

# Lilly Reports Second-Quarter 2015 Results, Revises 2015 Financial Guidance

- Revenue increased 1 percent with the inclusion of Novartis Animal Health and higher volume for several products, including Cyramza and Trulicity; these factors were largely offset by the unfavorable effect of foreign exchange rates and the residual impact of Cymbalta and Evista patent expirations.
- Second-quarter 2015 earnings per share were \$0.56 (reported), or \$0.90 (non-GAAP).
- 2015 EPS guidance has been revised to be in the range of \$2.20 to \$2.30 on a reported basis and \$3.20 to \$3.30 on a non-GAAP basis, reflecting solid underlying performance in the first six months of the year.
- Significant pipeline progress, including multiple regulatory approvals, submissions and positive Phase III data readouts, reinforce the company's commitment to its innovation-based strategy.

INDIANAPOLIS, July 23, 2015 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced financial results for the second quarter of 2015.

\$ in millions, except per share data		Seco	%	<u>.</u>			
		<u>2015</u>	<u>2014</u>	Char	<u>ige</u>		
Revenue - Reported	\$	4,978.7		\$	4,935.6	1	%
Net Income - Reported		600.8			733.5	(18)	%
EPS - Reported	0.56				0.68	(18)	%
Revenue - non-GAAP		4,978.7			5,211.2	(4)	%
Net Income - non-GAAP		954.8			798.1	20	%
EPS - non-GAAP		0.90			0.74	22	%

Certain financial information for 2015 and 2014 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. Non-GAAP measures in 2014 include the results of Novartis Animal Health as if the acquisition and the financing for the acquisition had occurred as of January 1, 2014. Non-GAAP financial measures for all periods presented also exclude amortization of intangibles primarily associated with costs of marketed products acquired or licensed from third parties. The company's 2015 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.

"Lilly remains on track to return to growth in 2015, driven by strong underlying business performance, including uptake of our recently launched products - Jardiance, Trulicity and Cyramza," said John C. Lechleiter, Ph.D., Lilly's chairman, president and chief executive officer. "With tangible results from launches of new medicines and continued progress in our pipeline, along with careful control of operational expenses, we are confident that our innovation-based strategy will continue to provide the basis for solid growth in the years ahead."

# Key Events Over the Last Three Months

- Cyramza® (ramucirumab) achieved a number of development and commercial milestones:
  - Approved and launched in the U.S. in combination with FOLFIRI (irinotecan, folinic acid, and 5-fluorouracil) chemotherapy for the treatment of patients with metastatic colorectal cancer with disease progression on or after prior therapy with bevacizumab, oxaliplatin, and a fluoropyrimidine.
  - Launched in Japan for patients with unresectable, advanced or recurrent gastric cancer.
  - Submitted in Japan for second-line metastatic colorectal cancer.
- The Japan Ministry of Health, Labor and Welfare approved Trulicity<sup>™</sup> (dulaglutide) as a treatment for type 2 diabetes.
   The company will co-promote Trulicity in Japan with Sumitomo Dainippon Pharma Co., Ltd.

- The U.S. Food and Drug Administration (FDA) approved Humalog<sup>®</sup> 200 units/mL KwikPen<sup>®</sup> (insulin lispro 200 units/mL;
   U-200), a pre-filled pen containing a concentrated formulation of Lilly's rapid-acting insulin Humalog<sup>®</sup> (insulin lispro 100 units/mL) to improve glycemic control in people with type 1 and type 2 diabetes.
- The European Commission granted marketing authorization for Synjardy® (empagliflozin/metformin) for the treatment of adults with type 2 diabetes. Synjardy is part of the company's diabetes collaboration with Boehringer Ingelheim.
- The FDA issued a Complete Response Letter for Synjardy, for the treatment of adults with type 2 diabetes. Boehringer Ingelheim submitted their response to the FDA and received a Class 1 status for an expected decision within two months.
- The company is encouraged by the FDA Oncologic Drugs Advisory Committee's review of data supporting necitumumab in combination with gemcitabine and cisplatin for use in first-line treatment of patients with advanced squamous non-small cell lung cancer. The company believes necitumumab represents a meaningful advancement. FDA action is expected by the end of the year.
- The company submitted ixekizumab in the EU for moderate-to-severe plaque psoriasis.
- The company announced results from an extension of the Phase III solanezumab trials, indicating the treatment effect
  was preserved in patients with mild Alzheimer's disease, compared to patients who began treatment at a later point,
  further suggesting a potential disease-modifying effect on underlying disease progression.
- The company announced collaborations with:
  - AstraZeneca to evaluate the safety and preliminary efficacy of AstraZeneca's investigational anti-PD-L1 immune checkpoint inhibitor, MEDI4736, in combination with Cyramza, as a treatment for patients with advanced solid tumors.
  - Immunocore Limited to explore the utility of Immunocore's lead T cell receptor-based investigational therapeutic, IMCgp100, in combination with Lilly's galunisertib and merestinib for the treatment of melanoma.
  - Sarah Cannon Research Institute to co-develop an investigational oncology compound, LY3023414, a PI3K/mTOR dual inhibitor.
  - BioNTech AG to discover novel cancer immunotherapies.
  - Sanford-Burnham Medical Research Institute to discover and develop immunological therapies.
  - Dana-Farber Cancer Institute to research new medicines under development to fight cancer.
- The UK Court of Appeal ruled that the Alimta<sup>®</sup> (pemetrexed disodium) vitamin regimen patents would be indirectly infringed by a generic competitor that had stated its intent to market certain alternative salt forms of pemetrexed in the United Kingdom, France, Italy and Spain prior to the patents' expiration in June 2021.
- The company announced plans to establish a new drug delivery and device innovation center in Cambridge, Massachusetts, and to expand its existing research and development center in San Diego, California.
- The company issued €2.1 billion of euro-denominated debt and repurchased \$1.65 billion principal amount of higher interest rate U.S. dollar-denominated debt.

