



## **Lilly Highlights Transformation Strategy for Wall Street, Reviews Robust Pipeline and Sets 2009 Financial Guidance**

- **Innovation and Patient-Centered Approach Expected to Drive Future Success**
- **Lilly Climbs into Top 10 Pharmaceutical Companies in Worldwide Sales and Is Fastest Growing in U.S.**
- **FIPNet Strategy Expands Global Reach and Improves R&D Productivity**
- **Company Aims to Reduce Cost of Bringing New Medicine to Market from \$1.2 Billion to \$800 Million by 2010.**
- **R&D Pipeline Boasts Unprecedented 59 Molecules in Clinical Development**
- **Investment in Biotechnology Capabilities Results in Expanded Large Molecule Portfolio**
- **ImClone Acquisition Creates Leading Oncology Franchise**
- **2009 EPS Guidance Set at \$4.00 to \$4.25, Including \$.30 to \$.35 of ImClone Dilution**
- **Excluding ImClone Dilution, 2009 EPS Expected to be \$4.35 to \$4.55**

New York - At its annual meeting with the investment community, Eli Lilly and Company (NYSE: LLY) today highlighted progress on its expanding pipeline of innovative molecules and marketed medicines, provided investors with sales and earnings guidance for 2009, and reviewed the transformation efforts that the company is making to excel in an increasingly challenging healthcare environment.

"Lilly continues to deliver strong financial results to our shareholders through an attractive combination of volume-based sales growth for key marketed products and an ongoing commitment to productivity and cost containment," commented John C. Lechleiter, Ph.D., Lilly's president and chief executive officer. "Our scientists are dedicated to maximizing the potential of our pipeline, which now boasts an unprecedented 59 molecules in clinical development, 40 percent of which are biotech-based. Lilly's success depends on innovation, and the promising molecules we are discussing at today's meeting bode well for the future of our company and the patients we serve."

"The pharmaceutical industry, however, continues to face major challenges, and we must act quickly and decisively to address them," noted Lechleiter. "We must respond to the demand for greater value among payers, providers and patients. We must also prepare for the wave of patent expirations that will come in the early part of the next decade. At Lilly, we recognize those challenges, and also recognize the tremendous opportunities that can be created by a company with a clear vision and a commitment to change. We are fundamentally transforming our business, and are doing so from a position of strength. Our strategy is to create value for our stakeholders by accelerating the flow of innovative new medicines that provide improved outcomes for individual patients."

### **Pipeline Progress - Expanding Biotech, Reducing Costs and Increasing Productivity**

Steven M. Paul, M.D., executive vice president, science and technology and president of Lilly Research Laboratories, explained how Lilly's strategy for research and development is designed to respond to the challenges of pharmaceutical R&D. "Lilly's goal is to substantially improve R&D productivity and reduce late-stage attrition, thereby lowering the cost to bring a new molecular entity (NME) to market, from \$1.2 billion in 2007 to \$800 million by 2010. Our most recent estimate of \$1.0 billion shows that we are making significant progress toward achieving this goal through our R&D transformation."

Dr. Paul then detailed several key U.S. and international examples of FIPNet transformation and their positive impact on R&D productivity. These examples include the sale of Lilly's Greenfield Laboratories site to Covance, the expansion of Chorus, Lilly's virtual drug development organization, the creation of a joint venture in India with Jubilant Organosys, and other risk-sharing collaborations with companies in both India and China.

Tom Bumol, Ph.D., vice president of biotech discovery research, explained how the company's biotechnology strategy is transforming the Lilly pipeline. "We see more and more that biotech is a key to sustaining pharmaceutical innovation for the future, and Lilly has more than eight decades of experience with biologicals. Today, Lilly is the fifth largest biopharmaceutical company based on biotherapeutic sales, and we are making the necessary investments to strengthen our leadership position. Over the past decade, we have built a new integrated biotechnology infrastructure, from discovery through development, and including delivery devices and manufacturing."

Highlighting Lilly's growing biotech prowess, Dr. Paul remarked, "With the addition of the ImClone cancer antibodies, currently 40 percent of Lilly's clinical stage pipeline and 50 percent of Lilly's late-stage pipeline are comprised of biotechnology-based molecules. Through the ImClone acquisition, we have simultaneously accelerated our emergence as both a biotech and cancer powerhouse, with a pipeline that we believe will provide a continuous flow of high value medicines."

Key late-stage and select mid-stage compounds in each of the company's core therapeutic areas were reviewed by Drs. Paul and Bumol.

