

LILLY ELI & CO
Form 8-K
March 13, 2008

UNITED STATES
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):

March 7, 2008

Eli Lilly and Company

(Exact name of registrant as specified in its charter)

Indiana

001-06351

35-0470950

(State or other jurisdiction
of incorporation)

(Commission
File Number)

(I.R.S. Employer
Identification No.)

Lilly Corporate Center, Indianapolis, Indiana

46285

(Address of principal executive offices)

(Zip Code)

Registrant's telephone number, including area code:

317-276-2000

Not Applicable

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))
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Item 2.05 Costs Associated with Exit or Disposal Activities.

On March 7, 2008, Eli Lilly and Company announced the termination of development of its AIR® Insulin program, which was being conducted in partnership with Alkermes, Inc. The program has been in phase III clinical development as a potential treatment for type 1 and type 2 diabetes. The company noted that this decision is not a result of any observations during AIR Insulin trials relating to the safety of the product, but rather was a result of increasing uncertainties in the regulatory environment, and a thorough evaluation of the evolving commercial and clinical potential of the product compared to existing medical therapies.

Lilly is in the process of contacting the clinical investigators conducting the current AIR Insulin clinical trials. Subject to protocols, the trials will be halted and the patients currently enrolled will be moved to other insulin therapy under the supervision of their physicians. In the U.S., Lilly will implement a patient assistance program to provide current clinical trial patients with appropriate financial support to fund their medications and diagnostic supplies through the end of 2008. Based upon further analysis, the company may also pursue a similar program in other regions.

As a result of the decision to terminate the development of AIR Insulin, Lilly will recognize a first-quarter 2008 charge to earnings related to the impairment of Lilly manufacturing assets, as well as wind-down costs associated with the termination of clinical trials and certain development activities, and costs associated with the patient assistance program. The exact amount of the charge has not yet been determined, but is estimated to be in the range of \$90 million to \$120 million, or \$0.05 to \$0.07 per share. Approximately 50 percent of this charge will require cash payments. On a reported basis, including the charge related to the termination of the AIR Insulin program, as well as the previously announced charge related to the BioMS in-licensing, Lilly now expects 2008 earnings per share to be in the range of \$3.73 to \$3.90.

Item 2.06 Material Impairments.

Please see Item 2.05 above.

This Form 8-K 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; regulatory actions regarding currently marketed 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; acquisitions and business development transactions; 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 February 29, 2008. The company undertakes no duty to update forward-looking statements.

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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 hereunto duly authorized.

Eli Lilly and Company

March 13, 2008

By: */s/ Arnold C. Hanish*

Name: Arnold C. Hanish

Title: Chief Accounting Officer