
**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): April 28, 2022

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))
-

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 April 28, 2022, announcing the financial results of Eli Lilly and Company for the quarter ended March 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 April 28, 2022.
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: April 28, 2022



April 28, 2022

Eli Lilly and Company

Lilly Corporate Center
Indianapolis, Indiana 46285
U.S.A.
+1.317.276.2000
www.lilly.com

For Release: Immediately

Refer to: Jordan Bishop; jordan.bishop@lilly.com; (317) 473-5712 (Media)
Kevin Hern; hern_kevin_r@lilly.com; (317) 277-1838 (Investors)

Solid First-Quarter Financial Results Reflect Lilly's Continued Momentum into 2022

- *Lilly's revenue growth in Q1 2022 increased 15%, driven by volume growth of 20%. Excluding revenue from COVID-19 antibodies and Alimta, Q1 2022 revenue grew 10%.*
- *Outside of revenue from COVID-19 antibodies, which grew \$660 million, revenue was driven by key growth products - consisting of Trulicity, Verzenio, Jardiance, Taltz, Olumiant, Emgality, Retevmo, Cyramza and Tyvyt - which contributed 13 percentage points of revenue growth and represented 61% of core revenue in Q1 2022.*
- *The company advanced its pipeline with a positive Phase 3 readout for tirzepatide for obesity or overweight, an announcement that the Phase 3 trial of Jardiance for people with chronic kidney disease will stop early due to clear positive efficacy, and a U.S. regulatory submission for mirikizumab for moderately-to-severely active ulcerative colitis.*
- *Q1 2022 EPS increased 41% to \$2.10 on a reported basis and increased 63% to \$2.62 on a non-GAAP basis. Q1 2022 reported and non-GAAP EPS are both inclusive of \$0.15 of acquired IPR&D and development milestone charges.*
- *2022 EPS guidance updated to be in the range of \$7.30 to \$7.45 on a reported basis and \$8.15 to \$8.30 on a non-GAAP basis, both inclusive of \$0.55 of acquired IPR&D and development milestone charges.*

INDIANAPOLIS, April 28, 2022 - Eli Lilly and Company (NYSE: LLY) today announced its financial results for the first quarter of 2022.

"Lilly delivered another quarter of volume-driven revenue growth led by key products and anticipates 2022 to be an exciting year with several potential approvals and new pipeline events," said David A. Ricks, Lilly's chair and CEO. "With the depth of our pipeline, and growth of our medicines in the market, we are well-positioned to help address health challenges in areas of significant unmet medical need, such as obesity, Alzheimer's disease and cancer."

Today, the company is sharing new notable announcements:

- Tirzepatide delivered up to 22.5% weight loss in adults with obesity or overweight in the 72-week Phase 3 SURMOUNT-1 study. Participants taking tirzepatide lost up to 52 lb. and 63% of participants taking tirzepatide 15 mg achieved at least 20% body weight reduction as a key secondary endpoint.
- Lilly submitted mirikizumab to the U.S. Food and Drug Administration (FDA) for the treatment of adults with moderately-to-severely active ulcerative colitis.

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

- The FDA approved Jardiance® to treat adults with heart failure regardless of left ventricular ejection fraction.
- Bebtelovimab received Emergency Use Authorization (EUA) from the FDA for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients.
- The FDA issued a Complete Response Letter (CRL) for sintilimab in combination with pemetrexed and platinum chemotherapy for the first-line treatment of people with nonsquamous non-small cell lung cancer.
- As anticipated, Lilly received a CRL from the FDA for the Olumiant® atopic dermatitis indication as the company was not in alignment with the FDA on the indicated population.
- Lebrikizumab combined with topical corticosteroids showed 70% of patients with moderate-to-severe atopic dermatitis experienced at least 75% reduction in disease severity at 16 weeks in the ADhere Phase 3 trial.
- More than 50% of patients with moderate-to-severe atopic dermatitis experienced at least 75% reduction in disease severity at 16 weeks with lebrikizumab in Lilly's pivotal Phase 3 atopic dermatitis ADvocate studies.
- Nearly 40% of adults with alopecia areata taking Olumiant 4-mg saw at least 80% scalp hair coverage at 52 weeks in Lilly's pivotal Phase 3 studies.
- Nearly two-thirds of patients responded to mirikizumab treatment at 12 weeks in Lilly's first-

in-class ulcerative colitis Phase 3 LUCENT-1 study.

