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Lilly Reports Fourth-Quarter and Full-Year 2016 Results

- *Fourth-quarter 2016 revenue increased 7 percent driven by volume growth from Trulicity and other new pharmaceutical products, while operating expenses remained flat.*
- *Fourth-quarter 2016 earnings per share were \$0.73 (reported), or \$0.95 (non-GAAP).*
- *Full-year 2016 revenue increased 6 percent to \$21.2 billion. Full-year 2016 earnings per share totaled \$2.58 (reported), or \$3.52 (non-GAAP).*
- *Significant pipeline progress continued with the FDA granting a new cardiovascular indication for Jardiance and approval for Synjardy XR and the European Commission granting a cardiovascular label update for Jardiance and conditional approval for Lartruvo.*
- *The company announced an agreement to acquire CoLucid Pharmaceuticals, Inc., which will enhance Lilly's existing portfolio in pain management for migraine, while adding a potential near-term launch to its late-stage pipeline.*
- *The company now expects 2017 EPS to be in the range of \$2.69 to \$2.79 on a reported basis. On a non-GAAP basis, the company has reaffirmed 2017 EPS to be in the range of \$4.05 to \$4.15.*
- *\$2.8 billion in cash was returned to shareholders in 2016 through dividends and share repurchases.*

Eli Lilly and Company (NYSE: LLY) today announced financial results for the fourth quarter and full year of 2016.

\$ in millions, except per share data	<u>Fourth Quarter</u>		<u>%</u>	<u>Full Year</u>		<u>%</u>
	<u>2016</u>	<u>2015</u>	<u>Change</u>	<u>2016</u>	<u>2015</u>	<u>Change</u>
Revenue	\$ 5,760.5	\$ 5,375.6	7%	\$ 21,222.1	\$ 19,958.7	6%
Net Income – Reported	771.8	478.4	61%	2,737.6	2,408.4	14%
EPS – Reported	0.73	0.45	62%	2.58	2.26	14%
Net Income – Non-GAAP	1,013.4	828.2	22%	3,735.6	3,656.3	2%
EPS – Non-GAAP	0.95	0.78	22%	3.52	3.43	3%

Certain financial information for 2016 and 2015 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 generally accepted accounting principles (GAAP) and include all revenue and expenses recognized during the periods. Non-GAAP measures exclude the items described in the reconciliation tables later in the release. The company's 2017 financial guidance is also 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.

“Newly launched products - including Trulicity, Cyramza, Jardiance and Taltz - led Lilly's volume-driven growth in 2016. Pipeline progress also continued with approvals of new products and new indications for existing products in our core therapeutic areas of diabetes, oncology and immunology,” said David A. Ricks, Lilly's president and CEO. “We expect this momentum to continue in 2017 and remain focused on launching new products, improving productivity and advancing our pipeline as we work to bring life-changing medicines to patients.”

Key Events Over the Last Three Months

Commercial

- Basaglar® (insulin glargine injection), part of the company's alliance with Boehringer Ingelheim, became available by prescription in the U.S.
- Galliprant® (grapiprant tablets) is now available to veterinarians for once-daily use in dogs with osteoarthritis. Galliprant is part of a collaboration between Lilly and Aratana Therapeutics, Inc.

Regulatory

- With respect to products on which we collaborate with Boehringer Ingelheim:
 - The U.S. Food and Drug Administration (FDA) approved and the company began

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- efforts to promote a new indication for Jardiance® (empagliflozin) tablets to reduce the risk of cardiovascular (CV) death in adults with type 2 diabetes and established CV disease.
- The FDA approved Synjardy® XR (empagliflozin and metformin hydrochloride extended-release) tablets for adults with type 2 diabetes.
 - The FDA approved supplemental new drug applications for Synjardy (empagliflozin/metformin hydrochloride), Synjardy XR and Glyxambi® (empagliflozin/linagliptin) to include data showing empagliflozin reduced the risk for CV death in adults with type 2 diabetes and established CV disease.
 - The European Commission granted approval to update the Jardiance label including a change to the indication statement and inclusion of data on the reduction of risk of CV death in patients with type 2 diabetes and established CV disease.
 - The European Commission granted marketing authorization for Glyxambi, a single pill combining Jardiance and Trajenta® (linagliptin), for use in adults with type 2 diabetes to improve blood sugar control when metformin and/or sulphonylurea and one of the monocomponents of Glyxambi do not provide adequate blood sugar control, or when a patient is already being treated with the free combination of Jardiance and Trajenta.
 - The European Commission granted conditional marketing authorization for Lartruvo™ (olaratumab), in combination with doxorubicin, to treat adults with advanced soft tissue sarcoma not amenable to curative treatment with radiotherapy or surgery and who have not been previously treated with doxorubicin. As part of a conditional marketing authorization, Lilly will need to provide results from an ongoing Phase 3 study. Until availability of the full data, the CHMP will review the benefits and risks of olaratumab annually to determine whether the conditional marketing authorization can be maintained.
 - The EMA's CHMP issued a positive opinion, recommending the approval of baricitinib, for the treatment of moderate-to-severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to, one or more disease-modifying anti-rheumatic drugs. Baricitinib may be used as monotherapy or in combination with
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methotrexate. Baricitinib is part of a development and commercialization collaboration with Incyte.

- The FDA extended the review period for the new drug application (NDA) for investigational baricitinib, a once-daily oral medication for the treatment of moderate to severe rheumatoid arthritis. The NDA for baricitinib was submitted to the FDA in January 2016. The FDA extended the action date to allow time to review additional data analyses recently submitted by Lilly in response to the FDA's information requests. The submission of the additional information has been determined by the FDA to constitute a Major Amendment to the NDA, resulting in an extension of the Prescription Drug User Fee Act goal date by three months.