### **Select Pipeline Developments**

- **Prasugrel** - The company continues to invest heavily in the ongoing development of prasugrel. Prasugrel, which Lilly is developing with its partner Daiichi Sankyo, continues to be under review with the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) for treatment of acute coronary syndrome (ACS) in patients undergoing percutaneous coronary intervention (PCI). Lilly remains in active dialogue with both regulatory agencies. In addition, prasugrel is also being studied in the TRILOGY trial in medically-managed ACS patients. TRILOGY will include approximately 10,000 patients at more than 800 hospitals in 35 countries and is structured as a superiority trial against clopidogrel. Since December, 2007, several follow-on data analyses of the TRITON TIMI-38 study have been published and presented regarding secondary endpoint data and data on relevant patient subpopulations. These include analyses of stent thrombosis, recurrent cardiovascular events and prasugrel's use in patients with either diabetes or STEMI (ST-Segment Elevation Myocardial Infarction).
- **Arzoxifene** - A five-year Phase III study, GENERATIONS, that enrolled more than 9,000 patients is expected to be completed in 2010. Two additional Phase III trials, FOUNDATION and NEXT, have already completed. The company expects to submit a New Drug Application (NDA) to the FDA in the fourth quarter of 2009. The submission will seek approval for three indications in postmenopausal women - treatment of osteoporosis, prevention of osteoporosis and reduction of risk of invasive breast cancer.
- **Exenatide once weekly** - The company continues to develop exenatide once weekly with its partners, Amylin Pharmaceuticals, Inc. and Alkermes, Inc. During 2008, the partners made significant progress toward commercialization of the molecule. A pre-NDA meeting was held with the FDA, commercial-scale production was begun at Amylin's Ohio facility, and the FDA has agreed to accept data from the DURATION-1 trial as an appropriate way to demonstrate comparability between clinical trial scale and commercial scale material from the Ohio facility. The companies anticipate regulatory submission to the FDA by the end of the first half of 2009. European regulatory submission is expected in late 2009.
- **Olanzapine long-acting injection** - The European Commission recently approved Zypadhera™, the company's long-acting injectable formulation of Zyprexa®. Zypadhera is approved in Europe for maintenance treatment of adult patients with schizophrenia who are sufficiently stabilized during acute treatment with oral Zyprexa. In the U.S., the company has submitted a complete response to the FDA's not approvable letter and is currently awaiting the FDA's final review.
- **Gamma Secretase Inhibitor** - In March 2008, the company began its first pivotal trial in Alzheimer's disease for the gamma secretase inhibitor, a small molecule designed to reduce the levels of the amyloid beta peptide in the brain. The trial, called IDENTITY, is actively enrolling and is ahead of schedule. A second pivotal trial, IDENTITY 2, was started in September 2008 and is also enrolling at a better-than-expected rate. Approximately 400 subjects have now been randomized in the two studies.
- **A-beta Antibody** - A monoclonal antibody, the company's A-beta antibody offers the potential for slowing down the progression of Alzheimer's disease. It is expected to enter Phase III in 2009.
- **Enzastaurin** - A Phase III clinical trial is currently under way for the use of enzastaurin as a maintenance therapy for diffuse large B-cell lymphoma. Because events are occurring at a slower rate than projected, the company is considering expanding enrollment and extending the trial. The company now expects U.S. regulatory submission to occur in mid-2013.
- **Teplizumab** - The company continues to collaborate with its partner, MacroGenics Inc., on teplizumab, which is currently being studied in a pivotal Phase II/III clinical trial for Type 1 diabetes.
- **Dirucotide (MBP8298)** - Along with its partner, BioMS, the company is studying dirucotide for the treatment of several types of multiple sclerosis (MS). There are two Phase III clinical trials ongoing targeting secondary progressive MS, one in Europe and Canada, and the other in the U.S. There is also a Phase II clinical trial underway in Europe for relapsing remitting MS.
- **Tasisulam (ASAP)** - Currently in Phase II, tasisulam has exhibited properties resembling a targeted agent as well as a cytotoxic. The company is testing the anti-tumor activity of tasisulam in several ongoing Phase II studies. Potential registration studies could begin in 2009.
- **GLP-Fc** - A Phase II/III adaptive, seamless trial was initiated in early 2008 for the company's leading proprietary GLP-1 asset, a novel Fc-fusion protein GLP-1 analog, or GLP-Fc. Two other Phase II studies of GLP-Fc are also underway in over 400 patients. The company expects safety and efficacy data from the first of these two studies to become available in 2009.
- **Inflammation** - The company has made a strong commitment to research in inflammation, as evidenced by four leading internal antibody candidates. IL-17 is progressing into larger Phase II clinical trials in the near future, while IL-23 entered Phase I in 2008. The company also anticipates initiating larger Phase II clinical trials for its BAFF antagonist antibody and IL-1beta in the near future.

