio[®], Mounjaro[®], Jardiance, Taltz[®], Trulicity[®], Retevmo[®], Emgality[®], Cyramza[®], Tyvyt[®] and Olumiant[®], grew 21% and represented 70% of revenue for Q4 2022.

Revenue in the U.S. decreased 10% to \$4.66 billion, driven by a 10% decrease in volume with prices remaining relatively flat. Excluding revenue from COVID-19 antibodies, revenue in the U.S. increased by 11%, primarily driven by volume from key growth products.

Revenue outside the U.S. decreased 6% to \$2.64 billion, driven by a 12% decrease from the unfavorable impact of foreign exchange rates and a 7% decrease due to lower realized prices, partially offset by a 12% increase in volume. The lower realized prices were primarily driven by the impact of government pricing in China from the volume-based procurement (VBP) for Humalog® and the National Reimbursement Drug List (NRDL) formulary for certain products, particularly Verzenio and Tyvyt. The increase in volume outside the U.S. was largely driven by key growth products and approximately \$130 million of one-time revenue associated with the sale of the company's rights to Alimta in Korea and Taiwan.

Gross margin decreased 3% to 57.8% in Q4 2022 compared with Q4 2021. Gross margin as a percent of revenue was 78.8%, an increase of 4.4 percentage points compared with Q4 2021. The increase in gross margin percent was primarily driven by lower sales of COVID-19 antibodies, partially offset by lower realized prices and increased expenses due to inflation and logistics costs.

In Q4 2022, research and development expenses increased 5% to \$2.00 billion, or 27% of revenue, driven by higher development expenses for late-stage assets, partially offset by the favorable impact of foreign exchange rates and lower development expenses for COVID-19 antibodies.

Marketing, selling and administrative expenses increased 3% to \$1.64 billion in Q4 2022, primarily driven by costs associated with launches of new products and indications, partially offset by the favorable impact of foreign exchange rates.

In Q4 2022, the company recognized acquired in-process research and development (IPR&D) and development milestone charges of \$240.1 million. In Q4 2021, the company recognized acquired IPR&D and development milestone charges of \$437.7 million, primarily related to a business development transaction with Foghorn Therapeutics Inc.

In Q4 2022, the company recognized asset impairment, restructuring and other special charges of \$38.1 million, primarily related to acquisition and integration costs associated with the closing of our acquisition of Akouos, Inc. In Q4 2021, the company recognized asset impairment, restructuring and other special charges of \$104.5 million, primarily related to impairment of an intangible asset from our acquisition of Loxo Oncology.

Operating income in Q4 2022 was \$1.84 billion compared with \$1.92 billion in Q4 2021. Operating margin percent, defined as operating income as a percent of revenue, was 25.1%, which includes a negative impact of approximately 330 basis points attributed to acquired IPR&D and development milestone charges.

Other income (expense) was income of \$260.0 million in Q4 2022 compared with expense of \$77.3 million in Q4 2021. The increase in other income (expense) was primarily driven by net gains on investments in equity securities in Q4 2022 compared with net losses on investments in equity securities in Q4 2021.

The effective tax rate was 7.6% in Q4 2022 compared with 6.2% in Q4 2021. The effective tax rate in Q4 2022 reflects the favorable tax impact of the implementation of the provision in the Tax Cuts and Jobs Act (the 2017 Tax Act) that requires capitalization and amortization of research and development expenses for tax purposes starting in 2022 and a net discrete tax benefit, partially offset by the tax impact of the mix of earnings in higher tax jurisdictions. The effective tax rate in Q4 2021 reflected a net discrete tax benefit and the tax impact of acquired IPR&D and development milestone charges.

In Q4 2022, net income and earnings per share (EPS) were \$1.94 billion and \$2.14, respectively, compared with \$1.73 billion and \$1.90 in Q4 2021. Q4 2022 EPS was inclusive of \$0.23 of acquired IPR&D and development milestone charges compared with \$0.39 in Q4 2021.

Fourth-Quarter Non-GAAP Measures

On a non-GAAP basis, Q4 2022 gross margin decreased 3% to \$5.88 billion compared with Q4 2021. Gross margin as a percent of revenue was 80.5%, an increase of 4.4 percentage points compared with Q4 2021. The increase in gross margin percent was primarily driven by lower sales of COVID-19 antibodies, partially offset by lower realized prices and increased expenses due to inflation and logistics costs.