- The company announced that the Jardiance Phase 3 EMPA-KIDNEY trial will stop early due to clear positive efficacy in people with chronic kidney disease.
- Adults hospitalized for acute heart failure were 36% more likely to experience a clinical benefit over 90 days if initiated on Jardiance following stabilization and prior to discharge compared with placebo in the Phase 3 EMPULSE trial.
- Lilly supplied 600,000 doses of bebtelovimab to the U.S. government in an ongoing effort to provide COVID-19 treatment options.
- The company announced the launch of the Lilly Institute for Genetic Medicine and a \$700 million investment to establish a new site in the Boston Seaport.

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>First Quarter</u>		<u>%</u>
	<u>2022</u>	<u>2021</u>	<u>Change</u>
Revenue	\$7,810.0	\$6,805.6	15%
Net Income – Reported	1,902.9	1,355.3	40%
EPS – Reported	2.10	1.49	41%
Net Income – Non-GAAP	2,372.8	1,465.5	62%
EPS – Non-GAAP	2.62	1.61	63%

A discussion of the non-GAAP financial measures is included under "Reconciliation of GAAP Reported to Selected Non-GAAP Adjusted Information (Unaudited)." Beginning in 2022, presentations of non-GAAP financial measures will not include adjustments for upfront charges and development milestones related to acquired in-process research and development (IPR&D). Non-GAAP financial measures for Q1 2021 have been adjusted to reflect this updated presentation.

First-Quarter Reported Results

In Q1 2022, worldwide revenue was \$7.81 billion, an increase of 15% compared with Q1 2021, primarily driven by a 20% increase in volume, partially offset by a 3% decrease due to lower realized prices and a 2% decrease due to the unfavorable impact of foreign exchange rates. Key growth products, consisting of Trulicity[®], Verzenio[®], Jardiance, Taltz[®], Olumiant, Emgality[®], Retevmo[®], Cyramza[®] and Tyvyt[®], contributed 13 percentage points of revenue growth and represented 61% of total revenue for Q1 2022, excluding revenue from COVID-19 antibodies. The company recognized worldwide revenue of \$1.47 billion from COVID-19 antibodies during Q1 2022 compared with \$810.1 million in Q1 2021. Excluding revenue from COVID-19 antibodies and Alimta[®], which lost exclusivity in certain major markets, worldwide revenue increased 10% in Q1 2022.

Revenue in the U.S. increased 31%, to \$5.17 billion, driven by a 32% increase in volume. The company recognized U.S. revenue from COVID-19 antibodies of \$1.46 billion in Q1 2022 compared to \$650.6 million in Q1 2021. Excluding revenue from COVID-19 antibodies and Alimta, revenue in the U.S. increased by 14% driven by key growth products.

Revenue outside the U.S. decreased 8%, to \$2.64 billion, driven by a 7% decrease due to lower realized prices and a 5% decrease due to the unfavorable impact of foreign exchange rates, partially offset by a 4% increase in volume. The lower realized prices were primarily driven by the impact of the National Reimbursement Drug List (NRDL) formulary for certain products in China, particularly Tyvyt. The increase in volume outside the U.S. was largely driven by key growth products and sales of the company's rights to Cialis[®] in Taiwan and Saudi Arabia, partially offset by decreased volume for

Alimta, Cymbalta[®] and Forteo[®] resulting from the entry of generic competition, as well as decreased volume for COVID-19 antibodies. Excluding revenue from COVID-19 antibodies and Alimta, revenue outside the U.S. increased by 5%.

Gross margin increased 16%, to \$5.74 billion, in Q1 2022 compared with Q1 2021. Gross margin as a percent of revenue was 73.5%, an increase of 1.1 percentage points compared with Q1 2021. The increase in gross margin percent was primarily driven by an unfavorable effect in Q1 2021 of foreign exchange rates on international inventories sold, partially offset by increased sales of COVID-19 antibodies and, to a lesser extent, lower realized prices.

In Q1 2022, research and development expenses decreased 4% to \$1.61 billion, or 21% of revenue, largely driven by lower development expenses for COVID-19 antibodies, partially offset by higher development expenses for late-stage assets.

Marketing, selling and administrative expenses decreased 1% to \$1.56 billion in Q1 2022.

In Q1 2022, the company recognized acquired IPR&D and development milestone charges of \$165.6 million primarily related to a purchase of a Priority Review Voucher. In Q1 2021, the company recognized acquired IPR&D and development milestone charges of \$312.0 million primarily related to business development transactions with Rigel Pharmaceuticals, Inc. and Precision BioSciences, Inc.

