Lilly Highlights Innovation-based Growth Strategy and Pipeline Developments; Announces 2022 Financial Guidance at Investment Community Meeting

December 15, 2021

- In today's presentations, Lilly will highlight newer medicines and upcoming launches expected to drive growth through the decade - showcasing how the company impacts millions of people and brings to life its purpose of creating medicines that make life better.

- Lilly also will reinforce its commitment to innovation and investment in science to create the next wave of new medicines for patients, share new information across its four therapeutic areas - including pipeline and regulatory updates and new data readouts for early-phase molecules - and provide visibility to future investments.

- The company announces initiation of rolling submission to FDA for pirtobrutinib in mantle cell lymphoma, reveals new phase 3 trials planned for tirzepatide in obesity outcomes, sleep apnea and kidney disease, and releases new biomarker data supporting donanemab efficacy.

- Lilly expects 2022 revenue to be between $27.8 billion and $28.3 billion, with key growth products driving two-thirds of core business revenue, excluding COVID-19 therapies; expects operating margin to be approximately 30 percent on a reported basis and approximately 32 percent on a non-GAAP basis, and expects earnings per share (EPS) to be in the range of $8.00 to $8.15 on a reported basis and $8.50 to $8.65 on a non-GAAP basis.

- The company now expects 2021 revenue to be between $28.0 billion and $28.3 billion and EPS to be in the range of $6.18 to $6.23 on a reported basis and $8.15 to $8.20 on a non-GAAP basis.

INDIANAPOLIS, Dec. 15, 2021 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) is providing extensive updates across its research and development (R&D) programs to highlight the company's strong pipeline and potential for future growth. At an investment community meeting today, the company is sharing key information across its four therapeutic areas – including pipeline updates and future R&D investments – along with 2022 financial guidance and updated 2021 guidance.

The company is on track to meet its goal of launching 20 new medicines over the 10-year period from 2014 to 2023. Over the last eight years, Lilly has delivered 16 new medicines and plans to launch five more medicines over the next two years, if approved, including tirzepatide, donanemab, pirtobrutinib, lebrikizumab and mirikizumab. These potential launches contribute to the company's expectations for top-tier, volume-driven growth over the next decade, as the number of people that can benefit from Lilly's innovative new medicines continues to increase.

"Lilly's accomplishments in recent years are impressive, but it's where we are going that most excites us. We've driven results over the last four years, successfully launched new medicines, and invested in high-impact R&D that has set us up for a truly exciting new era," said David A. Ricks, Lilly's chairman and CEO. "Bringing new practice-changing medicines to patients is our top priority. We have a remarkable opportunity ahead of us to make life better for millions more people around the world."

The company is providing details on its diabetes and obesity, immunology, oncology and neuroscience R&D programs, sharing a number of new pipeline updates and previously undisclosed data. Lilly also will provide insight into its ongoing R&D investments that reflect the company's conviction around key emerging trends in biopharma innovation.

"I'm very optimistic about the future for Lilly and the patients we serve. In addition to our promising late-stage pipeline, our labs are making new discoveries to bring life-changing medicines to patients who need them," said Daniel Skovronsky, M.D., Ph.D., Lilly's chief scientific and medical officer, and president of Lilly Research Laboratories. "Lilly has significantly improved our development speed and clinical success rates and will continue to apply this focus as we work to maximize the impact of our existing medicines and create new ones.

"Genetic medicines, including modalities such as RNA therapeutics and viral-delivered gene therapies, are poised to contribute to the next generation of breakthrough treatments for a wide array of diseases," Skovronsky continued. "Today, Lilly will share more about our new capabilities and increased investment in this space, along with new preclinical and clinical data for genetic medicines in our neuroscience and cardiovascular disease research portfolios."

Diabetes and Obesity

Building on its historic foundation of helping people with diabetes, Lilly is expanding its strategic focus to breakthrough medications that disrupt the disease cascade caused by obesity and type 2 diabetes progression, highlighted by tirzepatide and supported by several early-phase incretin assets.

The U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) have accepted Lilly's New Drug Application and Marketing Authorization Application, respectively, for tirzepatide for the treatment of adults with type 2 diabetes. Lilly also submitted tirzepatide to the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan and in six additional markets. Lilly plans to initiate additional tirzepatide studies that include phase 3 studies in obesity related outcomes and obstructive sleep apnea, as well as a phase 2 mechanism of action study in kidney disease.

