Lilly Reports Solid Fourth-Quarter and Full-Year 2021 Financial Results, Recent Late-Stage Pipeline Successes Set Up Next Wave of Innovative Medicines for Patients

February 3, 2022

- Revenue in the fourth quarter of 2021 increased 8 percent, driven by volume growth of 11 percent. Excluding COVID-19 antibodies, fourth-quarter 2021 revenue grew 6 percent.

- Full-year 2021 revenue increased 15 percent, driven by volume growth of 16 percent. Excluding COVID-19 antibodies, full-year 2021 revenue grew 10 percent.

- Key growth products, consisting of Trulicity, Taltz, Verzenio, Jardiance, Olumiant, Emgality, Retevmo, Cyramza and Tyvyt, contributed 14 percentage points of revenue growth and represented 61 percent of total revenue in the fourth quarter of 2021, excluding revenue from COVID-19 antibodies.

- Notable recent pipeline events include positive Phase 3 readouts for lebrikizumab for moderate-to-severe atopic dermatitis and mirikizumab for moderately-to-severely active ulcerative colitis that support regulatory submissions in 2022.

- Fourth-quarter 2021 earnings per share (EPS) decreased 18 percent to $1.90 on a reported basis and increased 8 percent to $2.49 on a non-GAAP basis. Full-year 2021 EPS decreased 10 percent to $6.12 on a reported basis and increased 20 percent to $8.16 on a non-GAAP basis.

- 2022 EPS guidance reaffirmed to be in the range of $8.00 to $8.15 on a reported basis and $8.50 to $8.65 on a non-GAAP basis.

INDIANAPOLIS, Feb. 3, 2022 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced financial results for the fourth quarter and full year of 2021 today.

"Lilly had a remarkable year of growth and pipeline success in 2021, despite the continued hardships from the pandemic," said David A. Ricks, Lilly's chair and CEO. "We have tremendous momentum moving into 2022 and beyond with strong revenue expectations, limited patent exposure, and an exciting pipeline of potential new medicines, which we hope will give us the opportunity to positively impact millions more lives in meaningful ways. Lilly is committed to continuing to innovate as the primary way to create value for patients and shareholders alike."

$ in millions, except per share data	Fourth Quarter		%	Full Year		%
	2021	2020	Change	2021	2020	Change
Revenue	$ 7,999.9	$ 7,440.0	8%	$ 28,318.4	$ 24,539.8	15%
Net Income – Reported	1,726.1	2,116.8	(18)%	5,581.7	6,193.7	(10)%
EPS – Reported	1.90	2.32	(18)%	6.12	6.79	(10)%
Net Income – Non-GAAP	2,267.8	2,107.7	8%	7,436.7	6,191.0	20%
EPS – Non-GAAP	2.49	2.31	8%	8.16	6.78	20%

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. The company's 2022 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.

Key Events Over the Last Three Months

Regulatory

- The U.S. Food and Drug Administration (FDA), Pharmaceuticals and Medical Devices Agency, and European Medicines

Agency accepted Lilly's New Drug Application (NDA) in the U.S. and Japan, and Marketing Authorization Application in the European Union, respectively, for tirzepatide for the treatment of adults with type 2 diabetes. Lilly also submitted tirzepatide to six additional markets.

- The company initiated a rolling submission to the FDA for pirtobrutinib, seeking accelerated approval in mantle cell lymphoma, with expectations to complete the submission in 2022 and regulatory action anticipated in early 2023.
- The FDA accepted a supplemental NDA (sNDA) and granted priority review for Jardiance® for adults with heart failure independent of left ventricular ejection fraction.
- The company received Breakthrough Therapy designation from the FDA for an additional amyloid plaque lowering agent, N3pG 4.
- Lilly's bamlanivimab and etesevimab, administered together, were authorized by the FDA as the first and only neutralizing antibody therapy for emergency use in COVID-19 patients under the age of 12.
- The FDA has updated the Fact Sheet for bamlanivimab and etesevimab to include a new Limitation for Authorized Use: due to the high frequency of the Omicron variant, these antibody therapies are not currently authorized in any U.S. region. Authorization status will change as needed, depending on prevalence and trends of variants of concern.
- The company submitted a request for Emergency Use Authorization for bebtelovimab for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients 12 years of age and older. Authentic virus analysis of bebtelovimab confirm earlier pseudovirus findings, which demonstrate Lilly's investigational antibody neutralizes all known variants of concern, including Omicron.
- The FDA accepted an sNDA and granted priority review for baricitinib for the treatment of COVID-19.
- Lilly is in ongoing discussion with the FDA regarding the status of the sNDA for Olumiant® for the treatment of adults with moderate-to-severe atopic dermatitis. At this point, the company does not have alignment with the FDA on the indicated population. Given the Agency's position, there is a possibility that this could lead to a Complete Response Letter.

Clinical

- Lilly's lebrikizumab demonstrated significant skin improvement and itch relief when combined with topical corticosteroids in people with atopic dermatitis in its third Phase 3 study that supports regulatory submission in 2022.
- Lilly's mirikizumab demonstrated superiority over placebo in a Phase 3 maintenance study in ulcerative colitis that supports regulatory submissions in 2022.
- Based on top-line efficacy results from two pivotal Phase 3 trials (SLE-BRAVE-I and II), the company has decided to discontinue the Phase 3 development program for Olumiant in adults with active systemic lupus erythematosus.

