



Eli Lilly and Company
Lilly Corporate Center
Indianapolis, Indiana 46285
U.S.A.

www.lilly.com

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Refer to: (317) 276-5795 – Mark Taylor (Media)
(317) 655-6874 – Philip Johnson (Investors)

Lilly Reports First-Quarter 2013 Results

- *Worldwide revenue was flat as growth in key products offset lower Zyprexa revenue following patent expirations.*
- *Cymbalta revenue increased 19 percent while Cialis increased 11 percent.*
- *Expense controls resulted in lower SG&A, offsetting growth in R&D expense.*
- *First quarter 2013 results include income of \$495 million related to the transfer to Amylin of exenatide commercial rights outside of the U.S.*
- *Tax rate comparisons benefited from the reinstatement of the U.S. R&D tax credit.*
- *First quarter earnings per share grew to \$1.42 (reported), or \$1.14 (non-GAAP).*
- *2013 earnings per share reconfirmed to be in the range of \$4.10 to \$4.25 (reported), or \$3.82 to \$3.97 (non-GAAP).*

Eli Lilly and Company (NYSE: LLY) today announced financial results for the first quarter of 2013.

\$ in millions, except per share data	<u>First Quarter</u>		<u>%</u>
	<u>2013</u>	<u>2012</u>	<u>Growth</u>
Total Revenue – Reported	\$5,602.0	\$5,602.0	0%
Net Income – Reported	1,548.0	1,011.1	53%
EPS – Reported	1.42	0.91	56%
Net Income – non-GAAP	1,247.7	1,026.9	22%
EPS – non-GAAP	1.14	0.92	24%

Financial results for 2013 and 2012 are 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 results exclude the items described in the

reconciliation tables later in the release. The non-GAAP results are presented in order to provide additional insights into the underlying trends in the company's business. The company's 2013 financial guidance is also being provided on both a reported and a non-GAAP basis.

“Lilly delivered solid financial results in the first quarter of 2013 despite numerous headwinds, as growth in several key products and regions offset the post-patent decline in Zyprexa, a weaker Japanese yen and a slowdown in parts of our animal health business,” said John C. Lechleiter, Ph.D., Lilly's chairman, president and chief executive officer. “We also continued to maintain strict expense controls this quarter. Most importantly, we have remained focused on advancing our late-stage pipeline, and are pleased to announce that we have received Fast Track designation from the FDA and have initiated a rolling submission for ramucirumab. Together with the recent submission of empagliflozin, these are the first two of what could be up to five U.S. regulatory submissions this year.”

Key Events Over the Last Three Months

- The company and its partner, Boehringer Ingelheim, submitted a New Drug Application (NDA) for the investigational sodium glucose co-transporter-2 (SGLT2) inhibitor empagliflozin to the U.S. Food and Drug Administration (FDA) for the treatment of type 2 diabetes mellitus in adults. In addition, the European Medicines Agency accepted for review a marketing authorization application for empagliflozin.
- The company received Fast Track designation from the FDA and initiated a rolling submission for ramucirumab as monotherapy treatment in second-line gastric cancer.
- The company announced that the primary endpoints related to reduction in HbA1c were met in the Phase 3 AWARD-2 and AWARD-4 studies for dulaglutide, an investigational GLP-1 receptor agonist being studied as a once-weekly treatment for type 2 diabetes.
- The Phase III rheumatoid arthritis (RA) program for tabalumab was discontinued due to lack of efficacy. The decision was not based on safety concerns. The tabalumab Phase III program for systemic lupus erythematosus is ongoing and will continue as planned.
- The company initiated a significant reduction in its U.S. Bio-Medicines sales force to adapt to changing customer requirements, evolutions in the U.S. health care environment and the upcoming loss of exclusivity for Cymbalta and Evista. Substantially all of the severance costs associated with this action were recognized in the fourth quarter of 2012. The

company will also implement a small increase in its diabetes sales force to prepare for the planned launches of late-stage pipeline products.

- The commercial rights to exenatide outside of the U.S. were transferred to Amylin Pharmaceuticals.
- The company agreed to end its U.S. co-promotion of Livalo[®] and return the rights back to its partner, Kowa Pharmaceuticals America, Inc.
- The Elanco animal health business announced that it will invest approximately \$100 million USD to purchase a minority equity stake in China Animal Healthcare Ltd., one of the leading players in the animal health industry in the People's Republic of China. The parties have also agreed to a framework to allow for future commercial collaboration activities.
- The company completed its previously-announced \$1.5 billion share repurchase program.

