Lilly Delivers First-Quarter 2021 Financial Results, Adjusts 2021 Financial Guidance

April 27, 2021

- Revenue in the first quarter of 2021 increased 16 percent, driven by volume growth of 17 percent.
- First-quarter 2021 revenue grew 7 percent excluding revenue of $810.1 million from COVID-19 antibodies and also excluding first-quarter 2020 revenue of approximately $250 million from increased customer buying patterns and patient prescription trends.
- Key growth products, consisting of Trulicity, Verzenio, Olumiant, Tyvyt, Emgality, Jardiance, Retevmo, Cyramza and Taltz, contributed 8 percentage points of revenue growth and represented approximately 46 percent of total revenue in the first quarter of 2021, or 52 percent of total revenue excluding revenue from COVID-19 antibodies.
- First-quarter 2021 operating expenses increased 11 percent, driven primarily by higher research and development investments, including expenses of $220 million to develop COVID-19 therapies. Excluding investment in COVID-19 therapies, total operating expense growth was less than 3 percent.
- Notable pipeline events included Emergency Use Authorization from the FDA for bamlanivimab and etesevimab together for the treatment of COVID-19, as well as positive data readouts for tirzepatide for type 2 diabetes, donanemab for Alzheimer's disease, mirikizumab for ulcerative colitis and baricitinib for alopecia areata.
- First-quarter 2021 earnings per share (EPS) decreased to $1.49 on a reported basis and increased to $1.87 on a non-GAAP basis.
- 2021 EPS guidance lowered to be in the range of $7.03 to $7.23 on a reported basis and adjusted to be in the range of $7.80 to $8.00 on a non-GAAP basis.

INDIANAPOLIS, April 27, 2021 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced financial results for the first quarter of 2021.

$ in millions, except per share data	First Quarter		%
	2021	2020	Change
Revenue	$6,805.6	$5,859.8	16%
Net Income – Reported	1,355.3	1,456.5	(7)%
EPS – Reported	1.49	1.60	(7)%
Net Income – Non-GAAP	1,701.9	1,471.1	16%
EPS – Non-GAAP	1.87	1.61	16%

Certain financial information for 2021 and 2020 is presented on both a reported and a non-GAAP basis. Some numbers in this press release may not add due to rounding. Reported results were prepared in accordance with U.S. generally accepted accounting principles (GAAP) and include all revenue and expenses recognized during the periods. Non-GAAP measures reflect adjustments for the items described in the reconciliation tables later in the release. Beginning in 2021, non-GAAP measures exclude gains and losses on investments in equity securities and 2020 amounts have been reclassified for comparability. The company's 2021 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.

"In the first quarter of 2021, Lilly continued to advance our core business and make strategic progress to drive future growth, all while delivering hundreds of thousands of doses of our COVID-19 antibodies to patients and receiving new data for our monoclonal antibody therapies and new authorizations around the world to help fight the COVID-19 pandemic," said David A. Ricks, Lilly's chairman and CEO. "Our key growth products gained volume and share, helped millions of patients with significant diseases, and represented over half of our core business. We also had a remarkable quarter in R&D beyond our COVID-19 efforts, reading out key late-stage successes with mirikizumab in ulcerative colitis, donanemab in Alzheimer's, tirzepatide in diabetes, and baricitinib in alopecia areata, while early-stage research continued to deliver and advance exciting clinical-stage molecules across our core therapeutic areas."

Key Events Over the Last Three Months
COVID-19

- The company took several steps in order to transition to supply bamlanivimab and etesevimab for administration together in the U.S. for the treatment of COVID-19.
    - The U.S. Food and Drug Administration (FDA) granted Emergency Use Authorization (EUA) for investigational bamlanivimab and etesevimab together. This therapy is authorized for the treatment of mild to moderate COVID-19 in patients aged 12 and older who are at high risk for progressing to severe COVID-19 and/or hospitalization. As part of its previously reported collaboration with the company, Amgen began manufacturing etesevimab.
    - In connection with this transition, the company requested the FDA revoke the EUA for bamlanivimab alone. This request was not due to any new safety concern. The FDA subsequently revoked the EUA for bamlanivimab alone.

