Lilly Announces Financial Guidance, Reviews Commercial Performance, and Highlights Promising Pipeline Opportunities at Investment Community Meeting

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INDIANAPOLIS, Dec. 19, 2018 /PRNewswire/ --

- *2019 revenue is expected to be between $25.3 billion and $25.8 billion, representing mid-single-digit growth driven by volume from newer medicines, including Trulicity, Taltz, Basaglar, Jardiance, Verzenio, Cyramza, Olumiant and Lartruvo, as well as the recent launch of Emgality.*
- *Earnings per share (EPS) for 2019 are expected to be in the range of $5.52 to $5.62 on a reported basis and $5.90 to $6.00 on a non-GAAP basis, each excluding approximately $.08 per share for the non-controlling interest in Elanco Animal Health.*
- *Having launched 10 new medicines over the past five years, the company expects continued pipeline progress in 2019, including U.S. regulatory action for nasal glucagon for hypoglycemia and lasmiditan for acute migraine, as well as new indications for several medicines.*
- *The company has revised its 2020 minimum financial expectations and now expects at least 6 percent compound annual revenue growth from 2015 to 2020 for the full company, and at least 7 percent compound annual revenue growth for its human pharmaceutical business.*
- *The company now expects 2018 EPS to be in the range of $2.80 to $2.85 on a reported basis. On a non-GAAP basis, the company has reaffirmed 2018 EPS to be in the range of $5.55 to $5.60.*

At a meeting today with the investment community, Eli Lilly and Company (NYSE: LLY) announced its 2019 financial guidance, updated certain elements of its 2018 guidance and 2020 minimum financial expectations, reviewed the performance of recently launched medicines and highlighted numerous potential new medicines in its clinical pipeline.

David A. Ricks, Lilly's chairman and chief executive officer, confirmed that the company is executing well against the company's priorities to launch with excellence, replenish the pipeline, improve productivity and develop talent.

"Over the past five years, Lilly has successfully launched 10 new medicines, bolstered our pipeline with new candidate medicines from our own labs and from external partners, reshaped the company to be more productive, and attracted world-class scientific talent to our labs," said Ricks. "Our actions over the past several years have positioned Lilly to deliver significant value to our key stakeholders. Most importantly, they have benefited patients, many of whose lives are better because of new Lilly medicines."

Ricks acknowledged Lilly's current strong performance, and expressed optimism for the company's future growth. "We are proud of what we have achieved at Lilly over the past several years, but we are determined to raise the bar higher. We see incredible scientific opportunities to address some of the most significant health challenges of an aging society. We aim to create new medicines over the next decade that will transform the care of serious illnesses, and provide valuable new treatment options for doctors and patients."

R&D Transformation is Leading to Impressive Pipeline Productivity
At today's meeting, Daniel Skovronsky, M.D., Ph.D., Lilly's Chief Scientific Officer and President of Lilly Research Laboratories, highlighted recent advancements that the company has made to improve R&D productivity and create new medicines that are either first-in-class or best-in-class.

- The company is reshaping its drug discovery engine, with the dual goal of decreasing the time from target identification to clinical testing to approximately three years, while also increasing the use of externally-derived innovation to access novel targets, modalities and discovery tools.
- Lilly has significantly improved the speed of its development activities and reduced the average time from first human dose of a potential new medicine to commercial launch by over two years.
- There has been a steady improvement in the success rate of Phase 3 molecules in Lilly's clinical pipeline due to a greater emphasis on target validation, patient population, molecule optimization, more robust Phase 2 data, and better Phase 3 design.

Skovronsky discussed the development plans and therapeutic potential for a number of promising late-stage pipeline opportunities and new indications for approved medicines in the company's five therapeutic areas of focus:

1. **Oncology** – Verzenio, pegilodecakin

2. **Pain –** Emgality, lasmiditan, tanezumab
3. **Neurodegeneration** – N3pG antibody, tau antibody, D1PAM
4. **Immunology** – Olumiant, mirikizumab
5. **Diabetes** – Insulins and Connected Care, Trulicity, tirzepatide

"Lilly has created an industry-leading late-stage development organization and now we are focused on transforming our drug discovery engine," said Skovronsky. "With an attractive clinical pipeline, two new molecules achieving regulatory submissions and three entering Phase 3 in 2018, we are continuing an impressive period of productivity for Lilly Research Labs, and are on pace to deliver on the company's goal to launch 20 new medicines in 10 years."

New Medicines Are Driving Volume-Based Revenue Growth and Positive Financial Outlook
Joshua Smiley, Lilly senior vice president and chief financial officer, highlighted the performance of several recently launched medicines and reviewed the company's 2018 and 2019 financial guidance, as well as certain minimum financial expectations for 2020.

