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Lilly Reports Fourth-Quarter and Full-Year 2014 Results, Updates 2015 Guidance

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- Fourth-quarter 2014 revenue declined 12 percent driven by the impact of U.S. patent expirations for Cymbalta and Evista and the unfavorable impact of foreign exchange rates, partially offset by strong volume growth in several other products.
- Fourth-quarter 2014 earnings per share were \$0.40 (reported), or \$0.75 (non-GAAP).
- Full-year 2014 revenue declined 15 percent to \$19.6 billion.
- Full-year 2014 earnings per share totaled \$2.23 (reported), or \$2.78 (non-GAAP).
- Approximately \$2.9 billion in cash was returned to shareholders in 2014 through dividends and share repurchases.
- 2015 EPS guidance is confirmed in the range of \$2.40 to \$2.50 (reported), or \$3.10 to \$3.20 (non-GAAP); revenue and other elements of guidance have been revised as a result of recent strengthening of the U.S. dollar compared with several other currencies.
- Clinical pipeline advancements during the fourth quarter included two FDA approvals, completion of a rolling FDA submission and a positive Phase III data readout.

Eli Lilly and Company (NYSE: LLY) today announced financial results for the fourth quarter and full year of 2014.

\$ in millions, except per share data	Fourth Quarter			Full Year		
	2014	2013	% Change	2014	2013	% Change
Total Revenue - Reported	\$ 5,121.3	\$ 5,808.8	(12)%	\$ 19,615.6	\$ 23,113.1	(15)%
Net Income - Reported	428.5	727.5	(41)%	2,390.5	4,684.8	(49)%
EPS - Reported	0.40	0.67	(40)%	2.23	4.32	(48)%
Net Income - non-GAAP	797.6	796.9	0%	2,987.6	4,502.6	(34)%
EPS - non-GAAP	0.75	0.74	1%	2.78	4.15	(33)%

Certain financial information for 2014 and 2013 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 period. Non-GAAP measures exclude the items described in the reconciliation tables later in the release. The non-GAAP measures are presented in order to provide additional insights into the underlying trends in the company's business. The company's 2015 financial guidance is also being provided on both a reported and a non-GAAP basis.

"While Lilly's fourth-quarter 2014 results continue to reflect the impact of patent expirations, we are moving to a period of growth led by diabetes, oncology and animal health," said John C. Lechleiter, Ph.D., Lilly's chairman, president and chief executive officer. "Despite the loss of significant revenue for Cymbalta and Evista following the expiration of our U.S. patents, we saw strong performance from many other products. At the same time, we made excellent progress with our innovation-based strategy, and we continue to advance our pipeline. Throughout the balance of this decade, we aim to drive revenue growth and expand margins as we offer new medicines to the people who need them."

Key Events Over the Last Three Months

- The acquisition of Novartis Animal Health was completed on January 1, 2015 in an all-cash transaction of approximately \$5.4 billion. As part of the approval, certain animal health assets in the U.S. relating to the Sentinel[®] canine parasiticide franchise were divested to Virbac for approximately \$410 million.
- The U.S. Food and Drug Administration (FDA) approved and the company launched Cyramza[®] (ramucirumab) in combination with docetaxel, for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with disease progression on or after platinum-based chemotherapy.
- The FDA approved and the company launched Cyramza in combination with paclitaxel as a treatment for people with advanced or metastatic gastric (stomach) or gastroesophageal junction (GEJ) adenocarcinoma whose cancer has progressed on or after prior fluoropyrimidine- or platinum-containing chemotherapy.

- The European Commission approved and the company launched Cyramza in combination with paclitaxel for the treatment of advanced gastric or GEJ adenocarcinoma following prior chemotherapy and as a monotherapy in this setting where treatment in combination with paclitaxel is not appropriate.
- The company completed its rolling FDA submission and the European submission for necitumumab in combination with gemcitabine and cisplatin for the first-line treatment of patients with locally advanced or metastatic squamous non-small cell lung cancer.
- The European Commission approved Trulicity™ (dulaglutide), a oneweekly GLP-1 receptor agonist treatment to help improve glycemic control in adults with type 2 diabetes. Trulicity has now launched in the U.S. and Europe.
- The company announced a worldwide licensing collaboration with Adocia focused on developing an ultra-rapid insulin, known as BioChaperone Lispro, for treatment in people with type 1 and type 2 diabetes. BioChaperone Lispro is currently in Phase Ib studies.
- The company announced an oncology clinical trial collaboration with Merck to evaluate the safety, tolerability and preliminary efficacy of Keytruda® (pembrolizumab), Merck's anti-PD-1 therapy, in combination with Lilly's pemetrexed (Alimta®), ramucirumab (Cyramza) and necitumumab in multiple clinical trials.
- The company announced a clinical trial collaboration with Bristol-Myers Squibb to evaluate the safety, tolerability and preliminary efficacy of Bristol-Myers Squibb's immunotherapy Opdivo® (nivolumab) in combination with Lilly's galunisertib (LY2157299) in multiple tumor types.
- The company and its partner, Boehringer Ingelheim, announced a change to the operational and financial structure of their diabetes alliance. Under the revised agreement, Lilly and Boehringer Ingelheim will continue co-promotion in 17 countries, representing approximately 90 percent of the alliance's anticipated market opportunity. In all other countries, the companies will exclusively commercialize the respective molecules they brought to the alliance.
- The company and Incyte Corporation announced that the primary endpoint of improved ACR20 response compared to placebo was met in the Phase III study of baricitinib in patients with moderately-to-severely active rheumatoid arthritis who previously failed one or more TNF inhibitors. The companies will share results of several ongoing Phase III studies in various disclosures in 2015.
- The company announced a dividend for the first quarter of 2015 of \$0.50 per share on outstanding common stock representing a 2 percent increase. The annual indicated rate is now \$2.00 per share.
- As part of its previously-announced share repurchase program, the company repurchased approximately \$300 million in company stock in the fourth quarter of 2014. For the full year 2014, the company returned approximately \$2.9 billion in cash to shareholders through both its dividend and share repurchase program.