Dr. Eric Rowinsky, M.D., executive vice president and chief medical officer of Lilly's wholly-owned subsidiary ImClone Systems, reviewed the numerous additional indications being pursued for Erbitux, as well as the later-stage oncology compounds currently in development.

- **ERBITUX®** - In addition to its approved indications, Erbitux is also being studied in numerous cancer types, including colorectal, head and neck, non-small cell lung, gastric and esophageal.
- **IMC-1121B** is a fully-human monoclonal antibody that targets the vascular endothelial growth factor (VEGF) receptor. Phase II studies are underway for metastatic melanoma, renal, liver, ovarian, prostate and non-small cell lung cancers. Metastatic breast cancer is in Phase III testing, while Phase III testing in gastric cancer is expected to begin in 2009.
- **IMC-A12** is a fully-human monoclonal antibody that targets the insulin-like growth factor-1 receptor (IGF-1R). Phase II testing is underway in breast, prostate, pancreatic, colorectal, liver and head and neck cancers, as well as sarcoma, with Phase III trials planned in 2009. IMC-A12 has the potential to work with a variety of other targeted agents.
- **IMC-11F8** is a potent, fully human monoclonal antibody that targets the epidermal growth factor receptor (EGFR). It is currently in Phase II studies for metastatic colorectal cancer with one or more Phase III trials planned in 2009.

In summarizing Lilly's research and development potential, Dr. Paul concluded, "Despite the challenges we face, the opportunities are also growing - the science has never been richer and there is no lack of unmet medical needs that we can address through our R&D efforts."

### **Commercial Performance - Top 10 in Worldwide Sales, Fastest Growing U.S. Pharma**

Derica Rice, Lilly's chief financial officer, provided an update on the company's commercial performance, focusing on the five key medicines that are driving top-line growth (Cymbalta®, Byetta®, Humalog®, Cialis®, and Alimta®), as well as the company's largest-selling product, Zyprexa, and Elanco, the company's animal health division.

"Lilly is completing another year of solid operating performance," said Rice. "The strong results we've seen year-to-date reflect an ongoing focus on execution across all geographies and across our product portfolio. This positions us for success in 2009 and will enable us to effectively deal with the patent expirations we will face in the next decade."

Through the first nine months of 2008, the company's sales have grown 12 percent on a pro forma basis, with fully half of that growth, or 6 percent, resulting from volume gains in most major geographic areas. According to rankings published by IMS, Lilly has moved into the top 10 pharmaceutical companies in worldwide sales. Among the top ten, Lilly was the fastest growing company in the U.S., the fourth fastest growing company in Europe and in the pharmerging markets, and the fifth fastest growing company in Japan. To maintain this growth, the company is focused on maximizing the value of its marketed product portfolio by investing in selected promotional efforts and pursuing multiple new indications and line extensions.

Cymbalta sales for the first three quarters have grown 28 percent in the U.S. and 74 percent internationally. In the U.S., Cymbalta is the only established branded medicine in the antidepressant category that is growing its share of market, and formulary access continues to be strong. U.S. Cymbalta sales are also expected to benefit from its recent FDA approval for fibromyalgia. Outside the U.S., Cymbalta continues to gain market share in most major international markets, with additional launches in 2008 in Australia, Canada and France.

Byetta, which the company markets along with its partner, Amylin Pharmaceuticals, has now been used by more than 1 million patients worldwide. In the U.S. sales for the first three quarters have grown 12 percent compared with the first three quarters of 2007, and efforts are underway to accelerate Byetta's adoption. In addition, a new indication for use as monotherapy is currently awaiting the FDA's final review. Outside the U.S., Byetta continues to be launched in new markets. In 2008, Byetta has been launched in France, Italy, Spain, Australia, Brazil and Mexico. Fueled by these new launches, Byetta sales are expected to double outside the U.S. in 2009.