There were no asset impairment, restructuring and other special charges recognized in Q1 2022. In Q1 2021, the company recognized asset impairment, restructuring and other special charges of \$211.6 million, largely related to an intangible asset impairment resulting from the decision to sell the rights to Qbrexza[®], as well as acquisition and integration costs associated with the acquisition of Prevail Therapeutics Inc.

Operating income in Q1 2022 was \$2.40 billion, compared to \$1.16 billion in Q1 2021. Operating margin percent, defined as operating income as a percent of revenue, was 30.8%, which includes a negative impact of approximately 210 basis points attributed to acquired IPR&D and development milestone charges.

Other income (expense) was expense of \$350.7 million in Q1 2022, compared with income of \$321.1 million in Q1 2021. The reduction in other income (expense) was primarily driven by net losses on investments in equity securities in Q1 2022 compared with net gains on investments in equity securities in Q1 2021.

The effective tax rate was 7.3% in Q1 2022, compared with 8.2% in Q1 2021. The lower effective tax rate in Q1 2022 was largely driven by decreased tax expense related to net losses in 2022 and net gains in 2021 on investments in equity securities and decreased tax expense related to 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, partially offset by a lower net discrete tax benefit compared to the same period in 2021.

In Q1 2022, net income and earnings per share (EPS) were \$1.90 billion and \$2.10, respectively, compared with \$1.36 billion and \$1.49 in Q1 2021. Q1 2022 EPS is inclusive of \$0.15 of acquired IPR&D and development milestone charges, compared with \$0.27 in Q1 2021.

First-Quarter Non-GAAP Measures

On a non-GAAP basis, Q1 2022 gross margin increased 16%, to \$5.94 billion compared with Q1 2021. Gross margin as a percent of revenue was 76.1%, an increase of 0.7 percentage points. The increase in gross margin percent was primarily driven by an unfavorable effect in Q1 2021 of foreign exchange rates on international inventories sold, partially offset by increased sales of COVID-19 antibodies and, to a lesser extent, lower realized prices.

Operating income on a non-GAAP basis increased \$1.03 billion, or 66%, to \$2.61 billion in Q1 2022 compared with Q1 2021. Operating margin percent was 33.4% on a non-GAAP basis, which includes a negative impact of approximately 210 basis points attributed to acquired IPR&D and development milestone charges.

Other income (expense) on a non-GAAP basis was income of \$37.7 million in Q1 2022, compared with income of \$34.6 million in Q1 2021.

The effective tax rate on a non-GAAP basis was 10.3% in Q1 2022, compared with 8.9% in Q1 2021. The higher effective tax rate for Q1 2022 reflects a lower net discrete tax benefit compared to the same period in 2021, partially offset by decreased tax expense related to the implementation of the 2017 Tax Act.

On a non-GAAP basis, in Q1 2022 net income and EPS were \$2.37 billion and \$2.62, respectively, compared with \$1.47 billion and \$1.61 in Q1 2021. Q1 2022 non-GAAP EPS is inclusive of \$0.15 of acquired IPR&D and development milestone charges, compared with \$0.27 in Q1 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>First Quarter</u> <u>2021</u>	<u>% Change</u>
Earnings per share (reported)	\$ 2.10	\$ 1.49	41%
Net losses (gains) on investments in equity securities	.34	(.25)	
Amortization of intangible assets	.18	.11	
Asset impairment, restructuring and other special charges	—	.19	
Partial reversal of COVID-19 antibodies inventory charge	—	.07	
Earnings per share (non-GAAP)	\$ 2.62	\$ 1.61	63%
<small>Numbers may not add due to rounding.</small>			
Acquired IPR&D and development milestone charges	.15	.27	(44)%

Selected Revenue Highlights

<i>(Dollars in millions)</i>		First Quarter		
Selected Products	2022	2021	% Change	
Trulicity	\$ 1,741.3	\$ 1,452.4	20%	
COVID-19 antibodies ^(a)	1,469.8	810.1	81%	
Humalog ^{®(b)}	618.2	617.0	0%	
Taltz	488.1	403.2	21%	
Verzenio	469.4	269.0	74%	
Jardiance ^(c)	419.4	312.0	34%	
Alimta	343.9	559.0	(38)%	
Humulin [®]	273.2	321.7	(15)%	
Olumiant ^(d)	255.6	193.8	32%	
Cyramza	230.3	240.5	(4)%	
Basaglar [®]	191.5	246.6	(22)%	
Emgality	149.3	119.5	25%	
Forteo	137.4	198.5	(31)%	
Tyvvyt	85.5	109.7	(22)%	
Retevmo	41.8	16.8	NM	
Total Revenue	7,810.0	6,805.6	15%	