Fourth-Quarter Reported Results

In the fourth quarter of 2014, worldwide total revenue was \$5.121 billion, a decrease of 12 percent compared with the fourth quarter of 2013. The revenue decline was comprised of 9 percent due to lower volume and 4 percent due to the unfavorable impact of foreign exchange rates, partially offset 1 percent due to higher prices. The 9 percent decrease in worldwide volume was driven by the loss of U.S. patent exclusivity for Cymbalta® in December 2013 and Evista® in March 2014, partially offset by volume gains for several other products. Total revenue in the U.S. decreased 19 percent to \$2.453 billion, driven by lower demand for Cymbalta and Evista following patent expirations as well as wholesaler buying patterns. Total revenue outside the U.S. decreased 3 percent to \$2.669 billion, primarily driven by the unfavorable impact of foreign exchange rates, partially offset by higher volume, including the impact of products acquired from Lohmann Animal Health.

Gross margin decreased 13 percent to \$3.868 billion in the fourth quarter of 2014 compared to the fourth quarter of 2013, driven by lower sales of Cymbalta and Evista due to the loss of U.S. patent protection. Gross margin as a percent of total revenue was 75.5 percent, a decrease of 0.6 percentage points compared with the fourth quarter of 2013. The decrease in gross margin percent was primarily due to lower sales of Cymbalta and Evista following U.S. patent expirations, largely offset by the favorable impact of foreign exchange rates on international inventories sold.

Total operating expenses in the fourth quarter of 2014, defined as the sum of research and development, and marketing, selling and administrative expenses, were \$2.986 billion, a decrease of 13 percent compared with the fourth quarter of 2013. Research and development expenses decreased 20 percent to \$1.186 billion, or 23.2 percent of total revenue, driven primarily by lower late-stage clinical development costs in the fourth quarter of 2014. Marketing, selling and administrative expenses decreased 8 percent to \$1.800 billion, due primarily to a reduction in sales and marketing activities for Cymbalta, as well as ongoing cost containment efforts.

In the fourth quarter of 2014, the company recognized acquired in-process research and development charges of \$105.2 million. These charges were comprised of \$55.2 million associated with revisions to the agreement between Lilly and Boehringer Ingelheim, and \$50.0 million related to the collaboration with Adocia. In the fourth quarter of 2013, the company recognized acquired in-process research and development charges of \$57.1 million related to the acquisition of all development and commercial rights from Arteaus Therapeutics for a calcitonin gene-related peptide (CGRP) antibody being studied for the prevention of frequent, recurrent migraine headaches.

In the fourth quarter of 2014, the company recognized asset impairment, restructuring and other special charges of \$401.0 million, comprised of \$189.7 million for asset impairments primarily associated with the closure of a manufacturing site in Puerto Rico, \$188.9 million associated with severance costs related to ongoing cost containment efforts to reduce the company's cost

structure and global workforce, and \$22.4 million associated with integration costs for the acquisition of Novartis Animal Health. In the fourth quarter of 2013, the company recognized asset impairment, restructuring and other special charges of \$35.4 million, primarily related to charges associated with restructuring to reduce the company's cost structure and global workforce.

Operating income in the fourth quarter of 2014 was \$376.4 million, a decrease of 58 percent compared to the fourth quarter of 2013, driven primarily by lower gross margin and higher asset impairment, restructuring and other special charges, partially offset by lower operating expenses.

Other income (expense) was income of \$137.2 million in the fourth quarter of 2014, compared with income of \$9.1 million in the fourth quarter of 2013. This difference was driven primarily by \$92.0 million of other income in 2014 associated with revisions to the agreement between Lilly and Boehringer Ingelheim, and net gains on investments.

The effective tax rate was 16.6 percent in the fourth quarter of 2014, compared with 20.0 percent in the fourth quarter of 2013. The effective tax rate for the fourth quarter of 2014 includes the benefit of the full-year renewal of the R&D tax credit in the U.S. at the end of 2014, partially offset by the tax impact of asset impairment, restructuring and other special charges.

In the fourth quarter of 2014, net income decreased 41 percent to \$428.5 million and earnings per share decreased 40 percent to \$0.40, compared with fourth quarter 2013 net income of \$727.5 million and earnings per share of \$0.67. The decreases in net income and earnings per share were driven by lower operating income, partially offset by increased other income and a lower effective tax rate in the fourth quarter of 2014. Earnings per share benefited slightly from a lower number of shares outstanding in the fourth quarter of 2014 compared to the fourth quarter of 2013.

Fourth-Quarter 2014 Non-GAAP Measures

On a non-GAAP basis, fourth-quarter 2014 operating income decreased \$110.7 million, or 11 percent, to \$882.6 million, driven by lower gross margin, partially offset by lower operating expenses. The effective tax rate decreased to 14.0 percent, compared with 20.5 percent in the fourth quarter of 2013. The effective tax rate for the fourth quarter of 2014 includes the full-year benefit of the renewal of the R&D tax credit in the U.S. at the end of 2014. Reflecting the benefit of the lower tax rate in the fourth quarter, net income remained flat at \$797.6 million and earnings per share increased 1 percent to \$0.75, compared with \$796.9 million and \$0.74, respectively, during the fourth quarter of 2013.