First-Quarter Reported Results

In the first quarter of 2013, worldwide total revenue was \$5.602 billion, which was flat compared with the first quarter of 2012. An increase of 4 percent due to higher prices was offset by decreases of 3 percent due to lower volume and 1 percent due to the unfavorable impact of foreign exchange rates. The decrease in volume was driven primarily by the loss of patent exclusivity for Zyprexa[®] in most major markets, partially offset by volume gains for certain other products. Total revenue in the U.S. increased 2 percent to \$3.137 billion due primarily to increased prices, partially offset by lower volume primarily due to the loss of patent exclusivity for Zyprexa. Total revenue outside the U.S. decreased by 2 percent to \$2.465 billion, driven by the loss of patent exclusivity for Zyprexa in markets other than Japan, the unfavorable impact of foreign exchange rates (primarily the Japanese yen), and, to a lesser extent, decreased prices, partially offset by increased volume in certain products.

Gross margin increased 1 percent to \$4.444 billion in the first quarter of 2013, as growth in other products offset the loss of patent exclusivity for Zyprexa. Gross margin as a percent of total revenue was 79.3 percent, an increase of 0.7 percentage points compared with the first quarter of 2012. The increase in gross margin percent was primarily due to higher prices and production volumes, partially offset by higher manufacturing expenses.

Total operating expense in the first quarter of 2013, defined as the sum of research and development, marketing, selling and administrative expenses, remained flat compared with the first quarter of 2012 at \$3.000 billion. Marketing, selling and administrative expenses decreased 11 percent to \$1.652 billion, reflecting the company's cost containment efforts. Research and development expenses increased 17 percent to \$1.348 billion, or 24.1 percent of total revenue, driven by expenses related to late-stage clinical trials, including approximately \$90 million of milestone payments made to Boehringer Ingelheim following the regulatory submissions for empagliflozin, and approximately \$60 million in costs related to the discontinuation of the rheumatoid arthritis program for tabalumab.

In the first quarter of 2013, the company recognized asset impairment, restructuring and other special charges of \$21.7 million, related to severance costs for actions the company is taking, primarily outside the U.S., to reduce its cost structure and global workforce. In the first quarter of 2012, the company recognized asset impairment, restructuring and other special charges of \$23.8 million, primarily related to the withdrawal of Xigris[®].

Operating income in the first quarter of 2013 was \$1.422 billion, an increase of 3 percent compared to the first quarter of 2012, as lower marketing, selling and administrative expenses, and higher gross margin, were partially offset by higher research and development expenses.

Other income (expense) was income of \$529.2 million in the first quarter of 2013, compared with expense of \$46.0 million in the first quarter of 2012. This increase was primarily related to income of \$495.4 million related to the transfer of exenatide commercial rights outside of the U.S. to Amylin during the first quarter of 2013.

The effective tax rate was 20.7 percent in the first quarter of 2013, compared with an effective tax rate of 24.3 percent in the first quarter of 2012. The decrease in the first quarter 2013 effective tax rate reflects the reinstatement of the R&D tax credit in the U.S. for the first quarter of 2013 as well as the one-time impact of the R&D tax credit for 2012 that was recorded in the first quarter of 2013, partially offset by the tax impact of the transfer of exenatide commercial rights outside of the U.S. to Amylin.

In the first quarter of 2013, net income and earnings per share increased to \$1.548 billion and \$1.42, respectively, compared with first-quarter 2012 net income of \$1.011 billion and earnings per share of \$0.91. The increases in net income and earnings per share were primarily driven by higher other income from the transfer of exenatide commercial rights outside of the U.S. to Amylin.

First-Quarter 2013 non-GAAP Results

On a non-GAAP basis, first-quarter 2013 operating income increased 3 percent to \$1.444 billion, as lower marketing, selling and administrative expenses and higher gross margin were partially offset by higher research and development expenses. The effective tax rate decreased to 15.5 percent, compared with 24.4 percent in the first quarter of 2012, primarily driven by the reinstatement of the R&D tax credit in the U.S. for the first quarter of 2013 as well as the one-time impact of the R&D tax credit for 2012 that was recorded in the first quarter of 2013. Net income and earnings per share were \$1.248 billion and \$1.14, respectively, compared with \$1.027 billion and \$0.92 during the first quarter of 2012. These increases were driven by a lower tax rate, higher other income and higher operating income.

