Lilly Reports Third-Quarter Financial Results, Updates Guidance

October 27, 2020

- Revenue in the third quarter of 2020 increased 5 percent driven by volume growth of 9 percent, while on a year-to-date basis revenue increased 6 percent driven by volume growth of 12 percent.

- Key growth products launched since 2014, consisting of Taltz, Trulicity, Verzenio, Jardiance, Olumiant, Emgality, Tyvyt, Baqsimi, Cyramza, Retevmo and Basaglar contributed nearly 9 percentage points of revenue growth and represented approximately 52 percent of total revenue for the quarter.

- Lilly continues to rapidly advance the development of potential therapeutics for the treatment of COVID-19 and has submitted requests for Emergency Use Authorization to the FDA for both bamlanivimab and baricitinib. The company anticipates its full-year 2020 COVID-19 research and development expense to be approximately $400 million.

- Third-quarter 2020 operating expenses increased 9 percent, driven by higher marketing and research and development investments, including expenses of $125 million to develop potential COVID-19 therapies.

- Third-quarter 2020 earnings per share (EPS) decreased to $1.33 on a reported basis and increased to $1.54 on a non-GAAP basis.

- 2020 EPS guidance lowered to be in the range of $6.20 to $6.40 on a reported basis and reaffirmed to be in the range of $7.20 to $7.40 on a non-GAAP basis.

INDIANAPOLIS, Oct. 27, 2020 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced financial results for the third quarter of 2020.

$ in millions, except per share data	Third Quarter 2020	2019	% Change
Revenue	$5,740.6	$5,476.6	5%
Net Income – Reported	1,208.4	1,253.9	(4)%
EPS – Reported	1.33	1.37	(3)%
Net Income – Non-GAAP	1,406.9	1,360.0	3%
EPS – Non-GAAP	1.54	1.48	4%

Certain financial information for 2020 and 2019 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), include all revenue and expenses recognized during the periods, and reflect Elanco Animal Health (Elanco) as discontinued operations during the first quarter of 2019. Non-GAAP measures reflect adjustments for the items described in the reconciliation tables later in the release, and assume that the disposition of Elanco occurred at the beginning of 2019 (including the benefit from the reduction in shares of common stock outstanding). The company's 2020 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.

"Lilly delivered solid financial results in the third quarter, as our key growth products continued to be the catalyst for volume-based revenue growth. Despite ongoing healthcare disruptions from the global pandemic, we remain confident in the strength of our underlying business and continue to manage our operations to deliver success over the long term," said David A. Ricks, Lilly's chairman and CEO. "At the same time, I am incredibly proud of the commitment and progress Lilly has made in the fight against COVID-19. In the third quarter, Lilly incurred expenses of $125 million to develop and rapidly advance potential new therapies from our labs to clinical testing, with the hope of soon offering a new treatment option for patients most at risk from the virus."

Key Events Over the Last Three Months

COVID-19

- The company submitted an initial request to the U.S. Food and Drug Administration (FDA) for Emergency Use Authorization for bamlanivimab (LY-CoV555) monotherapy in higher-risk patients who have been recently diagnosed with mild-to-moderate COVID-19.
- The company announced proof-of-concept data from an interim analysis of the BLAZE-1 clinical trial, showing a reduced rate of hospitalization for patients treated with bamlanivimab. The randomized, double-blind, placebo-controlled Phase 2

study evaluated bamlanivimab for the treatment of symptomatic COVID-19 in the outpatient setting. The trial enrolled mild-to-moderate recently diagnosed COVID-19 patients across four groups.

- Additional data from an interim analysis of the BLAZE-1 clinical trial showed that combination therapy with two of Lilly's SARS-CoV-2 neutralizing antibodies, bamlanivimab and etesevimab (LY-CoV016), reduced viral load, symptoms and COVID-related hospitalization and ER visits.
- The company announced the initiation of BLAZE-2, a Phase 3 trial studying bamlanivimab for the prevention of SARS-CoV-2 infection and COVID-19 in residents and staff at long-term care facilities in the U.S.
- The company announced a global antibody manufacturing collaboration with Amgen to significantly increase the supply capacity available for Lilly's potential COVID-19 therapies.
- The independent data safety monitoring board from the ACTIV-3 clinical trial being run by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), recommended that no additional COVID-19 patients in the trial's hospitalized setting receive bamlanivimab. This recommendation was based on trial data suggesting that bamlanivimab is unlikely to help hospitalized COVID-19 patients recover from this advanced stage of their disease. All other studies of bamlanivimab remain ongoing, and the company remains confident that bamlanivimab monotherapy may prevent progression of disease for those earlier in the course of COVID-19.
- The company entered into an agreement with the Bill & Melinda Gates Foundation, as part of the COVID-19 Therapeutics Accelerator, to facilitate access to future Lilly therapeutic antibodies under development for the potential prevention and treatment of COVID-19 to benefit low- and middle-income countries.
- The company and Incyte Corporation presented data showing baricitinib in combination with remdesivir reduced time to recovery and improved clinical outcomes for patients with COVID-19 infection compared with remdesivir. Based on this data, the companies submitted an initial request to the FDA for Emergency Use Authorization.