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>% Change</u>
	<u>2014</u>	<u>2013</u>	
Earnings per share (reported)	\$ 0.40	\$ 0.67	(40)%
Acquired in-process research and development ^(a)	.06	.03	
Asset impairment, restructuring and other special charges	.34	.03	
Income associated with revisions to the agreement between Lilly and Boehringer Ingelheim	(.06)	-	
Earnings per share (non-GAAP)	\$ 0.75	\$ 0.74	1%

Numbers do not add due to rounding.

(a) Acquired in-process research and development charges in 2014 are associated with revisions to the agreement between Lilly and Boehringer Ingelheim and the collaboration agreement with Adocia. Charges in 2013 are related to the acquisition of the CGRP antibody.

Full-Year 2014 Reported Results

For the full-year 2014, worldwide total revenue decreased 15 percent to \$19.616 billion compared to 2013. This decrease was comprised of 13 percent due to volume, 2 percent due to the unfavorable impact of foreign exchange rates, and 1 percent due to lower prices. Total revenue in the U.S. decreased 29 percent to \$9.134 billion due to lower demand for Cymbalta and Evista following patent expirations as well as wholesaler buying patterns. Total revenue outside the U.S. increased 3 percent to \$10.482 billion due to higher volume, partially offset by the unfavorable impact of foreign exchange rates.

Gross margin decreased 19 percent to \$14.683 billion in 2014. Gross margin as a percent of total revenue was 74.9 percent, a decrease of 3.9 percentage points compared with 2013. The decrease was primarily driven by lower sales of Cymbalta and Evista following U.S. patent expirations.

Total operating expenses decreased 10 percent in 2014. Research and development expenses decreased 14 percent to \$4.734 billion, or 24.1 percent of total revenue, driven primarily by lower late-stage clinical development costs. Research and development expenses in 2013 included approximately \$100 million of milestone payments made to Boehringer Ingelheim following regulatory submissions for empagliflozin. Marketing, selling and administrative expenses decreased 7 percent to \$6.621 billion, driven primarily by the reduction in U.S. sales and marketing activities for Cymbalta and Evista, as well as ongoing cost containment efforts, partially offset by a \$119.0 million charge associated with the U.S. Branded Prescription Drug Fee in 2014.

In 2014, the company recognized acquired in-process research and development charges of \$200.2 million. These charges were comprised of \$55.2 million associated with revisions to the agreement between Lilly and Boehringer Ingelheim, \$50.0 million related to the collaboration with Adocia, \$50.0 million related to an agreement with AstraZeneca to co-develop and commercialize AZD3293, an oral beta secretase cleaving enzyme (BACE) inhibitor as a potential treatment for Alzheimer's disease, and \$45.0 million related to a collaboration agreement with Immunocore to research and potentially develop novel T cell-based cancer therapies. In 2013, the company recognized acquired in-process research and development charges of \$57.1 million related to the acquisition of rights from Arteus Therapeutics for the CGRP antibody.

In 2014, the company recognized asset impairment, restructuring, and other special charges of \$468.7 million. These charges are comprised of \$225.5 million associated with severance costs related to ongoing cost containment efforts to reduce the company's cost structure and global workforce, \$204.4 million of asset impairments primarily associated with the closure of a manufacturing site in Puerto Rico, and \$38.8 million associated with integration costs for the acquisition of Novartis Animal Health. In 2013, the company recognized charges of \$120.6 million for asset impairment, restructuring and other special charges. These charges were comprised of \$62.1 million for restructuring to reduce the company's cost structure and global workforce and \$58.5 million associated with the closure of a production facility in Germany.

Operating income in 2014 decreased 50 percent compared to 2013 to \$2.660 billion, driven by lower gross margin, higher asset impairment, restructuring and other special charges, and higher acquired in-process research and development charges, partially offset by lower operating expenses.

Other income (expense) was income of \$340.5 million in 2014, compared with income of \$518.9 million in 2013. Other income in 2014 included net gains of \$216.4 million on investments and \$92.0 million of other income associated with revisions to the agreement between Lilly and Boehringer Ingelheim. Other income in 2013 included \$495.4 million related to the termination of the exenatide collaboration with Amylin Pharmaceuticals and \$50.0 million of milestones received from Boehringer Ingelheim for regulatory submissions of the new insulin glargine product.

The effective tax rate was 20.3 percent in 2014, compared with 20.5 percent in 2013.

For the full-year 2014, net income decreased 49 percent to \$2.390 billion and earnings per share decreased 48 percent to \$2.23, compared to full-year 2013 net income of \$4.685 billion and earnings per share of \$4.32. The decreases in net income and earnings per share were driven by lower operating income and decreased other income. Earnings per share benefited slightly from a lower number of shares outstanding in 2014 compared to 2013.

Full-Year 2014 non-GAAP Measures

Operating income decreased 38 percent to \$3.448 billion driven by lower gross margin, partially offset by lower operating expenses. The effective tax rate for 2014 and 2013 was 19.2 percent. Net income decreased 34 percent and earnings per share decreased 33 percent to \$2.988 billion and \$2.78, 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>2014</u>	<u>2013</u>	<u>% Change</u>
Earnings per share (reported)	\$ 2.23	\$ 4.32	(48)%
U.S. Branded Prescription Drug Fee ^(a)	.11	-	
Acquired in-process research and development ^(b)	.12	.03	
Asset impairment, restructuring and other special charges	.38	.08	
Income associated with revisions to the agreement between Lilly and Boehringer Ingelheim	(.06)	-	
Income related to the termination of the exenatide collaboration with Amylin	-	(.29)	
Earnings per share (non-GAAP)	\$ 2.78	\$ 4.15	(33)%

Numbers do not add due to rounding.