#### Second-Quarter Reported Results

In the second quarter of 2015, worldwide revenue was \$4.979 billion, an increase of 1 percent compared with the second quarter of 2014. The revenue growth included increases of 8 percent due to increased volume and 1 percent due to higher prices, largely offset by a decrease of 8 percent due to the unfavorable impact of foreign exchange rates. The 8 percent increase in volume was primarily due to the inclusion of revenue from Novartis Animal Health, and to a lesser extent increased volume for several products, including Cyramza and Trulicity. These worldwide volume increases were partially offset by lower demand for Cymbalta<sup>®</sup> and Evista<sup>®</sup>, largely due to U.S. patent expirations in December 2013 and March 2014, respectively. Revenue in the U.S. increased 6 percent to \$2.528 billion, driven primarily by higher prices, the inclusion of revenue from Novartis Animal Health and increased volume for several products, partially offset by patent expirations for Cymbalta and Evista. Revenue outside the U.S. decreased 4 percent to \$2.451 billion, driven by the unfavorable impact of foreign exchange rates, partially offset by the inclusion of revenue from Novartis Animal Health and increased volume for the majority of pharmaceutical products, due in part to wholesaler buying patterns in Japan.

Gross margin remained relatively flat at \$3.760 billion in the second quarter of 2015, as the favorable impact of foreign exchange rates on international inventories sold and the inclusion of Novartis Animal Health were largely offset by the foreign exchange impact on revenue and inventory step-up and amortization costs. Gross margin as a percent of revenue was 75.5 percent, a decrease of 0.4 percentage points compared with the second quarter of 2014. The decrease in gross margin percent was primarily due to the inclusion of Novartis Animal Health and inventory step-up and amortization costs, largely offset by the impact of foreign exchange rates on international inventories sold.

Operating expenses in the second quarter of 2015, defined as the sum of research and development and marketing, selling and administrative expenses, were \$2.805 billion, a decrease of 2 percent compared with the second quarter of 2014. Research and development expenses decreased 2 percent to \$1.169 billion, or 23.5 percent of revenue, driven primarily by the favorable impact of foreign exchange rates, partially offset by expenses of Novartis Animal Health. Marketing, selling and administrative expenses decreased 2 percent to \$1.635 billion, due to the favorable impact of foreign exchange rates and ongoing cost-containment measures, partially offset by expenses of Novartis Animal Health and marketing and selling expenses related to new product launches.

In the second quarter of 2015, the company recognized acquired in-process research and development charges of \$80.0 million. These charges included a \$50.0 million payment to Hanmi Pharmaceutical Co., Ltd., related to a previously announced exclusive license and collaboration agreement for Hanmi's oral Bruton's tyrosine kinase (BTK) inhibitor for the treatment of autoimmune and other diseases, and a \$30.0 million payment to BioNTech AG related to a research collaboration to discover novel cancer immunotherapies. There were no acquired in-process research and development charges in the second quarter of 2014.

In the second quarter of 2015, the company recognized asset impairment, restructuring and other special charges of \$72.4 million. The charges primarily relate to integration costs for Novartis Animal Health, asset impairments and severance costs. There were no asset impairment, restructuring and other special charges in the second quarter of 2014.

Operating income in the second quarter of 2015 was \$803.0 million, a decline of 9 percent compared with the second quarter of 2014, driven by higher acquired in-process research and development charges and asset impairment, restructuring and other special charges, partially offset by lower operating expenses.

Other income (expense) was an expense of \$123.3 million in the second quarter of 2015, compared with income of \$53.8 million in the second quarter of 2014. Other expense in 2015 was driven by a net charge of \$152.7 million related to the repurchase of \$1.65 billion of debt.