Regulatory

- The FDA approved, and the company began commercializing, two additional doses of Trulicity®, expanding the label of once-weekly Trulicity to include 3.0 mg and 4.5 mg doses.
- The European Commission approved Olumiant® for the treatment of adult patients with moderate-to-severe atopic dermatitis (AD) who are candidates for systemic therapy.
- The FDA informed the company and Pfizer that it intends to hold an Advisory Committee meeting to discuss the Biologics License Application (BLA) for tanezumab. The meeting is expected to occur in March 2021 and, as a result, the FDA's review of the tanezumab BLA will extend beyond the current PDUFA date in December 2020. The FDA's review of the BLA is ongoing and the Agency has not requested new clinical studies to be completed at this time.

Clinical

- The company presented additional data for Verzenio® at the European Society for Medical Oncology (ESMO) 2020 Virtual Congress. Verzenio, in combination with standard adjuvant endocrine therapy (ET), significantly decreased the risk of breast cancer recurrence by 25 percent compared to standard adjuvant ET alone for people with hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) high-risk early breast cancer.

Business Development/Other Developments

- The company added its Insulin Value Program, featuring a $35 copay card, to its comprehensive suite of insulin affordability solutions in the U.S. for people with diabetes. Anyone with commercial insurance, and those without insurance at all, can fill their monthly prescription of Lilly insulins for $35 through this program.
- The company and Innovent Biologics, Inc. announced a global expansion of their strategic alliance for TYVYT®. Lilly and Innovent currently co-commercialize Tyvyt in China. Under the terms of the expanded license agreement, Lilly will obtain an exclusive license for Tyvyt for geographies outside of China and plans to pursue registration of Tyvyt in the U.S. and other markets. In return, Innovent will receive an upfront payment of $200 million and will be eligible for up to $825 million in success-based regulatory and sales-based milestones, as well as tiered double-digit royalties on net sales. Both companies will also retain the right to study Tyvyt in combination with other medicines as part of their own clinical programs. The transaction closed in the fourth quarter of 2020.
- The company announced a definitive agreement to acquire Disarm Therapeutics, a privately-held biotechnology company creating a new class of disease-modifying therapeutics for patients with axonal degeneration.

Third-Quarter Reported Results

In the third quarter of 2020, worldwide revenue was $5.741 billion, an increase of 5 percent compared with the third quarter of 2019, driven by a 9 percent increase in volume and a 1 percent increase due to the favorable impact of foreign exchange rates, partially offset by a 5 percent decrease due to lower realized prices. Key growth products launched since 2014, consisting of Taltz®, Trulicity, Verzenio, Jardiance®, Olumiant, Emgality®, Tyvyt, Baqsimi ™, Cyramza®, Retevmo ™and Basaglar®, contributed nearly 9 percentage points of revenue growth and represented approximately 52 percent of total revenue for the quarter.

Revenue in the U.S. increased 3 percent, to $3.161 billion, driven by a 7 percent increase in volume, partially offset by a 4 percent decrease due to lower realized prices. Increased U.S. volume for key growth products, including Trulicity, Taltz, Verzenio, Emgality, Jardiance, Retevmo, Cyramza, Baqsimi, and Olumiant was partially offset by lower volume for certain other products, including Forteo® and Tradjenta®. The decrease in realized prices in the U.S. was primarily driven by changes to estimates for rebates and discounts, most notably impacting Trulicity, as well as increased rebates to gain and maintain broad commercial access across the portfolio, partially offset by modest list price increases.

Revenue outside the U.S. increased 7 percent, to $2.579 billion, driven by a 12 percent increase in volume and a 1 percent increase due to the favorable impact of foreign exchange rates, partially offset by a 7 percent decrease due to lower realized prices. The increase in volume outside the U.S. was driven primarily by the inclusion of Tyvyt and Alimta® in government reimbursement programs in China, as well as solid volume gains in major international markets for key growth products, including Trulicity, Olumiant, Verzenio, Jardiance, Taltz, Basaglar, Emgality, Baqsimi and Cyramza, partially offset by decreased volume for Forteo, Trajenta, Humalog® and Humulin®. The decrease in realized prices outside the U.S. was driven primarily by the inclusion of Tyvyt and Alimta in government reimbursement programs in China and bi-annual government mandated price decreases in Japan.

Gross margin increased 3 percent, to $4.414 billion, in the third quarter of 2020 compared with the third quarter of 2019. Gross margin as a percent of revenue was 76.9 percent, a decrease of 1.6 percentage points compared with the third quarter of 2019. The decrease in gross margin percent was primarily due to the unfavorable effect of foreign exchange rates on international inventories sold, higher amortization of intangibles expense related to Retevmo, and lower realized prices on revenue, partially offset by greater manufacturing efficiencies and favorable product mix.

