



December 9, 2005

Lilly Tells Wall Street It's Uniquely Positioned To Deliver Sustained Growth

- Anticipate 2006 Earnings of \$3.10 to \$3.20 Per Share, Representing Top-Tier Pharma Growth - 2005 Earnings Expected to be at High End of Company's Guidance Range - No Major Patent Expirations Expected Through This Decade - Nearly Tripled Product Portfolio with an Unprecedented 9 New Product Launches in 4 Years, Along With 9 New Indications and Line Extensions - Newer Products Driving Growth; Anticipated to be Nearly One-Quarter of 2006 Revenue - Increased Productivity 15% in 2005 and Steady Increases Expected Going Forward; Six Sigma Significant Contributor - Rich Pipeline Result of One of the Most Productive R&D Organizations and Industry-Leading Partnering Capabilities as Ranked by Biotech Companies - Late-Stage Pipeline Includes 5 High-Potential Products with Submissions Expected Over Next 4 Years, Plus a Number of New Indications and Line Extensions - Company's Capabilities in Both Biotech Large Molecule and Traditional Small Molecule Combine for Key Competitive Advantage - Anticipate Near-Term U.S. Submissions of Arxxant for Diabetic Retinopathy and Cymbalta for Generalized Anxiety Disorder; Recently Submitted Byetta for Type 2 Diabetes in Europe and Cialis for ED in Japan

NEW YORK, Dec 09, 2005 /PRNewswire-FirstCall via COMTEX News Network/ -- Eli Lilly and Company (NYSE: LLY) today reviewed at its major meeting with the investment community the company's expanding product portfolio, rich pipeline, and productivity gains as well as provided investors guidance regarding 2005 and 2006 growth prospects.

Lilly Uniquely Positioned to Deliver Sustained Growth, Including Top-Tier Pharma Earnings Growth in 2006

"Given our products, pipeline and the fact that we expect no major patent expirations for the rest of this decade, Lilly is uniquely positioned to deliver sustained earnings growth," said Sidney Taurel, chairman and chief executive officer for Lilly. "For 2006, we anticipate earnings per share of \$3.10 to \$3.20, which represents 8 to 12 percent growth compared with expected 2005 adjusted earnings. This growth rate is nearly double the average Wall Street consensus forecast for large-cap pharmaceutical companies."

Unprecedented New Product Flow Driving Growth; Newer Products Anticipated to be Nearly One-Quarter of 2006 Revenue

"Our strategy of independence, innovation and partnering has proven to be the right one and remains the best approach even in today's turbulent business climate," said Taurel. "This strategy has enabled us to nearly triple our portfolio of innovative products with an unprecedented nine new product launches and nine new indications and line extensions since 2001. And we continue to expand into new markets such as our recent submissions of Byetta(R) in Europe for type 2 diabetes, Cialis(R) in Japan for erectile dysfunction, and Cymbalta(R) in key European markets."

Charles E. Golden, executive vice president and chief financial officer for Lilly, said, "Our nine new products are accounting for an increasing portion of our sales -- up from 11 percent at the end of 2004 to 18 percent this year, and they should grow to about 24 percent of revenues next year. The success of our earnings growth next year depends in large part on our success with driving the growth of Cymbalta and our other new products, as well as by the performance of Zyprexa(R) and our ability to manage costs and increase the productivity of our resources."

Encouraged by Zyprexa and Cymbalta Performance

"We are somewhat encouraged by Zyprexa's recent U.S. performance where the erosion of Zyprexa prescriptions slowed in recent months. Our goals are to further stabilize U.S. Zyprexa sales and sustain modest growth on a global basis," said John C. Lechleiter, Ph.D., president and chief operating officer for Lilly. "Also, despite an overall flat U.S. antidepressant market in 2005, Cymbalta has led all branded and promoted products in share-of-market growth during this period. In addition, the product is launching very strongly overseas. For example, Cymbalta had the best antidepressant launch ever in Germany."

Lechleiter said, "Looking ahead on additional indications, I am pleased to announce today that two studies of Cymbalta for generalized anxiety disorder are now complete, and we anticipate making a U.S. submission in 2006. We are also progressing on our fibromyalgia indication, which is in Phase 3 studies."