Non-GAAP results in the first quarter of 2013 exclude items totaling \$0.28 of income. For the first quarter of 2012, expenses totaling \$0.01 per share were excluded. For further detail, see the reconciliation below as well as the footnotes to the non-GAAP income statement later in this press release.

	<u>First Quarter</u>		
	<u>2013</u>	<u>2012</u>	<u>% Change</u>
Earnings per share (reported)	\$1.42	\$0.91	56%
Asset impairment, restructuring and other special charges	0.01	0.01	
Income from the transfer of exenatide commercial rights	(0.29)	-	
Earnings per share (non-GAAP)	<u>\$1.14</u>	<u>\$0.92</u>	24%

Revenue Highlights

(Dollars in millions)	First Quarter		% Change
	2013	2012	Over/(Under) 2012
Cymbalta [®]	\$1,328.2	\$1,114.9	19%
Humalog [®]	632.7	590.3	7%
Alimta [®]	616.8	606.8	2%
Cialis	515.0	461.8	11%
Humulin [®]	311.9	307.7	1%
Zyprexa	284.8	562.7	(49)%
Forteo [®]	281.5	271.3	4%
Evista [®]	240.6	256.2	(6)%
Strattera [®]	166.7	158.9	5%
Effient [®]	115.9	115.8	0%
Animal Health	499.1	490.7	2%
Total Revenue	\$5,602.0	\$5,602.0	0%

Cymbalta

For the first quarter of 2013, Cymbalta generated \$1.328 billion in revenue, an increase of 19 percent compared with the first quarter of 2012. U.S. sales of Cymbalta increased 23 percent, to \$1.057 billion, driven by higher prices. Revenue outside the U.S. was \$271.3 million, an increase of 5 percent, driven primarily by increased demand, partially offset by lower prices.

Humalog

For the first quarter of 2013, worldwide Humalog sales increased 7 percent, to \$632.7 million. Sales in the U.S. increased 9 percent to \$378.2 million, driven by the favorable impact of wholesaler buying patterns and higher net effective selling prices. Sales outside the U.S. increased 5 percent to \$254.5 million, due to increased demand, partially offset by the unfavorable impact of foreign exchange rates.

Alimta

For the first quarter of 2013, Alimta generated sales of \$616.8 million, an increase of 2 percent compared with the first quarter of 2012. U.S. sales of Alimta increased 2 percent, to \$262.1 million, driven by increased volume and higher prices. Sales outside the U.S. increased 1 percent, to \$354.7 million, driven by increased demand, partially offset by lower prices and, to a lesser extent, the unfavorable impact of foreign exchange rates.

Cialis

Cialis sales for the first quarter of 2013 increased 11 percent to \$515.0 million. U.S. sales of Cialis were \$214.2 million in the first quarter, a 20 percent increase compared with the first quarter of 2012, driven primarily by higher prices. Sales of Cialis outside the U.S. increased 6 percent, to \$300.8 million, driven by higher prices and increased demand, partially offset by the unfavorable impact of foreign exchange rates.

Humulin

Worldwide Humulin sales increased 1 percent in the first quarter of 2013, to \$311.9 million. U.S. sales increased 5 percent to \$163.4 million, driven by higher prices, largely offset by lower demand. Sales outside the U.S. decreased 3 percent, to \$148.5 million, driven primarily by the unfavorable impact of foreign exchange rates and decreased demand.

Zyprexa

In the first quarter of 2013, Zyprexa sales totaled \$284.8 million, a decrease of 49 percent compared with the first quarter of 2012 due to the loss of patent exclusivity in 2011 in the U.S. and most major international markets. U.S. sales of Zyprexa decreased 84 percent to \$32.0 million. Zyprexa sales in international markets decreased 30 percent, to \$252.8 million. Zyprexa sales in Japan were approximately \$115 million and were negatively affected by the weakening Japanese yen.

Forteo

First-quarter 2013 sales of Forteo were \$281.5 million, a 4 percent increase compared with the first quarter of 2012. U.S. sales of Forteo decreased 9 percent to \$111.5 million, driven primarily by lower net effective selling prices. Sales outside the U.S. increased 14 percent, to \$170.0 million, due primarily to increased demand in Japan, partially offset by the unfavorable impact of foreign exchange rates.

Evista

Evista sales for the first quarter of 2013 decreased 6 percent to \$240.6 million. U.S. sales of Evista remained relatively flat at \$171.6 million, driven by decreased demand, offset by higher prices. Sales outside the U.S. decreased 18 percent to \$69.0 million, driven by lower volume and, to a lesser extent, the unfavorable impact of foreign exchange rates and lower prices.