Total operating expenses in the third quarter of 2020, defined as the sum of research and development and marketing, selling, and administrative expenses, increased 9 percent to $3.035 billion compared with the third quarter of 2019. Research and development expenses increased 6 percent to $1.465 billion, or 25.5 percent of revenue, driven primarily by approximately $125 million of higher development expenses for COVID-19 antibody therapies and baricitinib, partially offset by lower development expenses for late-stage assets. Marketing, selling, and administrative expenses increased 11 percent to $1.569 billion, primarily due to higher marketing expenses for key growth products, reflecting increased promotion to physicians and consumers in connection with increases in healthcare utilization around the world.

There were no acquired in-process research and development charges recognized in the third quarter of 2020. In the third quarter of 2019, the company recognized acquired in-process research and development charges of $77.7 million related to business development transactions with Centrexion Therapeutics Corporation and AC Immune SA.

In the third quarter of 2020, the company recognized asset impairment, restructuring and other special charges of $101.4 million. These charges were primarily related to severance costs incurred as a result of actions taken worldwide to reduce the company's cost structure. There were no asset impairment, restructuring and other special charges recognized in the third quarter of 2019.

Operating income in the third quarter of 2020 was $1.278 billion, compared to $1.431 billion in the third quarter of 2019. The decrease in operating income was primarily driven by higher marketing and research and development expenses, and higher asset impairment, restructuring and other special charges, partially offset by higher gross margin and the absence of acquired in-process research and development charges. Operating margin, defined as operating income as a percent of revenue, was 22.3 percent and was unfavorably impacted by approximately 220 basis points due to COVID-19 investments.

Other income was $158.9 million in the third quarter of 2020, compared with other expense of $24.9 million in the third quarter of 2019. The increase in other income was driven primarily by higher net gains on investment securities.

The effective tax rate was 15.9 percent in the third quarter of 2020, compared with 10.8 percent in the third quarter of 2019. The higher effective tax rate in the third quarter of 2020 was driven primarily by a mix of earnings in higher tax jurisdictions and a lower net discrete tax benefit compared to the same period in 2019.

In the third quarter of 2020, net income and earnings per share were $1.208 billion and $1.33, respectively, compared with net income of $1.254 billion and earnings per share of $1.37 in the third quarter of 2019. The decrease in net income and earnings per share in the third quarter of 2020 was primarily driven by lower operating income and, to a lesser extent, higher income tax expense, partially offset by higher other income.

Third-Quarter Non-GAAP Measures

On a non-GAAP basis, third-quarter 2020 gross margin increased 4 percent, to $4.541 billion compared with the third quarter of 2019. Gross margin as a percent of revenue was 79.1 percent, a decrease of 0.5 percentage points. The decrease in gross margin percent was primarily due to the unfavorable effect of foreign exchange rates on international inventories sold and lower realized prices, partially offset by greater manufacturing efficiencies and favorable product mix.

Operating income on a non-GAAP basis decreased $58.8 million, or 4 percent, to $1.506 billion in the third quarter of 2020 compared with the third quarter of 2019, due primarily to higher marketing and research and development expenses, partially offset by higher gross margin. Operating margin of 26.2 percent on a non-GAAP basis was unfavorably impacted by approximately 220 basis points due to COVID-19 investments.

The effective tax rate on a non-GAAP basis was 15.5 percent in the third quarter of 2020, compared with 11.7 percent in the third quarter of 2019. The higher effective tax rate for the third quarter of 2020 was driven by a mix of earnings in higher tax jurisdictions and a lower net discrete tax benefit compared to the same period in 2019.

On a non-GAAP basis, in the third quarter of 2020 net income increased 3 percent, to $1.407 billion, while earnings per share increased 4 percent, to $1.54, compared with $1.360 billion and $1.48, respectively, in the third quarter of 2019. The increase in net income and earnings per share was driven primarily by higher other income and higher gross margin, partially offset by higher marketing and research and development expenses and, to a lesser extent, higher income tax expense.

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" table later in this press release.

	Third Quarter

	2020	2019	% Change
Earnings per share (reported)	**$1.33**	**$1.37**	**(3)%**
Asset impairment, restructuring and other special charges	0.11	—	
Amortization of intangible assets	0.11	.05	
Acquired in-process research and development	—	.07	
Earnings per share (non-GAAP)	**$1.54**	**$1.48**	**4%**

Numbers may not add due to rounding.