The effective tax rate was 11.6 percent in the second quarter of 2015, compared with 22.0 percent in the second quarter of 2014. The decrease in the 2015 effective tax rate was primarily due to the tax impact of the net charge related to the repurchase of debt, acquired in-process research and development charges, and asset impairment, restructuring and other special charges. The 2015 effective tax rate also reflected a net discrete tax benefit of approximately \$24 million. Neither period includes the benefit of certain expired U.S. tax provisions, including the R&D tax credit.

In the second quarter of 2015, net income decreased 18 percent to \$600.8 million, and earnings per share decreased 18 percent to \$0.56, compared with \$733.5 million and \$0.68, respectively, in the second quarter of 2014. The declines in net income and earnings per share were driven by charges related to the repurchase of debt and lower operating income, partially offset by a lower effective tax rate.

# Second-Quarter 2015 Non-GAAP Measures

On a non-GAAP basis, worldwide revenue was \$4.979 billion in the second quarter of 2015, a decline of 4 percent compared with the second quarter of 2014. The revenue decline was driven by the unfavorable impact of foreign exchange rates and lower demand for Cymbalta and Evista following U.S. patent expirations, partially offset by increased volume for several products, including Cyramza and Trulicity, and higher prices. U.S. revenue increased 3 percent to \$2.528 billion, driven primarily by higher prices and increased volume for several products, partially offset by the patent expirations for Cymbalta and Evista. Revenue outside the U.S. decreased 11 percent to \$2.451 billion, driven by the unfavorable impact of foreign exchange rates, partially offset by increased volumes for the majority of pharmaceutical products.

Gross margin decreased 1 percent to \$3.945 billion in the second quarter of 2015, as the negative impact of foreign exchange rates on revenue was largely offset by the favorable impact of foreign exchange rates on international inventories sold and increased volume. Gross margin as a percent of revenue was 79.2 percent, an increase of 2.5 percentage points compared with the second quarter of 2014. The increase in gross margin percent was due to the impact of foreign exchange rates on international inventories sold.

Operating expenses in the second quarter of 2015 were \$2.769 billion, a decline of 7 percent compared with the second quarter of 2014. Research and development expenses decreased 5 percent to \$1.169 billion, or 23.5 percent of revenue, driven primarily by the favorable impact of foreign exchange rates. Marketing, selling and administrative expenses decreased 8 percent to \$1.600 billion, due to the favorable impact of foreign exchange rates, cost reductions in the combined animal health organization and ongoing cost-containment measures, partially offset by marketing and selling expenses related to new product launches.

Other income (expense) was income of \$29.4 million in the second quarter of 2015, compared with income of \$18.3 million in the second quarter of 2014.

The effective tax rate decreased to 20.8 percent, compared with 23.1 percent in the second quarter of 2014, due primarily to a discrete tax benefit of approximately \$24 million in 2015.

Net income increased 20 percent to \$954.8 million, and earnings per share increased 22 percent to \$0.90, compared with \$798.1 million and \$0.74, respectively, in the second quarter of 2014. The increases were driven primarily by a decrease in operating expenses and a lower effective tax rate, partially offset by lower gross margin. Earnings per share benefited slightly from a lower number of shares outstanding in the second quarter of 2015 compared with the second quarter of 2014.

For further detail, see the reconciliation below as well as the Reconciliation of GAAP Reported to Selected Non-GAAP Adjusted Information table later in this release.

	<u>S</u>	econd Quar	<u>ter</u>	
	<u>2015</u>		<u>2014</u>	% Change
Earnings per share (reported)	\$ 0.56	\$	0.68	(18)%
Novartis Animal Health 2014 results	_		(.02)	
Novartis Animal Health inventory step-up	.05		_	
Amortization of intangible assets	.10		.08	
Acquired in-process research and development	.05		_	
Net charge related to repurchase of debt	.09		_	
Asset impairment, restructuring and other special charges	.05		_	
Earnings per share (non-GAAP)	\$ 0.90	\$	0.74	22%

Numbers may not add due to rounding.

# Year-to-Date Results

For the first six months of 2015, worldwide revenue remained relatively flat at \$9.623 billion compared with the same period in 2014. Reported net income and earnings per share were \$1.130 billion and \$1.06, respectively. Net income and earnings per share, on a non-GAAP basis, were \$1.879 billion and \$1.76, respectively.

For further detail, see the reconciliation below as well as the Reconciliation of GAAP Reported to Selected Non-GAAP Adjusted Information table later in this release.

		2		
	<u>2015</u>		<u>2014</u>	% Change
Earnings per share (reported)	\$ 1.06	\$	1.36	(22)%
Novartis Animal Health 2014 results	_		(.05)	
Novartis Animal Health inventory step-up	.09		_	
Amortization of intangible assets	.20		.16	
Acquired in-process research and development	.20		.02	
Net charge related to repurchase of debt	.09		_	
Asset impairment, restructuring and other special charges	 .12			
Earnings per share (non-GAAP)	\$ 1.76	\$	1.48	19%

Numbers may not add due to rounding.