Strattera

During the first quarter of 2013, Strattera generated \$166.7 million of sales, an increase of 5 percent compared with the first quarter of 2012. U.S. sales increased 1 percent to \$105.5 million, due to the favorable impact of wholesaler buying patterns. Sales outside the U.S. increased 13 percent to \$61.2 million driven by increased demand in Japan, partially offset by lower prices and the unfavorable impact of foreign exchange rates.

Effient

Effient sales were \$115.9 million in the first quarter of 2013, which were relatively flat with the first quarter of 2012. U.S. Effient sales decreased 7 percent to \$83.7 million, driven by the unfavorable impact of wholesaler buying patterns, and lower net effective selling prices. Sales in the U.S. were also negatively affected by increased market pressure due to the generic entry of a competitor's product. Sales outside the U.S. increased 24 percent to \$32.2 million driven by higher demand.

Animal Health

Worldwide sales of animal health products in the first quarter of 2013 were \$499.1 million, an increase of 2 percent compared with the first quarter of 2012. U.S. sales grew 9 percent, to \$295.2 million, due primarily to increased demand for Trifexis, partially offset by lower demand for food animal products. Sales outside the U.S. decreased 8 percent, to \$203.9 million, driven primarily by decreased volume in food animal products. The volume decrease in food animal products outside the U.S. was due to transition stocking in 2012 associated with the Janssen acquisition, as well as weakness in demand in many emerging markets consistent with broader industry trends.

2013 Financial Guidance

The company reconfirmed most of its 2013 financial guidance and still expects full-year 2013 earnings per share to be in the range of \$4.10 to \$4.25 on a reported basis, or \$3.82 to \$3.97 on a non-GAAP basis.

	2013 Expectations	2012 Results	% Change
Earnings per share (reported)	\$4.10 to \$4.25	\$3.66	12% to 16%
Asset impairment, restructuring and other special charges	.01	0.16	
Income from the transfer of exenatide commercial rights	(0.29)	(0.43)	
Earnings per share (non-GAAP)	\$3.82 to \$3.97	\$3.39	13% to 17%

The company still anticipates 2013 revenue of between \$22.6 billion and \$23.4 billion. Despite the initial impact of the U.S. Cymbalta patent expiration in the fourth quarter of 2013 and the loss of the anticipated 15 percent revenue sharing obligation on worldwide exenatide sales, the company expects overall revenue growth, driven by a portfolio of products including Humalog, Humulin, Cialis, Strattera, Forteo, Alimta, Cymbalta outside the U.S., Effient, Tradjenta[®] and Axiron[®], as well as animal health products. In addition, significant revenue growth is expected in the emerging markets, particularly China, while a continued weakening of the yen could dampen revenue growth in Japan.

The company still anticipates that gross margin as a percent of revenue will be approximately 78 percent.

Marketing, selling and administrative expenses are still expected in the range of \$7.1 billion to \$7.4 billion. Research and development expenses are now expected to be in the range of \$5.3 billion to \$5.6 billion.

On a reported basis, other income and deductions is now expected to be in a range between \$440 million and \$590 million of income in 2013. On a non-GAAP basis, other income and deductions is now expected to be in a range between \$50 million of expense to \$100 million of income, which excludes \$495.4 million of exenatide-related income recognized upon the transfer of exenatide commercial rights outside the U.S. to Amylin.

On a reported basis, the 2013 tax rate is now expected to be approximately 20.5 percent. On a non-GAAP basis, the 2013 tax rate is now expected to be approximately 19.0 percent. Both tax rates for 2013 include the one-time impact associated with the R&D tax credit for 2012 that was recorded in 2013 resulting from the delay in the enactment of the American Taxpayer Relief Act of 2012.

Operating cash flows are still expected to be more than sufficient to allow for capital expenditures of approximately \$900 million, fund potential business development activity and pay the company's dividend. In addition, the company has completed its previously-announced \$1.5 billion share repurchase program.

Webcast of Conference Call

As previously announced, investors and the general public can access a live webcast of the first-quarter 2013 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 10:00 a.m. Eastern Daylight Time (EDT) and will be available for replay via the website.

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of pharmaceutical products by applying the latest research from its own worldwide laboratories and from collaborations with eminent scientific organizations. Headquartered in Indianapolis, Ind., Lilly provides answers – through medicines and information – for some of the world's most urgent medical needs. Additional information about Lilly is available at www.lilly.com.