Year-to-Date Reported Results

For the first nine months of 2020, worldwide revenue increased 6 percent to $17.100 billion, compared with $16.206 billion in the same period in 2019. The increase in revenue was driven by a 12 percent increase in volume, partially offset by a 6 percent decrease due to lower realized prices. For the first nine months of 2020, operating income was $4.066 billion, an increase of 14 percent compared to the same period of 2019. Reported net income and earnings per share for the first nine months of 2020 were $4.077 billion and $4.47, respectively, compared with $6.823 billion and $7.24 in the same period of 2019. The decreases in net income and earnings per share in the first nine months of 2020 were driven primarily by the approximate $3.7 billion gain recognized on the disposition of Elanco in 2019, partially offset by higher other income and higher operating income for the first nine months of 2020.

Year-to-Date Non-GAAP Measures

For the first nine months of 2020, operating income was $4.809 billion on a non-GAAP basis, an increase of 7 percent compared to the same period of 2019. Net income and earnings per share, on a non-GAAP basis, were $4.727 billion and $5.18, respectively, compared with $3.985 billion and $4.31 in the same period of 2019.

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" table later in this press release.

	Year-to-Date		
	2020	2019	% Change
Earnings per share (reported)	**$ 4.47**	**$ 7.24**	**(38)%**
Discontinued operations	—	(3.91)	
Earnings per share from continuing operations (reported)	**4.47**	**3.33**	**34%**
Acquired in-process research and development	.30	.20	
Amortization of intangible assets	.25	.13	
Asset impairment, restructuring and other special charges	.17	.44	
Lartruvo® charges	—	.14	
Impact of reduced shares outstanding for non-GAAP reporting[(a)]	—	.07	
Earnings per share (non-GAAP)	**$ 5.18**	**$ 4.31**	**20%**

Numbers may not add due to rounding.

(a) Non-GAAP earnings per share assume that the disposition of Elanco occurred at the beginning of 2019 and, therefore, exclude the approximately 65.0 million shares of Lilly common stock retired in the Elanco exchange offer.

Selected Revenue Highlights

Selected Revenue Highlights

(Dollars in millions)	Third Quarter			Year-to-Date		
Selected Products	2020	2019	% Change	2020	2019	% Change
Trulicity	$1,106.6	$1,011.5	9%	$3,565.7	$2,919.7	22%
Humalog[(a)]	656.9	648.9	1%	1,907.8	2,057.3	(7)%
Alimta	578.0	508.2	14%	1,677.2	1,585.1	6%
Taltz	454.5	340.0	34%	1,293.2	946.3	37%
Humulin	305.9	321.8	(5)%	935.2	942.1	(1)%
Basaglar	248.2	263.2	(6)%	842.3	805.4	5%
Jardiance[(b)]	310.8	240.7	29%	840.3	676.2	24%
Forteo	266.9	370.7	(28)%	791.9	1,044.4	(24)%
Cyramza	252.7	240.0	5%	748.4	680.1	10%
Verzenio	234.4	157.2	49%	631.1	400.6	58%
Olumiant	162.0	114.6	41%	446.7	299.1	49%
Emgality	91.5	47.7	92%	252.9	96.3	NM
Tyvyt	84.4	46.6	81%	205.9	96.6	NM
Baqsimi	20.9	6.2	NM	52.3	6.2	NM
Retevmo	11.6	—	NM	17.9	—	NM
Total Revenue	5,740.6	5,476.6	5%	17,099.8	16,205.5	6%

[(a)] Humalog includes Insulin Lispro

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

NM – not meaningful

Trulicity

Third-quarter 2020 worldwide Trulicity revenue was $1.107 billion, an increase of 9 percent compared with the third quarter of 2019. U.S. revenue increased 5 percent, to $791.2 million, driven by increased demand, partially offset by lower realized prices. Trulicity's lower realized prices in the U.S. were primarily due to changes to estimates for rebates and discounts, higher contracted rebates and changes to segment mix, partially offset by modest list price increases. Revenue outside the U.S. was $315.4 million, an increase of 23 percent, driven by increased volume, partially offset by lower realized prices.

Humalog

For the third quarter of 2020, worldwide Humalog revenue increased 1 percent compared with the third quarter of 2019, to $656.9 million. Revenue in the U.S. increased 10 percent, to $390.1 million, driven primarily by higher demand. Revenue outside the U.S. decreased 9 percent, to $266.9 million, driven primarily by decreased volume.

Alimta

For the third quarter of 2020, worldwide Alimta revenue increased 14 percent compared with the third quarter of 2019, to $578.0 million. U.S. revenue increased 3 percent, to $291.9 million, primarily driven by increased volume and, to a lesser extent, higher realized prices. Revenue outside the U.S. increased 27 percent to $286.1 million, primarily driven by increased volume in Germany and China, partially offset by lower realized prices.

Taltz

For the third quarter of 2020, worldwide Taltz revenue increased 34 percent compared with the third quarter of 2019, to $454.5 million. U.S. revenue increased 30 percent, to $326.2 million, driven by increased demand and, to a lesser extent, higher realized prices. Revenue outside the U.S. increased 44 percent, to $128.3 million, primarily driven by increased volume.