"Lilly has dramatically upgraded the quality of its revenue base over the past five years through the launch and uptake of 10 new medicines, which together are expected to account for over 45 percent of human pharmaceutical sales in 2019," noted Smiley. "These 10 medicines are launching in some of the fastest growing categories and continue to deliver growth through increased volume, not price, meaning more and more people around the world are benefitting from Lilly medicines."

At today's meeting, Mr. Smiley highlighted the strong U.S. performance and market share gains of several of these medicines, including Trulicity, Jardiance, Taltz and Verzenio, as well as the early progress for Emgality and international growth opportunities across the portfolio.

"We are encouraged by the commercial execution across our new launches, and are excited about their prospects for future growth," added Smiley. "The success of these medicines gives us confidence that we will continue to deliver strong results and generate significant cash balances in 2019 and beyond. Based on these growth prospects, we are pleased to today announce a 15 percent increase in our dividend."

2018 Financial Guidance
The company has revised certain elements of its 2018 financial guidance on a reported basis. Earnings per share on a reported basis are now expected to be in the range of $2.80 to $2.85, while non-GAAP earnings per share for 2018 are still expected to be in the range of $5.55 to $5.60.

	2018 Expectations*	% Change from 2017
Earnings per share (reported)	**$2.80 to $2.85**	**NM**
Acquired in-process research and development	1.82	
Amortization of intangible assets	.43	
Asset impairment, restructuring and other special charges	.41	
Income taxes[(a)]	.05	
Other, net	.03	
Earnings per share (non-GAAP)	**$5.55 to $5.60**	**30% to 31%**

Numbers may not add due to rounding

* 2018 Expectations are pending finalization of estimates, accounting policy elections, and guidance issued for tax reform.

(a) Relates to adjustments to the 2017 Toll Tax for U.S. tax reform proposed regulations and tax expenses associated with the separation of the Elanco animal health business.

The following table summarizes the company's 2018 financial guidance.

	2018 Guidance*	
	Prior	Revised
Revenue	$24.3 to $24.5 billion	Unchanged
Gross Margin % of Revenue (reported)	Approx. 73.5%	Unchanged
Gross Margin % of Revenue (non-GAAP)	Approx. 76%	Unchanged
Marketing, Selling & Administrative	$6.3 to $6.5 billion	Unchanged
Research & Development	$5.2 to $5.4 billion	Unchanged
Other Income/(Expense)	$75 to $200 million	Unchanged
Tax Rate (reported)	Approx. 22.5%	Approx. 23%
Tax Rate (non-GAAP)	Approx. 16%	Unchanged
Earnings per share (reported)	$3.04 to $3.09	$2.80 to $2.85
Earnings per share (non-GAAP)	$5.55 to $5.60	Unchanged

* Certain elements of 2018 guidance are pending finalization of estimates, accounting policy elections, and guidance issued for tax reform.

Non-GAAP adjustments are consistent with the earnings per share table above.

2019 Financial Guidance

Lilly today issued its 2019 financial guidance. The individual elements of the 2019 financial guidance outlined below include fully consolidated financial expectations for both the company's human pharmaceutical business and Elanco Animal Health, with the exception of earnings per share, which excludes approximately $0.08 per share for the non-controlling interest in Elanco. Lilly expects to divest its remaining ownership in Elanco through a tax-efficient transaction within one year of Elanco's initial public offering, and will restate 2019 financial guidance at that time to reflect Elanco as discontinued operations.

Earnings per share for 2019 are expected to be in the range of $5.52 to $5.62 on a reported basis and $5.90 to $6.00 on a non-GAAP basis.

	2019 Expectations*
Earnings per share (reported)	**$5.52 to $5.62**
Acquired in-process research and development	.07
Asset impairment, restructuring and other special charges	.03
Amortization of intangible assets	.28
Earnings per share (non-GAAP)	**$5.90 to $6.00**

Numbers may not add due to rounding

* 2019 Expectations are pending finalization of estimates, accounting policy elections, and guidance issued for tax reform.

The company anticipates 2019 revenue between $25.3 billion and $25.8 billion. Revenue growth is expected to be driven by volume from newer medicines including Trulicity®, Taltz®, Basaglar®, Jardiance®, Verzenio ™, Cyramza®, Olumiant® and Lartruvo ™. Revenue growth is also expected to benefit from the recent launch of Emgality ™, and could benefit from the potential approval and launch of nasal glucagon and lasmiditan. Revenue growth is expected to be partially offset by lower revenue for Cialis® and other products that have lost patent exclusivity. Revenue growth is also expected to be partially offset by the negative impact of foreign exchange rates, as well as continued price pressures in the U.S and some international markets.