Select Revenue Highli	<u>ghts</u>									
(Dollars in millions)		Seco	nd Quart	er			Ye	ar-to-Date		
		2015		2014	_ % C	hange	 2015	_	2014	% Change
Humalog <sup>®</sup>	\$	654.3	\$	700.1		(7)%	\$ 1,338.2	\$	1,350.1	(1)%
Alimta		664.3		711.6		(7)%	1,237.4		1,343.6	(8)%
Cialis <sup>®</sup>		567.9		567.8		0%	1,106.2		1,100.2	1%
Humulin <sup>®</sup>		316.4		352.4		(10)%	632.1		668.6	(5)%
Forteo <sup>®</sup>		328.4		308.6		6%	621.4		608.9	2%
Cymbalta		274.1		401.3		(32)%	561.1		879.5	(36)%
Zyprexa <sup>®</sup>		253.7		243.8		4%	473.2		526.9	(10)%
Strattera <sup>®</sup>		191.8		197.4		(3)%	365.5		351.8	4%
Effient <sup>®</sup>		128.8		133.6		(4)%	250.6		252.9	(1)%
Trajenta <sup>®(a)</sup>		80.0		90.3		(11)%	162.4		167.1	(3)%
Cyramza		87.7		13.7		NM	155.2		13.7	NM
Evista		59.7		108.3		(45)%	126.5		258.3	(51)%
Animal Health		840.8		601.2		40%	1,590.5		1,128.6	41%

Total Revenue 4,978.7 4,935.6 1% 9,623.4 9,618.7 0%

<sup>(a)</sup>Trajenta revenue includes Jentadueto<sup>®</sup> NM - not meaningful

# **Humalog**

For the second quarter of 2015, worldwide Humalog sales decreased 7 percent to \$654.3 million. Sales in the U.S. decreased 3 percent to \$399.7 million, driven primarily by lower net effective selling prices. Sales outside the U.S. decreased 11 percent to \$254.6 million, driven by the unfavorable impact of foreign exchange rates, partially offset by increased volume and higher prices.

### **Alimta**

For the second quarter of 2015, Alimta generated sales of \$664.3 million, a decline of 7 percent compared with the second quarter of 2014. U.S. sales of Alimta increased 3 percent to \$330.0 million, driven by higher prices. Sales outside the U.S. decreased 14 percent to \$334.3 million, driven by the unfavorable impact of foreign exchange rates and, to a lesser extent, lower prices, partially offset by increased volume.

# Cialis

Cialis sales for the second quarter of 2015 remained flat at \$567.9 million. U.S. sales of Cialis were \$309.5 million, a 16 percent increase compared with the second quarter of 2014, driven by higher prices, partially offset by decreased volume. Sales of Cialis outside the U.S. decreased 14 percent to \$258.4 million, driven by the unfavorable impact of foreign exchange rates, partially offset by increased volume.

### Humulin

Worldwide Humulin sales of \$316.4 million for the second quarter of 2015 decreased 10 percent compared with the second quarter of 2014. U.S. sales increased 4 percent to \$188.1 million, driven primarily by increased demand and higher prices. Sales outside the U.S. decreased 25 percent to \$128.3 million, driven by decreased volume, primarily in Brazil, and the unfavorable impact of foreign exchange rates.

#### Forteo

Second-quarter 2015 sales of Forteo were \$328.4 million, a 6 percent increase compared with the second quarter of 2014. U.S. sales of Forteo increased 13 percent to \$144.6 million, driven by higher prices, partially offset by decreased demand. Sales outside the U.S. increased 2 percent to \$183.8 million, as increased volume, primarily due to wholesaler buying patterns in Japan, was largely offset by the unfavorable impact of foreign exchange rates.

# **Cymbalta**

For the second quarter of 2015, Cymbalta generated \$274.1 million of sales, a decline of 32 percent compared with the second quarter of 2014. U.S. sales of Cymbalta decreased 64 percent to \$40.5 million, due to the loss of U.S. patent exclusivity in December 2013. Sales of Cymbalta outside the U.S. were \$233.6 million, a decline of 19 percent, driven by the unfavorable impact of foreign exchange rates and the loss of exclusivity in 2014. This was partially offset by increased volume in Japan, primarily due to wholesaler buying patterns.

### **Zyprexa**

In the second quarter of 2015, Zyprexa sales totaled \$253.7 million, an increase of 4 percent compared with the second quarter of 2014. U.S. sales of Zyprexa were \$57.6 million. Zyprexa sales outside the U.S. decreased 4 percent to \$196.1 million, due to the unfavorable impact of foreign exchange rates, partially offset by increased volume in Japan, primarily due to wholesaler buying patterns.

