

NEOSE TECHNOLOGIES INC
Form 8-K
August 16, 2005

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):

August 15, 2005

Neose Technologies, Inc.

(Exact name of registrant as specified in its charter)

Delaware

000-27718

13-3549286

(State or other jurisdiction
of incorporation)

(Commission
File Number)

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

102 Witmer Road, Horsham, Pennsylvania

19044

(Address of principal executive offices)

(Zip Code)

Registrant's telephone number, including area code:

215-315-9000

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 8.01 Other Events.

As announced on July 19, 2005, Neose Technologies, Inc. (the "Company") anticipated the receipt of a formal letter from the U.S. Food and Drug Administration (the "FDA") outlining the additional manufacturing and preclinical information it needs in order to complete its review of the Company's investigational new drug application (the "IND") for NE-180. On August 15, 2005, the Company received the anticipated letter. Consistent with the FDA's original oral communications to the Company, the letter contained the same material requirements for additional information required by the FDA prior to further review of the IND. The Company has established a target of the fourth quarter of 2005 to submit a complete response to the letter. Once the Company's complete response is received, the FDA will have 30 days to reply, and with its reply may either allow the commencement of a Phase I clinical trial or request additional information.

The Company's "Safe Harbor" Statement under the Private Securities Litigation Reform Act of 1995: Statements in this Current Report on Form 8-K regarding the Company's business that are not historical facts are "forward-looking statements" that involve risks and uncertainties, including without limitation the risk that the Company will not complete its response to the FDA by the fourth quarter of 2005 and that the Company will not receive clearance from the FDA to initiate a Phase I clinical trial. For a discussion of these risks and uncertainties, any of which could cause the Company's actual results to differ from those contained in the forward-looking statement, see the section of the Company's Annual Report on Form 10-K for the year ended December 31, 2004, entitled "Factors Affecting the Company's Prospects" and discussions of potential risks and uncertainties in the Company's subsequent filings with the SEC.

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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.

Neose Technologies, Inc.

August 16, 2005

By: *C. Boyd Clarke*

Name: C. Boyd Clarke

Title: President and Chief Executive Officer