Increasing Productivity Bolstering Earnings and Value Proposition to Stakeholders

Lilly is utilizing several tools to increase productivity and lower its cost structure, including applying Six Sigma across its global operations, which is expected to free up resources, accelerate R&D output, enhance customer satisfaction, and improve earnings with a portion of the overall benefit; expanding the use of biomarkers to more than 90 percent of the company's clinical candidates to facilitate earlier development decisions; maintaining the July 2004 hiring limits that have already reduced headcount by 3,100 or nearly 7 percent, without using disruptive layoffs; and leveraging outsourcing when the work represents non-core business or can be done at a lower cost and similar quality. Lilly's initial efforts have resulted in productivity increasing about 15 percent in 2005 compared with 2004 as measured by adjusted operating income per Lilly employee (1).

"And this is just the beginning," said Steven M. Paul, M.D., executive vice president, science and technology, for Lilly. "For example, Lilly's goals include reducing the cost of developing a new medicine by one-third by the end of the decade -- from about \$1.2 billion per new molecular entity (NME) to \$800 million. Through our commitment to innovation, we believe we are addressing the expectations of a global marketplace that is demanding medical progress that society can afford."

Enviably Pipeline Result of Productive R&D and Successful Partnering

Taurel said, "Even after our recent surge of launches, our pipeline remains robust because we have built one of the most productive R&D organizations in the industry and have worked hard to be a partner that other companies want to work with. In fact, biotech companies that took part in a respected IBM survey ranked Lilly number one in our partnering capabilities."

Lilly outlined its enviable pipeline, which includes 26 NMEs and 38 new indications and line extensions in clinical development. This pipeline features potential first-in-class and best-in-class therapies for diseases with significant unmet medical needs. Lilly's late-stage pipeline includes five high-potential products with submissions anticipated over the next four years, plus a number of new indications and line extensions on existing products. Lilly's early-to-mid-stage pipeline includes a number of molecules in two of the industry's fastest-growing therapeutic areas -- oncology and diabetes care -- as well as high potential sectors of neuroscience and cardiovascular disease. The company reviewed a number of developments within both its late-stage and early-to-mid-stage pipelines.

Select Late-Stage Pipeline Developments:

- * Prasugrel -- More than 750 sites are up and running and enrollment is progressing very well in the 13,000 patient head-to-head study of prasugrel, which Lilly and its partner Sankyo Company, Ltd. are developing for acute coronary syndromes, versus clopidogrel. This Phase 3 study is expected to be completed in early 2007, with submission anticipated in the second half of that year.
- * Arzoxifene -- The registration studies for the prevention and treatment of osteoporosis are fully enrolled with more than 9,000 patients, and submission is anticipated in 2009.
- * Inhaled insulin -- In mid-2005, Lilly and its partner Alkermes, Inc. began enrolling patients in two Phase 3 trials for inhaled insulin, marking the start of a comprehensive clinical registration program that will include a number of other studies.
- * Enzastaurin -- Lilly plans to begin registration clinical trials in early 2006 for enzastaurin for its lead indication of glioblastoma (brain cancer), with submission anticipated in 2008.
- * Arxxant(TM) -- Lilly expects to submit Arxxant for diabetic retinopathy by the end of February 2006, with European submission expected in mid-2006.

Select Early-to-Mid-Stage Pipeline Developments:

- * Oncology -- Lilly expects to start five Phase 1 studies of oncology agents in 2006 and five more in 2007, including beginning clinical work on the first of two agents that inhibit TGF-beta signaling. In addition, with Lilly's newest subsidiary, Applied Molecular Evolution, the company will initiate clinical trials soon with AME133, an antibody to CD20, for non-Hodgkin's lymphoma. Lilly and its partner, Isis Pharmaceuticals, Inc., anticipate Phase 2 trials to begin in late 2006 for the survivin antisense oligonucleotide.
- * Diabetes Care and Obesity -- By the end of 2006, Lilly expects to have at least five anti-obesity compounds in clinical development, including a molecule with a novel mechanism of action in Phase 2. In addition, Lilly is focusing on developing innovative medicines that are aimed at blocking or slowing the progression of diabetes at all points of the continuum of the disease. Inhaled insulin is Lilly's lead project in this comprehensive effort, which also includes an oral DPP-IV inhibitor for type 2 diabetes currently in Phase 1; naveglitazar, an oral PPAR alpha/gamma agonist, for type 2 diabetes that has completed Phase 2 studies; and a long-acting release formulation of Byetta for type 2 diabetes currently in Phase 2.