Gross margin as a percent of revenue rate is expected to be approximately 75.0 percent on a reported basis and 76.5 percent on a non-GAAP basis.

Marketing, selling and administrative expenses are expected to be in the range of $6.4 billion to $6.7 billion. Research and development expenses are expected to be in the range of $5.6 billion to $5.8 billion.

Other income (expense) is expected to be expense between $75 million and $225 million.

The 2019 effective tax rate is expected to be approximately 16 percent on both a reported basis and on a non-GAAP basis, pending finalization of estimates, accounting policy elections, and guidance issued for tax reform.

The following table summarizes the company's 2019 financial guidance.

	2019 Guidance*
Revenue	$25.3 to $25.8 billion
Gross Margin % of Revenue (reported)	Approx. 75.0%
Gross Margin % of Revenue (non-GAAP)	Approx. 76.5%
Marketing, Selling & Administrative	$6.4 to $6.7 billion
Research & Development	$5.6 to $5.8 billion
Other Income/(Expense)	$(225) to $(75) million
Tax Rate (reported)	Approx. 16%
Tax Rate (non-GAAP)	Approx. 16%
Earnings per share (reported)	$5.52 to $5.62
Earnings per share (non-GAAP)	$5.90 to $6.00

* Certain elements of 2019 guidance are pending finalization of estimates, accounting policy elections, and guidance issued for tax reform.

Non-GAAP adjustments are consistent with the earnings per share table above.

2020 Minimum Financial Expectations
The company has revised its 2020 minimum financial expectations and now expects at least 6 percent compound annual revenue growth from 2015 to 2020 for the full company, and at least 7 percent compound annual revenue growth for the human pharmaceutical business.

Certain financial guidance information for 2019 and 2018 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 are prepared in accordance with U.S. generally accepted accounting principles (GAAP) and include all revenue and expenses recognized during the periods. Non-GAAP measures exclude the items described in the reconciliation tables contained in this press release. The non-GAAP measures are presented to provide additional insights into the underlying trends in the company's business. This press release does not constitute an offer of any securities for sale.

Webcast of Conference Call and Investor Materials
As previously announced, investors and the general public can access a live webcast of the 2018 investment community meeting conference call and investor materials through a link on Lilly's website at www.investor.lilly.com. The conference call will be held today beginning at 9:00 a.m. Eastern time (ET) 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 http://newsroom.lilly.com/social-channels. 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 from these forward-looking statements due to various factors. There are significant risks and uncertainties in pharmaceutical research and development. There can be no guarantees that pipeline products will succeed in clinical testing, will receive the necessary clinical and manufacturing regulatory approvals, or will prove to be commercially successful. The company's results may also be affected by such factors as the timing of anticipated regulatory approvals and launches of new products; market uptake of recently launched products; competitive developments affecting current products; the expiration of intellectual property protection for certain of the company's products; the company's ability to protect and enforce patents and other intellectual property; the impact of governmental actions regarding pricing, importation, and reimbursement for pharmaceuticals, including U.S. health care reform; regulatory compliance problems or government investigations; regulatory actions regarding currently marketed products; unexpected safety or efficacy concerns associated with the company's products; issues with product supply stemming from manufacturing difficulties or disruptions; regulatory changes or other developments; changes in patent law or regulations related to data-package exclusivity; litigation involving current or future products; the extent to which third-party indemnification obligations relating to product liability litigation and similar matters will be performed; unauthorized disclosure of trade secrets or other confidential data stored in the company's information systems and networks; changes in tax law and regulations, including the impact of tax reform legislation enacted in December 2017 and related guidance; changes in inflation, interest rates, and foreign currency exchange rates; asset impairments and restructuring charges; changes in accounting standards promulgated by the Financial Accounting Standards Board and the U.S. Securities and Exchange Commission (SEC); acquisitions and business development transactions and related integration considerations; and the impact of exchange rates and global macroeconomic conditions, including the effect of the pending exit of the United Kingdom from the European Union; and uncertainties and risks related to timing and potential value to both Elanco and Lilly of the planned separation of the Elanco animal health business, including business, industry and market risks, as well as risks involving realizing the anticipated tax-free nature of the separation. 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 Form 10-Qs 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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Basaglar® (insulin glargine injection, Lilly)
Cialis® (tadalafil, Lilly)
Cyramza® (ramucirumab, Lilly)
Emgality ™(galcanezumab-gnlm, Lilly)
Jardiance® (empagliflozin, Boehringer Ingelheim)
Lartruvo ™(olaratumab, Lilly)
Olumiant® (baricitinib, Lilly)
Taltz® (ixekizumab, Lilly)
Trulicity® (dulaglutide, Lilly)
Verzenio ™(abemaciclib, Lilly)

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