#### Strattera

During the second quarter of 2015, Strattera generated \$191.8 million of sales, a decline of 3 percent compared with the second quarter of 2014. U.S. sales decreased 7 percent to \$121.1 million, driven primarily by lower net effective selling prices. Sales outside the U.S. increased 4 percent to \$70.7 million, driven by increased volume, primarily due to wholesaler buying patterns in Japan, partially offset by the unfavorable impact of foreign exchange rates.

# **Effient**

Effient sales were \$128.8 million in the second quarter of 2015, a decrease of 4 percent compared with the second quarter of 2014. U.S. Effient sales increased 2 percent to \$102.0 million, as higher prices were largely offset by decreased demand. Sales outside the U.S. decreased 19 percent to \$26.8 million, driven by the unfavorable impact of foreign exchange rates.

# **Evista**

Evista sales for the second quarter of 2015 were \$59.7 million, a decline of 45 percent compared to the second quarter of 2014. U.S. sales of Evista decreased 75 percent to \$13.7 million, due to the loss of U.S. patent exclusivity in March 2014. Sales outside the U.S. decreased 14 percent to \$46.0 million, driven by the unfavorable impact of foreign exchange rates.

# **Animal Health**

In the second quarter of 2015, worldwide animal health sales totaled \$840.8 million, an increase of 40 percent compared with the second quarter of 2014. U.S. animal health sales increased 24 percent to \$410.0 million, and animal health sales outside the U.S. increased 60 percent to \$430.8 million. The increases were primarily driven by the inclusion of revenue from Novartis Animal Health.

Including the sales of Novartis Animal Health in 2014, worldwide animal health sales decreased 4 percent, U.S. animal health sales increased 1 percent and animal health sales outside the U.S. decreased 9 percent. The increase in U.S. animal health sales was driven by increased volume in companion animal products and to a lesser extent higher prices, partially offset by decreased volume in food animal products. The decrease in animal health sales outside the U.S. was driven by the unfavorable impact of foreign exchange rates, partially offset by increased volume, primarily in food animal products, and to a lesser extent higher prices. Including the sales of Novartis Animal Health in 2014 and excluding the unfavorable impact of foreign exchange rates, worldwide animal health sales increased 3 percent.

# 2015 Financial Guidance

The company has revised certain elements of its 2015 financial guidance on a reported basis and on a non-GAAP basis. Full-year 2015 earnings per share are now expected to be in the range of \$2.20 to \$2.30 on a reported basis. On a non-GAAP basis, full-year 2015 earnings per share are now expected to be in the range of \$3.20 to \$3.30.

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	2015
	Expectations
Earnings per share (reported)	\$2.20 to \$2.30
Amortization of intangible assets including the impact of the transfer of Erbitux rights	.39
Acquired in-process research and development charges	.21
Net charge related to repurchase of debt	.09
Asset impairment, restructuring, integration and inventory step-up costs, primarily related to the acquisition of Novartis Animal Health	.31
Earnings per share (non-GAAP)	\$3.20 to \$3.30

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

The company now anticipates 2015 revenue of between \$19.7 billion and \$20.0 billion, reflecting solid underlying performance for the first six months of the year, including the launch trajectories of Jardiance, Trulicity and Cyramza.

The company still expects that gross margin as a percent of revenue will be approximately 74.5 percent on a reported basis. On a non-GAAP basis, gross margin as a percent of revenue is still expected to be approximately 78.0 percent, reflecting the exclusion of inventory step-up costs associated with the acquisition of Novartis Animal Health as well as amortization of intangibles.

Marketing, selling, and administrative expenses on a reported basis are still expected to be in the range of \$6.4 billion to \$6.7 billion. On a non-GAAP basis, marketing, selling, and administrative expenses are still expected to be in the range of \$6.3 billion to \$6.6 billion. Research and development expenses are still expected to be in the range of \$4.7 billion to \$4.9 billion.

Other income (expense) is now expected to be in a range between \$50 million of expense and \$0 on a reported basis due to the net charge related to the repurchase of debt. On a non-GAAP basis, other income (expense) is now expected to be in a range between \$100 million and \$150 million of income, reflecting net gains on investments realized to date.

The 2015 tax rate is now expected to be approximately 14.5 percent on a reported basis, primarily due to the tax impact of the net charge related to the repurchase of debt. The non-GAAP tax rate is now expected to be approximately 21.0 percent. Both rates assume 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 non-GAAP 2015 tax rate would be approximately 1.5 percentage points higher.