^(a) 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

^(b) Humalog includes Insulin Lispro

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

^(d) Olumiant includes sales of baricitinib that were made pursuant to EUA or similar regulatory authorizations

NM – not meaningful

Trulicity

For Q1 2022, worldwide Trulicity revenue was \$1.74 billion, an increase of 20% compared with Q1 2021. U.S. revenue increased 18%, to \$1.31 billion, driven by increased demand, partially offset by lower realized prices as well as wholesale and retail buying patterns. Revenue outside the U.S. was \$427.4 million, an increase of 27%, driven by increased volume, partially offset by the unfavorable impact of foreign exchange rates and, to a lesser extent, lower realized prices.

Humalog

For Q1 2022, worldwide Humalog revenue remained flat compared with Q1 2021, at \$618.2 million. Revenue in the U.S. increased 11%, to \$368.9 million, primarily driven by higher realized prices due to changes to estimates for rebates and discounts in both periods and, to a lesser extent, increased demand. However, the company expects a decline for realized Humalog prices in the U.S. for the remainder of 2022, largely driven by patient assistance programs. Revenue outside the U.S. decreased 12%, to \$249.3 million, driven by decreased volume, the unfavorable impact of foreign exchange rates and, to a lesser extent, lower realized prices.

Taltz

For Q1 2022, worldwide Taltz revenue increased 21% compared with Q1 2021, to \$488.1 million. U.S. revenue increased 23%, to \$307.2 million, driven by increased demand and higher realized prices due to segment mix, partially offset by specialty pharmacy buying patterns. Revenue outside the U.S. increased 18%, to \$180.8 million, driven by increased volume, partially offset by lower realized prices and the unfavorable impact of foreign exchange rates.

Verzenio

For Q1 2022, worldwide Verzenio revenue increased 74% compared with Q1 2021, to \$469.4 million. U.S. revenue was \$301.5 million, an increase of 74%, primarily driven by increased demand. Revenue outside the U.S. was \$167.9 million, an increase of 74%, largely driven by increased volume, partially offset by the unfavorable impact of foreign exchange rates.

Jardiance

The company's worldwide Jardiance revenue during Q1 2022 was \$419.4 million, an increase of 34% compared with Q1 2021. U.S. revenue increased 52%, to \$229.8 million, primarily driven by increased demand. Revenue outside the U.S. was \$189.7 million, an increase of 18%, 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.

Alimta

For Q1 2022, worldwide Alimta revenue decreased 38% compared with Q1 2021, to \$343.9 million. U.S. revenue decreased 3%, to \$254.3 million, driven by decreased volume, partially offset by higher realized prices. Revenue outside the U.S. decreased 70%, to \$89.7 million, largely driven by decreased volume due to entry of generic competition in certain markets 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. An alternative form of pemetrexed launched in the U.S. during Q1 2022 and the company expects multiple generics to launch in Q2 2022, causing a rapid and severe decline in revenue.

Olumiant

For Q1 2022, worldwide Olumiant revenue increased 32% compared with Q1 2021, to \$255.6 million. U.S. revenue was \$71.3 million, representing growth of \$46.6 million compared with Q1 2021. Revenue outside the U.S. was \$184.3 million, an increase of 9%, driven by increased volume, partially offset by the unfavorable impact of foreign exchange rates and lower realized prices. Increased volume

worldwide was partially driven by utilization of Olumiant for the treatment of hospitalized patients with COVID-19.

Emgality

For Q1 2022, Emgality generated worldwide revenue of \$149.3 million, an increase of 25% compared with Q1 2021. U.S. revenue was \$108.3 million, an increase of 7%, driven by increased demand, partially offset by lower realized prices. Revenue outside the U.S. was \$41.0 million, an increase of \$23.0 million compared with Q1 2021, driven by increased demand.

Tyvyt

For Q1 2022, the company's Tyvyt revenue in China was \$85.5 million, a decrease of 22% compared with Q1 2021, driven by lower realized prices due to the impact of the NRDL formulary in China on Tyvyt, largely offset by increased demand.

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.