Clinical

- The company announced that solanezumab did not meet the primary endpoint in a Phase 3 study of people with mild dementia due to Alzheimer's disease. Lilly will not pursue regulatory submissions for solanezumab for the treatment of mild dementia due to Alzheimer's disease.

Business Development/Other

- The company announced an agreement to acquire CoLucid Pharmaceuticals, Inc. for \$46.50 per share or approximately \$960 million. Lilly will add lasmiditan, in development for the acute treatment of migraine, to its Phase 3 pipeline.
- The company completed the acquisition of Boehringer Ingelheim Vetmedica, Inc.'s U.S. feline, canine and rabies vaccines portfolio.
- The U.S. Court of Appeals for the Federal Circuit upheld the decision of the U.S. District Court for the Southern District of Indiana and ruled in the company's favor regarding validity and infringement of the vitamin regimen patent for Alimta® (pemetrexed for injection).
- The company and AstraZeneca announced a worldwide agreement to co-develop MEDI1814, an antibody selective for amyloid-beta 42, which is currently in Phase 1 trials as a potential disease-modifying treatment for Alzheimer's disease.
- The company announced the expansion of an existing immuno-oncology collaboration with Merck to add a new study of Lilly's Lartruvo with Keytruda® (pembrolizumab) in patients with previously treated advanced or metastatic soft tissue sarcoma.

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- The company announced that people who use Lilly insulin can access discounted prices for their purchases starting January 1, 2017. The discounts, provided by Lilly through a partnership with Express Scripts, may reduce costs for people who pay full retail prices at U.S. pharmacies, such as those who have no insurance or are in the deductible phase of their high-deductible insurance plans.
 - As part of its previously announced share repurchase program, the company paid \$300 million to repurchase company stock in the fourth quarter of 2016. For the full year 2016, the company returned \$2.8 billion in cash to shareholders through both its dividend and share repurchase program.

Fourth-Quarter Reported Results

In the fourth quarter of 2016, worldwide revenue was \$5.760 billion, an increase of 7 percent compared with the fourth quarter of 2015. The revenue increase was driven by an 8 percent increase due to volume, a 1 percent favorable impact of foreign exchange rates, and a realized price decrease of 1 percent, primarily due to lower realized prices outside the U.S. The increase in worldwide volume was driven by Trulicity® and other new pharmaceutical products, including Jardiance, Taltz®, Cymaza® and Basaglar. The increase in volume was also driven by Humalog®, Humulin® and companion animal products. The total volume increase was partially offset by decreased volumes for Alimta, Zyprexa® and Cymbalta®.

Revenue in the U.S. increased 14 percent to \$3.223 billion, driven primarily by increased volumes for Trulicity, Humalog, Taltz, Jardiance, Humulin and companion animal products. Realized prices increased U.S. revenue by 1 percent, reflecting a favorable adjustment of approximately \$130 million related to changes in estimates for rebates and discounts, primarily related to Humalog.

Revenue outside the U.S. decreased 1 percent to \$2.537 billion, as lower realized prices and volume from the loss of exclusivity for Alimta in several countries, Zyprexa in Japan, and Cymbalta in Europe and Canada were largely offset by increased volume for several new pharmaceutical products,

including Cyramza, Trulicity, Basaglar and Jardiance, and the favorable impact of foreign exchange rates, primarily the Japanese yen, partially offset by other foreign currencies.

Gross margin increased 8 percent to \$4.295 billion in the fourth quarter of 2016 compared with the fourth quarter of 2015. Gross margin as a percent of revenue was 74.6 percent, an increase of 0.4 percentage points compared with the fourth quarter of 2015. The increase in gross margin percent was primarily due to increased volume in the U.S. and efficiencies in manufacturing processes.

Operating expenses in the fourth quarter of 2016, defined as the sum of research and development, and marketing, selling and administrative expenses, remained flat at \$3.241 billion. Research and development expenses were flat at \$1.451 billion, or 25.2 percent of revenue. Marketing, selling and administrative expenses remained flat at \$1.790 billion, as reduced spending on late-life-cycle products was largely offset by increased expenses related to new products.

In the fourth quarter of 2016, the company recognized an acquired in-process research and development charge of \$30.0 million associated with an agreement with AstraZeneca to co-develop MEDI1814. In the fourth quarter of 2015, the company recognized acquired in-process research and development charges of \$199.0 million, primarily associated with the acquisition of worldwide rights to an intranasal glucagon from Locemia Solutions.

In the fourth quarter of 2016, the company recognized asset impairment, restructuring and other special charges of \$147.6 million. The charges are primarily associated with global severance costs and integration costs related to the acquisition of Novartis Animal Health. In the fourth quarter of 2015, the company recognized asset impairment, restructuring and other special charges of \$144.9 million, comprised of severance costs, integration costs related to the acquisition of Novartis Animal Health and asset impairments.

Operating income in the fourth quarter of 2016 was \$876.2 million, an increase of \$476.3 million compared with the fourth quarter of 2015, due to higher revenue and lower acquired in-process research and development charges.

Other income (expense) was income of \$15.8 million in the fourth quarter of 2016, compared with income of \$44.7 million in the fourth quarter of 2015.

The effective tax rate was an expense of 13.5 percent in the fourth quarter of 2016, compared with a benefit of 7.6 percent in the fourth quarter of 2015. The lower effective tax rate in the fourth quarter of 2015 is primarily due to the inclusion of full-year benefits for certain U.S. tax provisions, including the R&D tax credit, reinstated in the fourth quarter of 2015, and the favorable tax impact of the acquired in-process research and development charges. The effective tax rate in the fourth quarter of 2016 was reduced by a net discrete tax benefit, including a tax benefit of approximately \$40 million for the early adoption of the new accounting standard related to stock-based compensation.

