

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

Current Report
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): October 3, 2013

ELI LILLY AND COMPANY
(Exact name of registrant as specified in its charter)

Indiana
(State or Other Jurisdiction
of Incorporation)

Lilly Corporate Center
Indianapolis, Indiana
(Address of Principal
Executive Offices)

001-06351
(Commission
File Number)

35-0470950
(I.R.S. Employer
Identification No.)

46285
(Zip Code)

Registrant's telephone number, including area code: (317) 276-2000

No Change

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 7.01. Regulation FD Disclosure.

On October 3, 2013, Eli Lilly and Company is holding a conference for investment analysts. In connection with the conference, the company issued a press release, a copy of which is furnished to the Commission as Exhibit 99.1 to this Form 8-K.

Item 9.01. Financial Statements and Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press release dated October 3, 2013

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ELI LILLY AND COMPANY
(Registrant)

By: /s/ James B. Lootens
Name: James B. Lootens
Title: Secretary and Deputy
General Counsel

Dated: October 3, 2013

Date: October 3, 2013

For Release: Immediately

Refer to: (317) 440-4699 - Scott MacGregor (media)
(317) 655-6874 - Phil Johnson (investors)
(317) 985-6303 - Ed Sagebiel (media)

Lilly details progress on achieving strategic business goals and its advancing pipeline to investment community

- *Company aims to overcome patent expirations through targeted growth initiatives, continued expense controls, and maturing Phase 3 pipeline*
- *Lilly expects to launch several new medicines beginning next year, returning the company to revenue growth and expanding margins after 2014*
- *To date, positive Phase 3 results have led to a record seven regulatory submissions of four molecules in 2013*
- *Lilly announces plan to supplement its annual dividend with share repurchases totaling \$5 billion over time*

INDIANAPOLIS - Eli Lilly and Company (NYSE:LLY) expects to launch several new medicines to treat unmet patient needs beginning next year, and return the company to revenue growth and expanding margins after 2014, senior executives told the investment community today at the company's global research and corporate headquarters.

Lilly also reaffirmed its near-term goals of generating at least \$20 billion in revenue, \$3 billion in net income and \$4 billion in operating cash flow through 2014, despite the impending loss of revenue due to patent expirations for two major products in the U.S., beginning in December of this year. The company also announced a new share repurchase program that will return an additional \$5 billion to shareholders over time.

The upbeat outlook demonstrates that Lilly has been successfully executing its long-term innovation strategy to weather the significant impact of patent expiries from 2011-2014 and

advance more medicines through late-stage development, approval and launch. The company's strategy to focus on development of innovative medicines has produced the strongest pipeline in Lilly's 137-year history, with 13 potential medicines in Phase 3, the final stage of clinical studies, or in regulatory review; and 26 more in Phase 2. This represents a total number in mid-to-late-stage development that is five times greater than the comparable total in 2004.

Launching several of those late-stage molecules will bring new medicines to patients and enable the company to return to revenue growth after 2014, John C. Lechleiter Ph.D., Lilly's chairman, president and chief executive officer, told analysts gathered at the investment event.

"We've undertaken extensive efforts to transform our company to address the challenge of patent expirations and the demands of patients and payers for greater value from medicine," Lechleiter said. "Today, we're seeing our strategy bear fruit, backed by clinical data that strengthens our confidence in our innovation-based strategy and in our ability to return to growth. We're determined to seize the tremendous opportunities before us and drive a new era of growth for Lilly and its shareholders, while delivering on our mission of improving the lives of patients."

Specifically, Lilly executives noted several key events this year that demonstrate progress in the company's innovation-based strategy:

- U.S. and European regulatory submissions for two medicines to treat type 2 diabetes: empagliflozin (with partner Boehringer Ingelheim) and dulaglutide.
- European submission of a new insulin glargine product to treat type 1 and type 2 diabetes.
- U.S. and EU regulatory submissions completed for ramucirumab as a single-agent treatment for patients with advanced gastric cancer who have had disease progression after initial chemotherapy.
- Second positive Phase III trial of ramucirumab in advanced gastric cancer, with the RAINBOW combination therapy trial demonstrating both improved overall survival and progression-free survival.
- Positive results for necitumumab for patients with metastatic squamous non-small cell lung cancer, which could form the basis for a regulatory submission as early as 2014.

In 2014, the company believes it could launch empagliflozin, dulaglutide, and ramucirumab, subject to regulatory approval.

“Lilly has successfully replenished and advanced our pipeline to drive growth post-2014, while building a sustainable R&D engine for the long-term,” said Jan M. Lundberg, Ph.D., executive vice president of science and technology and president of Lilly Research Laboratories. “We’ve filed for regulatory approval for an unprecedented number of investigational medicines this year with three in diabetes and one in oncology. In the future we expect to maintain a steady state of Phase 3 programs in the mid-to-high single digits, with a robust Phase 1 and Phase 2 pipeline to fill in behind.”