2022 Financial Guidance

The company has updated certain elements of its 2022 financial guidance on both a reported and non-GAAP basis. EPS for 2022 is now expected to be in the range of \$7.30 to \$7.45 on a reported basis and \$8.15 to \$8.30 on a non-GAAP basis. The company's 2022 financial guidance reflects adjustments shown in the reconciliation table below.

	2022 Expectations	% Change vs 2021
Earnings per share (reported)	\$7.30 to \$7.45	19% to 22%
Amortization of intangible assets	.51	
Net losses on investments in equity securities	.34	
Earnings per share (non-GAAP)	\$8.15 to \$8.30	10% to 12%
<small>Numbers may not add due to rounding</small>		
Acquired IPR&D and development milestone charges	\$.55	

Beginning in 2022, presentations of non-GAAP financial measures will not include adjustments for upfront charges and development milestones related to acquired IPR&D. Non-GAAP financial measures for Q1 2021 have been adjusted to reflect this updated presentation.

The company now anticipates 2022 revenue to be between \$28.8 billion and \$29.3 billion. This \$1.0 billion increase reflects additional COVID-19 antibodies revenue from the sale of 600,000 doses of bebtelovimab to the U.S. government in Q1 2022. An unfavorable impact from foreign exchange rates on revenue is offset by strength of the core business. The U.S. government has an option to purchase an additional 500,000 doses of bebtelovimab no later than July 31, 2022, but it is uncertain whether the option will be exercised, and any associated revenue is not included in guidance.

Gross margin percent is now expected to be approximately 76% on a reported basis and 78% on a non-GAAP basis. The majority of this roughly 200 basis point reduction is due to the impact of Q1 bebtelovimab sales and, to a lesser extent, increased manufacturing costs due to inflation.

Research and development expenses were increased by \$100 million and are now expected to be between \$7.1 billion and \$7.3 billion, driven by investment in late-stage pipeline assets.

The company is now providing 2022 financial guidance for acquired IPR&D and development milestone charges, which are expected to be approximately \$520 million, reflecting Q1 2022 charges of \$166 million, with the remainder primarily related to a charge associated with the buy-out of future obligations that were contingent upon the development, regulatory and commercial successes of the company's mutant-selective PI3K α inhibitor. This financial guidance does not include any impact from potential or pending business development transactions.

Operating margin percent has been reduced by 200 basis points and is now expected to be approximately 28% on a reported basis and approximately 30% on a non-GAAP basis primarily due to the negative impact attributable to acquired IPR&D and development milestone charges.

Other income (expense) for 2022 is now expected to be expense in the range of \$500 million to \$400 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 net losses on investments in equity securities during Q1 2022.

The company's financial results for Q1 2022 include the favorable impact related to the implementation of the provision of the 2017 Tax Act that requires capitalization and amortization of research and development expenses for tax purposes. The company's financial guidance assumes this provision of the 2017 Tax Act will be deferred or repealed by Congress effective for 2022. If this provision of the 2017 Tax Act is not deferred or repealed by Congress effective for 2022, the company expects the reported and non-GAAP tax rates to be approximately 10% to 11%.

The following table summarizes the company's updated 2022 financial guidance:

	2022 Guidance	
	<u>Prior</u>	<u>Updated</u>
Revenue	\$27.8 to \$28.3 billion	\$28.8 to \$29.3 billion
Gross Margin % of Revenue (reported)	Approx. 78%	Approx. 76%
Gross Margin % of Revenue (non-GAAP)	Approx. 80%	Approx. 78%
Marketing, Selling & Administrative	\$6.4 to \$6.6 billion	Unchanged
Research & Development	\$7.0 to \$7.2 billion	\$7.1 to \$7.3 billion
Acquired IPR&D & Development Milestones	N/A	Approx. \$520 million
Other Income/(Expense) (reported)	\$(100) million to \$0	\$(500) to \$(400) million
Other Income/(Expense) (non-GAAP)	\$(100) million to \$0	Unchanged
Tax Rate	Approx. 13% to 14%	Unchanged
Earnings per Share (reported)	\$8.00 to \$8.15	\$7.30 to \$7.45
Earnings per Share (non-GAAP)	\$8.50 to \$8.65	\$8.15 to \$8.30
Operating Margin % (reported)	Approx. 30%	Approx. 28%
Operating Margin % (non-GAAP)	Approx. 32%	Approx. 30%
Non-GAAP guidance reflects adjustments presented in the earnings per share table above.		