Humulin

For the third quarter of 2020, worldwide Humulin revenue decreased 5 percent compared with the third quarter of 2019, to $305.9 million. U.S. revenue decreased 2 percent, to $214.0 million, driven by lower realized prices and lower volume. Revenue outside the U.S. decreased 11 percent, to $91.9 million, primarily due to decreased volume, partially offset by higher realized prices.

Basaglar

For the third quarter of 2020, worldwide Basaglar revenue was $248.2 million, a decrease of 6 percent compared with the third quarter of 2019. U.S. revenue decreased 12 percent, to $178.5 million, driven by lower realized prices and, to a lesser extent, decreased demand caused by competitive pressures. Revenue outside the U.S. increased 15 percent, to $69.7 million, driven by increased volume, partially offset by lower realized prices. Basaglar is part of the company's alliance with Boehringer Ingelheim. Lilly reports as cost of sales payments made to Boehringer Ingelheim for royalties and for its portion of the gross margin in 2020 and 2019, respectively.

Jardiance

The company's worldwide Jardiance revenue during the third quarter of 2020 was $310.8 million, an increase of 29 percent compared with the third quarter of 2019. U.S. revenue increased 16 percent, to $163.3 million, driven by increased demand. Revenue outside the U.S. was $147.5 million, an increase of 47 percent, driven by increased volume and, to a lesser extent, the favorable 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 and its portion of Jardiance's gross margin in 2020 and 2019, respectively.

Forteo

For the third quarter of 2020, worldwide Forteo revenue decreased 28 percent compared with the third quarter of 2019, to $266.9 million. U.S. revenue decreased 17 percent, to $144.6 million, driven by lower demand, partially offset by higher realized prices. Revenue outside the U.S. decreased 37 percent to $122.3 million, primarily driven by decreased volume and lower realized prices.

The company expects further volume declines for Forteo as a result of the anticipated entry of generic and biosimilar competition following the loss of patent exclusivity in the third quarter of 2019 in the U.S., Japan and major European markets.

Cyramza

For the third quarter of 2020, worldwide Cyramza revenue was $252.7 million, an increase of 5 percent compared with the third quarter of 2019. U.S. revenue was $94.5 million, an increase of 14 percent, primarily driven by increased demand and higher realized prices. Revenue outside the U.S. was $158.2 million, and was relatively flat compared with the third quarter of 2019.

Verzenio

For the third quarter of 2020, worldwide Verzenio revenue increased 49 percent compared with the third quarter of 2019, to $234.4 million. U.S. revenue was $158.9 million, an increase of 27 percent, primarily driven by increased demand and, to a lesser extent, higher realized prices. Revenue outside the U.S. was $75.5 million, an increase of $43.1 million compared with the third quarter of 2019, primarily driven by increased volume.

Olumiant

For the third quarter of 2020, Olumiant generated worldwide revenue of $162.0 million. U.S. revenue was $14.5 million. Revenue outside the U.S. was $147.5 million, an increase of 44 percent compared with the third quarter of 2019, primarily driven by increased volume.

Emgality

For the third quarter of 2020, Emgality generated worldwide revenue of $91.5 million, an increase of $4.0 million compared with the second quarter of 2020. U.S. revenue was $81.4 million, an increase of $0.8 million compared with the second quarter of 2020. Revenue outside of the U.S. was $10.1 million in the third quarter of 2020.

Tyvyt

The company's Tyvyt revenue in China during the third quarter of 2020 was $84.4 million, an increase of $20.3 million compared with the second quarter of 2020. Tyvyt is part of the company's alliance with Innovent in China. 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.

Baqsimi

For the third quarter of 2020, Baqsimi generated worldwide revenue of $20.9 million, an increase of $7.2 million compared with the second quarter of 2020. U.S revenue was $17.0 million, while revenue outside the U.S. was $3.9 million.

Retevmo

For the third quarter of 2020, Retevmo generated U.S. revenue of $11.6 million. Retevmo was approved by the FDA and launched in the U.S. during the second quarter of 2020.

2020 Financial Guidance

The company has updated certain elements of its 2020 financial guidance to reflect management's current expectations for underlying business performance.

Earnings per share for 2020 are now expected to be in the range of $6.20 to $6.40 on a reported basis and are still expected to be in the range of $7.20 to $7.40 on a non-GAAP basis.

Key management assumptions related to the COVID-19 pandemic that support the company's 2020 guidance include:

- Healthcare activity will continue the positive trends seen in the third quarter of 2020, returning to historical levels as health care providers utilize telehealth or in-person visits to see patients despite additional COVID-19 outbreaks;
- New patient prescriptions will continue to improve in the U.S.;
- Pricing headwinds from increased utilization of patient affordability programs and changes in segment mix due to increased U.S. unemployment will continue to be modest; and
- Promotional spend will constitute a mix of in-person customer interactions, direct-to-consumer advertising, and investments in digital promotion.