In the fourth quarter of 2016, net income increased 61 percent to \$771.8 million, and earnings per share increased 62 percent to \$0.73, compared with \$478.4 million and \$0.45, respectively, in the fourth quarter of 2015. The increases in net income and earnings per share were driven by higher operating income, partially offset by a higher effective tax rate.

Fourth-Quarter Non-GAAP Measures

On a non-GAAP basis, fourth quarter 2016 gross margin increased 7 percent to \$4.457 billion. Gross margin as a percent of revenue was 77.4 percent, an increase of 0.1 percentage point compared with the fourth quarter of 2015. The increase in gross margin percent was primarily due to increased volume in the U.S. and efficiencies in manufacturing processes.

Operating income increased \$305.5 million, or 33 percent, to \$1.218 billion in the fourth quarter of 2016, due to higher revenue.

The effective tax rate increased 4.4 percentage points to 17.9 percent compared with the fourth quarter of 2015. The higher effective tax rate is primarily due to the inclusion of full-year benefits for certain U.S. tax provisions, including the R&D tax credit, reinstated in the fourth quarter of 2015, partially offset by a higher net discrete tax benefit in the fourth quarter of 2016.

In the fourth quarter of 2016, net income and earnings per share increased 22 percent to \$1.013 billion, and \$0.95, respectively, compared with \$828.2 million, and \$0.78, respectively, in the fourth quarter of 2015. The increases in net income and earnings per share were driven by higher operating income, partially offset by a higher effective tax rate.

For further detail of 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.

	<u>Fourth Quarter</u>		
	<u>2016</u>	<u>2015</u>	<u>% Change</u>
Earnings per share (reported)	\$ 0.73	\$ 0.45	62%
Amortization of intangible assets	.11	.11	
Asset impairment, restructuring and other special charges	.10	.10	
Acquired in-process research and development	.02	.12	
Earnings per share (non-GAAP)	<u>\$ 0.95</u>	<u>\$ 0.78</u>	22%
Numbers may not add due to rounding.			

Full-Year Reported Results

For the full year 2016, worldwide revenue increased 6 percent compared with 2015 to \$21.222 billion. Higher revenue was due to increased volume, as realized prices and the impact of foreign exchange rates were relatively flat. The worldwide volume increase was primarily driven by Trulicity and other new pharmaceutical products, including Cyramza, Jardiance and Taltz, as well as Humalog and Erbitux (due to the transfer of commercialization rights in North America to Lilly). The volume increases were partially offset by the impact of the loss of exclusivity for Cymbalta in Europe and Canada, Zyprexa in Japan, and Alimta in several countries.

Revenue in the U.S. increased 14 percent to \$11.506 billion, driven by increased volume for several pharmaceutical products, including Trulicity, Humalog, Erbitux (due to the transfer of commercialization rights in North America to Lilly), Taltz and Jardiance, partially offset by lower volumes for Zyprexa. U.S. revenue also benefited from reductions to the Cymbalta reserve for expected product returns of approximately \$175 million in 2016, favorably affecting both volume and price.

Revenue outside the U.S. decreased 1 percent to \$9.716 billion as lower realized prices and volume from the losses of exclusivity for Cymbalta in Europe and Canada, Zyprexa in Japan, and Alimta in several countries were largely offset by increased volume for several new pharmaceutical products, including Cyramza and Trulicity.

Gross margin increased 4 percent to \$15.567 billion in 2016. Gross margin as a percent of revenue was 73.4 percent, a decrease of 1.4 percentage points compared with 2015. The decline in gross margin percent was primarily due to a lower benefit from foreign exchange rates on international inventories sold.

Total operating expenses increased 3 percent to \$11.696 billion in 2016. Research and development expenses increased 9 percent to \$5.244 billion, or 24.7 percent of revenue, driven primarily by higher

late-stage clinical development costs and, to a lesser extent, higher charges related to development milestones. Marketing, selling and administrative expenses decreased 1 percent to \$6.452 billion, as reduced spending on late-life-cycle products was largely offset by expenses related to new products.

In 2016, the company recognized an acquired in-process research and development charge of \$30.0 million associated with the agreement with AstraZeneca to co-develop MEDI1814. In 2015, the company recognized acquired in-process research and development charges of \$535.0 million resulting from business development activity, primarily a collaboration with Pfizer and the acquisition of worldwide rights to Locemia's intranasal glucagon.

In 2016, the company recognized asset impairment, restructuring and other special charges of \$382.5 million. The charges are primarily associated with integration and severance costs related to the acquisition of Novartis Animal Health, other global severance costs, and asset impairments related to the closure of an animal health manufacturing facility in Ireland. In 2015, the company recognized asset impairment, restructuring, and other special charges of \$367.7 million related to severance costs, integration costs for Novartis Animal Health and asset impairments.

Operating income in 2016 increased 29 percent compared with 2015 to \$3.459 billion, as higher gross margin and lower acquired in-process research and development charges were partially offset by increased research and development costs.

Other income (expense) was expense of \$84.8 million in 2016, compared with income of \$100.6 million in 2015. Other expense in 2016 included a \$203.9 million charge related to the impact of the Venezuelan financial crisis, including the significant deterioration of the bolívar, partially offset by net gains of \$101.6 million on investments. Other income in 2015 included net gains of \$236.7 million on investments, partially offset by a net charge of \$152.7 million related to the repurchase of \$1.65 billion of debt.

The effective tax rate was 18.9 percent in 2016, compared with 13.7 percent in 2015. The higher effective tax rate for 2016 reflects several factors in both years: in 2016, the unfavorable tax effect of the charge related to the impact of the Venezuelan financial crisis and certain asset impairment, restructuring and other special charges; and in 2015, the favorable tax impact of the acquired in-process research and development charges, net charges related to the repurchase of debt and asset impairment, restructuring and other special charges. The higher effective tax rate was partially offset by a net discrete tax benefit.