    - The European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) issued a positive scientific opinion for bamlanivimab alone and bamlanivimab administered together with etesevimab.
    - The U.S. government agreed to purchase a minimum of 100,000 doses of bamlanivimab and etesevimab together for a purchase price of $210 million. This purchase agreement was subsequently modified to enable the supply of etesevimab to complement doses of bamlanivimab the U.S. government already purchased. In addition, the purchase agreement with the U.S. government for bamlanivimab alone was terminated, and orders were cancelled for the remaining 350,856 doses that were scheduled to be delivered by the end of March 2021.
- The company announced new data from the randomized, double-blind, placebo-controlled BLAZE-1 Phase 3 study, demonstrating bamlanivimab and etesevimab together reduced COVID-19 related hospitalizations and deaths by 87 percent in high-risk patients recently diagnosed with COVID-19.
- The company, Vir Biotechnology, Inc. and GlaxoSmithKline plc announced top-line data from the expanded Phase 2 trial studying low-risk adult patients with mild to moderate COVID-19. Results showed that investigational bamlanivimab co-administered with VIR-7831 (also known as GSK4182136) 500 mg demonstrated a 70 percent relative reduction in persistently high viral load at day 7 compared to placebo, meeting the primary endpoint.
- The company and Incyte announced results of a Phase 3 study evaluating baricitinib 4 mg once daily plus standard of care (SoC) versus placebo plus SoC in patients hospitalized with COVID-19. The trial did not meet statistical significance on the primary endpoint, which was defined as a difference in the proportion of participants progressing to the first occurrence of non-invasive ventilation including high flow oxygen or invasive mechanical ventilation including extracorporeal membrane oxygenation (ECMO) or death by day 28. However, in the study, treatment with baricitinib in addition to SoC resulted in a significant reduction in death from any cause by 38 percent by day 28.

Regulatory

- The FDA extended the review period for the supplemental New Drug Application (sNDA) for baricitinib for the treatment of adults with moderate to severe atopic dermatitis. The FDA extended the action date to allow time to review additional data analyses submitted by Lilly in response to recent information requests from the FDA. The Prescription Drug User Fee Act (PDUFA) action date has been extended three months to early in the third quarter of 2021.
- The company and Pfizer Inc. announced the outcome of the FDA Joint Arthritis Advisory Committee and Drug Safety and Risk Management Advisory Committee on tanezumab. There was a single voting question focused on whether the proposed risk evaluation and mitigation strategy (REMS) for tanezumab will ensure its benefits outweigh its risks, and the Committee voted 1 in favor and 19 against. The companies will continue to work with the FDA as the agency continues its review of the tanezumab application.

Clinical

- The company announced that mirikizumab met the primary and all key secondary endpoints in a Phase 3 induction study evaluating the efficacy and safety of mirikizumab for the treatment of patients with moderate to severe ulcerative colitis.
- The company announced that the development program for mirikizumab will henceforth focus on the ulcerative colitis and Crohn's disease indications. While the OASIS program generated positive results for mirikizumab with safety and efficacy similar to other IL-23p19s, the company no longer plans to submit mirikizumab for regulatory approval in psoriasis in any geography.
- The company presented results at the International Conference on Alzheimer's and Parkinson Diseases 2021 from a Phase 2 trial for donanemab that expanded on previously reported top-line data that found donanemab met its primary endpoint and showed significant slowing of decline compared to placebo on the integrated Alzheimer's Disease Rating Scale (iADRS), a composite measure of cognition and daily function, in patients with early symptomatic Alzheimer's disease.
- The company announced positive top-line results from three Phase 3 clinical trials of tirzepatide in adults with type 2 diabetes in terms of A1C and body weight reductions from baseline. The three trials compared tirzepatide to titrated insulin degludec, to placebo, both as an add-on to titrated insulin glargine, and to injectable semaglutide 1 mg.
- The company and Incyte announced top-line results from two Phase 3 studies evaluating the efficacy and safety of once-daily baricitinib 2-mg and 4-mg in adults with severe alopecia areata. In both studies, both doses of baricitinib met the primary efficacy endpoint at week 36, demonstrating a statistically significant improvement in scalp hair regrowth compared to those randomized to placebo.

Business Development/Other Developments

- The company announced several executive leadership transitions, including the appointment of Anat Ashkenazi as senior vice president and chief financial officer on February 9, 2021, the appointment of Edgardo Hernandez as senior vice president and president of manufacturing operations effective May 2, 2021, the appointment of Diogo Rau as senior vice president and chief information and digital officer effective May 17, 2021, and the appointment of Alonzo Weems as senior vice president, enterprise risk management and chief ethics and compliance officer effective June 27, 2021.
- The Lilly board of directors elected Kimberly H. Johnson as a new member, effective February 16, 2021. She serves on

both the Compensation Committee and the Ethics and Compliance Committee.