(a) Final regulations from the IRS modified the timing of when the company must recognize the expense. In addition to the accounting for the fee that was imposed and paid in 2014, the company accrued in 2014 for the fee that will be imposed and paid in 2015.

(b) Acquired in-process research and development charges in 2014 are associated with revisions to the agreement between Lilly and Boehringer Ingelheim, and collaboration agreements with Adocia, AstraZeneca and Immunocore Limited. Charges in 2013 are related to the acquisition of the CGRP antibody.

Revenue Highlights

% Change Over/

% Change Over/

(Dollars in millions)	Fourth Quarter			Full-Year		
	2014	2013	(Under) 2013	2014	2013	(Under) 2013
Alimta	\$ 725.0	\$ 726.2	0%	\$ 2,792.0	\$ 2,703.0	3%
Humalog®	729.1	733.9	(1)%	2,785.2	2,611.2	7%
Cialis®	622.4	588.3	6%	2,291.0	2,159.4	6%
Cymbalta	367.3	883.2	(58)%	1,614.7	5,084.4	(68)%
Humulin®	395.6	369.5	7%	1,400.1	1,315.8	6%
Forteo®	380.8	359.8	6%	1,322.0	1,244.9	6%
Zyprexa®	253.1	348.2	(27)%	1,037.3	1,194.8	(13)%
Strattera®	194.9	201.1	(3)%	738.5	709.2	4%
Effient®	137.8	130.6	6%	522.2	508.7	3%
Evista	72.1	275.9	(74)%	419.8	1,050.4	(60)%
Animal Health	633.3	578.4	9%	2,346.6	2,151.5	9%
Total Revenue	\$ 5,121.3	\$ 5,808.8	(12)%	\$ 19,615.6	\$ 23,113.1	(15)%

Alimta

For the fourth quarter of 2014, Alimta generated sales of \$725.0 million, which were flat compared with the fourth quarter of 2013. U.S. sales of Alimta increased 3 percent, to \$342.3 million, driven by increased volume, partially offset by lower net effective selling prices. Sales outside the U.S. decreased 3 percent, to \$382.7 million, driven by the unfavorable impact of foreign exchange rates and, to a lesser extent, lower prices, partially offset by higher volume.

For the full year of 2014, worldwide Alimta sales increased 3 percent to \$2.792 billion. U.S. Alimta sales for 2014 were \$1.230 billion, a 2 percent increase driven by increased volume. Alimta sales outside the U.S. were \$1.562 billion, a 5 percent increase driven by higher volume, partially offset by the unfavorable impact of foreign exchange rates and lower prices.

Humalog

For the fourth quarter of 2014, worldwide Humalog sales decreased 1 percent, to \$729.1 million. Sales in the U.S. decreased 2 percent to \$424.1 million, driven by lower net effective selling prices as a result of payer contracts and greater Medicaid and Medicare utilization, as well as wholesaler buying patterns, largely offset by increased demand. Sales outside the U.S. increased 2 percent to \$305.0 million, driven by increased volume, largely offset by the unfavorable impact of foreign exchange rates.

For the full year of 2014, worldwide Humalog sales increased 7 percent to \$2.785 billion. U.S. Humalog sales for 2014 were \$1.628 billion, a 7 percent increase driven by increased demand, partially offset by lower net effective selling prices as a result of payer contracts and greater Medicaid and Medicare utilization, as well as wholesaler buying patterns. Humalog sales outside the U.S. were \$1.158 billion, a 6 percent increase driven by increased volume and, to a lesser extent, higher prices, partially offset by the unfavorable impact of foreign exchange rates.

Cialis

Cialis sales for the fourth quarter of 2014 increased 6 percent to \$622.4 million. U.S. sales of Cialis were \$317.9 million in the fourth quarter, a 14 percent increase compared with the fourth quarter of 2013, driven by higher prices, partially offset by wholesaler buying patterns. Sales of Cialis outside the U.S. decreased 1 percent, to \$304.5 million, driven by the unfavorable impact of foreign exchange rates, partially offset by increased volume and higher prices.

For the full year of 2014, worldwide Cialis sales increased 6 percent to \$2.291 billion. U.S. Cialis sales for 2014 were \$1.040 billion, a 10 percent increase driven by higher prices, partially offset by wholesaler buying patterns. Cialis sales outside the U.S. were \$1.251 billion, a 3 percent increase driven by higher prices and increased volume, partially offset by the unfavorable impact of foreign exchange rates.

Cymbalta

For the fourth quarter of 2014, Cymbalta generated \$367.3 million in revenue, a decrease of 58 percent compared with the fourth quarter of 2013. U.S. sales of Cymbalta decreased 89 percent, to \$62.8 million, due to the loss of U.S. patent exclusivity in December 2013. Sales of Cymbalta outside the U.S. remained flat at \$304.5 million, as the unfavorable impact of foreign exchange rates was offset by increased volume.

For the full year of 2014, worldwide Cymbalta sales decreased 68 percent to \$1.615 billion. U.S. Cymbalta sales for 2014 were \$420.5 million, a 89 percent decrease due to the loss of U.S. patent exclusivity in December 2013. Sales of Cymbalta outside the U.S. were \$1.194 billion, a 6 percent increase driven by increased volume, partially offset by the unfavorable impact of foreign exchange rates.