For the full year 2016, net income and earnings per share increased 14 percent to \$2.738 billion, and \$2.58, respectively, compared with \$2.408 billion, and \$2.26, respectively, in 2015. The increases in net income and earnings per share were due to higher operating income, partially offset by lower other income and a higher effective tax rate.

Full-Year Non-GAAP Measures

On a non-GAAP basis for the full year 2016, operating income increased \$183.3 million, or 4 percent, to \$4.555 billion, as higher gross margin was partially offset by higher operating expenses. The effective tax rate was 20.1 percent in 2016, compared with 20.9 percent in 2015. Net income increased 2 percent and earnings per share increased 3 percent to \$3.736 billion, and \$3.52, respectively.

For further detail of 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.

	<u>Full Year</u>		
	<u>2016</u>	<u>2015</u>	<u>% Change</u>
Earnings per share (reported)	\$ 2.58	\$ 2.26	14%
Amortization of intangible assets	.44	.39	
Asset impairment, restructuring and other special charges	.29	.25	
Venezuela charge	.19	—	
Acquired in-process research and development	.02	.33	
Novartis Animal Health inventory step-up	—	.10	
Net charge related to repurchase of debt	—	.09	
Earnings per share (non-GAAP)	\$ 3.52	\$ 3.43	3%
Numbers may not add due to rounding.			

Select Revenue Highlights

<i>(Dollars in millions)</i>						
Established Pharmaceutical Products	Fourth Quarter			Full Year		
	2016	2015	% Change	2016	2015	% Change
Humalog	\$ 819.8	\$ 798.7	3%	\$ 2,768.8	\$ 2,841.9	(3)%
Cialis	676.3	638.4	6%	2,471.6	2,310.7	7%
Alimta	541.6	627.2	(14)%	2,283.3	2,493.1	(8)%
Forteo	422.5	377.9	12%	1,500.0	1,348.3	11%
Humulin®	355.3	358.6	(1)%	1,365.9	1,307.4	4%
Cymbalta	181.8	223.6	(19)%	930.5	1,027.6	(9)%
Strattera®	243.2	221.6	10%	854.7	784.0	9%
Zyprexa	153.0	229.1	(33)%	725.3	940.3	(23)%
Erbitux	153.7	176.2	(13)%	687.0	485.0	42%
Effient®	140.9	140.3	0%	535.2	523.0	2%
New Pharmaceutical Products						
Trulicity	337.0	112.5	NM	925.5	248.7	NM
Cyramza	177.1	117.5	51%	614.1	383.8	60%
Jardiance ^(a)	76.1	14.6	NM	201.9	60.2	NM
Taltz	61.3	—	NM	113.1	—	NM
Basaglar	39.5	7.3	NM	86.1	11.1	NM
Portrazza®	3.8	0.6	NM	14.8	0.6	NM
Lartruvo	11.9	—	NM	11.9	—	NM
Subtotal	706.7	252.5	NM	1,967.4	704.4	NM
Animal Health	837.6	811.7	3%	3,158.2	3,181.0	(1)%
Total Revenue	\$ 5,760.5	\$ 5,375.6	7%	\$ 21,222.1	\$ 19,958.7	6%

^(a) Jardiance includes Glyxambi and Synjardy
 NM – not meaningful
 Numbers may not add due to rounding

Selected Established Pharmaceutical Products

Humalog

For the fourth quarter of 2016, worldwide Humalog revenue increased 3 percent compared with the fourth quarter of 2015 to \$819.8 million. Revenue in the U.S. increased 3 percent to \$524.8 million, as increased demand was partially offset by lower realized prices. Realized prices in the fourth quarter of both 2015 and 2016 reflect benefits related to estimates for rebates and discounts, with the benefit in 2016 being larger. Revenue outside the U.S. increased 3 percent to \$295.0 million, driven by increased volume, partially offset by the unfavorable impact of foreign exchange rates.

For the full year 2016, worldwide Humalog revenue decreased 3 percent to \$2.769 billion. U.S.

Humalog revenue for 2016 was \$1.685 billion, a 5 percent decrease, driven by lower realized prices, partially offset by increased demand. Humalog revenue outside the U.S. was \$1.084 billion, a 1 percent increase, driven by increased volume and, to a lesser extent, higher realized prices, partially offset by the unfavorable impact of foreign exchange rates.

Cialis

For the fourth quarter of 2016, worldwide Cialis revenue increased 6 percent to \$676.3 million. U.S. revenue of Cialis was \$413.8 million in the fourth quarter, a 7 percent increase compared with the fourth quarter of 2015, driven by higher realized prices, partially offset by decreased demand. Revenue of Cialis outside the U.S. increased 4 percent, to \$262.5 million, driven by increased volume and higher realized prices, partially offset by the unfavorable impact of foreign exchange rates.

For the full year 2016, worldwide Cialis revenue increased 7 percent to \$2.472 billion. U.S. Cialis revenue for 2016 was \$1.469 billion, a 17 percent increase, driven by higher realized prices. Cialis revenue outside the U.S. was \$1.002 billion, a 5 percent decline, driven by the unfavorable impact of foreign exchange rates and decreased volume, partially offset by higher realized prices.

Alimta

For the fourth quarter of 2016, Alimta generated worldwide revenue of \$541.6 million, which decreased 14 percent compared with the fourth quarter of 2015. U.S. revenue of Alimta decreased 5 percent, to \$269.8 million, driven by decreased demand due to competitive pressure, partially offset by higher realized prices. Revenue outside the U.S. decreased 21 percent, to \$271.7 million, driven primarily by the loss of exclusivity in several countries and to a lesser extent lower realized prices.

