Lilly Announces 2023 Financial Guidance, Plans to Launch up to Four New Medicines

December 13, 2022

- *Lilly expects to deliver strong financial and operational performance in 2023, highlighted by volume-driven revenue growth; potential launches for donanemab, mirikizumab, lebrikizumab and pirtobrutinib; potential regulatory submissions for tirzepatide in obesity; and numerous other anticipated pipeline advancements.*
- *Continued pipeline progress in 2023 includes expected initiation of Phase 3 clinical trials for retatrutide (GGG tri-agonist) in obesity and orforglipron (oral GLP-1 NPA) in type 2 diabetes and obesity, and key Phase 3 readouts, which include donanemab for early Alzheimer's disease and mirikizumab for Crohn's disease.*
- *2023 revenue expected to be between $30.3 billion and $30.8 billion, driven by key growth products.*
- *2023 EPS expected to be in the range of $7.65 to $7.85 on a reported basis and $8.10 to $8.30 on a non-GAAP basis.*
- *The company reaffirmed its 2022 financial guidance on both a reported and non-GAAP basis.*
- *Fifth consecutive 15% annual increase in dividend for 2023, doubling since 2018 and underscoring increasing confidence in the company's outlook.*

INDIANAPOLIS, Dec. 13, 2022 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced its 2023 financial guidance, highlighted by expected volume-based revenue growth and increased investments to maximize future value. The company will review potential key events for the upcoming year, including important data readouts for several investigational medicines in its clinical pipeline and the possibility of multiple regulatory submissions and approvals, in a call with investors today.

"Lilly is exiting 2022 with momentum. Our approved and available medicines are early in their life cycles and showed accelerated growth during the year, led by a strong Mounjaro launch. In addition, several of our late-stage medicines for serious diseases were submitted for approval this year, and will hopefully launch in 2023," said David A. Ricks, Lilly's chair and CEO. "We continue to innovate and are beginning new pivotal studies for the next group of potential breakthrough treatments. In the decade ahead, we are well-positioned to create significant value for patients with challenging conditions, health systems struggling to manage chronic disease, and of course, our shareholders."

Anat Ashkenazi, Lilly's executive vice president and chief financial officer, outlined the company's expectations for its growth prospects: "We believe we have the potential to deliver top-tier, volume-driven revenue growth through at least 2030 with groundbreaking medicines. In addition to the tremendous on-going launch of Mounjaro in type 2 diabetes and expected future opportunities to treat obesity and obesity-related metabolic outcomes with tirzepatide, we plan to invest in our four significant potential new launches next year. With limited patent expirations this decade, we believe these potential new medicines and the continued scaling of our key growth products will fuel our next wave of growth. Lilly is committed to maximizing long-term value for stakeholders and we look forward to delivering further in 2023."

2022 Financial Guidance

The company reaffirmed its 2022 financial guidance on both a reported and 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)	**$6.50 to $6.65**	**6% to 9%**
Net losses on investments in equity securities(1)	.52	
Amortization of intangible assets	.51	
Asset impairment, restructuring, and other special charges	.17	
Earnings per share (non-GAAP)	**$7.70 to $7.85**	**4% to 6%**
Numbers may not add due to rounding		
Acquired IPR&D and development milestone charges(2)	$.67	

(1) The company's guidance does not reflect the impact of net gains or losses on investments in equity securities during Q4 2022.

(2) The company's guidance does not include any acquired IPR&D or development milestone charges incurred during Q4 2022.

The company reaffirmed its 2022 financial guidance, as set forth in the following table:

	2022 Guidance
Revenue	$28.5 to $29.0 billion
Gross Margin % of Revenue (reported)	Approx. 76%
Gross Margin % of Revenue (non-GAAP)	Approx. 78%
Marketing, Selling & Administrative	$6.4 to $6.6 billion
Research & Development	$7.1 to $7.3 billion
Acquired IPR&D & Development Milestones	Approx. $670 million
Other Income/(Expense) (reported)	$(700) to $(600) million
Other Income/(Expense) (non-GAAP)	$(100) million to $0
Tax Rate	Approx. 13% to 14%
Earnings per Share (reported)	$6.50 to $6.65
Earnings per Share (non-GAAP)	$7.70 to $7.85
Operating Margin % (reported)	Approx. 26%
Operating Margin % (non-GAAP)	Approx. 29%

Non-GAAP guidance reflects adjustments presented in the earnings per share table above.