Humulin

Worldwide Humulin sales increased 7 percent in the fourth quarter of 2014, to \$395.6 million. U.S. sales increased 9 percent to \$210.9 million, driven by increased demand and higher prices. Sales outside the U.S. increased 5 percent, to \$184.7 million, driven by increased volume, partially offset by the unfavorable impact of foreign exchange rates.

For the full year of 2014, worldwide Humulin sales increased 6 percent to \$1.400 billion. U.S. Humulin sales for 2014 were \$713.1 million, a 5 percent increase, primarily driven by increased demand, partially offset by wholesaler buying patterns. Humulin sales outside the U.S. were \$687.0 million, a 8 percent increase, driven by increased volume, partially offset by the unfavorable impact of foreign exchange rates.

Forteo

Fourth-quarter 2014 sales of Forteo were \$380.8 million, an 6 percent increase compared with the fourth quarter of 2013. U.S. sales of Forteo increased 17 percent to \$183.0 million, driven by higher prices, partially offset by wholesaler buying patterns. Sales outside the U.S. decreased 3 percent to \$197.8 million, driven by the unfavorable impact of foreign exchange rates, largely offset by increased volume.

For the full year of 2014, worldwide Forteo sales increased 6 percent to \$1.322 billion. U.S. Forteo sales for 2014 were \$539.0 million, a 5 percent increase driven by higher prices, partially offset by decreased volume. Forteo sales outside the U.S. were \$783.0 million, a 7 percent increase driven by increased volume, primarily in Japan, partially offset by the unfavorable impact of foreign exchange rates, primarily the Japanese yen.

Zyprexa

In the fourth quarter of 2014, Zyprexa sales totaled \$253.1 million, a decrease of 27 percent compared with the fourth quarter of 2013. U.S. sales of Zyprexa decreased 13 percent to \$34.2 million. Zyprexa sales outside the U.S. decreased 29 percent, to \$218.9 million, due to decreased volume in emerging markets, the unfavorable impact of foreign exchange rates and lower prices.

For the full year of 2014, worldwide Zyprexa sales decreased 13 percent to \$1.037 billion. U.S. sales of Zyprexa decreased 3 percent to \$119.8 million. Zyprexa sales outside the U.S. were \$917.5 million, a 14 percent decrease driven by decreased volume, the unfavorable impact of foreign exchange rates, primarily the Japanese yen, and lower prices.

Strattera

During the fourth quarter of 2014, Strattera generated \$194.9 million of sales, a decrease of 3 percent compared with the fourth quarter of 2013. U.S. sales decreased 6 percent to \$119.1 million, driven primarily by decreased volume. Sales outside the U.S. increased 2 percent to \$75.8 million, driven by increased volume, largely offset by the unfavorable impact of foreign exchange rates.

For the full year of 2014, worldwide Strattera sales increased 4 percent to \$738.5 million. U.S. Strattera sales for 2014 were \$452.5 million, a 1 percent increase driven by higher prices, partially offset by decreased volume. Strattera sales outside the U.S. were \$286.0 million, a 9 percent increase driven by increased volume, primarily in Japan, partially offset by the unfavorable impact of foreign exchange rates, primarily the Japanese yen.

Effient

Effient sales were \$137.8 million in the fourth quarter of 2014, an increase of 6 percent compared with the fourth quarter of 2013. U.S. Effient sales increased 10 percent to \$106.7 million, driven by higher prices, partially offset by wholesaler buying patterns. Sales outside the U.S. decreased 8 percent to \$31.1 million, driven primarily by the unfavorable impact of foreign exchange rates.

For the full year of 2014, worldwide Effient sales increased 3 percent to \$522.2 million. U.S. Effient sales for 2014 were \$394.5 million, a 5 percent increase driven by higher prices, partially offset by wholesaler buying patterns. Effient sales outside the U.S. were \$127.7 million, a 3 percent decrease driven by lower volume.

Evista

Evista sales for the fourth quarter of 2014 decreased 74 percent to \$72.1 million. U.S. sales of Evista decreased 91 percent to \$19.4 million, due to the loss of U.S. patent exclusivity in March 2014. Sales outside the U.S. decreased 21 percent to \$52.7 million, driven primarily by lower prices and the unfavorable impact of foreign exchange rates.

For the full year of 2014, worldwide Evista sales decreased 60 percent to \$419.8 million. U.S. Evista sales for 2014 were \$207.2 million, a 73 percent decrease due to the loss of U.S. patent exclusivity in March 2014. Evista sales outside the U.S. were \$212.6 million, a 24 percent decrease driven primarily by the expiration of a supply agreement in 2013, and to a lesser extent the unfavorable impact of foreign exchange rates.

Animal Health

In the fourth quarter of 2014, worldwide animal health sales totaled \$633.3 million, an increase of 9 percent compared with the fourth quarter of 2013, driven primarily by increased volume for food animal products, due in part to the acquisition of Lohmann Animal Health, and higher prices, partially offset by the unfavorable impact of foreign exchange rates. U.S. animal health sales increased 5 percent, to \$322.1 million due to higher prices for both food and companion animal products, partially offset by lower volume for companion animal products due to competitive pressure. Animal health sales outside the U.S. were \$311.2

million, a 14 percent increase, driven by increased volume for food animal products, due in part to the acquisition of Lohmann Animal Health and, to a lesser extent, higher prices, partially offset by the unfavorable impact of foreign exchange rates.