For the full year 2016, worldwide Alimta revenue decreased 8 percent to \$2.283 billion. U.S. Alimta revenue for 2016 was \$1.101 billion, a 5 percent decline, driven by decreased demand due to competitive pressure. Alimta revenue outside the U.S. was \$1.182 billion, an 11 percent decline, driven primarily by the loss of exclusivity in several countries.

Forteo

Fourth-quarter 2016 worldwide revenue for Forteo was \$422.5 million, a 12 percent increase compared with the fourth quarter of 2015. U.S. revenue increased 23 percent to \$229.3 million, driven by higher realized prices. Revenue outside the U.S. increased 1 percent to \$193.1 million, driven by increased volume and the favorable impact of foreign exchange rates, largely offset by lower realized prices.

For the full year 2016, worldwide Forteo revenue increased 11 percent to \$1.500 billion. U.S. Forteo revenue for 2016 was \$770.5 million, a 26 percent increase driven by higher realized prices. Forteo revenue outside the U.S. was \$729.4 million, a 1 percent decline, driven by lower realized prices, largely offset by increased volume and the favorable impact of foreign exchange rates.

Humulin

Worldwide Humulin revenue for the fourth quarter of 2016 decreased 1 percent compared with the fourth quarter of 2015 to \$355.3 million. U.S. revenue increased 5 percent to \$221.8 million, driven by

increased demand, largely offset by lower realized prices. Revenue outside the U.S. decreased 9 percent, to \$133.5 million, driven by the unfavorable impact of foreign exchange rates, lower realized prices and decreased volume.

For the full year 2016, worldwide Humulin revenue increased 4 percent to \$1.366 billion. U.S. revenue for 2016 was \$861.8 million, a 13 percent increase, driven by increased demand and, to a lesser extent, higher realized prices. The increase in realized prices resulted from a change in estimate of a government rebate in the first quarter of 2016. Revenue outside the U.S. was \$504.1 million, a 7 percent decline, driven by the unfavorable impact of foreign exchange rates and, to a lesser extent, decreased volume and lower realized prices.

New Pharmaceutical Products

Trulicity

Fourth-quarter 2016 worldwide Trulicity revenue was \$337.0 million. U.S. revenue was \$268.1 million, driven by growth in the GLP-1 market and increased share of market for Trulicity. Revenue outside the U.S. was \$69.0 million.

For the full year 2016, worldwide Trulicity revenue was \$925.5 million. U.S. revenue was \$737.6 million, driven by growth in the GLP-1 market and increased share of market for Trulicity. Revenue outside the U.S. was \$187.9 million.

Cyramza

For the fourth quarter of 2016, worldwide Cyramza revenue was \$177.1 million, an increase of 51 percent compared with the fourth quarter of 2015. U.S. revenue was \$63.6 million, a decline of 8 percent, due to competitive pressure. Revenue outside the U.S. was \$113.5 million, primarily due to strong uptake for the gastric cancer indication in Japan.

For the full year 2016, worldwide Cyramza revenue was \$614.1 million, an increase of 60 percent compared with 2015. U.S. revenue was \$270.1 million, a decline of 3 percent, due to competitive pressure. Revenue outside the U.S. was \$344.0 million, primarily due to strong uptake for the gastric cancer indication in Japan.

Jardiance

The company's worldwide Jardiance revenue during the fourth quarter of 2016 was \$76.1 million. U.S. revenue was \$55.8 million, driven by growth in the SGLT2 class and increased share of market for Jardiance. Revenue outside the U.S. was \$20.4 million. Jardiance is part of the company's alliance with Boehringer Ingelheim, and Lilly reports as revenue a portion of Jardiance's gross margin.

For the full year 2016, worldwide Jardiance revenue was \$201.9 million. U.S. revenue was \$144.5 million, driven by growth in the SGLT2 class and increased share of market for Jardiance. Revenue outside the U.S. was \$57.4 million.

Taltz

For the fourth quarter of 2016, Taltz, a treatment for moderate-to-severe plaque psoriasis, generated worldwide revenue of \$61.3 million. U.S. revenue was \$59.5 million due to increased share of market for Taltz.

For the full year 2016, Taltz generated worldwide revenue of \$113.1 million. U.S. revenue was \$110.8 million.

Basaglar

For the fourth quarter of 2016, Basaglar, a treatment to control high blood sugar in adults and children with type 1 diabetes and adults with type 2 diabetes, generated worldwide revenue of \$39.5 million. Basaglar launched in the U.S. in mid-December 2016 and generated revenue of \$15.8 million, largely due to initial wholesaler and retailer stocking. Basaglar is part of the company's alliance with Boehringer Ingelheim.

For the full year 2016, Basaglar generated worldwide revenue of \$86.1 million.

Portrazza

For the fourth quarter of 2016, Portrazza, a first-line treatment for metastatic squamous non-small cell lung cancer, generated worldwide revenue of \$3.8 million.

For the full year 2016, Portrazza generated worldwide revenue of \$14.8 million.

Lartruvo

For the fourth quarter and full year of 2016, Lartruvo, a treatment in combination with doxorubicin for adults with advanced soft tissue sarcoma not amenable to curative treatment with radiotherapy or surgery and who have not been previously treated with doxorubicin, generated worldwide revenue of \$11.9 million. Lartruvo was launched in the U.S. and certain European countries in the fourth quarter of 2016.

Animal Health

In the fourth quarter of 2016, worldwide animal health revenue totaled \$837.6 million, an increase of 3 percent compared with the fourth quarter of 2015. U.S. animal health revenue increased 2 percent to \$389.0 million, due to increased revenue for companion animal products reflecting new launches and expanding relationships with distributors, largely offset by decreased revenue for food animal products due to market access pressures. Animal health revenue outside the U.S. increased 4 percent to \$448.6 million, primarily due to increased revenue for food animal products. Excluding the impact of foreign exchange rates, worldwide animal health revenue increased 4 percent.