Operating income on a non-GAAP basis decreased \$160.5 million, or 7%, to \$2.00 billion in Q4 2022 compared with Q4 2021. Operating margin percent was 27.4% on a non-GAAP basis, which includes a negative impact of approximately 330 basis points attributed to acquired IPR&D and development milestone charges.

The effective tax rate on a non-GAAP basis was 7.3% in Q4 2022 compared with 8.5% in Q4 2021. The lower effective tax rate for Q4 2022 reflects the favorable tax impact of the implementation of the 2017 Tax Act and a higher net discrete tax benefit compared to the same period in 2021, partially offset by the tax impact of the mix of earnings in higher tax jurisdictions.

On a non-GAAP basis, Q4 2022 net income and EPS were \$1.89 billion and \$2.09, respectively, compared with \$1.97 billion and \$2.17 in Q4 2021. Q4 2022 non-GAAP EPS was inclusive of \$0.23 of acquired IPR&D and development milestone charges compared with \$0.39 in Q4 2021.

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 (Unaudited)" table later in this press release.

	<u>2022</u>	<u>Fourth Quarter</u> <u>2021</u>	<u>% Change</u>
Earnings per share (reported)	\$ 2.14	\$ 1.90	13%
Amortization of intangible assets	.11	.19	
Asset impairment, restructuring and other special charges	.03	.09	
Net (gains) losses on investments in equity securities	(.19)	.06	
Partial reversal of COVID-19 antibodies inventory charges	—	(.07)	
Earnings per share (non-GAAP)	<u>\$ 2.09</u>	<u>\$ 2.17</u>	(4)%
<small>Numbers may not add due to rounding.</small>			
Acquired IPR&D and development milestone charges	.23	.39	(41)%

Selected Revenue Highlights

<i>(Dollars in millions)</i>	Fourth Quarter			Full Year		
	2022	2021	% Change	2022	2021	% Change
Selected Products						
Trulicity	\$ 1,936.2	\$ 1,883.7	3%	\$ 7,439.7	\$ 6,471.9	15%
Verzenio	808.0	404.1	100%	2,483.5	1,349.9	84%
Taltz	707.8	647.4	9%	2,482.0	2,212.8	12%
Jardiance ^(a)	612.3	431.9	42%	2,066.0	1,490.8	39%
Humalog ^(b)	548.3	601.7	(9)%	2,060.6	2,453.0	(16)%
COVID-19 antibodies ^(c)	38.0	1,063.1	(96)%	2,023.5	2,239.3	(10)%
Humulin [®]	234.0	298.8	(22)%	1,019.4	1,222.6	(17)%
Cyramza	277.8	270.4	3%	971.4	1,033.0	(6)%
Alimta	236.6	434.9	(46)%	927.7	2,061.4	(55)%
Olumiant ^(d)	205.8	306.0	(33)%	830.5	1,115.1	(26)%
Basaglar [®]	201.7	242.4	(17)%	760.4	892.5	(15)%
Emgality	175.6	161.5	9%	650.9	577.2	13%
Forteo [®]	160.0	184.0	(13)%	613.1	801.9	(24)%
Mounjaro	279.2	—	NM	482.5	—	NM
Tyvyt	57.5	77.8	(26)%	293.3	418.1	(30)%
Retevmo	64.6	38.6	67%	191.9	114.7	67%
Total Revenue	7,301.8	7,999.9	(9)%	28,541.4	28,318.4	1%

^(a) Jardiance includes Glyxambi[®], Synjardy[®] and Trijardy[®] XR
^(b) Humalog includes Insulin Lispro
^(c) COVID-19 antibodies include sales for bamlanivimab administered alone, for bamlanivimab and etesevimab administered together, and for bebtelovimab, and were made pursuant to EUAs or similar regulatory authorizations
^(d) Olumiant includes sales of baricitinib that were made pursuant to EUA or similar regulatory authorizations
NM – not meaningful

Trulicity

For Q4 2022, worldwide Trulicity revenue was \$1.94 billion, an increase of 3% compared with Q4 2021. U.S. revenue increased 5% to \$1.53 billion, driven by increased demand, partially offset by lower realized prices. Revenue outside the U.S. was \$409.8 million, a decrease of 6%, driven by the unfavorable impact of foreign exchange rates and to a lesser extent, lower realized prices, partially offset by increased demand. On a constant currency basis, revenue outside the U.S. increased 8%. Lilly experienced intermittent delays in fulfilling certain U.S. Trulicity orders during Q4 2022. Actions to manage strong demand across the company's incretin portfolio, including measures to minimize existing patient impact in international markets, also affected volume.