Lilly is disclosing new data from several assets in its robust early-phase incretin platform focused on obesity. The company's incretin platform is focused on delivering therapeutics with bariatric surgery-like weight loss with related metabolic benefits and developing convenient, easy-to-use oral incretins.

As it has for nearly 100 years, Lilly continues to work to transform diabetes care through insulin innovation. Lilly's novel weekly insulin is on track to progress to phase 3 studies in 2022, and the company is advancing a new generation of insulin medicines with its pre-clinical efforts in glucose-sensing insulin.

Immunology

Over the last decade, Lilly has established a presence in immunology, with Taltz® and Olumiant® addressing patient needs across dermatology and rheumatology. Positive late-stage readouts in 2021 for mirikizumab in moderate-to-severely active ulcerative colitis and lebrikizumab in moderate-to-severe atopic dermatitis provide the potential to help even more patients suffering from disease.

In addition, Lilly has built a deep early-and mid-stage portfolio of novel immunology opportunities that represent potential first-in-class or best-in-class assets from both internal and external innovation. Lilly is sharing new data from several of these molecules, including proof of concept phase 1b atopic dermatitis data for its IL-2 conjugate, in collaboration with Nektar Therapeutics, and is announcing plans to move into additional phase 2 studies.

Oncology

Propelled by the acquisition of Loxo Oncology, Lilly has established a renewed presence in oncology, with a portfolio focused on high-conviction assets. The company's oncology portfolio, including Verzenio®, Retevmo® and pirtobrutinib, has the potential to deliver meaningful growth over the course of the decade.

Lilly initiated a rolling submission to the FDA for pirtobrutinib, seeking accelerated approval in mantle cell lymphoma, with expectations to complete the submission in 2022 and regulatory action anticipated in early 2023. Lilly continues to invest to maximize the potential of Verzenio for patients, and intends to initiate a phase 3 study to evaluate earlier treatment of prostate cancer in mid-2022.

The company also is providing an overview of several promising early-phase and pre-clinical programs that are expected to deliver new data and potential new trials starting in 2022.

Neuroscience

Lilly is an established leader in neuroscience with a more than 30-year commitment to advancing Alzheimer's disease research. The company is focused on its work to slow, then halt and eventually prevent age-related neurodegeneration in the decades ahead.

Lilly is providing new biomarker data from donanemab from the phase 2 TRAILBLAZER-ALZ study. Lilly initiated a rolling submission for donanemab to the FDA for accelerated approval in early Alzheimer's disease, which it expects to complete in the coming months, likely by the end of the first quarter.

The company is also sharing phase 1 data from its next-generation amyloid-lowering antibody, N3PG-IV, noting plans to move this antibody into pivotal trials in 2022. The company has a number of early phase and pre-clinical programs for Alzheimer's and other neurodegenerative diseases with novel targets and new modalities and is highlighting the significant growth in its early pain pipeline.

Strong Financial Outlook Fueled by New Innovative Medicines

"We believe the continued uptake of our key growth products – which we expect will account for more than two-thirds of core business revenue in 2022 – coupled with our anticipated upcoming launches will allow Lilly to deliver top-tier, volume-driven revenue growth through at least 2030," said Anat Ashkenazi, Lilly senior vice president and chief financial officer. "Lilly remains committed to prioritizing long-term growth, as we maintain significant investment in our exciting pipeline, fund new launches to ensure we can reach more patients in the coming years and continue to expand operating margin."

Updated 2021 Financial Guidance

The company has updated certain elements of its 2021 financial guidance on both a reported and non-GAAP basis. Earnings per share for 2021 are now expected to be in the range of $6.18 to $6.23 on a reported basis and $8.15 to $8.20 on a non-GAAP basis. The company's 2021 financial guidance reflects adjustments shown in the reconciliation table below.

	2021 Expectations	**% Change** from 2020
Earnings per share (reported)	**$6.18 to $6.23**	**(9)% to (8)%**
Acquired IPR&D[(a)]	.77	
Amortization of intangible assets	.54	
Charge related to repurchase of higher-cost debt	.35	
Asset impairment, restructuring and other special charges[(b)]	.29	
COVID-19 antibodies inventory charges	.24	
Net gains on investments in equity securities	(.22)	
Earnings per share (non-GAAP)	**$8.15 to $8.20**	**20% to 21%**

Numbers may not add due to rounding

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

(b) updated to include additional asset impairment primarily related to

a contract-based intangible asset recognized as a result of our acquisition of Loxo Oncology. This impairment is a result of a decision by Bayer to discontinue the development of a phase 1 molecule related to our contact-based intangible asset.

