

LILLY ELI & CO
Form 8-K
February 05, 2009

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):

January 30, 2009

Eli Lilly and Company

(Exact name of registrant as specified in its charter)

Indiana

(State or other jurisdiction
of incorporation)

001-06351

(Commission
File Number)

35-0470950

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

Lilly Corporate Center, Indianapolis, Indiana

(Address of principal executive offices)

46285

(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 1.01 Entry into a Material Definitive Agreement.

The company has reached resolution with the United States Attorney for the Eastern District of Pennsylvania (EDPA) and the Office of Consumer Litigation of the Department of Justice regarding the previously-reported government investigation into the company's past U.S. marketing and promotional practices for the antipsychotic medication Zyprexa(R) (olanzapine). As part of this resolution, the company has entered into the following agreements.

1. Plea Agreement

Under this agreement, the company agreed to plead guilty to one misdemeanor violation of the Food, Drug, and Cosmetic Act. The misdemeanor plea is for the off-label promotion of Zyprexa between September of 1999 and March of 2001. Specifically, the plea states that Lilly promoted Zyprexa in elderly populations as treatment for dementia, including Alzheimer's dementia, although Zyprexa is not approved for such uses. As part of this agreement, the company has agreed to pay \$615 million. The plea agreement was approved by the federal court in Philadelphia on January 30, 2009.

2. Settlement Agreement

The company entered into a settlement agreement resolving the federal government's civil investigation. Even though the company disagrees with and does not admit to the civil allegations, the company has agreed to settle the dispute over these allegations. Under terms for the resolution of the civil investigations, the company has agreed to make payments totaling nearly \$800 million. Approximately \$438 million has been paid to the federal government and approximately \$362 million will be made available for payment to settling states. The settlement agreement would have been null and void had the federal court in Philadelphia not accepted the plea agreement described above.

3. Corporate Integrity Agreement

The company entered into a corporate integrity agreement with the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS). This agreement requires Lilly to maintain its compliance program and to undertake a set of defined corporate integrity obligations for five years. The terms of the corporate integrity agreement are largely consistent with the company's existing compliance program. They also provide for an independent third-party review organization to assess and report on the company's systems, processes, policies, procedures and practices. The effective date of the corporate integrity agreement is February 13, 2009.

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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

February 5, 2009

By: *James B. Lootens*

Name: James B. Lootens

Title: Secretary and Deputy General Counsel