Lundberg noted that in the 2013 - 2014 timeframe, the company expects data readouts or pipeline advancements for nine of the assets in late-stage development. These include the three potential launches noted above, the regulatory submissions of necitumumab and the new insulin glargine product, and new data readouts for four other late-stage assets by the end of 2014. Lundberg also said the company anticipates seeing clinical readouts for the vast majority of its Phase 2 assets during this period.

Business outlook

Chief Financial Officer Derica Rice highlighted the company’s strategy to deliver on its financial goals through 2014 and grow revenue and expand margins post-2014.

“To prepare Lilly for 2014 and beyond, we committed to replenishing and advancing our pipeline, driving revenue in our growth engines and key marketed products, and increasing productivity and reducing our cost structure,” Rice said. “We’ve taken these commitments seriously and made substantial progress toward achieving our near-term goals, and we’re confident that this progress positions us for future success.”

Near-term business outlook (through 2014)

In the near-term, Rice said the company still expects to hit its financial goals in 2014, noting:

- Selling, general and administrative expenses will decline as the company realizes the full benefit of the restructuring efforts in Europe and the U.S. sales organizations as well as savings from ending the direct-to-consumer promotion of Cymbalta[®].
- The company will realize additional efficiencies in research and development and benefit from a substantial reduction in R&D costs as the pipeline progresses through Phase 3 into regulatory submission.

Rice noted that market factors, including the devaluation of the Yen and slower market growth in key emerging market countries, have moderated the company's near-term revenue growth expectations. These headwinds will make it challenging for the company to meet the minimum revenue goal of \$20 billion in 2014, but Rice said the company is focused on finding appropriate ways to achieve this goal. Rice also said the company can and will take additional actions to achieve its 2014 net income and operating cash flow targets through reductions in operating expenses.

"Current consensus for 2014 is in-line with our net income goal, although we may get there in a different way," Rice said. "For instance, current consensus may underestimate the impact of the Cymbalta and Evista[®] patent expirations on our gross margin percent and our ability to reduce operating expenses, while it may overestimate our tax rate, which is trending in the low 20s percent. As usual, we'll provide specific 2014 line-item guidance in January."

Medium-term business outlook (post-2014)

Moving beyond 2014, Lilly expects continuing revenue growth in four of its five businesses: Diabetes, Oncology, Emerging Markets and Animal Health. The fifth, Bio-Medicines, loses U.S. marketing exclusivity on Cymbalta in 2013 and Evista in 2014, but is then expected to provide a large, stable and profitable revenue base moving ahead.

- In Diabetes, Lilly expects continued growth for currently marketed products (insulins and Trajenta[®]), with additional growth driven by the potential launches of empagliflozin, dulaglutide, the company's insulin glargine product and its novel basal insulin.
- In Oncology, Lilly has patents that could provide exclusivity for Alimta[®] into the early 2020s in the U.S. and Europe, and sees significant growth opportunities from the potential launches of necitumumab and ramucirumab.
- In Emerging Markets, the company sees continued strong underlying demand for pharmaceuticals in key Lilly therapeutic areas, led by Diabetes.
- In Animal Health, strong global demand for animal-based protein and a growing companion animal market provide a strong platform for continued growth. Rice noted that the company intends to augment its strong organic growth in animal health with continued business development.
- After the U.S. patent losses from Cymbalta and Evista, Rice said mid-term revenue in Bio-Medicines should be relatively stable, anchored by continued growth from Axiron[®], Cialis[®], Forteo[®], Strattera[®] and Effient[®]. Later in the decade, Bio-Medicines could

provide significant revenue growth through a combination of launches of new molecules currently in Phase 3 development, including solanezumab, evacetrapib, baricitinib, ixekizumab, tabalumab and edivoxetine.

“With positive Phase 3 data on a number of assets, we’ve begun to de-risk our expectations for mid-term revenue growth,” Rice said. “I am confident in our outlook to return to a period of growth and expanding margins.”

Rice said the company still expects over time to lower SG&A as a percent of revenue to the range of 28 percent to 30 percent and R&D expense as a percent of revenue to a range of 18 percent to 20 percent. This would allow the company to achieve a total operating expense efficiency of approximately 50 percent of revenue by 2019, if not earlier.

Dividends and share repurchase

Lilly also reconfirmed today that it expects to maintain its dividend at least at its current level and announced that it will supplement its annual dividend of approximately \$2 billion per year with share repurchases totaling \$5 billion over time.

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. ET and last until approximately 12:30 p.m. The webcast will be available for replay over the next 12 months.

About Eli Lilly and Company

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. C-LLY

This press release contains management's current intentions and expectations for the future, all of which are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. The words "estimate", "project", "intend", "expect", "believe", "target" and similar expressions are intended to identify forward-looking statements. Actual results may differ materially due to various factors. There are significant risks and uncertainties in pharmaceutical research and development. There can be no guarantees with respect to pipeline products that the products will receive the necessary clinical and manufacturing regulatory approvals or that they will prove to be commercially successful. Pharmaceutical products can develop unexpected safety or efficacy concerns. The company's financial outlook 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)

Strattera[®] (atomoxetine, Lilly)

Tradjenta[®] (linagliptin, Boehringer Ingelheim)