Verzenio

For Q4 2022, worldwide Verzenio revenue increased 100% compared with Q4 2021 to \$808.0 million. U.S. revenue was \$552.7 million, an increase of 119%, primarily driven by increased demand. Revenue outside the U.S. was \$255.3 million, an increase of 69%, driven by increased demand, partially offset by the unfavorable impact of foreign exchange rates and lower realized prices primarily due to the impact of the NRDL formulary in China.

Taltz

For Q4 2022, worldwide Taltz revenue increased 9% compared with Q4 2021 to \$707.8 million. U.S. revenue increased 9% to \$512.0 million, driven by increased demand, partially offset by lower realized prices. Revenue outside the U.S. increased 11% to \$195.8 million, driven by increased volume, partially offset by the unfavorable impact of foreign exchange rates and lower realized prices.

Jardiance

The company's worldwide Jardiance revenue for Q4 2022 was \$612.3 million, an increase of 42% compared with Q4 2021. U.S. revenue increased 51% to \$363.1 million, primarily driven by increased demand and to a lesser extent, an increased Q4 2022 royalty from Boehringer Ingelheim for exceeding certain annual thresholds. Revenue outside the U.S. was \$249.2 million, an increase of

30%, primarily driven by increased demand, 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.

Humalog

For Q4 2022, worldwide Humalog revenue decreased 9% compared with Q4 2021 to \$548.3 million. U.S. revenue increased 8% to \$336.0 million, driven by higher realized prices due to changes in estimates for rebates and discounts in both periods. Revenue outside the U.S. decreased 27% to \$212.3 million, driven by lower realized prices due to the impact of VBP in China and the unfavorable impact of foreign exchange rates.

Alimta

For Q4 2022, worldwide Alimta revenue decreased 46% compared with Q4 2021 to \$236.6 million. U.S. revenue decreased 83% to \$53.2 million, driven by decreased demand due to generic competition. Revenue outside the U.S. increased 63% to \$183.4 million, driven by approximately \$130 million of one-time revenue associated with the sale of the company's rights to Alimta in Korea and Taiwan, partially offset by decreased demand due to generic competition, lower realized prices, and the unfavorable impact of foreign exchange rates.

The company expects continued volume and revenue decline for Alimta as a result of generic competition due to the loss of patent exclusivity in major markets.

Olumiant

For Q4 2022, worldwide Olumiant revenue decreased 33% compared with Q4 2021 to \$205.8 million. U.S. revenue decreased 50% to \$43.5 million, driven by a decline in utilization for COVID-19 treatment, partially offset by increased utilization for the treatment of alopecia areata.

Revenue outside the U.S. was \$162.3 million, a decrease of 26%, driven by the unfavorable impact of foreign exchange rates and a decline in utilization for COVID-19 treatment.

Emgality

For Q4 2022, Emgality generated worldwide revenue of \$175.6 million, an increase of 9% compared with Q4 2021. U.S. revenue was \$132.0 million, an increase of 9%, driven by increased demand and higher realized prices, partially offset by wholesaler buying patterns. Revenue outside the U.S. was \$43.7 million, an increase of 8%, primarily driven by increased volume, partially offset by the unfavorable impact of foreign exchange rates and lower realized prices.

Mounjaro

For Q4 2022, worldwide Mounjaro revenue was \$279.2 million. U.S. revenue was \$256.7 million. Mounjaro launched in the U.S. for the treatment of type 2 diabetes in June 2022.

Tyvyt

For Q4 2022, the company's Tyvyt revenue in China was \$57.5 million, a decrease of 26% compared with Q4 2021, driven by the impact of the NRDL formulary in China as well as increased competitive pressures and impacts from COVID-19 disruptions.