For the full year of 2014, worldwide animal health sales increased 9 percent to \$2.347 billion, driven primarily by increased volume for food animal products, due in part to the acquisition of Lohmann Animal Health, and higher prices, partially offset by decreased volume for companion animal products and the unfavorable impact of foreign exchange rates. Animal health sales in the U.S. increased 4 percent to \$1.274 billion, driven by increased volume in food animal products and higher prices, partially offset by decreased volume in companion animal products due to competitive pressure. Animal health sales outside the U.S. increased 16 percent to \$1.072 billion, driven by increased volume for food animal products, due in part to the acquisition of Lohmann Animal Health and, to a lesser extent, higher prices, partially offset by the unfavorable impact of foreign exchange rates.

2015 Financial Guidance

The company has revised certain elements of its 2015 financial guidance solely to reflect the recent strengthening of the U.S. dollar compared with several other currencies. The company still expects full-year 2015 earnings per share to be in the range of \$2.40 to \$2.50 on a reported basis. On a non-GAAP basis, full year 2015 earnings per share are still expected to be in the range of \$3.10 to \$3.20.

	2015 Expectations
Earnings per share (reported)	\$2.40 to \$2.50
Exclusion of amortization of intangible assets	.44
Exclusion of Novartis Animal Health and Lohmann integration and inventory step-up costs	.27
Earnings per share (non-GAAP)	\$3.10 to \$3.20

Amortization and inventory step-up costs associated with the Novartis Animal Health acquisition are subject to final acquisition accounting adjustments. Numbers do not add due to rounding.

The company now anticipates 2015 revenue of between \$19.5 billion and \$20.0 billion. The acquisition of Novartis Animal Health is expected to add significant revenue.

The company now anticipates that gross margin as a percent of revenue will be approximately 75.0 percent in 2015 on a reported basis and 78.0 percent on a non-GAAP basis, reflecting the exclusion of inventory step-up costs associated with the acquisition of Novartis Animal Health as well as amortization of intangibles.

On a reported basis, marketing, selling and administrative expenses are now expected to be in the range of \$6.5 billion to \$6.8 billion. On a non-GAAP basis, marketing, selling and administrative expenses are now expected to be in the range of \$6.3 billion to \$6.6 billion, reflecting the exclusion of amortization of intangibles. Research and development expenses are now expected to be in the range of \$4.7 billion to \$4.9 billion reflecting an expected increase in Phase III trial expenses and the inclusion of Novartis Animal Health.

Other income (expense) is still expected to be in a range between \$75 million and \$125 million of income in 2015 on a reported and non-GAAP basis.

The 2015 tax rate is still expected to be approximately 18.5 percent on a reported basis and 21.5 percent on a non-GAAP basis, assuming a full-year 2015 benefit of the R&D tax credit and other tax provisions up for extension. If these items are not extended, the 2015 tax rate would be approximately 1.5 percentage points higher. The 2015 expected reported tax rate includes the tax impact of costs associated with the Novartis Animal Health and Lohmann Animal Health acquisitions and amortization of intangibles.

Capital expenditures are still expected to be approximately \$1.3 billion.

The company's 2015 financial guidance does not include a potential charge related to the collaboration with Pfizer to develop and commercialize tanezumab, an NGF monoclonal antibody being studied for the treatment of pain. As previously communicated, if the partial clinical hold for the molecule is removed and Lilly and Pfizer move forward with development, Lilly will pay a \$200 million upfront fee to Pfizer. This charge would cause Lilly's reported tax rate to be roughly 1 percentage point lower and would reduce reported EPS by approximately \$0.12.

The following table summarizes the company's 2015 financial guidance.

2015 Guidance	
Prior	Revised
_____	_____

Total Revenue	\$20.3 to \$20.8 billion	\$19.5 to \$20.0 billion
Gross Margin % of Revenue (reported)	Approx. 73.5%	Approx. 75.0%
Gross Margin % of Revenue (non-GAAP)	Approx. 76.5%	Approx. 78.0%
Marketing, Selling & Admin (reported)	\$6.7 to \$7.0 billion	\$6.5 to \$6.8 billion
Marketing, Selling & Admin (non-GAAP)	\$6.5 to \$6.8 billion	\$6.3 to \$6.6 billion
Research & Development	\$4.8 to \$5.0 billion	\$4.7 to \$4.9 billion
Other Income/(Expense)	\$75 to \$125 million	\$75 to \$125 million
Tax Rate (reported)	Approx. 18.5%	Approx. 18.5%
Tax Rate (non-GAAP)	Approx. 21.5%	Approx. 21.5%
Earnings per Share (reported)	\$2.40 to \$2.50	\$2.40 to \$2.50
Earnings per Share (non-GAAP)	\$3.10 to \$3.20	\$3.10 to \$3.20
Capital Expenditures	Approx. \$1.3 billion	Approx. \$1.3 billion

Webcast of Conference Call

As previously announced, investors and the general public can access a live webcast of the fourth-quarter 2014 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" 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 with respect to pipeline products that the products will receive the necessary clinical and manufacturing regulatory approvals or that they will prove to be commercially successful. Pharmaceutical products can develop unexpected safety or efficacy concerns. 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 SEC; acquisitions and business development transactions; 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 U.S. Securities and Exchange Commission. 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, Lilly)

Cialis[®] (tadalafil, Lilly)

Cymbalta[®] (duloxetine hydrochloride, Lilly)

Cyramza[®] (ramucirumab, Lilly)

Effient[®] (prasugrel, Lilly)