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

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

	2015 G	uidance
	Prior	Revised
Revenue	\$19.5 to \$20.0 billion	\$19.7 to \$20.0 billion
Gross Margin % of Revenue (reported)	Approx. 74.5%	Approx. 74.5%
Gross Margin % of Revenue (non-GAAP)	Approx. 78.0%	Approx. 78.0%
Marketing, Selling & Admin (reported)	\$6.4 to \$6.7 billion	\$6.4 to \$6.7 billion
Marketing, Selling & Admin (non-GAAP)	\$6.3 to \$6.6 billion	\$6.3 to \$6.6 billion
Research & Development	\$4.7 to \$4.9 billion	\$4.7 to \$4.9 billion
Other Income/(Expense) (reported)	\$75 to \$125 million	(\$50 million) to \$0
Other Income/(Expense) (non-GAAP)	\$75 to \$125 million	\$100 to \$150 million
Tax Rate (reported)	Approx. 16.5%	Approx. 14.5%
Tax Rate (non-GAAP)	Approx. 21.5%	Approx. 21.0%
Earnings per share (reported)	\$2.21 to \$2.31	\$2.20 to \$2.30
Earnings per share (non-GAAP)	\$3.10 to \$3.20	\$3.20 to \$3.30
Capital Expenditures	Approx. \$1.3 billion	Approx. \$1.3 billion

The company's 2015 financial guidance is subject to final acquisition accounting adjustments for the acquisitions of Novartis Animal Health and Erbitux rights.

# **Webcast of Conference Call**

As previously announced, investors and the general public can access a live webcast of the second-quarter 2015 financial results conference call through a link on Lilly's website at <a href="www.lilly.com">www.lilly.com</a>. The conference call will begin at 9:00 a.m. Eastern Daylight Time (EDT) 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 volunteerism. To learn more about Lilly, please visit us at <a href="https://www.lilly.com">www.lilly.com</a> and <a href="https://www.lilly.com">http://www.lilly.com</a>/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. 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 U.S. Securities and Exchange Commission (SEC); acquisitions and business development transactions and related integration considerations; 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-K filed with the SEC. You should not place undue reliance on forward-looking statements, which speak only as of the date of this release. Except as is required by law, the company expressly disclaims any obligation to publicly release any revisions to forward-looking statements to reflect events after the date of this release.

Alimta® (pemetrexed disodium, Lilly)

Cialis<sup>®</sup> (tadalafil, Lilly)

Cymbalta® (duloxetine hydrochloride, Lilly)

Cyramza<sup>®</sup> (ramucirumab, Lilly)

Effient® (prasugrel, Lilly)

Erbitux® (cetuximab, Bristol-Myers Squibb Company)

Evista® (raloxifene hydrochloride, Lilly)

Forteo® (teriparatide of recombinant DNA origin injection, Lilly)

Glyxambi<sup>®</sup> (empagliflozin/linagliptin, Boehringer Ingelheim)

Humalog<sup>®</sup> (insulin lispro injection of recombinant DNA origin, Lilly)

Humulin® (human insulin of recombinant DNA origin, Lilly)

Jardiance® (empagliflozin, Boehringer Ingelheim)

Jentadueto<sup>®</sup> (linagliptin/metformin, Boehringer Ingelheim)

Sentinel® (lufenuron and milbemycin oxime, Virbac)

Strattera® (atomoxetine hydrochloride, Lilly)

Synjardy<sup>® (</sup>empagliflozin/metformin, Boehringer Ingelheim)

Traienta® (linagliptin, Boehringer Ingelheim)

Trulicity™ (dulaglutide, Lilly)

Zyprexa<sup>®</sup> (olanzapine, Lilly)

# Eli Lilly and Company Employment Information

December 31, 2014

Worldwide Employees

Revenue

41.120\*

39.135

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

		onins Ended			SIX WIGHTIS ETIQEQ							
		Ju	ne 30,			June 30,						
	2015		2014	% Chg.		2015		2014	% Chg.			
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<sup>\*</sup>Employment totals reflect additions from the acquisition of Novartis Animal Health.

Cost of sales Research and development		1,218.4 1,169.5	1,189.7 1,195.4	2% (2)%	2,411.1 2,208.8	2,412.4 2,304.7	0% (4)%
Marketing, selling and administrative Acquired in-process research and development		1,635.4 80.0	1,663.9	(2)% NM	3,158.9 336.0	3,148.8	0% NM
Asset impairment, restructuring and oth special charges	ner	72.4	 	NM	180.4	 31.4	NM
Operating income		803.0	886.6	(9)%	1,328.2	1,721.4	(23)%
Net interest income (expense)		(16.2)	(1.9)		(35.7)	(5.3)	
Net other income (expense)		(107.1)	 55.7		5.1	 115.1	
Other income (expense)		(123.3)	 53.8	NM	(30.6)	 109.8	NM
Income before income taxes		679.7	940.4	(28)%	1,297.6	1,831.2	(29)%
Income taxes		78.9	 206.9	(62)%	167.3	 369.8	(55)%
Net income	\$	600.8	\$ 733.5	(18)%	\$ 1,130.3	\$ 1,461.4	(23)%
Earnings per share - diluted	\$	0.56	\$ 0.68	(18)%	\$ 1.06	\$ 1.36	(22)%
Dividends paid per share	\$	0.50	\$ 0.49	2%	\$ 1.00	\$ 0.98	2%
Weighted-average shares outs (thousands) - diluted	tanding	1,065,584	1,076,418		1,066,335	1,076,387	