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.

2023 Financial Guidance

The company has updated its tax rate and EPS guidance and reaffirmed all other elements of its 2023 financial guidance. The previous tax rate guidance of approximately 16% for 2023 assumed deferral or repeal of the 2017 Tax Act provision that requires capitalization of research and development expenses. Such a deferral or repeal did not occur in 2022. Given the uncertainty as to whether any change to this provision will be enacted in 2023, the company has updated the tax rate

guidance to be approximately 13% and 2023 EPS guidance has been increased to the range of \$7.90 to \$8.10 on a reported basis and \$8.35 to \$8.55 on a non-GAAP basis. The company's 2023 financial guidance reflects adjustments shown in the reconciliation table below.

	2023 Expectations
Earnings per share (reported)	\$7.90 to \$8.10
Amortization of intangible assets	.45
Earnings per share (non-GAAP)	\$8.35 to \$8.55
Numbers may not add due to rounding	
The company's 2023 financial guidance does not include any acquired IPR&D and development milestone charges either incurred or that may potentially be incurred in 2023.	

The following table summarizes the company's updated 2023 financial guidance:

	Prior	2023 Guidance
Revenue	\$30.3 to \$30.8 billion	<u>Updated</u> Unchanged
Gross Margin % of Revenue (reported)	Approx. 77%	Unchanged
Gross Margin % of Revenue (non-GAAP)	Approx. 79%	Unchanged
Marketing, Selling & Administrative	\$6.9 to \$7.1 billion	Unchanged
Research & Development	\$8.2 to \$8.4 billion	Unchanged
Other Income/(Expense)	\$(200) to \$(100) million	Unchanged
Tax Rate	Approx. 16%	Approx. 13%
Earnings per Share (reported)	\$7.65 to \$7.85	\$7.90 to \$8.10
Earnings per Share (non-GAAP)	\$8.10 to \$8.30	\$8.35 to \$8.55
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 Q4 2022 financial results conference call through a link on Lilly's website at investor.lilly.com/webcasts-and-presentations. The conference call will begin at 10 a.m. Eastern time today and will be available for replay via the website.

Non-GAAP Financial Measures

Certain financial information for 2022 and 2021 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. This press release and related materials provide certain GAAP and non-GAAP figures excluding the impact of foreign exchange rates. Lilly recalculates current period figures on a constant currency basis by keeping constant the exchange rates from the base period. Beginning in 2022, presentations of non-GAAP financial measures do not include adjustments for upfront charges and development milestones related to acquired IPR&D. Non-GAAP financial measures for Q4 and fiscal year 2021 have been adjusted to reflect this updated presentation. The company's 2023 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.

About Lilly

Lilly unites caring with discovery to create medicines that make life better for people around the world. We've been pioneering life-changing discoveries for nearly 150 years, and today our medicines help more than 47 million people across the globe. Harnessing the power of biotechnology, chemistry and genetic medicine, our scientists are urgently advancing new discoveries to solve some of the world's most significant health challenges, redefining diabetes care, treating obesity and curtailing its most devastating long-term effects, advancing the fight against Alzheimer's disease, providing solutions to some of the most debilitating immune system disorders, and

transforming the most difficult-to-treat cancers into manageable diseases. With each step toward a healthier world, we're motivated by one thing: making life better for millions more people. That includes delivering innovative clinical trials that reflect the diversity of our world and working to ensure our medicines are accessible and affordable. To learn more, visit Lilly.com and Lilly.com/newsroom. F-LLY

Cautionary Statement Regarding Forward-Looking Statements

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 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 and outcome 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 information technology systems, networks, and facilities, or those of third parties with whom the company shares its data; the impact of global macroeconomic conditions, trade disruptions, disputes, unrest, war, regional dependencies, or other costs, uncertainties and risks related to engaging in business globally; 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, disruptions, or shortages, including as a result of unpredictability and variability in demand, labor shortages, third-party performance, quality, or regulatory actions related to our facilities; dependence on certain products for a significant percentage of our total revenue; reliance on third-party relationships and outsourcing arrangements; the impact of public health outbreaks, epidemics, or pandemics, such as the COVID-19 pandemic; regulatory changes or other developments; regulatory actions regarding operations and 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; changes in accounting and reporting standards promulgated by the Financial Accounting Standards Board and the Securities and Exchange Commission (SEC); regulatory compliance problems or government investigations; and actual or perceived deviation from environmental-, social-, or governance-related requirements or expectations. For additional information about the factors that could cause actual results or events 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)
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)
Jaypirca™ (pirtobrutinib, Lilly)
Mounjaro® (tirzepatide injection, Lilly)
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, Innovent)
Verzenio® (abemaciclib, Lilly)