- The company and Rigel Pharmaceuticals, Inc. announced a global exclusive license agreement and strategic collaboration to co-develop and commercialize Rigel's R552, a receptor-interacting serine/threonine-protein kinase 1 (RIPK1) inhibitor, for all indications including autoimmune and inflammatory diseases. Pursuant to the collaboration, Lilly will lead all clinical development of brain penetrating RIPK1 inhibitors in central nervous system (CNS) diseases.
- The company and Welldoc, Inc. announced a collaboration and licensing agreement to integrate Welldoc's software into Lilly's connected insulin solutions currently in development. Under the terms of the agreement, Lilly and Welldoc will collaborate to create a new version of the BlueStar® insulin management solution that integrates insulin dosing data for several Lilly insulins. Lilly will commercialize the pen platform, which will include the new app and Lilly's connected insulin pen solutions.
- The company announced a research collaboration and license agreement with Biolojic Design Ltd. that will leverage Biolojic's AI-based multibody platform to discover and develop a potential novel antibody-based therapy for the treatment of diabetes.

First-Quarter Reported Results

In the first quarter of 2021, worldwide revenue was $6.806 billion, an increase of 16 percent compared with the first quarter of 2020, driven by a 17 percent increase in volume and a 3 percent increase due to the favorable impact of foreign exchange rates, partially offset by a 4 percent decrease due to lower realized prices. The company recognized worldwide revenue of $810.1 million in the first quarter of 2021 for its COVID-19 antibodies. Key growth products, consisting of Trulicity®, Verzenio®, Olumiant®, Tyvyt®, Emgality®, Jardiance®, Retevmo®, Cyramza® and Taltz®, contributed 8 percentage points of revenue growth and represented approximately 46 percent of total revenue for the first quarter of 2021, or 52 percent of total revenue excluding revenue from COVID-19 antibodies. The company estimates worldwide volume growth in the first quarter of 2020 was favorably impacted by increased customer buying patterns and patient prescription trends resulting from the COVID-19 pandemic that increased worldwide revenue by approximately $250 million, including approximately $200 million in the U.S. and approximately $50 million outside the U.S. Excluding $810.1 million of revenue in the first quarter of 2021 from COVID-19 antibodies and approximately $250 million of revenue in the first quarter of 2020 from increased customer buying patterns and patient prescription trends, worldwide revenue in the first quarter of 2021 grew by 7 percent.

Revenue in the U.S. increased 18 percent, to $3.941 billion, driven by a 24 percent increase in volume, partially offset by a 6 percent decrease due to lower realized prices. The company recognized U.S. revenue of $650.6 million in the first quarter of 2021 for COVID-19 antibodies. Excluding COVID-19 antibodies, revenue in the U.S. declined by 1 percent, reflecting the impact of customer buying patterns and patient prescription trends in the first quarter of 2020 resulting from the COVID-19 pandemic. Increased U.S. volume for certain key growth products, including Trulicity, Taltz, Verzenio, Retevmo, Emgality, Jardiance and Olumiant was partially offset by lower volume for other products, including Alimta®, Basaglar®, Forteo® and Cialis®. The decrease in realized prices in the U.S. in the first quarter of 2021 was primarily driven by increased rebates to gain broad commercial access for Taltz, partially offset by modest list price increases. Segment mix was not a major driver of U.S. price performance in the first quarter of 2021, as increased utilization in more highly-rebated government segments was offset by lower utilization in the 340B segment, primarily for the diabetes portfolio.

Revenue outside the U.S. increased 13 percent, to $2.864 billion, driven by a 9 percent increase in volume and a 6 percent increase due to the favorable impact of foreign exchange rates, partially offset by a 2 percent decrease due to lower realized prices. The increase in volume outside the U.S. was driven primarily by increased volume for key growth products, including Olumiant, Tyvyt, Verzenio, Trulicity, Taltz, Jardiance, Emgality, Cyramza and Retevmo, as well as $159.5 million of revenue recognized for COVID-19 antibodies. Revenue outside the U.S. was also impacted by volume gains for Alimta, partially offset by decreased volume for Cialis, Forteo, Cymbalta® and Humalog®. The decrease in realized prices outside the U.S. was driven primarily by Trulicity, Olumiant and Forteo.

