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Lilly Reports Solid Start to the Year With First-Quarter 2012 Results, Raises EPS Guidance

- *Worldwide revenue declined 4 percent in the first quarter of 2012, driven by Zyprexa patent expirations, partially offset by significant growth in other products and key regions.*
- *Cymbalta revenue increased 23 percent due to strong growth in both the U.S. and international markets, while Effient revenue more than doubled.*
- *Elanco Animal Health revenue grew 33 percent, driven by gains in both the food animal and companion animal portfolios.*
- *China remained Lilly's fastest-growing market, with revenue growth of 41 percent.*
- *Continued investment in research and development supported robust Phase III pipeline of 12 potential new medicines.*
- *First quarter earnings per share were \$.91 (reported), or \$.92 (non-GAAP).*
- *2012 earnings per share guidance range raised to \$3.14 - \$3.29 (reported), or \$3.15-\$3.30 (non-GAAP)*

Eli Lilly and Company (NYSE: LLY) today announced financial results for the first quarter of 2012.

\$ in millions, except per share data	First Quarter		%
	<u>2012</u>	<u>2011</u>	<u>Change</u>
Total Revenue – Reported	\$5,602.0	\$5,839.2	(4)%
Net Income – Reported	1,011.1	1,055.9	(4)%
EPS – Reported	0.91	0.95	(4)%
Net Income – non-GAAP	1,026.9	1,374.9	(25)%
EPS – non-GAAP	0.92	1.24	(26)%

Financial results for 2012 and 2011 are presented on both a reported and a non-GAAP basis. 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. The non-GAAP results are presented in order to provide additional insights into the underlying trends in the company's business. The company's 2012 financial guidance is also being provided on both a reported and a non-GAAP basis.

"Lilly's financial results in the first quarter represent a solid start to the year and support our decision to increase our 2012 EPS guidance. Notwithstanding the negative effect of the expiration of the Zyprexa patent in the U.S. and many international markets, Lilly demonstrated strong underlying growth in other products and key regions; specifically, Cymbalta, Forteo, Effient, diabetes care and our animal health portfolio, as well as our fast-growing affiliate in China," said John C. Lechleiter, Ph.D., Lilly's chairman, president and chief executive officer. "We continue to invest appropriately in our pipeline, with 12 potential new medicines now in Phase III clinical trials. We strongly believe that our innovation-based strategy will enable Lilly to return to steady growth following a period of multiple patent expirations."

Key Events Over the Last Three Months

- The U.S. Food and Drug Administration (FDA) approved Amyvid™, a radioactive diagnostic agent indicated for brain imaging of beta-amyloid plaques in patients with cognitive impairment who are being evaluated for Alzheimer's Disease and other causes of cognitive decline.
- Japan's Ministry of Health, Labor and Welfare approved Zyprexa® for treatment of depression in bipolar disorder and Cymbalta® for treatment of diabetic peripheral neuropathic pain.
- The FDA issued a Complete Response Letter for the Erbitux® filing in first-line non-small cell lung cancer, which was based on the pivotal FLEX study. Lilly and its partner, Bristol-Myers Squibb, do not plan to resubmit the FLEX filing, but will continue to market Erbitux in the U.S. for certain types of head and neck cancer and colorectal cancer.
- The European Commission granted marketing authorization to Byetta® (exenatide twice-daily) as an adjunctive therapy to basal insulin, with or without metformin and/or Actos® (pioglitazone), for the treatment of type 2 diabetes in adults who have not achieved adequate glycemic control with these agents.

First-Quarter Reported Results

In the first quarter of 2012, worldwide total revenue was \$5.602 billion, a decrease of 4 percent compared with the first quarter of 2011. This 4 percent revenue decline was comprised of a decrease of 7 percent due to lower volume, partially offset by an increase of 4 percent in prices. Foreign exchange rates had a negligible impact. (Numbers do not add due to rounding). The decrease in volume was driven by the loss of patent exclusivity for Zyprexa in most major markets, partially offset by volume gains for other products. Total revenue in the U.S. remained relatively flat at \$3.085 billion due to the loss of patent exclusivity for Zyprexa, offset by increased prices and, to a lesser extent, increased volume in other products. Total revenue outside the U.S. decreased by 9 percent to \$2.517 billion, driven by the loss of patent exclusivity for Zyprexa, partially offset by increased volume in other products including Cymbalta, Forteo[®], Humalog[®], Efient[®] and the animal health portfolio, as well as a 41 percent revenue increase in China.