Humalog sales for the first three quarters have grown 15 percent in the U.S. and 29 percent internationally. The U.S. performance includes accelerating growth in total prescriptions, an improvement that is in part due to the 2008 launch of a new pre-filled pen called the Humalog KwikPen™. The new pen has also been launched in Japan, the U.K. and Germany. Additional launches in the European Union are expected in 2009.

Cialis generated more than \$1 billion in worldwide sales in the first three quarters of 2008, with international markets accounting for nearly two-thirds of the total. Cialis is now available in more than 100 countries and is the market leader in more than 20 of them. U.S. sales and share of market for Cialis have been aided by the 2008 launch of a once daily formulation. Cialis is also being studied for new indications in pulmonary arterial hypertension (PAH) and benign prostatic hyperplasia (BPH). In 2008, the company filed regulatory applications for the PAH indication in the U.S., Japan, Europe, Canada and Mexico. The company also anticipates initiating enrollment in additional Phase III trials in BPH in the first quarter of 2009. In November, 2008, the company licensed the U.S. rights for the PAH indication to United Therapeutics.

Worldwide sales of Alimta have grown 37 percent in the first three quarters of 2008 compared with the same period in 2007. Alimta is now approved in 92 countries and remains the most successfully launched cytotoxic in history, having sold over \$3 billion since its introduction in early 2004. Near-term opportunities for Alimta are being pursued in non-small cell lung cancer,

particularly in patients with nonsquamous cell histology. Other indications being studied include locally advanced non-small cell lung cancer and advanced, metastatic head and neck cancer.

Zyprexa continues to provide a stable revenue base, despite generic competition in Germany and Canada and the entry of generic versions of competitor products in several markets including the U.S. In the U.S., retail market volume trends remain stable while institutional market volume is growing for the first time in five years. Future Zyprexa sales should benefit from a long-acting formulation, olanzapine LAI, which was recently approved in Europe and is under review by the FDA.

The company's animal health division, Elanco, has produced solid growth in 2008 and is expected to deliver double-digit earnings growth during the early part of the next decade, when several of the company's pharmaceutical products lose patent protection. Elanco sales have increased 15 percent through the third quarter, driven by volume expansion in emerging markets and the acquisition of Ivy Animal Health in 2007, as well as the strong U.S. launch of Comfortis™, a companion animal flea medicine. Companion animal is both the largest and fastest growing animal health segment. The company expects strong future growth in the companion animal segment and plans to launch several new products over the next three years in the U.S. and internationally. In addition, after the acquisition of the Posilac® brand, Elanco is now ranked at the top of the dairy segment and is also at the top of the medicated feed additive segment.

### **2008 Financial Guidance**

The company has reconfirmed its full-year 2008 financial guidance on a pro forma non-GAAP basis and has lowered its guidance on a reported basis. On a reported basis, the company now expects to record a loss of \$1.56 to \$2.06 per share. The change from earlier guidance of earnings per share of \$2.44 to \$2.49 results from an estimated \$4.05 to \$4.50 per share charge related to the ImClone acquisition which closed in November, 2008. Excluding significant items, the company has reiterated its pro forma non-GAAP earnings per share guidance of \$3.97 to \$4.02 per share. All other aspects of the company's 2008 guidance remain unchanged.

#### 2008 Earnings Per Share Expectations:

	2008 Expectations	2007 Results	% Growth
<b>Earnings (Loss) per share (reported)</b>	<b>(\$1.56) to (\$2.06)</b>	<b>\$2.71</b>	
Estimated financial impact of ImClone acquisition, including in-process research and development and other charges	4.05 to 4.50	-	
Charges related to Zyprexa investigations	1.33	-	
Asset impairments and restructuring charges (included in asset impairments, restructuring and other special charges)	.25	.15	
Asset impairments (included in cost of sales)	.04	-	
In-process research and development charges associated with SGX acquisition (2008), ICOS, Hypnion, and Ivy acquisitions (2007) and in-licensing transactions with BioMS and TransPharma (2008) and OSI, MacroGenics and Glenmark (2007)	.10	.63	
Benefit from resolution of IRS audit	(.19)	-	
Charge for a reduction in expected insurance recoveries	-	.06	
Pro forma as if the ICOS acquisition was completed on January 1, 2007	-	(.01)	
<b>Earnings per share (pro forma non-GAAP)</b>	<b>\$3.97 to \$4.02</b>	<b>\$3.54</b>	<b>12% to 14%</b>

### **2009 Financial Guidance**

In 2009, the company expects earnings per share of \$4.00 to \$4.25 on both a reported and non-GAAP basis. Excluding the estimated dilution impact of \$0.30 to \$0.35 per share related to the ImClone acquisition, earnings per share would be expected to be in the range of \$4.35 to \$4.55, reflecting growth of 8 percent to 15 percent compared to 2008 non-GAAP earnings per share.