Gross margin increased 6 percent, to $4.927 billion, in the first quarter of 2021 compared with the first quarter of 2020. Gross margin as a percent of revenue was 72.4 percent, a decrease of 6.9 percentage points compared with the first quarter of 2020. The decrease in gross margin percent was primarily due to unfavorable product mix driven by sales of COVID-19 antibodies, the unfavorable effect of foreign exchange rates on international inventories sold, higher amortization of intangibles expense related to Retevmo, charges resulting from excess inventory of COVID-19 antibodies due in part to the termination of the purchase agreement with the U.S. government for bamlanivimab following discontinuation of the product's distribution on its own in the U.S., and, to a lesser extent, the impact of lower realized prices on revenue.

Total operating expenses in the first quarter of 2021, defined as the sum of research and development and marketing, selling, and administrative expenses, increased 11 percent to $3.261 billion compared with the first quarter of 2020. Research and development expenses increased 21 percent to $1.685 billion, or 24.8 percent of revenue, driven primarily by approximately $220 million of research and development expenses for COVID-19 antibody therapies and baricitinib, as well as higher research and development expenses for late-stage assets. Marketing, selling, and administrative expenses increased 2 percent to $1.576 billion.

In the first quarter of 2021, the company recognized acquired in-process research and development charges of $299.3 million related to business development transactions with Rigel Pharmaceuticals, Inc., Precision BioSciences, Inc., Merus N.V., and Asahi Kasei Pharma Corporation. In the first quarter of 2020, the company recognized acquired in-process research and development charges of $52.3 million related to a business development transaction with Sitryx Therapeutics Ltd.

In the first quarter of 2021, the company recognized asset impairment, restructuring and other special charges of $211.6 million. These charges related primarily to an intangible asset impairment resulting from the decision to sell the rights to QBREXZA®, as well as acquisition and integration costs associated with the acquisition of Prevail Therapeutics Inc. In the first quarter of 2020, the company recognized asset impairment, restructuring and other special charges of $59.9 million, related primarily to acquisition and integration costs associated with the acquisition of Dermira, Inc.

Operating income in the first quarter of 2021 was $1.155 billion, compared to $1.591 billion in the first quarter of 2020. The decrease in operating income was primarily driven by higher research and development expenses, higher acquired in-process research and development charges, and higher asset impairment, restructuring and other special charges, partially offset by higher gross margin. Operating margin, defined as operating income as a percent of revenue, was 17.0 percent.

Other income was $321.1 million in the first quarter of 2021, compared with other income of $89.1 million in the first quarter of 2020. The increase in other income was driven primarily by higher net gains on investment securities.

The effective tax rate was 8.2 percent in the first quarter of 2021, as compared with 13.3 percent in the first quarter of 2020. The effective tax rates for both periods were reduced by net discrete tax benefits, with a larger net discrete tax benefit reflected in the first quarter of 2021.

In the first quarter of 2021, net income and earnings per share were $1.355 billion and $1.49, respectively, compared with net income of $1.457 billion and earnings per share of $1.60 in the first quarter of 2020. The decrease in net income and earnings per share in the first quarter of 2021 was primarily driven by lower operating income, partially offset by higher other income and lower income tax expense.

First-Quarter Non-GAAP Measures

On a non-GAAP basis, first-quarter 2021 gross margin increased 9 percent, to $5.134 billion compared with the first quarter of 2020. Gross margin as a percent of revenue was 75.4 percent, a decrease of 4.9 percentage points. The decrease in gross margin percent was primarily due to unfavorable product mix driven by sales of COVID-19 antibodies, the unfavorable effect of foreign exchange rates on international inventories sold, and, to a lesser extent, the impact of lower realized prices on revenue.

Operating income on a non-GAAP basis increased $111.8 million, or 6 percent, to $1.873 billion in the first quarter of 2021 compared with the first quarter of 2020, due primarily to higher gross margin, partially offset by higher research and development expenses. Operating margin was 27.5 percent on a non-GAAP basis.

Other income was $34.6 million in the first quarter of 2021, compared with other expense of $72.6 million in the first quarter of 2020. The increase in other income was driven primarily by a favorable patent settlement in Europe for Alimta in the first quarter of 2021.

The effective tax rate on a non-GAAP basis was 10.8 percent in the first quarter of 2021, as compared with 12.9 percent in the first quarter of 2020. The effective tax rates for both periods were reduced by net discrete tax benefits, with a larger net discrete tax benefit reflected in the first quarter of 2021.

On a non-GAAP basis, in the first quarter of 2021 net income increased 16 percent, to $1.702 billion, while earnings per share increased 16 percent, to $1.87, compared with $1.471 billion and $1.61, respectively, in the first quarter of 2020. The increase in net income and earnings per share was driven primarily by higher operating income and higher other income.

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.