2023 Financial Guidance

Earnings per share (EPS) for 2023 is expected to be in the range of $7.65 to $7.85 on a reported basis and $8.10 to $8.30 on a non-GAAP basis. The company's 2023 financial guidance reflects the adjustment shown in the reconciliation table below.

	2023 Expectations
Earnings per share (reported)	**$7.65 to $7.85**
Amortization of intangible assets	.45
Earnings per share (non-GAAP)	**$8.10 to $8.30**

Numbers may not add due to rounding.
The company's 2023 financial guidance does not include any impact from potential or pending business development transactions or potential development milestone charges.

The company anticipates 2023 revenue between $30.3 billion and $30.8 billion, driven by volume increases from key growth products. This growth is expected to be partially offset by lower revenue for Alimta® due to its loss of patent exclusivity, no anticipated COVID-19 antibody revenue, and the continued negative impact of foreign exchange rates.

Gross margin as a percent of revenue for 2023 is expected to be approximately 77% on a reported basis and approximately 79% on a non-GAAP basis.

Marketing, selling and administrative expenses for 2023 are expected to be in the range of $6.9 billion to $7.1 billion. Research and development expenses are expected to be in the range of $8.2 billion to $8.4 billion.

Consistent with 2022, the company is not including any potential or pending acquired in-process research and development (IPR&D) and development milestone charges in its initial 2023 guidance and expects to update EPS guidance each quarter as acquired IPR&D and development milestone charges are incurred.

Other income (expense) is expected to be expense in the range of $100 million to $200 million on both a reported and non-GAAP basis.

The 2023 effective tax rate is expected to be approximately 16% on both a reported basis and non-GAAP basis. This assumes the provision in the 2017 Tax Act that requires capitalization and amortization of research and development expenses for tax purposes is deferred or repealed by U.S. Congress this year, effective for the full year 2022 as well as 2023. The tax rate increase also includes the impact from recently enacted Puerto Rico legislation that will become effective starting in 2023, as well as the impact from an expected increase in the proportion of earnings in higher tax jurisdictions.

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

	2023 Guidance
Revenue	$30.3 to $30.8 billion
Gross Margin % of Revenue (reported)	Approx. 77%
Gross Margin % of Revenue (non-GAAP)	Approx. 79%
Marketing, Selling & Administrative	$6.9 to $7.1 billion

Research & Development	$8.2 to $8.4 billion
Other Income/(Expense)	$(200) million to $(100) million
Tax Rate	Approx. 16%
Earnings per Share (reported)	$7.65 to $7.85
Earnings per Share (non-GAAP)	$8.10 to $8.30

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 2023 financial guidance 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

The company uses non-GAAP financial measures that differ from financial statements reported in conformity with U.S. generally accepted accounting principles ("GAAP"), and this press release and related materials includes a description of certain non-GAAP items that may affect the company's financial expectations for 2022 and 2023. The company's non-GAAP financial measures adjust reported results to exclude amortization of intangibles and items that are typically highly variable, difficult to predict, and/or 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 financial measures provide useful information to investors in evaluating the company's performance. They can assist in making meaningful period-over-period comparisons and in identifying operating trends that would otherwise be masked or distorted by the items subject to the adjustments. Management uses these non-GAAP financial measures internally to evaluate the performance of the company's business, including to allocate resources and to evaluate results relative to incentive compensation targets. Investors should consider these non-GAAP financial measures in addition to, not as a substitute for or superior to, measures of financial performance prepared in accordance with GAAP.

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", "forecast" 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 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; 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 demand, labor shortages, third-party performance, or 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. In addition, the company may not be able to reliably predict the impact of specified items in its 2023 guidance beyond the next 12 months, and the variability of factors discussed in these forward-looking statements could have a significant and unpredictable impact on the company's future GAAP results. 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.

Alimta® (pemetrexed disodium, Lilly)

Mounjaro® (tirzepatide injection, Lilly)

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