

ABBOTT LABORATORIES  
Form 8-K  
June 23, 2005

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D. C. 20549

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**FORM 8-K**

**CURRENT REPORT**  
Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act of 1934

**June 23, 2005**

Date of Report (Date of earliest event reported)

**ABBOTT LABORATORIES**

(Exact name of registrant as specified in its charter)

**Illinois**

**1-2189**

**36-0698440**

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(State or other Jurisdiction  
of Incorporation)

(Commission File Number)

(IRS Employer  
Identification No.)

**100 Abbott Park Road  
Abbott Park, Illinois 60064-6400**

(Address of principal executive offices)(Zip Code)

Registrant's telephone number, including area code: **(847) 937-6100**

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**

**Xinlay Expanded Access Program**

Abbott Laboratories has received U.S. Food and Drug Administration (FDA) permission to initiate an expanded access program for the investigational agent known as Xinlay (atrasentan) in the U.S. for eligible men with late-stage, hormone-refractory prostate cancer. The program will begin later this summer.

Expanded access programs are designed to make investigational agents available at the earliest opportunity for the treatment of patients with a serious disease for which no comparable or satisfactory alternative drug or other therapy is available.

A new drug application (NDA) for Xinlay is currently under review by the FDA and is based on Phase II and III clinical trials in men with metastatic hormone-refractory prostate cancer. The NDA submission contains clinical data regarding disease progression and delay in time to onset of bone pain.

Among American men, prostate cancer is the second most common cancer, after skin cancer, and is the second leading cause of cancer death. This year in the United States, an estimated 230,000 men will be diagnosed with prostate cancer, and 30,000 will die from the disease. The incidence of prostate cancer is expected to increase to more than 300,000 annually over the next decade, as baby boomers begin to reach the target age for detection.

For the thousands of patients whose prostate cancer spreads to other organs, the disease remains incurable. For these patients, treatment options are limited and many patients no longer respond to hormone therapy. The cancer in hormone-refractory prostate cancer patients often spreads to their bones and patients are left with few treatment options. Bone pain from metastases is one of the more disabling manifestations of advanced prostate cancer.

**About Xinlay**

Xinlay is an investigational, oral, once-daily, non-hormonal, non-chemotherapy, agent that belongs to a class of compounds known as selective endothelin-A receptor antagonists (SERA). SERAs antagonize the effect of endothelin -1 (ET-1), one of the proteins thought to be involved in the stimulation of the spread of cancer cells.

Xinlay is currently being studied in several stages of prostate cancer. Trials are ongoing in men with hormone-refractory prostate cancer that has not spread (non-metastatic), as well as in hormone-naive men (prostate cancer patients who have not received hormone therapy) with rising prostate-specific antigen (PSA) following prostate cancer surgery. Additionally, Xinlay is being evaluated in combination trials with approved treatments for advanced prostate cancer.



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The information in Item 7.01 of this report is being furnished, not filed, pursuant to Regulation FD. Accordingly, the information in Item 7.01 of this report will not be incorporated by reference into any registration statement filed by Abbott under the Securities Act of 1933, as amended, unless specifically identified therein as being incorporated therein by reference. The furnishing of the information in this report is not intended to, and does not, constitute a determination or admission by Abbott, that the information in this report is material or complete, or that investors should consider this information before making an investment decision with respect to any security of Abbott.

**SIGNATURE**

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.

**ABBOTT LABORATORIES**

Date: June 23, 2005

By: /s/ Thomas C. Freyman  
Thomas C. Freyman  
Executive Vice President, Finance and  
Chief Financial Officer