	First Quarter		
	2021	2020	% Change
Earnings per share (reported)	**$1.49**	**$1.60**	**(7)%**
Acquired in-process research and development	.26	.05	
Asset impairment, restructuring and other special charges	.19	.06	
Amortization of intangible assets	.11	.05	
COVID-19 antibodies excess inventory charges	.07	—	
Net gains on investments in equity securities	(.25)	(.14)	
Earnings per share (non-GAAP)	**$1.87**	**$1.61**	**16%**

Numbers may not add due to rounding.

Selected Revenue Highlights

Selected Revenue Highlights

(Dollars in millions)

	First Quarter		
Selected Products	2021	2020	% Change
Trulicity	$ 1,452.4	$ 1,229.4	18%
COVID-19 antibodies[(a)]	810.1	—	NM
Humalog[(b)]	617.0	695.8	(11)%
Alimta	559.0	560.1	(0)%
Taltz	403.2	443.5	(9)%
Humulin®	321.7	315.7	2%
Jardiance[(c)]	312.0	267.5	17%
Verzenio	269.0	188.0	43%
Basaglar	246.6	303.7	(19)%
Cyramza	240.5	239.0	1%
Forteo	198.5	272.4	(27)%
Olumiant	193.8	139.7	39%
Emgality	119.5	74.0	61%
Tyvyt	109.7	57.4	91%
Retevmo	16.8	—	NM
Total Revenue	6,805.6	5,859.8	16%

(a) COVID-19 antibodies include sales for bamlanivimab administered alone as well as sales for bamlanivimab and etesevimab administered together and were made pursuant to Emergency Use Authorizations

(b) Humalog includes Insulin Lispro

(c) Jardiance includes Glyxambi®, Synjardy®, and Trijardy® XR
NM – not meaningful

Impact of COVID-19 on First-Quarter 2020 Revenue
In the first quarter of 2020, the company estimated that revenue for many of its products was favorably impacted by increased customer buying patterns and patient prescription trends resulting from the COVID-19 pandemic that increased revenue by approximately $250 million worldwide, including approximately $200 million in the U.S. and approximately $50 million outside the U.S. The company believes that this increase in U.S. revenue primarily impacted its portfolio of diabetes medicines, with estimated increases of approximately $70 million to $80 million for insulin products and approximately $30 million to $40 million for Trulicity. The company also estimated that U.S. revenue for Taltz was favorably impacted by approximately $20 million to $25 million.

Trulicity
First-quarter 2021 worldwide Trulicity revenue was $1.452 billion, an increase of 18 percent compared with the first quarter of 2020. U.S. revenue increased 20 percent, to $1.117 billion, driven by increased demand, partially offset by lower realized prices. Trulicity's lower realized prices in the U.S. were primarily due to higher contracted rebates, partially offset by a favorable segment mix that reflected lower utilization in the 340B segment, and modest list price increases. Revenue outside the U.S. was $335.7 million, an increase of 12 percent, driven by increased volume and, to a lesser extent, favorable foreign exchange rates, partially offset by lower realized prices.

Humalog
For the first quarter of 2021, worldwide Humalog revenue decreased 11 percent compared with the first quarter of 2020, to $617.0 million. Revenue in the U.S. decreased 17 percent, to $332.7 million, driven by lower realized prices as higher contracted rebates and discounts were partially offset by lower utilization in the 340B segment. Revenue outside the U.S. decreased 4 percent, to $284.4 million, driven by decreased volume, partially offset by the favorable impact of foreign exchange rates.

Alimta
For the first quarter of 2021, worldwide Alimta revenue remained flat compared with the first quarter of 2020, at $559.0 million. U.S. revenue decreased 19 percent, to $261.1 million, primarily driven by lower volume as a result of customer buying patterns and, to a lesser extent, lower realized prices. Revenue outside the U.S. increased 26 percent to $297.8 million, primarily driven by increased volume in Germany and, to a lesser extent, the favorable impact of foreign exchange rates.

The company expects volume declines in the second half of 2021 for Alimta as a result of the anticipated entry of generic competition due to the loss of patent exclusivity in Japan and major European markets.

Taltz
For the first quarter of 2021, worldwide Taltz revenue decreased 9 percent compared with the first quarter of 2020, to $403.2 million. U.S. revenue decreased 24 percent, to $249.6 million, primarily due to increased rebates to gain commercial access which resulted in lower realized prices, partially offset by increased demand. Revenue outside the U.S. increased 32 percent, to $153.6 million, primarily driven by increased volume and, to a lesser extent, the favorable impact of foreign exchange rates.