For the full year 2016, worldwide animal health revenue totaled \$3.158 billion, a decline of 1 percent compared with the full year 2015. U.S. animal health revenue increased 1 percent, to \$1.564 billion, primarily due to uptake of new companion animal products, partially offset by decreased revenue for food animal products. Animal health revenue outside the U.S. was \$1.594 billion, a 3 percent decline driven by the unfavorable impact of foreign exchange rates. Excluding the impact of foreign exchange rates, worldwide animal health revenue increased 1 percent.

2017 Financial Guidance

The company has revised certain elements of its 2017 financial guidance. Earnings per share for 2017 are now expected to be in the range of \$2.69 to \$2.79 on a reported basis, primarily due to the estimated acquired in-process research and development charge related to the planned acquisition of CoLucid Pharmaceuticals. Earnings per share for 2017 are still expected to be \$4.05 to \$4.15 on a non-GAAP basis.

	<u>2017</u> <u>Expectations</u>	<u>% Change</u>
Earnings per share (reported)	\$2.69 to \$2.79	4% to 8%
Acquired in-process research and development charge related to the planned acquisition of CoLucid Pharmaceuticals ⁽¹⁾	.80	
Amortization of intangible assets ⁽¹⁾	.45	
Inventory step-up costs associated with the acquisition of Boehringer Ingelheim Vetmedica's U.S. feline, canine and rabies vaccines portfolio ⁽¹⁾⁽²⁾	.06	
Asset impairment, restructuring and other special charges, including Novartis Animal Health integration costs	.05	
Earnings per share (non-GAAP)	<u>\$4.05 to \$4.15</u>	15% to 18%
⁽¹⁾ Subject to acquisition accounting adjustments		
⁽²⁾ Subject to final inventory quantities purchased		
Numbers may not add due to rounding		

The company still anticipates 2017 revenue between \$21.8 billion and \$22.3 billion. Excluding the impact of foreign exchange rates, the company expects revenue growth from animal health products and a number of established pharmaceutical products including Trajenta, Forteo and Humalog, as well as higher revenue from new products including Trulicity, Taltz, Basaglar, Cyramza, Jardiance and Lartruvo.

Marketing, selling and administrative expenses are still expected to be in the range of \$6.4 billion to \$6.6 billion. Research and development expenses are still expected to be in the range of \$4.9 billion to \$5.1 billion.

The 2017 tax rate is now expected to be approximately 24.5 percent on a reported basis, primarily due to the non-deductibility of the estimated acquired in-process research and development charge related to the planned acquisition of CoLucid Pharmaceuticals. The 2017 tax rate on a non-GAAP basis is still expected to be approximately 22.0 percent.

The following table summarizes the company's 2017 financial guidance:

	2017 Guidance	
	<u>Prior</u>	<u>Revised</u>
Revenue	\$21.8 to \$22.3 billion	Unchanged
Gross Margin % of Revenue (reported)	Approx. 73.5%	Unchanged
Gross Margin % of Revenue (non-GAAP)	Approx. 77.0%	Unchanged
Marketing, Selling & Administrative	\$6.4 to \$6.6 billion	Unchanged
Research & Development	\$4.9 to \$5.1 billion	Unchanged
Other Income/(Expense)	\$0 to \$100 million	Unchanged
Tax Rate (reported)	Approx. 20.0%	Approx. 24.5%
Tax Rate (non-GAAP)	Approx. 22.0%	Unchanged
Earnings per Share (reported)	\$3.51 to \$3.61	\$2.69 to \$2.79
Earnings per Share (non-GAAP)	\$4.05 to \$4.15	Unchanged
Capital Expenditures	Approx. \$1.2 billion	Unchanged
Non-GAAP adjustments are consistent with 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 and full-year 2016 financial results conference call through a link on Lilly's website at www.lilly.com. The conference call will be held today from 9:00 a.m. to 10:30 a.m. Eastern Standard Time (EST) and will be available for replay via the website.

Lilly is a global healthcare leader that unites caring with discovery to 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 voluntarism. To learn more about Lilly, please visit us at www.lilly.com and <http://newsroom.lilly.com/social-channels>. F-LLY

This press release contains management's current intentions and expectations for the future, all of which are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. The words "estimate", "project", "intend", "expect", "believe", "target", "anticipate" and similar expressions are intended to identify forward-looking statements. Actual results may differ materially due to various factors. There are significant risks and uncertainties in pharmaceutical research and development. There can be no guarantees that pipeline products will receive the necessary clinical and manufacturing regulatory approvals or that they will prove to be commercially successful. The company's results may also be affected by such factors as the timing of anticipated regulatory approvals and launches of new products; market uptake of recently launched products; competitive developments affecting current products; the expiration of intellectual property protection for certain of the company's products; the company's ability to protect and enforce patents and other intellectual property; the impact of governmental actions regarding pricing, importation, and reimbursement for pharmaceuticals, including U.S. health care reform; regulatory compliance problems or government investigations; regulatory actions regarding currently marketed products; unexpected safety or efficacy concerns associated with the company's products; issues with product supply stemming from manufacturing difficulties or disruptions; regulatory changes or other developments; changes in patent law or regulations related to data-package exclusivity; litigation involving current or future products; the extent to which third-party indemnification obligations relating to product liability litigation and similar matters will be performed; unauthorized disclosure of trade secrets or other confidential data stored in the company's information systems and networks; changes in tax law and regulations; changes in inflation, interest rates, and foreign currency exchange rates; asset impairments and restructuring charges; changes in accounting standards promulgated by the Financial Accounting Standards Board and the Securities and Exchange Commission (SEC); acquisitions and business development transactions and related integration costs; and the impact of exchange rates and global macroeconomic conditions. For additional information about the factors that could cause actual results to differ materially from forward-looking statements, please see the company's latest Form 10-Q and Form 10-K filed with the SEC. You should not place undue reliance on forward-looking statements, which

speaking only as of the date of this release. Except as is required by law, the company expressly disclaims any obligation to publicly release any revisions to forward-looking statements to reflect events after the date of this release.