NM - not meaningful

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

			ee Months End June 30, 2015		Three Months Ended June 30, 2014					
	_	GAAP Reported	ustments <sup>(c)</sup>	Non-GAAP Adjusted	 GAAP Reported	Adj	justments <sup>(d)</sup>		Non-GAAP Adjusted	
Revenue	\$	4,978.7	\$ _	\$ 4,978.7	\$ 4,935.6	\$	275.6	\$	5,211.2	
Cost of sales		1,218.4	(184.5)	1,033.9	1,189.7		27.0		1,216.7	
Operating expenses <sup>(b)</sup>		2,804.9	(35.8)	2,769.1	2,859.3		115.1		2,974.4	
Acquired in-process research and development		80.0	(80.0)	_	_		_		_	
Asset impairment, restructuring and other special charges		72.4	(72.4)	_	_		_		_	
Other income (expense)		(123.3)	152.7	29.4	53.8		(35.5)		18.3	
Income taxes		78.9	171.3	250.3	206.9		33.3		240.2	
Net income	\$	600.8	\$ 354.1	\$ 954.8	\$ 733.5	\$	64.6	\$	798.1	
Earnings per share - diluted	\$	0.56	\$ 0.33	\$ 0.90	\$ 0.68	\$	0.06	\$	0.74	

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

items that are typically highly variable, difficult to predict, and of a size that could have a substantial impact on the company's reported operations for a period. Non-GAAP adjusted amounts for 2014 assume the Novartis Animal Health acquisition was completed on January 1, 2014. Beginning in 2015, non-GAAP financial measures for periods presented also exclude amortization of intangibles primarily associated with costs of marketed products acquired or licensed from third parties. 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 June 30, 2015, include the following:

(Dollars in millions, except per share data)	Amortization <sup>(i)</sup> IPR&D <sup>(ii)</sup>			Inve	ntory step- up <sup>(iii)</sup>	urchase of debt <sup>(iv)</sup>	specified ems <sup>(v)</sup>	Total Adjustments		
Revenue	\$	_	\$	_	\$	_	\$ _	\$ _	\$	_
Cost of sales		(116.1)		_		(68.4)	_	_		(184.5)
Operating expenses		(35.8)		_		_	_	_		(35.8)
Acquired in-process research and development		_		(80.0)		_	_	_		(80.0)
Asset impairment, restructuring and other special charges		_		_		_	_	(72.4)		(72.4)
Other income (expense)		_		_		_	152.7	_		152.7
Income taxes		49.5		28.0		19.5	53.5	20.8		171.3
Net income	\$	102.4	\$	52.0	\$	48.9	\$ 99.3	\$ 51.6	\$	354.1
Earnings per share - diluted	\$	0.10	\$	0.05	\$	0.05	\$ 0.09	\$ 0.05	\$	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 included a \$50.0 million payment to Hanmi Pharma 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 and a \$30.0 million payment to BioNTech AG related to a research collaboration to discover novel cancer immunotherapies.
- 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.
- (d) Adjustments to certain GAAP reported measures for the three months ended June 30, 2014, include the following:

(Dollars in millions, except per share data)	 rartis Animal Health <sup>(i)</sup>	egacy ortization <sup>(ii)</sup>	Total	Adjustments
Revenue	\$ 275.6	\$ _	\$	275.6
Cost of sales	122.8	(95.8)		27.0
Operating expenses	151.4	(36.3)		115.1
Acquired in-process research and development	_	_		_
Asset impairment, restructuring and other special charges	_	_		_
Other income (expense)	(35.5)	_		(35.5)
Income taxes	(11.9)	45.2		33.3
Net income	\$ (22.2)	\$ 86.8	\$	64.6
Earnings per share - diluted	\$ (0.02)	\$ 0.08	\$	0.06

Numbers may not add due to rounding.

- i. Inclusion of the results of Novartis Animal Health as if the acquisition and the financing for the acquisition had occurred as of January 1, 2014. Amounts reflect GAAP reported measures of Novartis Animal Health, adjusted as follows:
  - 1. Exclude results associated with the Sentinel<sup>®</sup> canine parasiticide franchise in the U.S., which was divested following the closing of the acquisition
  - 2. Exclude amortization of intangibles
  - 3. Exclude integration and inventory step-up costs
  - 4. Other miscellaneous adjustments.
- ii. Exclude legacy amortization of intangibles primarily associated with costs of marketed products acquired or licensed from third parties.