Gross margin decreased 5.5 percent to \$4.404 billion in the first quarter of 2012. Gross margin as a percent of total revenue was 78.6 percent, reflecting a decrease of 1.2 percentage points compared with the first quarter of 2011. The decrease in gross margin percent was primarily due to lower sales of Zyprexa following its patent expiration in most major markets, partially offset by the impact of foreign exchange rates on international inventories sold.

Total operating expense, defined as the sum of research and development, marketing, selling and administrative expenses, increased 3 percent compared with the first quarter of 2011. Marketing, selling and administrative expenses increased 3 percent to \$1.848 billion, driven by the diabetes collaboration with Boehringer Ingelheim and increased expense for newer pharmaceutical and animal health products, partially offset by lower administrative expenses. Research and development expenses increased 2 percent to \$1.151 billion, or 20.6 percent of total revenue, driven by expenses related to the diabetes collaboration with Boehringer Ingelheim and other late-stage clinical trial costs.

In the first quarter of 2012, the company recognized an asset impairment, restructuring and other special charge of \$23.8 million primarily related to the withdrawal of Xigris[®]. In the first quarter of 2011, the company recognized a charge of \$76.3 million for restructuring related to severance costs from previously announced strategic actions that the company is taking to reduce its cost structure,

as well as a \$388.0 million in-process research and development (IPR&D) charge associated with the diabetes collaboration with Boehringer Ingelheim.

Operating income in the first quarter of 2012 was \$1.381 billion, an increase of 7 percent compared to the first quarter of 2011, due primarily to the prior year IPR&D charge mentioned previously, partially offset by decreased revenue as a result of the loss of Zyprexa patent exclusivity.

Other income (expense) was a net expense of \$46.0 million, compared with net expense of \$11.2 million in the first quarter of 2011. The increase in other expense was driven by the recognition in the first quarter of 2011 of a gain on an equity investment and an insurance recovery, partially offset by increased interest income in the first quarter of 2012.

The effective tax rate was 24.3 percent in the first quarter of 2012, compared with an effective tax rate of 17.1 percent in the first quarter of 2011. The increase in the effective tax rate was driven primarily by the tax benefit in 2011 of the IPR&D charge described above, as well as the expiration of the R&D tax credit in the U.S. at the end of 2011.

Net income and earnings per share decreased to \$1.011 billion and \$0.91, respectively, compared with first-quarter 2011 net income of \$1.056 billion and earnings per share of \$0.95. The decreases in net income and earnings per share were primarily due to lower gross margin and the increase in the effective tax rate, partially offset by the IPR&D charge in the first quarter of 2011.

First-Quarter 2012 non-GAAP Results

On a non-GAAP basis, first quarter 2012 operating income decreased 20 percent to \$1.405 billion, due to lower gross margin resulting from the loss of patent exclusivity for Zyprexa in most major markets and, to a lesser extent, increased operating expenses. The effective tax rate was 24.4 percent, compared with 20.9 percent in the first quarter of 2011, primarily due to the expiration of the R&D tax credit at the end of 2011, as well as the inclusion of a discrete item in the first quarter of 2012 due to changes in estimates concerning certain prior-year tax items. Net income and earnings per share decreased 25 and 26 percent, to \$1.027 billion and \$0.92, respectively. These decreases were driven primarily by lower operating income.