Humulin
For the first quarter of 2021, worldwide Humulin revenue increased 2 percent compared with the first quarter of 2020, to $321.7 million. U.S. revenue increased 2 percent, to $219.0 million, driven by higher realized prices, partially offset by decreased demand. Revenue outside the U.S. increased 1 percent, to $102.7 million, primarily due to the favorable impact of foreign exchange rates and higher realized prices, largely offset by decreased volume.

Jardiance
The company's worldwide Jardiance revenue during the first quarter of 2021 was $312.0 million, an increase of 17 percent compared with the first quarter of 2020. U.S. revenue increased 5 percent, to $151.2 million, driven by increased demand. Revenue outside the U.S. was $160.8 million, an increase of 31 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.

Verzenio
For the first quarter of 2021, worldwide Verzenio revenue increased 43 percent compared with the first quarter of 2020, to $269.0 million. U.S. revenue was $172.8 million, an increase of 34 percent, primarily driven by increased demand and, to a lesser extent, higher realized prices. Revenue outside the U.S. was $96.2 million, an increase of 64 percent, primarily driven by increased volume.

Basaglar
For the first quarter of 2021, worldwide Basaglar revenue was $246.6 million, a decrease of 19 percent compared with the first quarter of 2020. U.S. revenue decreased 24 percent, to $175.2 million, driven by decreased demand caused by competitive pressures and, to a lesser extent, lower realized prices. Revenue outside the U.S. decreased 3 percent, to $71.4 million, driven by lower realized prices and decreased volume, partially offset by the favorable impact of foreign exchange rates. Basaglar is part of the company's alliance with Boehringer Ingelheim. Lilly reports as cost of sales payments made to Boehringer Ingelheim for royalties.

Cyramza
For the first quarter of 2021, worldwide Cyramza revenue was $240.5 million, an increase of 1 percent compared with the first quarter of 2020. U.S. revenue was $80.2 million, a decrease of 10 percent, primarily driven by decreased demand and lower realized prices. Revenue outside the U.S. was $160.3 million, an increase of 7 percent, driven by the favorable impact of foreign exchange rates and increased volume.

Forteo
For the first quarter of 2021, worldwide Forteo revenue decreased 27 percent compared with the first quarter of 2020, to $198.5 million. U.S. revenue decreased 20 percent, to $97.7 million, driven by decreased demand, partially offset by higher realized prices. Revenue outside the U.S. decreased 33 percent to $100.8 million, driven by decreased volume and, to a lesser extent, lower realized prices.

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

Olumiant

For the first quarter of 2021, worldwide Olumiant revenue increased 39 percent compared with first quarter of 2020, to $193.8 million. U.S. revenue was $24.7 million. Revenue outside the U.S. was $169.1 million, an increase of 32 percent, driven by increased volume and, to a lesser extent, the favorable impact of foreign exchange rates, partially offset by lower realized prices.

Emgality

For the first quarter of 2021, Emgality generated worldwide revenue of $119.5 million, an increase of 61 percent compared with the first quarter of 2020. U.S. revenue was $101.5 million, an increase of 51 percent driven by higher realized prices and, to a lesser extent, increased demand. Revenue outside of the U.S. was $18.0 million.

Tyvyt

For the first quarter of 2021, the company's Tyvyt revenue in China was $109.7 million, an increase of 91 percent compared with the first quarter of 2020.

Tyvyt is part of the company's alliance with Innovent. Lilly reports total sales of Tyvyt made by Lilly as revenue, with payments made to Innovent for its portion of the gross margin reported as cost of sales. Lilly also reports as revenue a portion of the gross margin for Tyvyt sales made by Innovent.

Retevmo

For the first quarter of 2021, Retevmo generated U.S. revenue of $16.8 million. Retevmo was approved by the FDA and launched in the U.S. during the second quarter of 2020.

2021 Financial Guidance

The company has updated certain elements of its 2021 financial guidance on a reported and a non-GAAP basis. Earnings per share for 2021 are now expected to be in the range of $7.03 to $7.23 on a reported basis and $7.80 to $8.00 on a non-GAAP basis. The update to the company's 2021 financial guidance on a reported basis reflects adjustments shown in the reconciliation table below. The update to the company's 2021 financial guidance on a non-GAAP basis reflects primarily lower expected revenue from COVID-19 antibody sales due to lower expected demand and higher expected research and development expenses.