	2020 Expectations	% Change from 2019
Earnings per share (reported)[a]	**$6.20 to $6.40**	**25% to 29%**
Acquired IPR&D[b]	.47	
Amortization of intangible assets	.36	
Asset impairment, restructuring and other special charges	.17	
Earnings per share (non-GAAP)	**$7.20 to $7.40**	**19% to 23%**

Numbers may not add due to rounding

[a] Reported earnings per share percent change from 2019 calculated based on change from 2019 earnings per share from continuing operations.

[b] Includes costs related to business development transactions with a pre-clinical stage company, Sitryx Therapeutics, AbCellera Biologics, Evox Therapeutics, Junshi Biosciences and Innovent. Excludes costs related to the acquisition of Disarm Therapeutics.

The company still anticipates 2020 revenue between $23.7 billion and $24.2 billion. Achieving the higher end of the range would likely require the inclusion of moderate revenue from potential COVID-19 treatments, which is possible but not certain at this point. Revenue growth is still expected to be driven by volume from key growth products including Trulicity, Taltz, Basaglar, Jardiance, Verzenio, Cyramza, Olumiant, Emgality, Baqsimi, Tyvyt, and Retevmo. Revenue growth is expected to be partially offset by lower revenue for products that have lost patent exclusivity. Revenue growth is also expected to be partially offset by a mid-single digit net price decline in the U.S. (driven primarily by rebates and legislated increases to Medicare Part D cost sharing, and patient affordability programs), as well as net price declines in China, Japan and Europe.

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

Marketing, selling and administrative expenses are now expected to be in the range of $6.0 billion to $6.1 billion, reflecting additional savings from reduced travel, meetings, and promotional activities. Research and development expenses are now expected to be in the range of $5.8 billion to $5.9 billion, with current expectations trending towards the higher end of the range, reflecting additional COVID-19 investments. The company anticipates its full-year 2020 COVID-19 research and development expenses to be approximately $400 million.

Operating margin is now expected to be 25 percent on a reported basis, 29 percent on a non-GAAP basis, and 31 percent on a non-GAAP basis excluding COVID-19 research and development investments of approximately $400 million and assuming no revenue in 2020 from COVID-19 treatments.

Other income (expense) is now expected to be in the range of $450 to $600 million of income, reflecting additional gains on investment securities in the third quarter of 2020.

The 2020 effective tax rate is still expected to be approximately 14 percent on both a reported basis and a non-GAAP basis.

The following table summarizes the company's 2020 financial guidance:

	2020 Guidance	
	Prior	Updated
Revenue	$23.7 to $24.2 billion	Unchanged
Gross Margin % of Revenue (reported)	Approx. 78%	Unchanged
Gross Margin % of Revenue (non-GAAP)	Approx. 80%	Unchanged
Marketing, Selling & Administrative	$6.0 to $6.2 billion	$6.0 to $6.1 billion
Research & Development	$5.6 to $5.9 billion	$5.8 to $5.9 billion
Other Income/(Expense)	$350 to $500 million	$450 to $600 million
Tax Rate	Approx. 14%	Unchanged
Earnings per share (reported)	$6.48 to $6.68	$6.20 to $6.40
Earnings per share (non-GAAP)	$7.20 to $7.40	Unchanged
Operating Margin (reported)	28%	25%
Operating Margin (non-GAAP)	31%	29%
Operating Margin (non-GAAP excluding COVID-19 R&D expense)	-	31%
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 third-quarter 2020 financial results conference call through a link on Lilly's website at www.lilly.com. The conference call will begin at 9:00 a.m. Eastern time (ET) today and will be available for replay via the website.

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. 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. There are significant risks and uncertainties in pharmaceutical research and development. There can be no guarantees that pipeline products will receive the necessary clinical and manufacturing regulatory approvals or that they 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 and the company's pipeline; 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 actions of governmental and private payers affecting the pricing of, reimbursement for, and access to pharmaceuticals; 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 past, current or future products; unauthorized disclosure, misappropriation, or compromise of trade secrets or other confidential data stored in the company's information systems, networks and facilities, or those of third parties with which the company shares its data; changes in tax law and regulations, including the impact of U.S. 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 Securities and Exchange Commission (SEC); acquisitions and business development transactions and related integration costs; information technology system inadequacies or operating failures; the impact of the evolving COVID-19 pandemic, and the global response thereto; reliance on third-party relationships and outsourcing arrangements; and global macroeconomic conditions. 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.