Revenue for 2021 is now expected to be in the range of $28.0 billion to $28.3 billion, reflecting additional revenue from COVID-19 antibodies associated with the recent purchase agreement with the U.S. Government and the channel impact of the updated 2022 NRDL formulary in China. Estimated revenue from COVID-19 antibodies is now expected to be approximately $2.1 billion.

Gross margin as a percent of revenue is still expected to be approximately 75 percent on a reported basis and is now expected to be approximately 78 percent on a non-GAAP basis.

Marketing, selling and administrative expenses are still expected to be in the range of $6.2 billion to $6.4 billion. Research and development expenses are still expected to be in the range of $6.9 billion to $7.1 billion.

Operating margin, defined as operating income as a percent of revenue, is now expected to be approximately 23 percent on a reported basis and still expected to be approximately 30 percent on a non-GAAP basis.

Other income (expense) is still expected to be expense in the range of $250 million to $150 million on a reported basis and is still expected to be expense in the range of $100 million to $0 on a non-GAAP basis. The estimate on a reported basis does not reflect fourth quarter mark-to-market activity for equity investments.

The 2021 effective tax rate is still expected to be approximately 11 percent on a reported basis and approximately 13 percent on a non-GAAP basis.

The following table summarizes the company's updated 2021 financial guidance.

	2021 Guidance	
	Prior	**Revised**
Revenue	$27.2 to $27.6 billion	$28.0 to $28.3 billion
Gross Margin % of Revenue (reported)	Approx. 75%	Unchanged
Gross Margin % of Revenue (non-GAAP)	Approx. 79%	Approx. 78%
Marketing, Selling & Administrative	$6.2 to $6.4 billion	Unchanged
Research & Development	$6.9 to $7.1 billion	Unchanged
Other Income/(Expense) (reported)	$(250) to $(150) million	Unchanged
Other Income/(Expense) (non-GAAP)	$(100) million to $0	Unchanged
Tax Rate (reported)	Approx. 11%	Unchanged
Tax Rate (non-GAAP)	Approx. 13%	Unchanged
Earnings per share (reported)	$6.38 to $6.48	$6.18 to $6.23
Earnings per share (non-GAAP)	$7.95 to $8.05	$8.15 to $8.20
Operating Margin (reported)	Approx. 24%	Approx. 23%
Operating Margin (non-GAAP)	Approx. 30%	Unchanged

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

2022 Financial Guidance

Earnings per share for 2022 are expected to be in the range of $8.00 to $8.15 on a reported basis and $8.50 to $8.65 on a non-GAAP basis.

	2022 Expectations
Earnings per share (reported)	**$8.00 to $8.15**
Amortization of intangible assets	0.50
Earnings per share (non-GAAP)	**$8.50 to $8.65**

The company anticipates 2022 revenue between $27.8 billion and $28.3 billion. Revenue growth is expected to be driven by volume growth from key products including Trulicity®, Verzenio, Taltz, Jardiance®, Cyramza®, Emgality®, Tyvyt®, Retevmo and Olumiant. This growth is expected to be partially offset by lower revenue for Alimta® due to its loss of patent exclusivity, and significantly lower anticipated COVID-19 antibody revenue.

Gross margin as a percent of revenue is expected to be approximately 78 percent on a reported basis and 80 percent on a non-GAAP basis.

Marketing, selling and administrative expenses are expected to be in the range of $6.4 billion to $6.6 billion. Research and development expenses are expected to be in the range of $7.0 billion to $7.2 billion.

Operating margin for 2022 is expected to be approximately 30 percent on a reported basis and approximately 32 percent on a non-GAAP basis.

Other income (expense) is expected to be expense between $100 million and $0 on both a reported basis and on a non-GAAP basis.

The 2022 effective tax rate is expected to be approximately 13 to 14 percent on both a reported basis and non-GAAP basis, assuming no significant changes to U.S. tax policy.

The following table summarizes the company's 2022 financial guidance.