Business Development/Other Developments

- The U.S. Government signed a purchase agreement for 614,000 additional doses of Lilly's bamlanivimab and etesevimab for the treatment or post-exposure prevention of COVID-19 for a total of $1.29 billion. There were approximately 435,000 doses delivered in fourth-quarter 2021 with most of the remaining doses already shipped in January 2022.
- New guidelines released by the World Health Organization on treatments for COVID-19 strongly recommend the use of baricitinib in combination with corticosteroids for severely or critically ill hospitalized COVID-19 patients.
- Lilly announced new investments to increase the company's manufacturing capacity for current and future medicines. Lilly plans to invest more than 400 million euros in a new site in Limerick, Ireland to expand the company's manufacturing network for biologic active ingredients. Lilly plans to invest more than $1 billion in a new site in Concord, North Carolina to manufacture parenteral (injectable) products and devices.
- Lilly and Foghorn Therapeutics Inc. announced a strategic collaboration for novel oncology targets using Foghorn's proprietary Gene Traffic Control® platform.
- The company and Entos Pharmaceuticals Inc. entered into a research and collaboration agreement to support the development of innovative therapies in multiple neurologic indications.
- Lilly and QILU Regor Therapeutics Inc. entered into a strategic collaboration to discover and develop novel therapies for metabolic disorders.
- The company announced a 15 percent dividend increase for shareholders beginning in the first quarter of 2022.
- Lilly and UNICEF announced a collaboration to help improve health outcomes for 10 million children and adolescents living with chronic, non-communicable diseases (NCD) through 2025. Lilly has committed $14.4 million in support of UNICEF's lifesaving work.

"Lilly closed 2021 with another solid quarter. Throughout the year we delivered strong top- and bottom-line growth, with volume-driven growth across key brands," said Anat Ashkenazi, Lilly's senior vice president and chief financial officer. "We continue to advance promising R&D opportunities and invest in potential launches that would bring needed therapies to patients worldwide. We expect to deliver top-tier revenue growth throughout the decade."

Fourth-Quarter Reported Results

In the fourth quarter of 2021, worldwide revenue was $8.000 billion, an increase of 8 percent compared with the fourth quarter of 2020, driven by an 11 percent increase in volume, partially offset by a 3 percent decrease due to lower realized prices. Key growth products, consisting of Trulicity®, Taltz®,

Verzenio®, Jardiance, Olumiant, Emgality®, Retevmo®, Cyramza® and Tyvyt®, contributed 14 percentage points of revenue growth and represented 61 percent of total revenue for the fourth quarter of 2021, excluding COVID-19 antibodies. The company recognized worldwide revenue of $1.063 billion from COVID-19 antibodies during the quarter compared with $871.2 million in the fourth quarter of 2020. Excluding revenue from COVID-19 antibodies, worldwide revenue increased by 6 percent in the fourth quarter.

Revenue in the U.S. increased 13 percent, to $5.176 billion, driven by a 14 percent increase in volume, partially offset by a 2 percent decrease due to lower realized prices. The company recognized U.S. revenue from COVID-19 antibodies of $1.029 billion in the fourth quarter of 2021 compared to $850.0 million in the fourth quarter of 2020. Excluding COVID-19 antibodies, revenue in the U.S. increased by 11 percent. The increase in U.S. volume was driven by certain key growth products, including Trulicity, Taltz, Jardiance, Verzenio and Olumiant.

Revenue outside the U.S. decreased 1 percent, to $2.824 billion, as a 7 percent increase in volume was more than offset by a 6 percent decrease due to lower realized prices and a 1 percent decrease due to the unfavorable impact of foreign exchange rates. The increase in volume outside the U.S. was primarily driven by increased volume for all key growth products, partially offset by decreased volume for Alimta®, Cymbalta® and Forteo® resulting from the entry of generic competition due to loss of exclusivity in certain major markets. The lower realized prices were primarily driven by the impact of the updated National Reimbursement Drug List (NRDL) formulary for certain products, largely Tyvyt, in China.

Gross margin increased 4 percent, to $5.950 billion, in the fourth quarter of 2021 compared with the fourth quarter of 2020. Gross margin as a percent of revenue was 74.4 percent, a decrease of 2.5 percentage points compared to the fourth quarter of 2020. The decrease in gross margin percent was driven by higher sales of COVID-19 antibodies.

Total operating expenses in the fourth quarter of 2021, increased 5 percent to $3.551 billion compared with the fourth quarter of 2020. Research and development expenses increased 7 percent to $1.959 billion, or 25 percent of revenue, primarily driven by higher development expenses for late-stage assets, partially offset by lower development expenses for COVID-19 therapies. Research and development expenses for COVID-19 therapies were approximately $40 million in the fourth quarter of 2021. Marketing, selling and administrative expenses increased 2 percent to $1.592 billion.

In the fourth quarter of 2021, the company recognized acquired in-process research and development charges of $376.6 million related to business development transactions with Foghorn Therapeutics Inc., Entos Pharmaceuticals Inc., and QILU Regor Therapeutics Inc. In the fourth quarter of 2020, the company recognized acquired in-process research and development charges of $366.3 million related to business development transactions with Innovent Biologics, Inc., Disarm Therapeutics, Inc., and Fochon Pharmaceuticals, Ltd.

In the fourth quarter of 2021, the company recognized asset impairment, restructuring and other special charges of $104.5 million primarily related to impairment of an intangible asset from our acquisition of Loxo Oncology. This impairment is a result of a decision by Bayer AG to discontinue the development of a Loxo Oncology Phase 1 molecule. In the fourth quarter of 2020, the company recognized income for asset impairment, restructuring and other special charges of $30.1 million, reflecting adjustments to prior period estimates for asset impairment and severance costs.