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

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

	Three Months Ended			Twelve Months Ended		
	2022	December 31, 2021	% Chg.	2022	December 31, 2021	% Chg.
Revenue	\$ 7,301.8	\$ 7,999.9	(9)%	\$ 28,541.4	\$ 28,318.4	1%
Cost of sales	1,548.1	2,050.2	(24)%	6,629.8	7,312.8	(9)%
Research and development	1,995.9	1,898.3	5%	7,190.8	6,930.7	4%
Marketing, selling and administrative	1,643.2	1,592.0	3%	6,440.4	6,431.6	—%
Acquired IPR&D and development milestones	240.1	437.7	(45)%	908.5	970.1	(6)%
Asset impairment, restructuring and other special charges	<u>38.1</u>	<u>104.5</u>	(64)%	<u>244.6</u>	<u>316.1</u>	(23)%
Operating income	1,836.4	1,917.2	(4)%	7,127.3	6,357.1	12%
Net interest income (expense)	(58.5)	(74.0)		(268.8)	(314.4)	
Net other income (expense)	<u>318.5</u>	<u>(3.3)</u>		<u>(52.1)</u>	<u>112.8</u>	
Other income (expense)	260.0	(77.3)	NM	(320.9)	(201.6)	59%
Income before income taxes	2,096.4	1,839.9	14%	6,806.4	6,155.5	11%
Income tax expense	<u>158.7</u>	<u>113.8</u>	39%	<u>561.6</u>	<u>573.8</u>	(2)%
Net income	<u>\$ 1,937.7</u>	<u>\$ 1,726.1</u>	12%	<u>\$ 6,244.8</u>	<u>\$ 5,581.7</u>	12%
Earnings per share - diluted	<u>\$ 2.14</u>	<u>\$ 1.90</u>	13%	<u>\$ 6.90</u>	<u>\$ 6.12</u>	13%
Dividends paid per share	\$.98	.85	15%	\$ 3.92	\$ 3.40	15%
Weighted-average shares outstanding (thousands) - diluted	904,732	909,555		904,619	911,681	

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 December 31, 2022			Three Months Ended December 31, 2021		
	GAAP Reported	Adjustments ^(b)	Non-GAAP Adjusted ^(a)	GAAP Reported	Adjustments ^(c)	Non-GAAP Adjusted ^(a)
Cost of sales	\$ 1,548.1	\$ (124.1)	\$ 1,424.0	\$ 2,050.2	\$ (137.4)	\$ 1,912.8
Asset impairment, restructuring and other special charges	38.1	(38.1)	—	104.5	(104.5)	—
Other income (expense)	260.0	(216.5)	43.5	(77.3)	70.6	(6.7)
Income tax expense	158.7	(9.7)	149.0	113.8	68.1	181.9
Net income	1,937.7	(44.6)	1,893.1	1,726.1	244.4	1,970.5
Earnings per share - diluted	2.14	(0.05)	2.09	1.90	0.27	2.17

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 December 31, 2022, include the following:

(Dollars in millions, except per share data)	Amortization ⁽ⁱ⁾	Equity investments ⁽ⁱⁱ⁾	Other specified items ⁽ⁱⁱⁱ⁾	Total
Cost of sales	\$ (124.1)	\$ —	\$ —	(124.1)
Asset impairment, restructuring and other special charges	—	—	(38.1)	(38.1)
Other income (expense)	—	(216.5)	—	(216.5)
Income tax expense	25.7	(43.7)	8.3	(9.7)
Net income	98.4	(172.8)	29.8	(44.6)
Earnings per share - diluted	0.11	(0.19)	0.03	(0.05)

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 net gains on investments in equity securities.
- iii. Exclude primarily the asset impairment, restructuring and other special charges primarily related to acquisition and integration costs associated with closing of the acquisition of Akouos, Inc.