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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 competitive developments affecting current products; market uptake of recently launched products; the timing of anticipated regulatory approvals and launches of new products; regulatory actions regarding currently marketed products; issues with product supply; regulatory changes or other developments; regulatory compliance problems or government investigations; patent disputes; changes in patent law or regulations related to data-package exclusivity; other litigation involving current or future products; the impact of governmental actions regarding pricing, importation, and reimbursement for pharmaceuticals, including U.S. health care reform and deficit-reduction measures; changes in tax laws, including the American Taxpayer Relief Act of 2012; asset impairments and restructuring charges; 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.

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Alimta[®] (pemetrexed, Lilly)
Axiron[®] (testosterone, Acrux Corp.)
Cialis[®] (tadalafil, Lilly)
Cymbalta[®] (duloxetine hydrochloride, 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)
Livalo[®] (pitavastatin, Kowa Pharmaceuticals)
Strattera[®] (atomoxetine hydrochloride, Lilly)
Tradjenta[®] (linagliptin, Boehringer Ingelheim)
Trifexis[®] (spinosad + milbemycin oxime, Lilly)
Xigris[®] (drotrecogin alfa (activated), Lilly)
Zyprexa[®] (olanzapine, Lilly)

Eli Lilly and Company Employment Information

	<u>March 31, 2013</u>	<u>December 31, 2012</u>
Worldwide Employees	38,100	38,350

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

	Three Months Ended		
	March 31		
	2013	2012	% Chg.
Total Revenue	\$ 5,602.0	\$ 5,602.0	0%
Cost of sales	1,158.3	1,197.9	(3)%
Research and development	1,348.1	1,151.5	17%
Marketing, selling and administrative	1,652.0	1,847.5	(11)%
Asset impairments, restructuring and other special charges	<u>21.7</u>	<u>23.8</u>	(9)%
Operating income	1,421.9	1,381.3	3%
Net interest income (expense)	(16.7)	(19.2)	
Other income (expense) – Special	495.4	-	
Net other income (expense)	<u>50.5</u>	<u>(26.8)</u>	
Other income (expense)	529.2	(46.0)	NM
Income before income taxes	1,951.1	1,335.3	46%
Income taxes	<u>403.1</u>	<u>324.2</u>	24%
Net income	\$ <u>1,548.0</u>	\$ <u>1,011.1</u>	53%
Earnings per share – diluted	\$ <u>1.42</u>	\$ <u>0.91</u>	56%
Dividends paid per share	\$ 0.49	\$ 0.49	0%
Weighted-average shares outstanding (thousands) – diluted	1,091,876	1,116,983	

NM – not meaningful

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

	Three Months Ended		
	March 31		
	2013(a)	2012(b)	% Chg.
Total Revenue	\$ 5,602.0	\$ 5,602.0	0%
Cost of sales	1,158.3	1,197.9	(3)%
Research and development	1,348.1	1,151.5	17%
Marketing, selling and administrative	<u>1,652.0</u>	<u>1,847.5</u>	(11)%
Operating income	1,443.6	1,405.1	3%
Net interest income (expense)	(16.7)	(19.2)	
Net other income (expense)	<u>50.5</u>	<u>(26.8)</u>	
Other income (expense)	33.8	(46.0)	NM
Income before income taxes	1,477.4	1,359.1	9%
Income taxes	<u>229.7</u>	<u>332.2</u>	(31)%
Net income	\$ <u>1,247.7</u>	\$ <u>1,026.9</u>	22%
Earnings per share – diluted	\$ <u>1.14</u>	\$ <u>0.92</u>	24%
Dividends paid per share	\$ 0.49	\$ 0.49	0%
Weighted-average shares outstanding (thousands) – diluted	1,091,876	1,116,983	

- (a) The first-quarter 2013 financial statements have been adjusted to eliminate asset impairments, restructuring and other special charges totaling \$21.7 million (pretax), or \$0.01 per share (after-tax), related to severance costs from actions the company is taking, primarily outside the U.S., to reduce its cost structure and global workforce. Additionally, they have been adjusted to eliminate income totaling \$495.4 million (pretax), or \$0.29 per share (after-tax), related to the transfer of exenatide commercial rights outside the U.S. to Amylin.
- (b) The first-quarter 2012 financial statements have been adjusted to eliminate asset impairments, restructuring and other special charges totaling \$23.8 million (pretax), or \$0.01 per share (after-tax), primarily related to the withdrawal of Xigris.