Operating income in the fourth quarter of 2021 was $1.917 billion, compared to$1.992 billion in the fourth quarter of 2020. The decrease in operating income was driven by higher operating expenses, as well as higher asset impairment, restructuring and other special charges, largely offset by higher gross margin. Operating margin percent, defined as operating income as a percent of revenue, was 24.0 percent.

Other income (expense) was expense of $77.3 million in the fourth quarter of 2021, compared with income of $477.0 million in the fourth quarter of 2020. The reduction in other income (expense) was primarily driven by net losses on investments in equity securities in the fourth quarter of 2021 compared with net gains on investments in equity securities in the fourth quarter of 2020.

The effective tax rate was 6.2 percent in the fourth quarter of 2021, compared with 14.3 percent in the fourth quarter of 2020. The lower effective tax rate in the fourth quarter of 2021 was primarily driven by net discrete tax items in both periods, as well as the tax benefit related to net losses on investments in equity securities compared with higher tax expense related to net gains on investments in equity securities in the fourth quarter of 2020.

In the fourth quarter of 2021, net income and EPS both decreased 18 percent, to $1.726 billion and $1.90, compared with $2.117 billion and $2.32, respectively, in the fourth quarter of 2020. Net income and EPS in the fourth quarter of 2021 decreased compared to the same period in 2020 driven by a reduction in other income (expense) and, to a lesser extent, lower operating income, partially offset by lower income tax expense.

Fourth-Quarter Non-GAAP Measures

On a non-GAAP basis, fourth quarter of 2021 gross margin increased 4 percent, to $6.087 billion compared with the fourth quarter of 2020. Gross margin as a percent of revenue was 76.1 percent, a decrease of 2.5 percentage points. The decrease in gross margin percent was driven by higher sales of COVID-19 antibodies.

Operating income on a non-GAAP basis increased $80.1 million, or 3 percent, to $2.536 billion in the fourth quarter of 2021 compared with the fourth quarter of 2020, due to higher gross margin, partially offset by higher operating expenses. Operating margin was 31.7 percent on a non-GAAP basis.

Other income (expense) on a non-GAAP basis was expense of $6.7 million in the fourth quarter of 2021, compared with expense of $31.0 million in the fourth quarter of 2020.

The effective tax rate on a non-GAAP basis was 10.3 percent in the fourth quarter of 2021, compared with 13.1 percent in the fourth quarter of 2020. The lower effective tax rate was primarily driven by net discrete tax items in both quarters.

On a non-GAAP basis, in the fourth quarter of 2021 net income and EPS both increased 8 percent, to $2.268 billion and $2.49, compared with $2.108 billion and $2.31, respectively, in the fourth quarter of 2020. The increases in net income and EPS were primarily driven by higher operating 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.

	Fourth Quarter		
	2021	2020	% Change
Earnings per share (reported)	**$ 1.90**	**$ 2.32**	**(18)%**
Acquired in-process research and development	.33	.35	

Amortization of intangible assets	.19	.11	
Asset impairment, restructuring and other special charges	.09	(.03)	
Net losses (gains) on investments in equity securities	.06	(.44)	
Partial reversal of COVID-19 antibodies inventory charge	(.07)	—	
Earnings per share (non-GAAP)	**$ 2.49**	**$ 2.31**	**8%**

Numbers may not add due to rounding.

Full Year Reported Results

For the full year of 2021, worldwide revenue increased 15 percent to $28.318 billion, compared with $24.540 billion in the same period in 2020. The increase in revenue was driven by a 16 percent increase in volume and, to a lesser extent, a 1 percent increase due to the favorable impact of foreign exchange rates, partially offset by a 2 percent decrease due to lower realized prices. The company recognized worldwide revenue of $2.239 billion from COVID-19 antibodies for the full year of 2021 compared with $871.2 million in 2020. Excluding revenue from COVID-19 antibodies, worldwide revenue increased by 10 percent.

Revenue in the U.S. increased 18 percent to $16.811 billion, driven by a 19 percent increase in volume, partially offset by a 1 percent decrease due to lower realized prices. The company recognized U.S. revenue of $1.978 billion from COVID-19 antibodies for the full year of 2021 compared to $850.0 million in 2020. Excluding revenue from COVID-19 antibodies, revenue in the U.S. increased by 11 percent. The increase in U.S. volume was driven by certain key growth products, including Trulicity, Taltz, Verzenio, Jardiance, Olumiant, Retevmo and Emgality.

Revenue outside the U.S. increased 12 percent to $11.507 billion, driven by a 13 percent increase in volume and, to a lesser extent, 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 increase in volume outside of the U.S. was primarily driven by increased volume for all key growth products. The lower realized prices were primarily driven by the price impacts of certain products on the NRDL formulary in China.

Gross margin increased 10 percent to $21.006 billion in 2021. Gross margin as a percent of revenue was 74.2 percent, a decrease of 3.5 percentage points compared with 2020. The decrease in gross margin percent was driven by higher sales of COVID-19 antibodies.

Total operating expenses increased 10 percent to $13.457 billion in 2021. Research and development expenses increased 15 percent to $7.026 billion, or 24.8 percent of revenue. The increase was primarily driven by higher development expenses for late-stage assets. Marketing, selling and administrative expenses increased 5 percent to $6.432 billion, primarily due to increased marketing costs to continue to drive growth for key products, investment in preparation for new launches, and lower marketing activities in 2020 as a result of pandemic-related spending reductions.