	2021 Expectations	% Change vs 2020
Earnings per share (reported)	**$7.03 to $7.23**	**4% to 6%**
Amortization of intangible assets	.50	
Acquired IPR&D	.26	
Asset impairment, restructuring and other special charges	.19	
COVID-19 antibodies excess inventory charges	.07	
Net gains on investments in equity securities	(.25)	
Earnings per share (non-GAAP)	**$7.80 to $8.00**	**15% to 18%**

Numbers may not add due to rounding

The company now anticipates 2021 revenue to be between $26.6 billion and $27.6 billion, including an estimated $1 billion to $1.5 billion of revenue from COVID-19 therapies. Revenue growth is additionally expected to be driven by volume from key growth products, including Trulicity, Taltz, Verzenio, Jardiance, Olumiant, Cyramza, Emgality, Tyvyt and Retevmo, as well as by COVID-19 therapies. Revenue growth is expected to be partially offset by lower revenue for products that have lost patent exclusivity. The company expects mid-single digit net price declines globally in 2021. In the U.S., the company expects low-to-mid-single digit net price declines, driven primarily by increased rebates to maintain broad commercial access and segment mix, partially offset by lower utilization in the 340B segment. Outside the U.S., the company expects net price declines in China, Japan, and Europe.

Gross margin as a percent of revenue for 2021 is still expected to be approximately 77 percent on a reported basis and approximately 79 percent on a non-GAAP basis.

Marketing, selling and administrative expenses for 2021 are still expected to be in the range of $6.2 billion to $6.4 billion. Research and development expenses for 2021 are now expected to be in the range of $6.9 billion to $7.1 billion, reflecting additional investments in potential therapies for Alzheimer's disease and approximately $400 million to $500 million of continued investment in COVID-19 therapies.

Operating margin for 2021 is now expected to be approximately 26 percent on a reported basis and approximately 31 percent on a non-GAAP basis.

Other income (expense) for 2021 is now expected to be income in the range of $150 million to $250 million on a reported basis and expense in the range of $100 million to $200 million on a non-GAAP basis.

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

The following table summarizes the company's 2021 financial guidance:

	2021 Guidance	
	Prior	Updated
Revenue	$26.5 to $28.0 billion	$26.6 to $27.6 billion
Gross Margin % of Revenue (reported)	Approx. 77%	Unchanged
Gross Margin % of Revenue (non-GAAP)	Approx. 79%	Unchanged
Marketing, Selling & Administrative	$6.2 to $6.4 billion	Unchanged
Research & Development	$6.5 to $6.7 billion	$6.9 to $7.1 billion

Other Income/(Expense) (reported)	$(300) to $(200) million	$150 to $250 million
Other Income/(Expense) (non-GAAP)	$(300) to $(200) million	$(200) to $(100) million
Tax Rate	Approx. 15%	Approx. 13%
Earnings per Share (reported)	$7.10 to $7.75	$7.03 to $7.23
Earnings per Share (non-GAAP)	$7.75 to $8.40	$7.80 to $8.00
Operating Margin (reported)	Approx. 30%	Approx. 26%
Operating Margin (non-GAAP)	Approx. 32%	Approx. 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 first-quarter 2021 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. 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's 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. 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)
Basaglar® (insulin glargine injection, Lilly)
Cialis® (tadalafil, Lilly)
Cymbalta (duloxetine, 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)
Olumiant® (baricitinib, Lilly)
QBREXZA® (Glycopyrronium cloth, Dermira)
Retevmo® (selpercatinib, Lilly)
Synjardy® (empagliflozin/metformin, Boehringer Ingelheim)
Taltz® (ixekizumab, Lilly)
Trijardy® XR (empagliflozin/linagliptin/metformin hydrochloride extended release tablets, Boehringer Ingelheim)
Trulicity® (dulaglutide, Lilly)
Tyvyt® (sintilimab injection, Lilly)
Verzenio® (abemaciclib, Lilly)

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Eli Lilly and Company Employment Information

	March 31, 2021	December 31, 2020
Worldwide Employees	34,690	34,960

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

	Three Months Ended March 31,		
	2021	2020	% Chg.
Revenue	$ 6,805.6	$ 5,859.8	16%
Cost of sales	1,878.6	1,215.1	55%
Research and development	1,684.8	1,392.1	21%
Marketing, selling and administrative	1,576.0	1,549.6	2%
Acquired in-process research and development	299.3	52.3	NM
Asset impairment, restructuring and other special charges	211.6	59.9	NM
Operating income	1,155.3	1,590.8	(27)%
Net interest income (expense)	(82.3)	(78.2)	
Net other income (expense)	403.4	167.3	
Other income (expense)	321.1	89.1	NM
Income before income taxes	1,476.4	1,679.9	(12)%
Income tax expense	121.1	223.4	(46)%
Net income	$ 1,355.3	$ 1,456.5	(7)%
Earnings per share - diluted	$ 1.49	$ 1.60	(7)%
Dividends paid per share	$ .850	.740	15%
Weighted-average shares outstanding (thousands) - diluted	912,419	911,713	