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Alimta® (pemetrexed disodium, Lilly)
 Basaglar® (insulin glargine injection, Lilly)
 Cialis® (tadalafil, Lilly)
 Cymbalta® (duloxetine hydrochloride, Lilly)
 Cyramza® (ramucirumab, Lilly)
 Effient® (prasugrel, Lilly)
 Erbitux® (cetuximab, Lilly)
 Forteo® (teriparatide of recombinant DNA origin injection, Lilly)
 Galliprant® (grapiprant tablets, Aratana Therapeutics)
 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)
 Keytruda® (pembrolizumab, Merck)
 Lartruvo™ (olaratumab, Lilly)
 Portrazza® (necitumumab, Lilly)
 Synjardy® (empagliflozin/metformin, Boehringer Ingelheim)
 Taltz® (ixekizumab, Lilly)
 Trajenta® (linagliptin, Boehringer Ingelheim)
 Trulicity® (dulaglutide, Lilly)
 Zyprexa® (olanzapine, Lilly)

Eli Lilly and Company Employment Information

	<u>December 31, 2016</u>	<u>December 31, 2015</u>
Worldwide Employees	41,975	41,275

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,		
	2016	2015	% Chg.	2016	2015	% Chg.
Revenue	\$ 5,760.5	\$ 5,375.6	7%	\$ 21,222.1	\$ 19,958.7	6%
Cost of sales	1,466.0	1,389.2	6%	5,654.9	5,037.2	12%
Research and development	1,450.6	1,444.2	0%	5,243.9	4,796.4	9%
Marketing, selling and administrative	1,790.1	1,798.4	0%	6,452.0	6,533.0	(1)%
Acquired in-process research and development	30.0	199.0	(85)%	30.0	535.0	(94)%
Asset impairment, restructuring and other special charges	147.6	144.9	2%	382.5	367.7	4%
Operating income	876.2	399.9	NM	3,458.8	2,689.4	29%
Net interest income (expense)	(19.5)	(20.4)		(76.5)	(74.2)	
Net other income (expense)	35.3	65.1		(8.3)	174.8	
Other income (expense)	15.8	44.7	(65)%	(84.8)	100.6	NM
Income before income taxes	892.0	444.6	NM	3,374.0	2,790.0	21%
Income taxes	120.2	(33.8)	NM	636.4	381.6	67%
Net income	\$ <u>771.8</u>	\$ <u>478.4</u>	61%	\$ <u>2,737.6</u>	\$ <u>2,408.4</u>	14%
Earnings per share – diluted	\$ <u>0.73</u>	\$ <u>0.45</u>	62%	\$ <u>2.58</u>	\$ <u>2.26</u>	14%
Dividends paid per share	\$ 0.51	\$ 0.50	2%	\$ 2.04	\$ 2.00	2%
Weighted-average shares outstanding (thousands) – diluted	1,061,498	1,064,893		1,061,825	1,065,720	

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, 2016			Three Months Ended December 31, 2015		
	GAAP Reported	Adjustments ^(c)	Non-GAAP Adjusted ^(a)	GAAP Reported	Adjustments ^(d)	Non-GAAP Adjusted ^(a)
Revenue	\$ 5,760.5	\$ —	\$ 5,760.5	\$ 5,375.6	\$ —	\$ 5,375.6
Cost of sales	1,466.0	(162.7)	1,303.3	1,389.2	(166.9)	1,222.3
Operating expenses ^(b)	3,240.7	(1.8)	3,238.9	3,242.6	(2.1)	3,240.5
Acquired in-process research and development	30.0	(30.0)	—	199.0	(199.0)	—
Asset impairment, restructuring and other special charges	147.6	(147.6)	—	144.9	(144.9)	—
Other income (expense)	15.8	—	15.8	44.7	—	44.7
Income taxes	120.2	100.5	220.7	(33.8)	163.1	129.3
Net income	\$ 771.8	241.6	\$ 1,013.4	\$ 478.4	349.8	\$ 828.2
Earnings per share – diluted	\$ 0.73	0.23	\$ 0.95	\$ 0.45	0.33	\$ 0.78

Numbers may not add due to rounding.

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

- (b) Operating expenses include research and development and marketing, selling and administrative expenses.
- (c) Adjustments to certain GAAP reported measures for the three months ended December 31, 2016, include the following:

(Dollars in millions, except per share data)	Amortization (i)	IPR&D (ii)	Other specified items ⁽ⁱⁱⁱ⁾	Total Adjustments
Revenue	\$ —	\$ —	\$ —	\$ —
Cost of sales	(162.7)	—	—	(162.7)
Operating expenses	(1.8)	—	—	(1.8)
Acquired in-process research and development	—	(30.0)	—	(30.0)
Asset impairment, restructuring and other special charges	—	—	(147.6)	(147.6)
Other income (expense)	—	—	—	—
Income taxes	50.8	10.5	39.1	100.5
Net income	\$ 113.7	\$ 19.5	\$ 108.4	\$ 241.6
Earnings per share – diluted	\$ 0.11	\$ 0.02	\$ 0.10	\$ 0.23

Numbers may not add due to rounding.

- 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 are related to an agreement with AstraZeneca to co-develop MEDI1814.
- iii. Exclude global severance costs and integration costs related to the acquisition of Novartis Animal Health.