Evista[®] (raloxifene hydrochloride, Lilly)
 Forteo[®] (teriparatide of recombinant DNA origin injection, Lilly)
 Humalog[®] (insulin lispro injection of recombinant DNA origin, Lilly)
 Humulin[®] (human insulin of recombinant DNA origin, Lilly)
 Jardiance[®] (empagliflozin, Boehringer Ingelheim)
 Keytruda[®] (pembrolizumab, Merck)
 Opdivo[®] (nivolumab, Bristol-Myers Squibb Company)
 Sentinel[®] (lufenuron and milbemycin oxime, Virbac)
 Strattera[®] (atomoxetine hydrochloride, Lilly)
 Trajenta[®] (linagliptin, Boehringer Ingelheim)
 Trulicity[™] (dulaglutide, Lilly)
 Zyprexa[®] (olanzapine, Lilly)

Eli Lilly and Company Employment Information

	<u>December 31, 2014</u>	<u>December 31, 2013</u>
Worldwide Employees	39,135*	37,925

*Employment totals as of December 31, 2014, reflect approximately 575 additions from the acquisition of Lohmann Animal Health.

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,		
	2014	2013	% Chg.	2014	2013	% Chg.
Total revenue	\$ 5,121.3	\$ 5,808.8	(12)%	\$ 19,615.6	\$ 23,113.1	(15)%
Cost of sales	1,253.1	1,386.5	(10)%	4,932.5	4,908.1	0%
Research and development	1,185.7	1,475.4	(20)%	4,733.6	5,531.3	(14)%
Marketing, selling and administrative	1,799.9	1,953.6	(8)%	6,620.8	7,125.6	(7)%
Acquired in-process research and development	105.2	57.1	84%	200.2	57.1	NM
Asset impairment, restructuring and other special charges	401.0	35.4	NM	468.7	120.6	NM
Operating income	376.4	900.8	(58)%	2,659.8	5,370.4	(50)%
Net interest income (expense)	(13.2)	(5.5)		(27.8)	(40.4)	
Other income - Special	—	—		—	495.4	
Net other income (expense)	150.4	14.6		368.3	63.9	
Other income (expense)	137.2	9.1	NM	340.5	518.9	(34)%
Income before income taxes	513.6	909.9	(44)%	3,000.3	5,889.3	(49)%
Income taxes	85.1	182.4	(53)%	609.8	1,204.5	(49)%
Net income	\$ <u>428.5</u>	\$ <u>727.5</u>	(41)%	\$ <u>2,390.5</u>	\$ <u>4,684.8</u>	(49)%
Earnings per share - diluted	\$ <u>0.40</u>	\$ <u>0.67</u>	(40)%	\$ <u>2.23</u>	\$ <u>4.32</u>	(48)%
Dividends paid per share	\$ 0.49	\$ 0.49	0%	\$ 1.96	\$ 1.96	0%
Weighted-average shares (thousands) - diluted	1,069,787	1,078,976		1,074,286	1,084,766	

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, 2014			Three Months Ended December 31, 2013		
	GAAP Reported	Adjustments	Non-GAAP Adjusted ^(a)	GAAP Reported	Adjustments	Non-GAAP Adjusted ^(a)
Total revenue	\$ 5,121.3	\$ —	\$ 5,121.3	\$ 5,808.8	\$ —	\$ 5,808.8
Cost of sales	1,253.1	—	1,253.1	1,386.5	—	1,386.5
Operating expenses ^(b)	2,985.6	—	2,985.6	3,429.0	—	3,429.0
Acquired in-process research and development ^(c)	105.2	(105.2)	—	57.1	(57.1)	—
Asset impairment, restructuring and other special charges ^(d)	401.0	(401.0)	—	35.4	(35.4)	—
Other income (expense) ^(e)	137.2	(92.0)	45.2	9.1	—	9.1
Income taxes	85.1	45.1	130.2	182.4	23.2	205.5
Net income	\$ 428.5	369.1	\$ 797.6	\$ 727.5	69.3	\$ 796.9
Earnings per share - diluted	\$ 0.40	0.35	\$ 0.75	\$ 0.67	0.07	\$ 0.74

Numbers do 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 items that are excluded when non-GAAP measures or expectations provided are typically highly variable, difficult to predict, and of a size that could have a substantial impact on the company's reported operations for a period. The company believes that these non-GAAP measures provide useful information to investors. Among other things, they may help investors evaluate the company's ongoing operations. They can assist in making meaningful period-over-period comparisons and in identifying operating trends that would otherwise be masked or distorted by the items subject to the adjustments. Management uses these non-GAAP measures internally to evaluate the performance of the business, including to allocate resources and to evaluate results relative to incentive compensation targets. Investors should consider these non-GAAP measures in addition to, not as a substitute for or superior to, measures of financial performance prepared in accordance with GAAP.
- (b) Operating expenses include research and development, marketing, selling and administrative expenses.
- (c) Certain GAAP reported measures have been adjusted to eliminate acquired in-process research and development expenses. During the three months ended December 31, 2014, amounts totaling \$105.2 million (pretax), or \$0.06 per share (after-tax), of expense were eliminated associated with revisions to the agreement between Lilly and Boehringer Ingelheim, and the acquired in-process research and development charge for the collaboration agreement with Adocia. During the three months ended December 31, 2013, amounts totaling \$57.1 million (pretax), or \$0.03 per share (after-tax), of expense were eliminated related to the acquired in-process research and development for the CGRP antibody.
- (d) Certain GAAP reported measures have been adjusted to eliminate asset impairment, restructuring and other special charges. During the three months ended December 31, 2014, amounts totaling \$401.0 million (pretax), or \$0.34 per share (after-tax), of expense were eliminated related to asset impairments primarily associated with the closure of a manufacturing site in Puerto Rico, severance costs related to ongoing cost containment efforts to reduce the Company's cost structure and global workforce, and integration costs for the acquisition of Novartis Animal Health. During the three months ended December 31, 2013, amounts totaling \$35.4 million (pretax), or \$0.03 per share (after-tax), of expense were eliminated primarily related to costs associated with restructuring to reduce the Company's cost structure and global workforce.
- (e) Certain GAAP reported measures have been adjusted to eliminate a portion of other income (expense). During the three months ended December 31, 2014, amounts totaling \$92.0 million (pretax), or \$0.06 per share (after-tax), of income were eliminated associated with revisions to the agreement between Lilly and Boehringer Ingelheim.