	2022 Guidance
Revenue	$27.8 to $28.3 billion
Gross Margin % of Revenue (reported)	Approx. 78%
Gross Margin % of Revenue (non-GAAP)	Approx. 80%
Marketing, Selling & Administrative	$6.4 to $6.6 billion
Research & Development	$7.0 to $7.2 billion
Other Income/(Expense)	$(100) million to $0
Tax Rate	Approx. 13 to 14%
Earnings per share (reported)	$8.00 to $8.15
Earnings per share (non-GAAP)	$8.50 to $8.65
Operating Margin (reported)	Approx. 30%
Operating Margin (non-GAAP)	Approx. 32%
Non-GAAP adjustments are consistent with the earnings per share table above.	

Webcast of Conference Call and Investor Materials
As previously announced, investors and the general public can access a live webcast of the Investment Community Meeting, including a presentation of the company's 2022 and updated 2021 guidance, through a link on Lilly's website at www.lilly.com. The conference call will begin at 9 a.m. Eastern time today and will be available for replay via the website.

About Eli Lilly and Company

Lilly is a global healthcare leader that unites caring with discovery to create medicines that make life better for people around the world. We were founded more than a century ago by a man committed to creating high-quality medicines that meet real needs, and today we remain true to that mission in all our work. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism. To learn more about Lilly, please visit us at www.lilly.com and www.lilly.com/news. F-LLY

This press release contains management's current intentions and expectations for the future, all of which are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. The words "estimate", "project", "intend", "expect", "believe", "target", "anticipate" and similar expressions are intended to identify forward-looking statements. Actual results may differ materially due to various factors. The following include some but not all of the factors that could cause actual results or events to differ materially from those anticipated, including the impact of the evolving COVID-19 pandemic and the global response thereto; uncertainties related to the company's efforts to develop potential treatments for COVID-19; the significant costs and uncertainties in the pharmaceutical research and development process, including with respect to the timing and process of obtaining regulatory approvals; the impact of acquisitions and business development transactions and related integration costs; the expiration of intellectual property protection for certain of the company's products and competition from generic and/or biosimilar products; the company's ability to protect and enforce patents and other intellectual property; changes in patent law or regulations related to data package exclusivity; competitive developments affecting current products and the company's pipeline; market uptake of recently launched products; information technology system inadequacies, breaches, or operating failures; unauthorized access, disclosure, misappropriation, or compromise of confidential information or other data stored in the company's IT systems, networks, and facilities, or those of third parties with whom the company shares its data; unexpected safety or efficacy concerns associated with the company's products; litigation, investigations, or other similar proceedings involving past, current, or future products or commercial activities as the company is largely self-insured; issues with product supply and regulatory approvals stemming from manufacturing difficulties or disruptions, including as a result of regulatory actions related to our facilities; reliance on third-party relationships and outsourcing arrangements; regulatory changes or other developments; regulatory actions regarding currently marketed products; continued pricing pressures and the impact of actions of governmental and private payers affecting pricing of, reimbursement for, and access to pharmaceuticals; devaluations in foreign currency exchange rates or changes in interest rates, and inflation; changes in tax law, tax rates, or events that differ from the company's assumptions related to tax positions; asset impairments and restructuring charges; the impact of global macroeconomic conditions and trade disruptions or disputes; changes in accounting and reporting standards promulgated by the Financial Accounting Standards Board and the Securities and Exchange Commission (SEC); and regulatory compliance problems or government investigations. In addition, the company may not be able to reliably predict the impact of specified items in its 2022 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 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. 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 includes a description of certain non-GAAP items that may affect the company's financial expectations for 2021 and 2022. 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.

Alimta® (pemetrexed disodium, Lilly)
Cyramza® (ramucirumab, Lilly)
Emgality® (galcanezumab-gnlm, Lilly)
Jardiance® (empagliflozin, Boehringer Ingelheim)
Olumiant® (baricitinib, Lilly)
Retevmo® (selpercatinib, Lilly)
Taltz® (ixekizumab, Lilly)
Trulicity® (dulaglutide, Lilly)
Tyvyt® (sintilimab injection, Lilly)
Verzenio® (abemaciclib, Lilly)

Refer to: Molly McCully; mccully_molly@lilly.com; 317-478-5423 (Media)
Kevin Hern; hern_kevin_r@lilly.com; 317-277-1838 (Investors)

View original content to download multimedia: https://www.prnewswire.com/news-releases/lilly-highlights-innovation-based-growth-strategy-and-pipeline-developments-announces-2022-financial-guidance-at-investment-community-meeting-301444845.html

SOURCE Eli Lilly and Company