Alimta® (pemetrexed disodium, Lilly)
Baqsimi ™(glucagon, Lilly)
Basaglar® (insulin glargine injection, Lilly)
Cyramza® (ramucirumab, Lilly)
Emgality® (galcanezumab-gnlm, Lilly)
Forteo® (teriparatide of recombinant DNA origin injection, Lilly)
Glyxambi® (empagliflozin/linagliptin, Boehringer Ingelheim)
Humalog® (insulin lispro injection of recombinant DNA origin, Lilly)

Humulin® (human insulin of recombinant DNA origin, Lilly)
Jardiance® (empagliflozin, Boehringer Ingelheim)
Lartruvo® (olaratumab, Lilly)
Olumiant® (baricitinib, Lilly)
Retevmo ™(selpercatinib, Lilly)
Synjardy® (empagliflozin/metformin, Boehringer Ingelheim)
Taltz® (ixekizumab, Lilly)
Tradjenta®(linagliptin, Boehringer Ingelheim)
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 Employment Information

	September 30, 2020	December 31, 2019
Worldwide Employees	35,065	33,755

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2020	2019	% Chg.	2020	2019	% Chg.
Revenue	$ 5,740.6	$ 5,476.6	5%	$17,099.8	$16,205.5	6%
Cost of sales	1,326.4	1,175.0	13%	3,763.5	3,438.6	9%
Research and development	1,465.4	1,380.9	6%	4,247.7	4,013.6	6%
Marketing, selling and administrative	1,569.1	1,412.3	11%	4,567.3	4,515.7	1%
Acquired in-process research and development	—	77.7	NM	294.1	239.6	23%
Asset impairment, restructuring and other special charges	101.4	—	NM	161.3	423.9	(62)%
Operating income	1,278.3	1,430.7	(11)%	4,065.9	3,574.1	14%
Net interest income (expense)	(83.8)	(90.1)		(243.2)	(237.5)	
Net other income (expense)	242.7	65.2		938.1	266.2	
Other income (expense)	158.9	(24.9)	NM	694.9	28.7	NM
Income before income taxes	1,437.2	1,405.8	2%	4,760.8	3,602.8	32%
Income tax expense	228.8	151.9	51%	683.9	460.6	48%
Net income from continuing operations	1,208.4	1,253.9	(4)%	4,076.9	3,142.2	30%
Net income from discontinued operations	—	—	NM	—	3,680.5	NM
Net income	$ 1,208.4	$ 1,253.9	(4)%	$ 4,076.9	$ 6,822.7	(40)%
Earnings from continuing operations - diluted	1.33	1.37	(3)%	4.47	3.33	34%
Earnings from discontinued operations - diluted	—	—	NM	—	3.91	NM
Earnings per share - diluted	$ 1.33	$ 1.37	(3)%	$ 4.47	$ 7.24	(38)%
Dividends paid per share	$ 0.740	$ 0.645	15%	$ 2.220	$ 1.940	15%
Weighted-average shares outstanding (thousands) - diluted	911,423	918,454		911,868	942,398	

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 September 30, 2020			Three Months Ended September 30, 2019		
	GAAP Reported	Adjustments[b]	Non-GAAP Adjusted[a]	GAAP Reported	Adjustments[c]	Non-GAAP Adjusted[a]

Cost of sales	**$ 1,326.4**	$ (126.5)	$ 1,199.9	**$ 1,175.0**	$ (56.6)	$ 1,118.4
Acquired in-process research and development	**—**	—	—	**77.7**	(77.7)	—
Asset impairment, restructuring and other special charges	**101.4**	(101.4)	—	**—**	—	—
Income tax expense	**228.8**	29.4	258.2	**151.9**	28.2	180.1
Net income	**1,208.4**	198.5	1,406.9	**1,253.9**	106.1	1,360.0
Earnings per share - diluted	**1.33**	0.22	1.54	**1.37**	0.11	1.48

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 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 assist in making meaningful period-over-period comparisons and in identifying operating trends that would otherwise be masked or distorted by the items subject to the adjustments. Management uses these non-GAAP measures internally to evaluate the performance of the business, including to allocate resources and to evaluate results relative to incentive compensation targets. Investors should consider these non-GAAP measures in addition to, not as a substitute for or superior to, measures of financial performance prepared in accordance with GAAP.

(b) Adjustments to certain GAAP reported measures for the three months ended September 30, 2020, include the following:

(Dollars in millions, except per share data)	Amortization [(i)]	Other specified items[(ii)]	**Total**
Cost of sales	$ (126.5)	$ —	**$(126.5)**
Asset impairment, restructuring and other special charges	—	(101.4)	**(101.4)**
Income tax expense	26.3	3.1	**29.4**
Net income	100.2	98.3	**198.5**
Earnings per share - diluted	0.11	0.11	**0.22**

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 primarily severance costs incurred as a result of actions taken worldwide to reduce the company's cost structure.