NM – not meaningful

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

	Three Months Ended March 31, 2021			Three Months Ended March 31, 2020		
	GAAP Reported	Adjustments[b]	Non-GAAP Adjusted[a]	GAAP Reported	Adjustments[c]	Non-GAAP Adjusted[a]
Cost of sales	**$ 1,878.6**	$ (207.2)	$ 1,671.4	**$ 1,215.1**	$ (58.6)	$ 1,156.5
Acquired in-process research and development	**299.3**	(299.3)	—	**52.3**	(52.3)	—
Asset impairment, restructuring and other special charges	**211.6**	(211.6)	—	**59.9**	(59.9)	—
Other income (expense)	**321.1**	(286.5)	34.6	**89.1**	(161.7)	(72.6)
Income tax expense	**121.1**	85.0	206.1	**223.4**	(5.5)	217.9
Net income	**1,355.3**	346.6	1,701.9	**1,456.5**	14.6	1,471.1
Earnings per share - diluted	**1.49**	**0.38**	1.87	**1.60**	0.01	1.61

Numbers may not add due to rounding.
The table above reflects only line items with non-GAAP adjustments.

(a) The company uses non-GAAP financial measures that differ from financial statements reported in conformity with U.S. generally accepted accounting principles (GAAP). The company's non-GAAP measures adjust reported results to exclude amortization of intangibles and other items that are typically highly variable, difficult to predict, and of a size that could have a substantial impact on the company's reported operations for a period. The company believes that these non-GAAP measures provide useful information to investors. Among other things, they may help investors evaluate the company's ongoing operations. They can also assist in making meaningful period-over-period comparisons and in identifying operating trends that would otherwise be masked or distorted by the items subject to the adjustments. Management uses these non-GAAP measures internally to evaluate the performance of the business, including to allocate resources and to evaluate results relative to incentive compensation targets. Investors should consider these non-GAAP measures in addition to, not as a substitute for or superior to, measures of financial performance prepared in accordance with GAAP.

(b) Adjustments to certain GAAP reported measures for the three months ended March 31, 2021, include the following:

(Dollars in millions, except per share data)	Amortization[(i)]	IPR&D[(ii)]	Other specified items[(iii)]	Equity investments[(iv)]	**Total**
Cost of sales	$ (125.7)	$ —	$ (81.5)	$ —	**$(207.2)**
Acquired in-process research and development	—	(299.3)	—	—	**(299.3)**
Asset impairment, restructuring and other special charges	—	—	(211.6)	—	**(211.6)**
Other income (expense)	—	—	—	(286.5)	**(286.5)**
Income tax expense	26.1	62.9	51.9	(55.9)	**85.0**
Net income	99.6	236.4	241.2	(230.6)	**346.6**
Earnings per share - diluted	0.11	0.26	0.26	(0.25)	**0.38**

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 Rigel Pharmaceuticals, Inc., Precision BioSciences, Inc., Merus N.V., and Asahi Kasei Pharma Corporation.

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

iv Exclude gains and losses on investments in equity securities.

(c) Adjustments to certain GAAP reported measures for the three months ended March 31, 2020, include the following:

(Dollars in millions, except per share data)	Amortization[(i)]	IPR&D[(ii)]	Other specified items[(iii)]	Equity investments[(iv)]	**Total**
Cost of sales	$ (54.4)	$ —	$ (4.2)	$ —	**$(58.6)**
Acquired in-process research and development	—	(52.3)	—	—	**(52.3)**
Asset impairment, restructuring and other special charges	—	—	(59.9)	—	**(59.9)**
Other income (expense)	—	—	—	(161.7)	**(161.7)**
Income tax expense	11.3	11.0	6.2	(34.0)	**(5.5)**
Net income	43.1	41.3	57.9	(127.7)	**14.6**
Earnings per share - diluted	0.05	0.05	0.06	(0.14)	**0.01**

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 a business development transaction with Sitryx.

iii Exclude primarily acquisition and integration costs associated with the acquisition of Dermira, Inc.

iv Exclude gains and losses on investments in equity securities.

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