For purposes of non-GAAP reporting, items totaling \$.01 and \$.29 per share in the first quarters of 2012 and 2011, respectively, have been 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>% Change</u>
	<u>2012</u>	<u>2011</u>	
Earnings per share (reported)	\$.91	\$.95	(4)%
In-process research and development charge associated with Boehringer Ingelheim collaboration	-	.23	
Asset impairment, restructuring, other special charges	.01	.06	
Earnings per share (non-GAAP)	\$.92	\$1.24	(26)%

Revenue Highlights

(Dollars in millions)	First Quarter		% Change
	2012	2011	Over/(Under) 2011
Cymbalta	\$1,114.9	\$908.8	23%
Alimta [®]	606.8	579.9	5%
Humalog	590.3	525.4	12%
Zyprexa	562.7	1,281.9	(56)%
Cialis [®]	461.8	434.4	6%
Humulin [®]	307.7	289.8	6%
Forteo	271.3	216.1	26%
Evista [®]	256.2	266.1	(4)%
Strattera [®]	158.9	138.7	15%
Effient	115.8	56.3	NM
Animal Health	490.7	369.8	33%
Total Revenue	\$5,602.0	\$5,839.2	(4)%

Cymbalta

For the first quarter of 2012, Cymbalta generated \$1.115 billion in revenue, an increase of 23 percent compared with the first quarter of 2011. U.S. sales of Cymbalta increased 24 percent, to \$857.6 million, driven by increased prices and higher demand. Revenue outside the U.S. was \$257.3 million, an increase of 18 percent, driven by higher demand.

Alimta

For the first quarter of 2012, Alimta generated sales of \$606.8 million, an increase of 5 percent compared with the first quarter of 2011. U.S. sales of Alimta increased 10 percent, to \$256.6 million, driven by increased demand and, to a lesser extent, higher prices. Sales outside the U.S. increased 1 percent, to \$350.2 million, due to increased demand, partially offset by lower prices in Japan.

Humalog

For the first quarter of 2012, worldwide Humalog sales increased 12 percent, to \$590.3 million. Sales in the U.S. increased 15 percent to \$348.4 million, driven by higher prices. Sales outside the U.S. increased 9 percent to \$241.9 million, due to increased demand.

Zyprexa

In the first quarter of 2012, Zyprexa sales totaled \$562.7 million, a decrease of 56 percent compared with the first quarter of 2011 due to the loss of patent exclusivity in the U.S. and most major international markets outside of Japan. The company expects further erosion of Zyprexa sales throughout 2012. U.S. sales of Zyprexa decreased 66 percent to \$202.8 million. Zyprexa sales in international markets decreased 47 percent, to \$359.9 million.

Cialis

Cialis sales for the first quarter of 2012 increased 6 percent to \$461.8 million. U.S. sales of Cialis were \$178.8 million in the first quarter, a 13 percent increase compared with the first quarter of 2011, driven by higher demand. Sales of Cialis outside the U.S. increased 2 percent, to \$283.0 million, driven by increased demand and higher prices, partially offset by the unfavorable impact of foreign exchange rates.

Humulin

Worldwide Humulin sales increased 6 percent in the first quarter of 2012, to \$307.7 million. U.S. sales increased 20 percent to \$155.1 million, driven primarily by higher prices. Sales outside the U.S. decreased 5 percent, to \$152.6 million, driven by the unfavorable impact of foreign exchange rates, lower prices, and decreased volume.

Forteo

First-quarter sales of Forteo were \$271.3 million, a 26 percent increase compared with the first quarter of 2011. U.S. sales of Forteo increased 9 percent to \$121.9 million due to higher prices, largely offset by decreased demand. Sales outside the U.S. increased 43 percent, to \$149.4 million, due primarily to increased demand in Japan.

Evista

Evista sales for the first quarter of 2012 decreased 4 percent to \$256.2 million. U.S. sales of Evista decreased 1 percent to \$171.7 million, driven by decreased demand, largely offset by higher prices. Sales outside the U.S. decreased 8 percent to \$84.5 million, driven by lower volume in Japan.

Strattera

During the first quarter of 2012, Strattera generated \$158.9 million of sales, an increase of 15 percent compared with the first quarter of 2011. U.S. sales increased 21 percent to \$104.8 million, due to higher prices. Sales outside the U.S. increased 4 percent, to \$54.1 million, driven primarily by higher demand, partially offset by lower prices.