In 2021, the company recognized acquired in-process research and development charges of $874.9 million resulting from business development transactions compared with $660.4 million in 2020.

In 2021, the company recognized asset impairment, restructuring and other special charges of $316.1 million. The charges were primarily related to an intangible asset impairment resulting from the sale of the rights to Qbrexza®, impairment of an intangible asset from Lilly's acquisition of Loxo Oncology, as well as acquisition and integration costs associated with the acquisition of Prevail Therapeutics Inc. In 2020, the company recognized asset impairment, restructuring and other special charges of $131.2 million. The charges were primarily related to severance costs incurred as a result of actions taken worldwide to reduce our cost structure.

Operating income in 2021 increased 5 percent compared with 2020 to $6.357 billion, as higher gross margin was partially offset by higher operating expenses, higher acquired in-process research and development charges, and higher asset impairment, restructuring and other special charges. Operating margin was 22.4 percent.

Other income (expense) was expense of $201.6 million in 2021 compared with income of $1.172 billion in 2020. The decrease was primarily driven by lower net gains on investments in equity securities and a charge of $405.2 million related to the repurchase of higher-cost debt.

For the full year of 2021, the effective tax rate was 9.3 percent, compared with an effective tax rate of 14.3 percent for the full year of 2020. The lower effective tax rate in 2021 was driven primarily by the tax impacts of acquired in-process research and development charges, lower net gains on investments in equity securities, as well as a net discrete tax benefit.

For the full year of 2021, net income and EPS both decreased 10 percent, to $5.582 billion and $6.12, compared with $6.194 billion and $6.79, respectively, in 2020. The decreases in net income and EPS were driven by a reduction in other income (expense), partially offset by lower income taxes and higher operating income.

Full Year Non-GAAP Measures

On a non-GAAP basis for the full year of 2021, gross margin increased 13 percent, to$21.914 billioncompared with the full year of 2020. Gross margin as a percent of revenue for the full year of 2021 was 77.4 percent, compared with 79.3 percent for the full year of 2020. The decrease in gross margin percent was driven by higher sales of COVID-19 antibodies.

Operating income on a non-GAAP basis increased 16 percent to $8.457 billiondriven by higher gross margin, partially offset by higher operating expenses. Operating margin was 29.9 percent.

Other income (expense) on a non-GAAP basis was income of $25.6 million for the full year of 2021, compared with expense of $150.8 million for the full year of 2020. The increase in other income (expense) was primarily driven by income from patent settlements in Europe for Alimta in 2021.

The effective tax rate on a non-GAAP basis was 12.3 percent for the full year of 2021, compared with 13.0 percent for the full year of 2020, driven primarily by a net discrete tax benefit in 2021.

On a non-GAAP basis, net income and EPS increased 20 percent to $7.437 billion and $8.16, respectively. The increases in net income and EPS were driven by higher operating 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.

	Full Year		
	2021	2020	% Change
Earnings per share (reported)	**$ 6.12**	**$ 6.79**	**(10)%**
Acquired in-process research and development	.77	.64	
Amortization of intangible assets	.53	.36	
Charge related to repurchase of higher-cost debt	.35	—	
Asset impairment, restructuring and other special charges	.28	.14	
COVID-19 antibodies inventory charges	.25	—	
Net gains on investments in equity securities	(.16)	(1.15)	
Earnings per share (non-GAAP)	**$ 8.16**	**$ 6.78**	**20%**

Numbers may not add due to rounding.

Selected Revenue Highlights

Selected Revenue Highlights

(Dollars in millions)	Fourth Quarter			Full Year		
Selected Products	2021	2020	% Change	2021	2020	% Change
Trulicity	$ 1,883.7	$ 1,502.4	25%	$ 6,471.9	$ 5,068.1	28%
Humalog®[a]	601.7	718.1	(16)%	2,453.0	2,625.9	(7)%
COVID-19 antibodies[b]	1,063.1	871.2	22%	2,239.2	871.2	NM
Taltz	647.4	495.3	31%	2,212.8	1,788.5	24%
Alimta	434.9	652.7	(33)%	2,061.4	2,329.9	(12)%
Jardiance[c]	431.9	313.6	38%	1,490.8	1,153.8	29%
Verzenio	404.1	281.6	43%	1,349.9	912.7	48%
Humulin®	298.8	324.4	(8)%	1,222.6	1,259.6	(3)%
Olumiant[d]	306.0	192.2	59%	1,115.1	638.9	75%
Cyramza	270.4	284.2	(5)%	1,033.0	1,032.6	0%
Basaglar®	242.4	282.1	(14)%	892.5	1,124.4	(21)%
Forteo	184.0	254.4	(28)%	801.9	1,046.3	(23)%
Emgality	161.5	109.9	47%	577.2	362.9	59%
Tyvyt	77.8	102.8	(24)%	418.1	308.7	35%
Retevmo	38.6	18.7	NM	114.7	36.6	NM
Total Revenue	7,999.9	7,440.0	8%	28,318.4	24,539.8	15%

[a] Humalog includes Insulin Lispro

[b] 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 (EUA)

[c] Jardiance includes Glyxambi®, Synjardy®, and Trijardy® XR

[d] Olumiant includes salesof baricitinib that were made pursuant to EUA

NM – not meaningful

Trulicity

For the fourth quarter of 2021, worldwide Trulicity revenue was $1.884 billion, an increase of 25 percent compared with the fourth quarter of 2020. U.S. revenue increased 25 percent, to $1.449 billion, primarily driven by increased demand. Revenue outside the U.S. was $435.1 million, an increase of 28 percent, driven by increased volume, partially offset by lower realized prices.