Webcast of Conference Call

As previously announced, investors and the general public can access a live webcast of the Q1 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 9 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. Beginning in 2022, presentations of non-GAAP financial measures will not include adjustments for upfront charges and development milestones related to acquired IPR&D. Non-GAAP financial measures for Q1 2021 have been adjusted to reflect this updated presentation. The company's 2022 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 impact of the evolving COVID-19 pandemic or any future pandemic, epidemic, or similar public health threat and the global response thereto; uncertainties related to the company's efforts to develop, manufacture, and distribute 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, trade disruptions, global disputes, unrest, war, or other costs, uncertainties and risks related to engaging in business in foreign jurisdictions; 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)
Cialis[®] (tadalafil, Lilly)
Cymbalta[®] (duloxetine, Lilly)
Cytaraza[®] (ramucirumab, Lilly)

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

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

	Three Months Ended March 31,		
	2022	2021	% Chg.
Revenue	\$ 7,810.0	\$ 6,805.6	15%
Cost of sales	2,072.1	1,878.6	10%
Research and development	1,610.1	1,672.1	(4)%
Marketing, selling and administrative	1,557.9	1,576.0	(1)%
Acquired IPR&D and development milestones	165.6	312.0	(47)%
Asset impairment, restructuring and other special charges	<u>—</u>	<u>211.6</u>	(100)%
Operating income	2,404.3	1,155.3	NM
Net interest income (expense)	(77.9)	(82.3)	
Net other income (expense)	<u>(272.8)</u>	<u>403.4</u>	
Other income (expense)	(350.7)	321.1	NM
Income before income taxes	2,053.6	1,476.4	39%
Income tax expense	<u>150.7</u>	<u>121.1</u>	24%
Net income	<u>\$ 1,902.9</u>	<u>\$ 1,355.3</u>	40%
Earnings per share - diluted	<u>\$ 2.10</u>	<u>\$ 1.49</u>	41%
Dividends paid per share	\$.98	.85	15%
Weighted-average shares outstanding (thousands) - diluted	906,350	912,419	

NM – not meaningful

Eli Lilly and Company

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

	Three Months Ended March 31, 2022			Three Months Ended March 31, 2021		
	GAAP Reported	Adjustments ^(b)	Non-GAAP Adjusted ^(a)	GAAP Reported	Adjustments ^(c)	Non-GAAP Adjusted ^(a)
Cost of sales	\$ 2,072.1	\$ (204.6)	\$ 1,867.5	\$ 1,878.6	\$ (207.2)	\$ 1,671.4
Asset impairment, restructuring and other special charges	—	—	—	211.6	(211.6)	—
Other income (expense)	(350.7)	388.4	37.7	321.1	(286.5)	34.6
Income tax expense	150.7	123.1	273.8	121.1	22.1	143.2
Net income	1,902.9	469.9	2,372.8	1,355.3	110.2	1,465.5
Earnings per share - diluted	2.10	0.52	2.62	1.49	0.12	1.61

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. Beginning in 2022, presentations of non-GAAP financial measures will not include adjustments for upfront charges and development milestones related to acquired IPR&D. Non-GAAP financial measures for Q1 2021 have been adjusted to reflect this updated presentation.

(b) Adjustments to certain GAAP reported measures for the three months ended March 31, 2022, include the following:

(Dollars in millions, except per share data)	Amortization ⁽ⁱ⁾	Equity investments ⁽ⁱⁱ⁾	Total
Cost of sales	\$ (204.6)	\$ —	(204.6)
Other income (expense)	—	388.4	388.4
Income tax expense	42.3	80.8	123.1
Net income	162.2	307.7	469.9
Earnings per share - diluted	0.18	0.34	0.52

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.

(c) Adjustments to certain GAAP reported measures for the three months ended March 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	\$ (125.7)	\$ —	\$ (81.5)	(207.2)
Asset impairment, restructuring and other special charges	—	—	(211.6)	(211.6)
Other income (expense)	—	(286.5)	—	(286.5)
Income tax expense	26.1	(55.9)	51.9	22.1
Net income	99.6	(230.6)	241.2	110.2
Earnings per share - diluted	0.11	(0.25)	0.26	0.12

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 an intangible asset impairment resulting from the decision to sell the rights to Qbrexza, charges resulting from excess inventory due in part to the discontinuation of bamlanivimab for use on its own, as well as acquisition and integration costs recognized as part of the closing of the acquisition of Preval Therapeutics Inc.