Effient

Effient sales were \$115.8 million in the first quarter of 2012, an increase of 106 percent compared with the first quarter of 2011. U.S. Effient sales increased 114 percent to \$89.8 million, driven by increased demand and higher prices. Sales outside the U.S. increased 82 percent to \$26.0 million due to higher demand.

Erbitux

Lilly recognizes net royalties received from its Erbitux collaboration partners and revenue from manufactured product sold to these partners. For the first quarter of 2012, Lilly recognized total revenue of \$113.3 million for Erbitux, an increase of 9 percent from the first quarter of 2011.

Animal Health

Worldwide sales of animal health products in the first quarter of 2012 were \$490.7 million, an increase of 33 percent compared with the first quarter of 2011. U.S. sales grew 33 percent, to \$269.6 million, due primarily to increased demand and the favorable impact from customer buying patterns. Sales outside the U.S. increased 32 percent, to \$221.1 million, driven primarily by the impact of the acquisition of certain Janssen animal health assets in Europe.

2012 Financial Guidance

The company has raised its 2012 earnings per share guidance and now expects full-year 2012 earnings per share to be in the range of \$3.14 to \$3.29 on a reported basis and \$3.15 to \$3.30 on a non-GAAP basis. All other elements of the company's 2012 financial guidance remain unchanged.

	2012 Expectations	2011 Results	% Change
Earnings per share (reported)	\$3.14 to \$3.29	\$3.90	(19)% to (16)%
In-process research and development charge associated with Boehringer Ingelheim collaboration	-	.23	
Asset impairment, restructuring, other special charges	.01	.29	
Earnings per share (non-GAAP)	\$3.15 to \$3.30	\$4.41	(29)% to (25)%

Numbers in the 2011 full-year column do not add due to rounding.

The company anticipates 2012 revenue of between \$21.8 and \$22.8 billion. This includes an expected decline of over \$3 billion in Zyprexa sales due to patent expirations in most markets outside of Japan. The reduction in revenue due to Zyprexa patent expirations is expected to be partially offset by growth in key franchises including Cymbalta, Cialis, Humalog, Humulin and Forteo, as well as continued growth of newer products such as Effient, Axiron[®] and Tradjenta[®]. The company also anticipates continued strong, double-digit revenue growth from its Elanco Animal Health business. Both Japan and Emerging Markets are expected to post continued strong underlying volume growth; however, overall revenue growth in these markets in 2012 will be adversely affected by pricing actions in Japan and by the expected impact of patent expirations, including Zyprexa, in some emerging market countries.

The company anticipates that gross margin as a percent of revenue will be approximately 77 percent in 2012.

As a result of ongoing productivity efforts, the company expects to keep 2012 operating expenses essentially flat compared to 2011. Marketing, selling and administrative expenses are expected to decline and be in the range of \$7.4 billion to \$7.8 billion. Research and development expense is expected to be flat to increasing and in the range of \$5.0 billion to \$5.3 billion.

Other income and deductions is expected to be in a range between net expense of \$50 million and net income of \$100 million in 2012.

The 2012 tax rate is expected to be approximately 21 percent, and assumes the extension of the R&D tax credit for the full year 2012.

Operating cash flows in 2012 are expected to be more than sufficient to fund capital expenditures of approximately \$800 million, as well as anticipated business development activity and the company's current dividend.

Webcast of Conference Call

As previously announced, investors and the general public can access a live webcast of the first-quarter 2012 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 forward-looking statements that are based on management's current expectations, but 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; changes in tax law; 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 affect the company's business, please see the company's latest Form 10-Q and Form 10-K filed with the U.S. Securities and Exchange Commission. The company undertakes no duty to update forward-looking statements.