For the full year of 2021, worldwide Trulicity revenue was $6.472 billion, an increase of 28 percent compared with the full year of 2020. U.S. revenue increased 28 percent, to $4.914 billion, driven by increased demand. Revenue outside the U.S. increased 26 percent, to $1.558 billion, driven by increased volume and, to a lesser extent, the favorable impact of foreign exchange rates, partially offset by lower realized prices.

Humalog

For the fourth quarter of 2021, worldwide Humalog revenue decreased 16 percent compared with the fourth quarter of 2020, to $601.7 million. Revenue in the U.S. decreased 25 percent, to $311.7 million, driven by lower realized prices resulting from changes to estimates for rebates and discounts in both periods. Revenue outside the U.S. decreased 4 percent, to $290.0 million, driven by decreased volume and lower realized prices.

For the full year of 2021, worldwide Humalog revenue decreased 7 percent, to $2.453 billion compared with the full year 2020. U.S. Humalog revenue for 2021 was $1.321 billion, an 11 percent decrease, primarily driven by lower realized prices. Humalog revenue outside the U.S. was $1.132 billion, a 1 percent decrease, driven by decreased volume and, to a lesser extent, lower realized prices, largely offset by the favorable impact of foreign exchange rates.

Due to competitive pressures, the company expects a continued price decline for Humalog in the U.S.

Taltz

For the fourth quarter of 2021, worldwide Taltz revenue increased 31 percent compared with the fourth quarter of 2020, to $647.4 million. U.S. revenue increased 36 percent, to $470.8 million, driven primarily by increased demand. Revenue outside the U.S. increased 18 percent, to $176.6 million,

driven by increased volume, partially offset by lower realized prices.

For the full year of 2021, Taltz generated worldwide revenue of $2.213 billion, an increase of 24 percent compared with the full year of 2020. U.S. revenue was $1.542 billion, an increase of 20 percent, driven by increased demand, partially offset by increased rebates to gain commercial access which resulted in lower realized prices. Revenue outside the U.S. was $670.4 million, an increase of 34 percent, primarily driven by increased volume.

Alimta

For the fourth quarter of 2021, worldwide Alimta revenue decreased 33 percent compared with the fourth quarter of 2020, to $434.9 million. U.S. revenue decreased 3 percent, to $322.0 million, driven primarily by customer buying patterns. Revenue outside the U.S. decreased 65 percent, to $112.8 million, primarily driven by decreased volume due to entry of generic competition in certain markets and, to a lesser extent, lower realized prices.

For the full year of 2021, worldwide Alimta revenue decreased 12 percent, to $2.061 billion compared with the full year of 2020. U.S. Alimta revenue for 2021 was $1.234 billion, a 2 percent decrease, driven by decreased volume, partially offset by higher realized prices. Alimta revenue outside the U.S. was $827.5 million, a 22 percent decrease, primarily driven by decreased volume due to entry of generic competition in certain markets and, to a lesser extent, lower realized prices, partially offset by the favorable impact of foreign exchange rates.

The company expects continued volume decline for Alimta as a result of the entry of generic competition due to the loss of patent exclusivity in Japan and major European markets. The company expects generic entrants in the U.S. beginning in the first quarter of 2022.

Jardiance

The company's worldwide Jardiance revenue during the fourth quarter of 2021 was $431.9 million, an increase of 38 percent compared with the fourth quarter of 2020. U.S. revenue increased 43 percent, to $240.5 million, primarily driven by increased demand. Revenue outside the U.S. was $191.4 million, an increase of 31 percent, driven by increased volume.

For the full year of 2021, the company's worldwide Jardiance revenue was $1.491 billion, an increase of 29 percent compared with the full year of 2020. U.S. revenue increased 30 percent, to $807.3 million, primarily driven by increased demand. Revenue outside the U.S. increased 28 percent, to $683.5 million, primarily driven by increased volume.

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 fourth quarter of 2021, worldwide Verzenio revenue increased 43 percent compared with the fourth quarter of 2020, to $404.1 million. U.S. revenue was $252.8 million, an increaseof 34 percent, driven by increased demand, partially offset by lower realized prices. Revenue outside the U.S. was $151.3 million, an increase of 62 percent, driven by increased volume, partially offset by the unfavorable impact of foreign exchange rates and lower realized prices.

For the full year of 2021, Verzenio generated worldwide revenue of $1.350 billion, an increase of 48 percent compared with the full year of 2020. U.S. revenue increased 35 percent to $834.9 million, driven by increased demand. Revenue outside of the U.S. increased 75 percent to $515.0 million, driven by increased volume.

Humulin

For the fourth quarter of 2021, worldwide Humulin revenue decreased 8 percent compared with the fourth quarter of 2020, to $298.8 million. U.S. revenue decreased 11 percent, to $199.4 million, driven by decreased demand and, to a lesser extent, lower realized prices. Revenue outside the U.S. decreased 1 percent, to $99.4 million, due to decreased volume, largely offset by higher realized prices.

For the full year of 2021, Humulin generated worldwide revenue of $1.223 billion, a decrease of 3 percent compared with the full year of 2020. U.S. revenue was $832.9 million, a 4 percent decrease, primarily driven by decreased demand and, to a lesser extent, lower realized prices. Revenue outside the U.S. was $389.6 million, a 1 percent decrease, due to decreased volume, largely offset by higher realized prices and the favorable impact of foreign exchange rates.