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

			Six Months End June 30, 2015			Six Months Ended June 30, 2014						
	-	GAAP Reported	Non-GAAP Adjustments <sup>(C)</sup> Adjusted		 GAAP Reported	Adj	justments <sup>(d)</sup>		Non-GAAP Adjusted			
Total revenue	\$	9,623.4	\$ —	\$	9,623.4	\$ 9,618.7	\$	527.4	\$	10,146.1		
Cost of sales		2,411.1	(364.9)		2,046.2	2,412.4		57.9		2,470.3		
Operating expenses <sup>(b)</sup>		5,367.7	(71.6)		5,296.1	5,453.5		242.7		5,696.2		
Acquired in-process research and development		336.0	(336.0)		_	_		_		_		
Asset impairment, restructuring and other special charges		180.4	(180.4)		_	31.4		(31.4)		_		
Other income (expense)		(30.6)	152.7		122.1	109.8		(55.7)		54.1		
Income taxes		167.3	357.4		524.7	369.8		68.0		437.8		
Net income	\$	1,130.3	748.3	\$	1,878.5	\$ 1,461.4		134.5	\$	1,595.9		
Earnings per share - diluted	\$	1.06	0.70	\$	1.76	\$ 1.36		0.12	\$	1.48		

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 items that are typically highly variable, difficult to predict, and of a size that could have a substantial impact on the company's reported operations for a period. Non-GAAP adjusted amounts for 2014 assume the Novartis Animal Health acquisition was completed on January 1, 2014. Beginning in 2015, non-GAAP financial measures for periods presented also exclude amortization of intangibles primarily associated with costs of marketed products acquired or licensed from third parties. 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 six months ended June 30, 2015, include the following:

(Dollars in millions, except per share data)		Amortization <sup>(i)</sup>		IPR&D <sup>(ii)</sup>	Inventory step-up (iii)		Repurchase of debt <sup>(iv)</sup>		Other specified items <sup>(v)</sup>		Total Adjustments	
Revenue	\$	_	\$	_	\$	_	\$	_	\$	_	\$	_
Cost of sales		(233.0)		_		(131.9)		_		_		(364.9)
Operating expenses		(71.6)		_		_		_		_		(71.6)
Acquired in-process research and development		_		(336.0)		_		_		_		(336.0)
Asset impairment, restructuring and other special charges		_		_		_		_		(180.4)		(180.4)
Other income (expense)		_		_		_		152.7		_		152.7
Income taxes		99.9		117.6		37.6		53.5		48.8		357.4
Net income	\$	204.7	\$	218.4	\$	94.3	\$	99.3	\$	131.6	\$	748.3
Earnings per share - diluted	\$	0.20	\$	0.20	\$	0.09	\$	0.09	\$	0.12	\$	0.70

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 included a \$200.0 million payment to Pfizer following the FDA decision allowing the resumption of the Phase III clinical program for tanezumab, a \$56.0 million charge associated with a collaboration with Innovent to develop potential oncology therapies, a \$50.0 million payment to Hanmi Pharma 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, and a \$30.0 million payment to BioNTech AG related to a research collaboration to discover novel cancer immunotherapies.
- 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.

(d) Adjustments to certain GAAP reported measures for the six months ended June 30, 2014, include the following:

(Dollars in millions, except per share data)		Animal Health <sup>(i)</sup>	Legacy	Amortization <sup>(ii)</sup>	Other specified items(iii)		Total Adjustments	
Revenue	\$	527.4	\$	_	\$	_	\$	527.4
Cost of sales		246.1		(188.2)		_		57.9
Operating expenses		315.4		(72.7)		_		242.7
Acquired in-process research and development		_		_		_		_
Asset impairment, restructuring and other special charges		_		_		(31.4)		(31.4)
Other income (expense)		(55.7)		_		_		(55.7)
Income taxes		(30.8)		89.4		9.4		68.0
Net income	\$	(59.1)	\$	171.6	\$	22.0	\$	134.5
Earnings per share - diluted	\$	(0.05)	\$	0.16	\$	0.02	\$	0.12

Numbers may not add due to rounding.

- i. Inclusion of the results of Novartis Animal Health as if the acquisition and the financing for the acquisition had occurred as of January 1, 2014. Amounts reflect GAAP reported measures of Novartis Animal Health, adjusted as follows:
  - 1. Exclude results associated with the Sentinel<sup>®</sup> canine parasiticide franchise in the U.S., which was divested following the closing of the acquisition
  - 2. Exclude amortization of intangibles
  - 3. Exclude integration and inventory step-up costs
  - 4. Other miscellaneous adjustments.
- ii. Exclude legacy amortization of intangibles primarily associated with costs of marketed products acquired or licensed from third parties.
- iii. Exclude costs primarily associated with restructuring to reduce the company's cost structure.

Refer to: Lauren Zierke; <u>lauren zierke@lilly.com</u>; (317) 277-6524 (Media) Philip Johnson; <u>johnson philip l@lilly.com</u>; (317) 655-6874 (Investors)



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