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Actos® (pioglitazone, Takeda Pharmaceuticals)
Alimta® (pemetrexed, Lilly)
Amyvid™ (florbetapir, Lilly)
Axiron® (testosterone, Acrux Corp.)
Byetta® (exenatide injection, Amylin Pharmaceuticals)
Bydureon™ (exenatide for extended-release injectable suspension, Amylin Pharmaceuticals)
Cialis® (tadalafil, Lilly)
Cymbalta® (duloxetine hydrochloride, Lilly)
Effient® (prasugrel, Lilly)
Erbix® (cetuximab, ImClone Systems, Lilly)
Evista® (raloxifene hydrochloride, Lilly)
Forteo® (teriparatide of recombinant DNA origin injection, Lilly)
Gemzar® (gemcitabine hydrochloride, Lilly)
Humalog® (insulin lispro injection of recombinant DNA origin, Lilly)
Humulin® (human insulin of recombinant DNA origin, Lilly)
Strattera® (atomoxetine hydrochloride, Lilly)
Trajenta® (linagliptin, Boehringer Ingelheim)
Xigris® (drotrecogin alfa (activated), Lilly)
Zyprexa® (olanzapine, Lilly)

Eli Lilly and Company Employment Information

	<u>March 31, 2012</u>	<u>December 31, 2011</u>
Worldwide Employees	38,270	38,080

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

	Three Months Ended		
	March 31		
	2012	2011	% Chg.
Total Revenue	\$ 5,602.0	\$ 5,839.2	(4)%
Cost of sales	1,197.9	1,180.1	2%
Research and development	1,151.5	1,124.0	2%
Marketing, selling and administrative	1,847.5	1,785.7	3%
Acquired in-process research and development	-	388.0	NM
Asset impairments, restructuring and other special charges	<u>23.8</u>	<u>76.3</u>	(69)%
Operating income	1,381.3	1,285.1	7%
Net interest income (expense)	(19.2)	(30.3)	
Net other income (expense)	<u>(26.8)</u>	<u>19.1</u>	
Other income (expense)	(46.0)	(11.2)	NM
Income before income taxes	1,335.3	1,273.9	5%
Income taxes	<u>324.2</u>	<u>218.0</u>	49%
Net income	\$ <u>1,011.1</u>	\$ <u>1,055.9</u>	(4)%
Earnings per share – basic and diluted	\$ <u>0.91</u>	\$ <u>0.95</u>	(4)%
Dividends paid per share	\$ 0.49	\$ 0.49	NM
Weighted-average shares outstanding (thousands) – basic	1,116,962	1,112,003	
Weighted-average shares outstanding (thousands) – diluted	1,116,983	1,112,026	

NM – not meaningful

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

	Three Months Ended		
	March 31		
	2012(a)	2011(b)	% Chg.
Total Revenue	\$ 5,602.0	\$ 5,839.2	(4)%
Cost of sales	1,197.9	1,180.1	2%
Research and development	1,151.5	1,124.0	2%
Marketing, selling and administrative	1,847.5	1,785.7	3%
Operating income	1,405.1	1,749.4	(20)%
Net interest income (expense)	(19.2)	(30.3)	
Net other income (expense)	(26.8)	19.1	
Other income (expense)	(46.0)	(11.2)	NM
Income before income taxes	1,359.1	1,738.2	(22)%
Income taxes	332.2	363.3	(9)%
Net income	\$ 1,026.9	\$ 1,374.9	(25)%
Earnings per share – basic and diluted	\$ 0.92	\$ 1.24	(26)%
Dividends paid per share	\$ 0.49	\$ 0.49	NM
Weighted-average shares outstanding (thousands) – basic	1,116,962	1,112,003	
Weighted-average shares outstanding (thousands) – diluted	1,116,983	1,112,026	

- (a) The first quarter 2012 has been adjusted to eliminate a charge of \$23.8 (pretax), or \$0.01 per share (after-tax) primarily related to the withdrawal of Xigris.
- (b) The first quarter 2011 has been adjusted to eliminate a restructuring charge of \$76.3 million (pretax), or \$0.06 (after-tax). This charge is related to severance costs from previously announced strategic actions that the company is taking to reduce its cost structure and global workforce. In addition, the first quarter 2011 financial statements have been adjusted to eliminate a charge of \$388.0 million (pretax), or \$0.23 per share (after-tax), for acquired in-process research and development associated with the collaboration with Boehringer Ingelheim.