Olumiant

For the fourth quarter of 2021, worldwide Olumiant revenue increased 59 percent compared with the fourth quarter of 2020, to $306.0 million. U.S. revenue was $87.7 million, representing growth of $62.8 million compared with the fourth quarter of 2020. Revenue outside the U.S. was $218.3 million, an increase of 30 percent, driven by increased volume, partially offset by lower realized prices. Increased volume worldwide was partially driven by utilization of Olumiant for the treatment of hospitalized patients with COVID-19.

For the full year of 2021, Olumiant generated worldwide revenue of $1.115 billion, an increase of 75 percentcompared with the full year of 2020. U.S. revenue was $324.1 million, an increase of $260.3 million. Revenue outside of the U.S. increased 38 percent, to $791.0 million, driven by increased volume and, to a lesser extent, the favorable impact of foreign exchange rates, partially offset by lower realized prices. Increased volume worldwide was partially driven by utilization of Olumiant for the treatment of hospitalized patients with COVID-19.

Cyramza

For the fourth quarter of 2021, worldwide Cyramza revenue decreased 5 percent compared with the fourth quarter of 2020, to $270.4 million. U.S. revenue was $91.9 million, a decrease of 12 percent, driven by decreased demand, partially offset by higher realized prices. Revenue outside the U.S. was $178.6 million, a decrease of 1 percent, driven by the unfavorable impact of foreign exchange rates and lower realized prices, largely offset by increased volume.

For the full year of 2021, worldwide Cyramza revenue remained essentially flat compared with the full year of 2020, at $1.033 billion. U.S. revenue decreased 6 percent, to $358.1 million, driven by decreased demand, partially offset by higher realized prices. Revenue outside the U.S. increased 4 percent, to $674.8 million, due to increased volume, partially offset by lower realized prices.

Basaglar

For the fourth quarter of 2021, worldwide Basaglar revenue was $242.4 million, a decrease of 14 percent compared with the fourth quarter of 2020. U.S. revenue decreased19 percent, to $165.0 million, driven by continued competitive pressures that resulted in lower realized prices and, to a lesser extent, decreased demand. Revenue outside the U.S. decreased 1 percent, to $77.4 million, primarily driven by lower realized prices, largely offset by increased volume.

For the full year of 2021, Basaglar generated worldwide revenue of $892.5 million, a decrease of 21 percent compared with the full year of 2020. U.S. revenue was $588.3 million, a decrease of 30 percent, driven by lower realized prices and, to a lesser extent, decreased demand. Revenue outside of the U.S. was $304.2 million, an increase of 8 percent, primarily driven by increased volume.

Due to competitive pressures, the company expects a continued price decline for Basaglar in the U.S. Basaglar is part of the company's alliance with Boehringer Ingelheim. Lilly reports as cost of sales payments made to Boehringer Ingelheim for royalties.

Forteo

For the fourth quarter of 2021, worldwide Forteo revenue decreased 28 percent compared with the fourth quarter of 2020, to $184.0 million. U.S. revenue decreased 10 percent, to $111.4 million, driven by decreased demand, partially offset by higher realized prices. Revenue outside the U.S. decreased 45 percent to $72.6 million, primarily driven by decreased volume.

For the full year of 2021, worldwide Forteo revenue decreased 23 percent to $801.9 million compared with the full year of 2020. U.S. Forteo revenue for 2021 was $441.6 million, a 13 percent decrease, driven by decreased demand, partially offset by higher realized prices. Forteo revenue outside the U.S. was $360.3 million, a 33 percent decrease, 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 entry of generic and biosimilar competition due to the loss of patent exclusivity in the U.S., Japan and major European markets.

Emgality

For the fourth quarter of 2021, Emgality generated worldwide revenue of $161.5 million, an increase of 47 percent compared with the fourth quarter of 2020. U.S. revenue was $121.0 million, an increase of 25 percent, driven by higher realized prices and increased demand. Revenue outside the U.S. was $40.4 million, an increase of $27.1 million compared with the fourth quarter of 2020, driven by increased demand.

For the full year of 2021, worldwide Emgality revenue was $577.2 million, an increase of 59 percent compared with the full year of 2020. U.S. revenue increased 33 percent, to $434.5 million, driven by higher realized prices and increased demand. Revenue outside the U.S. was $142.7 million, an increase of $105.7 million primarily due to increased demand.

Tyvyt

For the fourth quarter of 2021, the company's Tyvyt revenue in China was $77.8 million, a decrease of 24 percent compared with the fourth quarter of 2020, primarily driven by lower realized prices due to the impact of the updated NRDL formulary in China on Tyvyt, partially offset by increased demand.

For the full year of 2021, the company's Tyvyt revenue in China was $418.1 million, an increase of 35 percent compared with the full year of 2020. This increase was due to increased volume and, to a lesser extent, the favorable impact of foreign exchange rates, partially offset by lower realized prices.

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 fourth quarter of 2021, Retevmo generated U.S. revenue of $31.4 million compared to revenue of $29.2 million in the third quarter of 2021. Outside the U.S., Retevmo, which launched during the second quarter of 2021, generated revenue of $7.2 million in the fourth quarter of 2021.

For the full year of 2021, worldwide Retevmo revenue was $114.7 million, an increase of $78.2 million compared with the full year 2020. Retevmo generated U.S. revenue of $99.4 million and revenue of $15.4 million outside the U.S. for the full year of 2021.