2009 Earnings Per Share Expectations:

	2009 <u>Expectations</u>	2008 <u>Expectations</u>	<u>% Growth</u>
<b>Earnings (Loss) per share (reported)</b>	<b>\$4.00 to \$4.25</b>	<b>(\$1.56) to (\$2.06)</b>	
Estimated financial impact of ImClone acquisition, including in-process research and development and other charges	-	4.05 to 4.50	
Charges related to Zyprexa investigations	-	1.33	
Asset impairments and restructuring charges (included in asset impairments, restructuring and other special charges)	-	.25	
Asset impairments (included in cost of sales)	-	.04	
In-process research and development charges associated with SGX acquisition and in-licensing transactions with BioMS and TransPharma	-	.10	
Benefit from resolution of IRS audit	-	(.19)	
<b>Earnings per share (non-GAAP)</b>	<b><u>\$4.00 to \$4.25</u></b>	<b><u>\$3.97 to \$4.02</u></b>	<b>0% to 7%</b>
2009 ImClone dilution impact	<u>.30 to .35</u>	<u>-</u>	
<b>Earnings per share (non-GAAP excl 2009 ImClone dilution impact)</b>	<b><u>\$4.35 to \$4.55</u></b>	<b><u>\$3.97 to \$4.02</u></b>	<b>8% to 15%</b>

The company expects robust volume growth in sales again in 2009, driven by Cymbalta, Alimta, Cialis, Humalog and the anticipated launch of prasugrel, as well as by the Elanco animal health division. However, due to the negative impact of weaker foreign currencies and the impact of generic competition in certain markets for Gemzar®, reported sales are expected to grow in the low-single digits.

The company expects gross margin as a percent of sales to increase substantially, driven by the strengthening dollar. This impact could be particularly pronounced in the first and second quarters of 2009.

Marketing, selling, and administrative expenses are projected to show flat to low-single digit growth while research and development expenses are projected to grow in the low-single digits. Operating expenses, as defined as the sum of marketing, selling and administrative expenses and research and development expenses, are expected to grow more slowly than sales, registering flat to low-single digit growth.

Other income is expected to contribute less than \$75 million, and the tax rate is expected to be approximately 22 percent. Capital expenditures are expected to remain level at approximately \$1.1 billion and the company expects continued strong operating cash flow.

In addition, the company reaffirmed its commitment to generate double-digit compound annual earnings per share growth between 2007 and 2011.

**Webcast of Investment Community Meeting**

A live webcast of the Lilly Investment Community meeting, along with presentation slides, is available through a link on Lilly's web site at [www.lilly.com](http://www.lilly.com). The meeting will start today at 8:30 a.m. Eastern Time and last until approximately 12:30 p.m. The webcast will be available for replay through January 9, 2009.

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of first-in-class and best-in-class 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. More information about Lilly is available at [www.lilly.com](http://www.lilly.com). C-LLY

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. The company's results may also be affected by such factors as competitive developments affecting current products; rate of sales growth of recently launched products; the timing of anticipated regulatory approvals and launches of new products; other regulatory developments and government investigations; patent disputes and other litigation involving current and future products; the impact of governmental actions regarding pricing, importation, and reimbursement for pharmaceuticals; business development transactions; changes in tax law; asset impairments and restructuring charges and the impact of exchange rates. For additional information about the factors that affect the company's business, please see the company's latest Form 10-K, filed

March 2008, and Form 10-Q filed November 2008. The company undertakes no duty to update forward-looking statements.

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Alimta® (pemetrexed, Lilly)

Byetta® (exenatide injection, Amylin Pharmaceuticals)

Cialis® (tadalafil, Lilly)

Comfortis™ (Lilly)

Cymbalta® (duloxetine hydrochloride, Lilly)

Erbix® (cetuximab, ImClone Systems, Lilly)

Gemzar® (gemcitabine hydrochloride, Lilly)

Humalog® (insulin lispro injection of recombinant DNA origin, Lilly)

KwikPen™ (Lilly)

Posilac® (recombinant bovine somatotropin, Lilly)

Zypadhera™ (Lilly)

Zyprexa® (olanzapine, Lilly)