(c) Adjustments to certain GAAP reported measures for the three months ended December 31, 2021, include the following:

(Dollars in millions, except per share data)	Amortization ⁽ⁱ⁾	Equity investments ⁽ⁱⁱ⁾	Other specified items ⁽ⁱⁱⁱ⁾	Total
Cost of sales	\$ (219.9)	\$ —	\$ 82.5	(137.4)
Asset impairment, restructuring and other special charges	—	—	(104.5)	(104.5)
Other income (expense)	—	70.6	—	70.6
Income tax expense	46.0	14.5	7.6	68.1
Net income	173.9	56.1	14.5	244.4
Earnings per share - diluted	0.19	0.06	0.02	0.27

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 net losses on investments in equity securities.
- iii. Exclude partial reversal of COVID-19 antibodies inventory charge and asset impairment, restructuring and other special charges primarily related to the impairment of a contract-based intangible asset from our acquisition of Loxo Oncology.

Eli Lilly and Company

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

	Twelve Months Ended December 31, 2022			Twelve Months Ended December 31, 2021		
	GAAP Reported	Adjustments ^(b)	Non-GAAP Adjusted ^(a)	GAAP Reported	Adjustments ^(c)	Non-GAAP Adjusted ^(a)
Cost of sales	\$ 6,629.8	\$ (574.1)	\$ 6,055.7	\$ 7,312.8	\$ (908.8)	\$ 6,404.0
Asset impairment, restructuring and other special charges	244.6	(244.6)	—	316.1	(316.1)	—
Other income (expense)	(320.9)	385.9	65.0	(201.6)	227.2	25.6
Income tax expense	561.6	263.0	824.6	573.8	300.1	873.9
Net income	6,244.8	941.6	7,186.4	5,581.7	1,152.0	6,733.7
Earnings per share - diluted	6.90	1.04	7.94	6.12	1.27	7.39

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 twelve months ended December 31, 2022, include the following:

(Dollars in millions, except per share data)	Amortization ⁽ⁱ⁾	Equity investments ⁽ⁱⁱ⁾	Other specified items ⁽ⁱⁱⁱ⁾	Total
Cost of sales	(574.1)	—	—	(574.1)
Asset impairment, restructuring and other special charges	—	—	(244.6)	(244.6)
Other income (expense)	—	385.9	—	385.9
Income tax expense	118.8	85.6	58.5	263.0
Net income	455.3	300.3	186.1	941.6
Earnings per share – diluted	0.50	0.33	0.21	1.04

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 net losses on investments in equity securities.
- iii. Exclude primarily the intangible asset impairment for GBA1 Gene Therapy (PR001) due to changes in estimated launch timing, as well as acquisition and integration costs associated with closing of the acquisition of Akouos, Inc.

(c) Adjustments to certain GAAP reported measures for the twelve months ended December 31, 2021, include the following:

(Dollars in millions, except per share data)	Amortization ⁽ⁱ⁾	Equity investments ⁽ⁱⁱ⁾	Repurchase of Debt ⁽ⁱⁱⁱ⁾	Other specified items ^(iv)	Total
Cost of sales	\$ (614.9)	\$ —	\$ —	(293.9)	(908.8)
Asset impairment, restructuring and other special charges	—	—	—	(316.1)	(316.1)
Other income (expense)	—	(178.0)	405.2	—	227.2
Income tax expense	127.8	(34.4)	85.1	121.5	300.1
Net income	487.1	(143.5)	320.1	488.5	1,152.0
Earnings per share - diluted	0.53	(0.16)	0.35	0.54	1.27

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 net gains on investments in equity securities.
- iii. Exclude charge related to the repurchase of higher-cost debt.
- iv. Exclude COVID-19 antibodies inventory charge and asset impairment, restructuring and other special charges primarily related to an intangible asset impairment resulting from the sale of rights to Qbrexza[®], the impairment of a contract-based intangible asset from our acquisition of Loxo Oncology, as well as acquisition and integration costs associated with the acquisition of Preveil Therapeutics Inc.