2022 Financial Guidance

The company has reaffirmed all elements of its 2022 financial guidance. EPS for 2022 are still expected to be in the range of $8.00 to $8.15 on a reported basis and $8.50 to $8.65 on a non-GAAP basis. The company's 2022 financial guidance reflects adjustments shown in the reconciliation table below.

	2022 Expectations	**% Change vs 2021**
Earnings per share (reported)	**$8.00 to $8.15**	**31% to 33%**
Amortization of intangible assets	.50	
Earnings per share (non-GAAP)	**$8.50 to $8.65**	**4% to 6%**
Numbers may not add due to rounding		

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

	2022 Guidance	
	Prior	Updated
Revenue	$27.8 to $28.3 billion	Unchanged

Gross Margin % of Revenue (reported)	Approx. 78%	Unchanged
Gross Margin % of Revenue (non-GAAP)	Approx. 80%	Unchanged
Marketing, Selling & Administrative	$6.4 to $6.6 billion	Unchanged
Research & Development	$7.0 to $7.2 billion	Unchanged
Other Income/(Expense)	$(100) million to $0	Unchanged
Tax Rate	Approx. 13 to 14%	Unchanged
Earnings per Share (reported)	$8.00 to $8.15	Unchanged
Earnings per Share (non-GAAP)	$8.50 to $8.65	Unchanged
Operating Margin (reported)	Approx. 30%	Unchanged
Operating Margin (non-GAAP)	Approx. 32%	Unchanged
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 fourth-quarter 2021 financial results conference call through a link on Lilly's website at www.lilly.com. The conference call will begin at 9 a.m. Eastern time today and will be available for replay via the website.

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 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)
Erbitux® (cetuximab, 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)
Third party trademarks used herein are trademarks of their respective owners.

Eli Lilly and Company Employment Information

	December 31, 2021	December 31, 2020
Worldwide Employees	35,238	34,960

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

	Three Months Ended December 31,			Twelve Months Ended December 31,		
	2021	2020	% Chg.	2021	2020	% Chg.
Revenue	$ 7,999.9	$ 7,440.0	8%	$28,318.4	$24,539.8	15%
Cost of sales	2,050.2	1,719.8	19%	7,312.8	5,483.3	33%
Research and development	1,959.4	1,838.0	7%	7,025.9	6,085.7	15%
Marketing, selling and administrative	1,592.0	1,553.9	2%	6,431.6	6,121.2	5%
Acquired in-process research and development	376.6	366.3	3%	874.9	660.4	32%
Asset impairment, restructuring and other special charges	104.5	(30.1)	NM	316.1	131.2	NM
Operating income	1,917.2	1,992.1	(4)%	6,357.1	6,058.0	5%
Net interest income (expense)	(74.0)	(83.4)		(314.4)	(326.6)	
Net other income (expense)	(3.3)	560.4		112.8	1,498.5	
Other income (expense)	(77.3)	477.0	NM	(201.6)	1,171.9	NM
Income before income taxes	1,839.9	2,469.1	(25)%	6,155.5	7,229.9	(15)%
Income tax expense	113.8	352.3	(68)%	573.8	1,036.2	(45)%
Net income	$ 1,726.1	$ 2,116.8	(18)%	$ 5,581.7	$ 6,193.7	(10)%
Earnings per share - diluted	$ 1.90	$ 2.32	(18)%	$ 6.12	$ 6.79	(10)%
Dividends paid per share	$ .85	.74	15%	$ 3.40	$ 2.96	15%
Weighted-average shares outstanding (thousands) - diluted	909,555	912,591		911,681	912,505	

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 December 31, 2021			Three Months Ended December 31, 2020		
	GAAP Reported	Adjustments[b]	Non-GAAP Adjusted[a]	GAAP Reported	Adjustments[c]	Non-GAAP Adjusted[a]
Cost of sales	**$ 2,050.2**	$ (137.4)	$ 1,912.8	**$ 1,719.8**	$ (127.3)	$ 1,592.5

Acquired in-process research and development	**376.6**	(376.6)	—	**366.3**	(366.3)	—
Asset impairment, restructuring and other special charges	**104.5**	(104.5)	—	**(30.1)**	30.1	—
Other income (expense)	**(77.3)**	70.6	(6.7)	**477.0**	(508.0)	(31.0)
Income tax expense	**113.8**	147.4	261.2	**352.3**	(35.4)	316.9
Net income	**1,726.1**	541.7	2,267.8	**2,116.8**	(9.1)	2,107.7
Earnings per share - diluted	**1.90**	0.59	2.49	**2.32**	(0.01)	2.31

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 December 31, 2021, include the following:

(Dollars in millions, except per share data)	Amortization[i]	IPR&D[ii]	Equity investments[iii]	Other specified items[iv]	**Total**
Cost of sales	$ (219.9)	$ —	$ —	$ 82.5	**$ (137.4)**
Acquired in-process research and development	—	(376.6)	—	—	**(376.6)**
Asset impairment, restructuring and other special charges	—	—	—	(104.5)	**(104.5)**
Other income (expense)	—	—	70.6	—	**70.6**
Income tax expense	46.0	79.3	14.5	7.6	**147.4**
Net income	173.9	297.3	56.1	14.5	**541.7**
Earnings per share - diluted	0.19	0.33	0.06	0.02	**0.59**

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

1. 1. 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 Foghorn Therapeutics Inc., QILU Regor Therapeutics Inc., and Entos Pharmaceuticals Inc.
   iii. Exclude gains and losses on investments in equity securities.
   iv. Exclude partial reversal of COVID-19 antibodies inventory charge and asset impairment, restructuring and other special charges primarily related to the impairment of a contract-based intangible asset from our acquisition of Loxo Oncology.