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, 2014

Twelve Months Ended
December 31, 2013

	GAAP Reported	Adjustments	Non-GAAP Adjusted ^(a)	GAAP Reported	Adjustments	Non-GAAP Adjusted ^(a)
Total revenue	\$ 19,615.6	\$ —	\$ 19,615.6	\$ 23,113.1	\$ —	\$ 23,113.1
Cost of sales	4,932.5	—	4,932.5	4,908.1	—	4,908.1
Operating expenses ^(b)	11,354.4	(119.0)	11,235.3	12,656.9	—	12,656.9
Acquired in-process research and development ^(c)	200.2	(200.2)	—	57.1	(57.1)	—
Asset impairment, restructuring and other special charges ^(d)	468.7	(468.7)	—	120.6	(120.6)	—
Other income (expense) ^(e)	340.5	(92.0)	248.5	518.9	(495.4)	23.5
Income taxes	609.8	98.9	708.7	1,204.5	(135.4)	1,069.0
Net income	\$ 2,390.5	597.1	\$ 2,987.6	\$ 4,684.8	(182.3)	\$ 4,502.6
Earnings per share - diluted	\$ 2.23	0.55	\$ 2.78	\$ 4.32	(0.17)	\$ 4.15

Numbers do 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 items that are excluded when non-GAAP measures or expectations provided are typically highly variable, difficult to predict, and of a size that could have a substantial impact on the company's reported operations for a period. The company believes that these non-GAAP measures provide useful information to investors. Among other things, they may help investors evaluate the company's ongoing operations. They can assist in making meaningful period-over-period comparisons and in identifying operating trends that would otherwise be masked or distorted by the items subject to the adjustments. Management uses these non-GAAP measures internally to evaluate the performance of the business, including to allocate resources and to evaluate results relative to incentive compensation targets. Investors should consider these non-GAAP measures in addition to, not as a substitute for or superior to, measures of financial performance prepared in accordance with GAAP.
- (b) Operating expenses include research and development, marketing, selling and administrative expenses. Certain GAAP reported measures have been adjusted to eliminate a portion of operating expenses. During the twelve months ended December 31, 2014, amounts totaling \$119.0 million (pretax), or \$0.11 per share (after-tax), of expense were eliminated related to a charge associated with the Branded Prescription Drug Fee.
- (c) Certain GAAP reported measures have been adjusted to eliminate acquired in-process research and development charges. During the twelve months ended December 31, 2014, amounts totaling \$200.2 million (pretax), or \$0.12 per share (after-tax), of expense were eliminated associated with revisions to the agreement between Lilly and Boehringer Ingelheim, and collaboration agreements with Adocia, AstraZeneca, and Immunocore Limited. During the twelve months ended December 31, 2013, amounts totaling \$57.1 million (pretax), or \$0.03 per share (after-tax), of expense were eliminated related to the CGRP antibody.
- (d) Certain GAAP reported measures have been adjusted to eliminate asset impairment, restructuring and other special charges. During the twelve months ended December 31, 2014, amounts totaling \$468.7 million (pretax), or \$0.38 per share (after-tax), of expense were eliminated associated with severance costs related to ongoing cost containment efforts to reduce the company's cost structure and global workforce, asset impairment primarily associated with the closure of a manufacturing site in Puerto Rico, and integration costs for the acquisition of Novartis Animal Health. During the twelve months ended December 31, 2013, amounts totaling \$120.6 million (pretax), or \$0.08 per share (after-tax), of expense were eliminated primarily related to the anticipated closure of a packaging and distribution facility in Germany as well as severance costs for actions taken to reduce cost structure and global workforce.
- (e) Certain GAAP reported measures have been adjusted to eliminate a portion of other income (expense). During the twelve months ended December 31, 2014, amounts totaling \$92.0 million (pretax), or \$0.06 per share (after-tax), of income were eliminated associated with revisions to the agreement between Lilly and Boehringer Ingelheim. During the twelve months ended December 31, 2013, amounts totaling \$495.4 million (pretax), or \$0.29 per share (after-tax), of income were eliminated related to the termination of the exenatide collaboration with Amylin.

Refer to:

(317) 277-6524 - Lauren Zierke (Media)

(317) 655-6874 - Philip Johnson (Investors)

The image shows the word "Lilly" written in a red, cursive script font. The letters are connected and have a fluid, handwritten appearance. The "L" is the largest and most prominent, followed by the "i", "l", "l", and "y".

Logo - <http://photos.prnewswire.com/prnh/20031219/LLYLOGO>

To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/lilly-reports-fourth-quarter-and-full-year-2014-results-updates-2015-guidance-300028390.html>

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