(c) Adjustments to certain GAAP reported measures for the three months ended September 30, 2019, include the following:

(Dollars in millions, except per share data)	Amortization [(i)]	IPR&D [(ii)]	Total
Cost of sales	$ (56.6)	$ —	**$(56.6)**
Acquired in-process research and development	—	(77.7)	**(77.7)**
Income tax expense	11.8	16.4	**28.2**
Net income	44.8	61.3	**106.1**
Earnings per share - diluted	0.05	0.07	**0.11**

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 costs associated with payments for acquired in-process research and development projects acquired in a transaction other than a business combination. These costs were related to business development transactions with Centrexion Therapeutics Corporation and AC Immune SA.

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

	Nine Months Ended September 30, 2020			Nine Months Ended September 30, 2019		
	GAAP Reported	Adjustments[b]	Non-GAAP Adjusted[a]	GAAP Reported	Adjustments[c]	Non-GAAP Adjusted[a]
Cost of sales	**$ 3,763.5**	$ (287.9)	**$** 3,475.6	**$ 3,438.6**	$ (236.4)	**$** 3,202.2
Acquired in-process research and development	**294.1**	(294.1)	—	**239.6**	(239.6)	—
Asset impairment, restructuring and other special charges	**161.3**	(161.3)	—	**423.9**	(423.9)	—
Income tax expense	**683.9**	93.3	777.2	**460.6**	57.2	517.8
Net income from continuing operations	**4,076.9**	650.0	4,726.9	**3,142.2**	842.7	3,984.9
Net income from discontinued operations	—	—	—	**3,680.5**	(3,680.5)	—
Net income	**4,076.9**	650.0	4,726.9	**6,822.7**	(2,837.8)	3,984.9
Earnings per share - diluted	**4.47**	0.71	5.18	**7.24**	(2.93)	4.31
Weighted-average shares outstanding (thousands) - diluted	**911,868**	—	911,868	**942,398**	(18,056)	924,342

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 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 assist in making meaningful period-over-period comparisons and in identifying operating trends that would otherwise be masked or distorted by the items subject to the adjustments. Management uses these non-GAAP measures internally to evaluate the performance of the business, including to allocate resources and to evaluate results relative to incentive compensation targets. Investors should consider these non-GAAP measures in addition to, not as a substitute for or superior to, measures of financial performance prepared in accordance with GAAP.

(b) Adjustments to certain GAAP reported measures for the nine months ended September 30, 2020, include the following:

(Dollars in millions, except per share data)	Amortization(i)	IPR&D(ii)	Other specified items(iii)	Total
Cost of sales	$ (283.7)	$ —	$ (4.2)	**$(287.9)**
Acquired in-process research and development	—	(294.1)	—	**(294.1)**
Asset impairment, restructuring and other special charges	—	—	(161.3)	**(161.3)**
Income tax expense	58.9	25.0	9.4	**93.3**
Net income	224.8	269.1	156.1	**650.0**
Earnings per share – diluted	0.25	0.30	0.17	**0.71**

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 costs associated with payments for acquired in-process research and development projects acquired in a transaction other than a business combination. These costs were related to both a business development transaction with a pre-clinical stage company as well as business development transactions with Sitryx, AbCellera Biologics Inc., Evox Therapeutics, and Junshi Biosciences.
iii. Exclude primarily severance costs incurred as a result of actions taken worldwide to reduce the company's cost structure, as well as acquisition and integration costs incurred as part of the closing of the acquisition of Dermira.

(c) Adjustments to certain GAAP reported measures for the nine months ended September 30, 2019, include the following:

(Dollars in millions, except per share data)	Amortization[(i)]	IPR&D[(ii)]	Other specified items[(iii)]	Reduced shares outstanding[(iv)]	Lartruvo charges[(v)]	Discontinued operations[(vi)]	**Total**
Cost of sales	$ (151.8)	$ —	$ —	$ —	$ (84.6)	$ —	**$ (236.4)**
Acquired in-process research and development	—	(239.6)	—	—	—	—	**(239.6)**
Asset impairment, restructuring and other special charges	—	—	(411.8)	—	(12.1)	—	**(423.9)**
Income tax expense	31.2	50.3	4.2	—	(28.5)	—	**57.2**
Net income	120.6	189.3	407.6	—	125.2	(3,680.5)	**(2,837.8)**
Earnings per share - diluted	0.13	0.20	0.44	0.07	0.14	(3.91)	**(2.93)**

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 costs associated with upfront payments for acquired in-process research and development projects acquired in a transaction other than a business combination. These costs were related to business development transactions with AC Immune SA, ImmuNext, Inc., Avidity Biosciences, Inc., and Centrexion Therapeutics Corporation.
iii. Exclude charges primarily associated with the accelerated vesting of Loxo Oncology employee equity awards as part of the closing of the acquisition of Loxo Oncology.
iv. Non-GAAP earnings per share assume that the disposition of Elanco occurred at the beginning of all periods presented and therefore include the benefit from the reduction in shares of common stock outstanding.
v. Exclude charges related to the suspension of promotion of Lartruvo.
vi. Exclude discontinued operations of Elanco.

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