* Neuroscience -- This fall, Lilly began Phase 2 trials of pruvanserin in insomnia and is exploring its potential in other central nervous system conditions. Lilly is also conducting Phase 1-b studies to evaluate two molecules for Alzheimer's disease, a gamma-secretase inhibitor and an A-beta antibody.

* Cardiovascular -- Lilly completed a Phase 2 study of Factor Xa inhibitor for thrombotic disorders and will present the encouraging results at the American Society of Hematology meeting on Monday, December 12. In addition, Lilly began an initial Phase 2 study in July for PPAR alpha agonist for atherosclerosis.

Company's Capabilities in Both Biotech Large Molecule and Traditional Small Molecule Combine for Key Competitive Advantage

Paul said, "The strong collaboration between our biotechnology and therapeutic areas -- a key competitive advantage for Lilly when compared with capabilities of even the large biotech firms -- is enabling us to apply protein-engineering principles to targets in cancer, Alzheimer's disease, diabetes, and chronic kidney disease. Additive to our portfolio of small molecules, we currently have 11 large-molecule NMEs and line extensions in clinical trials. During the next 12 months, we expect to add five more large-molecule NMEs and three line extensions. In fact, bioproducts now account for fully one-third of our pipeline, which is in addition to the eight bioproducts we already have on the market."

Lilly Focused on Delivering Better Patient Outcomes through Answers that Matter

Lechleiter said, "Lilly is focused on the customer -- doctors, payers, and above all, patients. In fact, earlier this year, the journal *In Vivo* praised what they called 'Lilly's Transparency Strategy.' We're delighted that *In Vivo* ranked us far ahead of the curve in implementing a more transparent, customer-focused approach -- for example by setting the high bar on clinical trial disclosure and establishing clear principles of medical research."

"More than ever, our sales force is positioning Lilly's products around the patients most likely to benefit from them, focusing on efficacy and being very clear about any potential for side effects," said Lechleiter. "We believe that focusing on desired patient outcomes will be a key to our success in the marketplace. Specifically, this better-patient-outcome approach will build credibility, more quickly differentiate Lilly's products, defend our products in formulary decision-making by helping us connect drug prices with the value of health outcomes, and prepare Lilly's sales force for tailored therapeutics. Ultimately, Lilly's vision is to lead in bringing the patient the right drug at the right dose at the right time."

Tailored Therapeutics Should Reduce Risk and Increase Value to Consumers and Payers

"We have already begun to pursue the development of tailored therapeutics through the application of biomarkers and other tools and technologies. This will be a big step forward for patients and their physicians and will offer payers greater value," Taurel said.

2005 Financial Guidance

Eliminating the second quarter 2005 product liability charge and excluding any potential fourth quarter unusual items, the company expects its fourth quarter and full year 2005 adjusted earnings per share will be at the top of its guidance range of \$.73 to \$.79 and \$2.80 to \$2.86, respectively, reflecting strong operating results and the benefit of a lower than expected tax rate of 21 percent. This 2005 adjusted earnings guidance range represents 9 to 11 percent growth compared with the recalculated 2004 earnings per share of \$2.58 (refer to "Reconciliation of 2005 Earnings Per Share Expectations" below for further description). The 2004 recalculated earnings per share assumes stock option expensing in 2004 and eliminates the 2004 charges for tax expense on the expected repatriation of earnings under the American Jobs Creation Act; asset impairments, restructuring and other special charges; and acquired in-process research and development charges related to the Applied Molecular Evolution, Inc. acquisition and the insomnia compound in-license.

Reported 2005 earnings per share is expected to be at the top of a range of \$1.90 to \$1.96, which compares with reported 2004 earnings per share of \$1.66.