- (d) Adjustments to certain GAAP reported measures for the three months ended December 31, 2015, include the following:

(Dollars in millions, except per share data)	Amortization (i)	IPR&D (ii)	Other specified items(iii)	Total Adjustments
Revenue	\$ —	\$ —	\$ —	\$ —
Cost of sales	(166.9)	—	—	(166.9)
Operating expenses	(2.1)	—	—	(2.1)
Acquired in-process research and development	—	(199.0)	—	(199.0)
Asset impairment, restructuring and other special charges	—	—	(144.9)	(144.9)
Other income (expense)	—	—	—	—
Income taxes	55.4	69.7	38.1	163.1
Net income	\$ 113.6	\$ 129.4	\$ 106.8	\$ 349.8
Earnings per share – diluted	\$ 0.11	\$ 0.12	\$ 0.10	\$ 0.33

Numbers may not add due to rounding.

- 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 are primarily related to a \$149.0 million payment to Locemia Solutions associated with the acquisition of worldwide rights to an intranasal glucagon.
- iii. Exclude costs associated with restructuring to reduce the company's cost structure, asset impairments, and integration costs associated with the acquisition of Novartis Animal Health.

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, 2016			Twelve Months Ended December 31, 2015		
	GAAP Reported	Adjustments ^(c)	Non-GAAP Adjusted ^(a)	GAAP Reported	Adjustments ^(d)	Non-GAAP Adjusted ^(a)
Revenue	\$ 21,222.1	\$ —	\$ 21,222.1	\$ 19,958.7	\$ —	\$ 19,958.7
Cost of sales	5,654.9	(675.7)	4,979.2	5,037.2	(669.7)	4,367.5
Operating expenses ^(b)	11,695.9	(7.6)	11,688.3	11,329.4	(109.5)	11,219.9
Acquired in-process research and development	30.0	(30.0)	—	535.0	(535.0)	—
Asset impairment, restructuring and other special charges	382.5	(382.5)	—	367.7	(367.7)	—
Other income (expense)	(84.8)	203.9	119.1	100.6	152.7	253.3
Income taxes	636.4	301.7	938.1	381.6	586.7	968.3
Net income	\$ 2,737.6	998.0	\$ 3,735.6	\$ 2,408.4	1,247.9	\$ 3,656.3
Earnings per share – diluted	\$ 2.58	0.94	\$ 3.52	\$ 2.26	1.17	\$ 3.43

Numbers may not add due to rounding.

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

- (b) Operating expenses include research and development and marketing, selling and administrative expenses.
- (c) Adjustments to certain GAAP reported measures for the twelve months ended December 31, 2016, include the following:

(Dollars in millions, except per share data)	Amortization ⁽ⁱ⁾	IPR&D ⁽ⁱⁱ⁾	Venezuela ⁽ⁱⁱⁱ⁾	Other specified items ^(iv)	Total Adjustments
Revenue	\$ —	\$ —	\$ —	\$ —	\$ —
Cost of sales	(675.7)	—	—	—	(675.7)
Operating expenses	(7.6)	—	—	—	(7.6)
Acquired in-process research and development	—	(30.0)	—	—	(30.0)
Asset impairment, restructuring and other special charges	—	—	—	(382.5)	(382.5)
Other income (expense)	—	—	203.9	—	203.9
Income taxes	214.0	10.5	—	77.2	301.7
Net income	\$ 469.3	\$ 19.5	\$ 203.9	\$ 305.3	\$ 998.0
Earnings per share – diluted	\$ 0.44	\$ 0.02	\$ 0.19	\$ 0.29	\$ 0.94

Numbers may not add due to rounding.

- 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 are related to an agreement with AstraZeneca to co-develop MEDI1814.
- iii. Exclude charge related to the impact of the Venezuelan financial crisis, including the significant deterioration of the bolivar.
- iv. Exclude integration and severance costs related to the acquisition of Novartis Animal Health, other global severance costs, and asset impairments related to the closure of an animal health manufacturing facility in Ireland.

- (d) Adjustments to certain GAAP reported measures for the twelve months ended December 31, 2015, include the following:

(Dollars in millions, except per share data)	Amortization(i)	IPR&D(ii)	Inventory step-up(iii)	Repurchase of debt(iv)	Other specified items(v)	Total Adjustments
Revenue	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —
Cost of sales	(516.7)	—	(153.0)	—	—	(669.7)
Operating expenses	(109.5)	—	—	—	—	(109.5)
Acquired in-process research and development	—	(535.0)	—	—	—	(535.0)
Asset impairment, restructuring and other special charges	—	—	—	—	(367.7)	(367.7)
Other income (expense)	—	—	—	152.7	—	152.7
Income taxes	206.2	187.3	43.6	53.5	96.2	586.7
Net income	\$ 419.9	\$ 347.8	\$ 109.4	\$ 99.3	\$ 271.6	\$ 1,247.9
Earnings per share – diluted	\$ 0.39	\$ 0.33	\$ 0.10	\$ 0.09	\$ 0.25	\$ 1.17

Numbers may not add due to rounding.

- 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 charges included a \$200.0 million payment to Pfizer following an FDA decision allowing the resumption of Phase III clinical trials for tanezumab, a \$149.0 million payment to Locemia Solutions associated with the acquisition of worldwide rights to an intranasal glucagon, a \$56.0 million payment to Innovent Biologics associated with a collaboration to develop potential oncology therapies, a \$50.0 million payment to Hanmi Pharmaceutical Co., Ltd., related to an exclusive license and collaboration agreement for Hanmi's oral Bruton's tyrosine kinase (BTK) inhibitor for the treatment of autoimmune and other diseases, \$30.0 million payment to BioNTech AG related to a research collaboration to discover novel cancer immunotherapies and \$50.0 million in payments for other technology collaborations.
- iii. Exclude inventory step-up costs associated with the acquisition of Novartis Animal Health.
- iv. Exclude a net charge associated with the repurchase of \$1.65 billion of debt.
- v. Exclude costs associated with restructuring to reduce the company's cost structure, asset impairments, and integration costs associated with the acquisition of Novartis Animal Health.