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

(Dollars in millions, except per share data)	Amortization [i]	IPR&D [ii]	Equity investments[iii]	Other specified items[iv]	**Total**
Cost of sales	$ (127.3)	$ —	$ —	$ —	**$ (127.3)**

Acquired in-process research and development	—	(366.3)	—	—	**(366.3)**
Asset impairment, restructuring and other special charges	—	—	—	30.1	**30.1**
Other income (expense)	—	—	(508.0)	—	**(508.0)**
Income tax expense	26.4	50.4	(106.7)	(5.5)	**(35.4)**
Net income	100.9	315.9	(401.3)	(24.6)	**(9.1)**
Earnings per share - diluted	0.11	0.35	(0.44)	(0.03)	**(0.01)**

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

1. 1.
   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 releated to business development transactions with Innovent Biologics, Inc., Disarm Therapeutics, Inc., and Fochon Pharmaceuticals, Ltd.
   iii. Exclude gains and losses on investments in equity securities.
   iv. Exclude adjustments to prior period estimates for asset impairment and severance costs.

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

	Twelve Months Ended December 31, 2021			Twelve Months Ended December 31, 2020		
	GAAP Reported	Adjustments[b]	Non-GAAP Adjusted[a]	GAAP Reported	Adjustments[c]	Non-GAAP Adjusted[a]
Cost of sales	**$ 7,312.8**	$ (908.8)	$ 6,404.0	**$ 5,483.3**	$ (415.2)	**$** 5,068.1
Acquired in-process research and development	**874.9**	(874.9)	—	**660.4**	(660.4)	—
Asset impairment, restructuring and other special charges	**316.1**	(316.1)	—	**131.2**	(131.2)	—
Other income (expense)	**(201.6)**	227.2	25.6	**1,171.9**	(1,322.7)	(150.8)
Income tax expense	**573.8**	472.0	1,045.8	**1,036.2**	(113.2)	923.0
Net income	**5,581.7**	1,855.0	7,436.7	**6,193.7**	(2.7)	6,191.0
Earnings per share - diluted	**6.12**	2.04	8.16	**6.79**	(0.01)	6.78

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 twelve months ended December 31, 2021, include the following:

(Dollars in millions, except per share data)	Amortization[i]	IPR&D[ii]	Equity investments[iii]	Repurchase of Debt[iv]	Other specified items[v]	Total

Cost of sales	$ (614.9)	$ —	$ —	$ —	(293.9)	**$ (908.8)**
Acquired in-process research and development	—	(874.9)	—	—	—	**(874.9)**
Asset impairment, restructuring and other special charges	—	—	—	—	(316.1)	**(316.1)**
Other income (expense)	—	—	(178.0)	405.2	—	**227.2**
Income tax expense	127.8	171.9	(34.4)	85.1	121.5	**472.0**
Net income	487.1	703.0	(143.5)	320.1	488.5	**1,855.0**
Earnings per share – diluted	0.53	0.77	(0.16)	0.35	0.54	**2.04**

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 Foghorn Therapeutics Inc., Rigel Pharmaceuticals, Inc., Precision Biosciences, Inc., Protomer Technologies Inc., Kumquat Biosciences Inc., Merus N.V., Lycia Therapeutics, Inc., QILU Regor Therapeutics Inc., Entos Pharmaceuticals Inc., ProQR Therapeutics N.V, MiNA Therapeutics Limited, and Asahi Kasei Pharma Corporation
- iii. Exclude gains and losses on investments in equity securities
- iv. Excludes charge related to the repurchase of higher-cost debt.
- v. Exclude COVID-19 antibodies inventory charge and asset impairment, restructuring and other special charges primarily related to an intangible asset impairment resulting from the sale of rights to Qbrexza, the impairment of a contract-based intangible asset from our acquisition of Loxo Oncology, as well as acquisition and integration costs associated with the acquisition of Prevail Therapeutics Inc.

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

(Dollars in millions, except per share data)	Amortization[(i)]	IPR&D[(ii)]	Equity investments[(iii)]	Other specified items[(iv)]	Total
Cost of sales	$ (411.0)	$ —	$ —	(4.2)	**$ (415.2)**
Acquired in-process research and development	—	(660.4)	—	—	**(660.4)**
Asset impairment, restructuring and other special charges	—	—	—	(131.2)	**(131.2)**
Other income (expense)	—	—	(1,322.7)	—	**(1,322.7)**
Income tax expense	85.3	75.5	(277.8)	3.8	**(113.2)**
Net income	325.7	584.9	(1,044.9)	131.6	**(2.7)**
Earnings per share - diluted	0.36	0.64	(1.15)	0.14	**(0.01)**

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

1. 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 Innovent Biologics, Inc., Petra Pharma Corporation, Disarm Therapeutics, Inc., Sitryx Therapeutics Limited, Fochon Pharmaceuticals, Ltd., AbCellera Biologics Inc., Evox Therapeutics Limited, and Shanghai Junshi Biosciences Co., Ltd.

iii. Exclude gains and losses on investments in equity securities.
iv. Exclude primarily severance costs incurred related to restructuring, as well as acquisition and integration costs as part of the closing of the acquisition of Dermira, Inc.

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