Reconciliation of 2005 Earnings Per Share Expectations:

	2005 Expectations	2004 Actual	% Growth
	-----	-----	-----
E.P.S. (reported)	\$1.90 to 1.96	\$1.66	
Eliminate charges:			
Product liability charge	.90	-	
Tax expense on the expected repatriation of earnings			

under the American Jobs Creation Act	-	.43	
Asset impairments, restructuring and other special charges	-	.38	
Acquired in-process R&D for AME acquisition and insomnia compound	-	.35	
	-----	-----	
E.P.S. (adjusted)	\$2.80 to \$2.86	\$2.82	
Proforma stock option expense for 2004	-	(.24)	
	-----	-----	
E.P.S. (adjusted with options expensed)	\$2.80 to \$2.86	\$2.58	9% to 11%
	=====	=====	

2006 Financial Guidance

The company expects 2006 earnings per share of \$3.10 to \$3.20, excluding any potential unusual items. This EPS represents 8 percent to 12 percent growth compared with the high end of the 2005 adjusted earnings per share range. Refer to "Reconciliation of 2006 Earnings Per Share Expectations" below for further description.

Reconciliation of 2006 Earnings Per Share Expectations:

	2006 Expectations	2005 Expectations	% Growth(2)
	-----	-----	-----
E.P.S. (reported)	\$3.10 to \$3.20	\$1.90 to \$1.96	
Eliminate charges:			
Product liability charge	-	.90	
	-----	-----	-----
E.P.S. (adjusted with options expensed)	\$3.10 to \$3.20	\$2.80 to \$2.86	8% to 12%
	=====	=====	

(2) Percent growth calculated vs. top end of 2005 adjusted EPS range.

For 2006, the company expects sales to grow 7 to 9 percent and gross margins as a percent of sales to improve modestly compared with 2005. In addition, the company expects operating expenses to grow in the mid-single digits in the aggregate, with marketing and administrative expenses accelerating while research and development expense growth moderates somewhat. However, Lilly will continue to be among the industry leaders in terms of research and development investment as a percent of sales. The company also expects other income to contribute approximately \$175 million to \$275 million; this ongoing net contribution is driven primarily by net interest income, Lilly ICOS joint venture after-tax profit, and partnering and out-licensing of molecules. The company also anticipates the effective tax rate to be approximately 21 percent. In terms of cash flow, the company expects capital expenditures to be about \$1.4 billion in both 2005 and 2006.

Stronger Cash Flows Anticipated in 2006

Golden said, "With accelerating earnings, flat capital expenditures, and a number of significant one-time events behind us, we expect our cash flow to improve in 2006. In anticipation of stronger cash flows, we plan to repurchase about \$500 million worth of Lilly stock under the \$3 billion share- repurchase program the company initiated in 2000. We believe this repurchase strategy strikes the right balance among reinvesting in the business, providing a solid dividend to shareholders, sustaining the company's financial strength and flexibility, and taking advantage of Lilly's current attractive share price. We expect to complete the \$500 million repurchase in the next several weeks, assuming stable market conditions."

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 website at 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 6, 2006.

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. F-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; 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 Exhibit 99 to the company's latest Form 10-Q filed November 2005. The company undertakes no duty to update forward-looking statements.

Arxxant(TM) (ruboxistaurin, Lilly)
Byetta(R) (exenatide injection, Amylin Pharmaceuticals)
Cialis(R) (tadalafil, ICOS), Lilly ICOS LLC
Cymbalta(R) (duloxetine hydrochloride, Lilly)
Zyprexa(R) (olanzapine, Lilly)

(1) Reconciliation of adjusted operating income per employee (\$ millions): For 2004, reported operating income of \$2,663.5 is increased by \$632.9 for the combined effect of the adjusting items listed in the table above (other than the American Jobs Creation Act tax expense). For 2005, projected operating income is increased by \$1,073.4 for the product liability charge listed in the table above.

(Logo: <http://www.newscom.com/cgi-bin/prnh/20031219/LLYLOGO>)

SOURCE Eli Lilly and Company

Terra Fox, +1-317-276-5795, or Phil Belt (on-site in New York), +1-317-431-6506, both of Eli Lilly and Company

<http://www.prnewswire.com>

Copyright (C) 2005 PR Newswire. All rights reserved.

News Provided by COMTEX