

AEOLUS PHARMACEUTICALS, INC.

Form 8-K

January 28, 2005

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 28, 2005

AEOLUS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

0-50481
(Commission File Number)

56-1953785
(IRS Employer ID Number)

P.O. Box 14287

Edgar Filing: AEOLUS PHARMACEUTICALS, INC. - Form 8-K

79 T. W. Alexander Drive

4401 Research Commons, Suite 200

Research Triangle Park, North Carolina
(Address of principal executive offices)

27709
(Zip Code)

Registrant's telephone number, including area code (919) 558-8688

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.

Based upon published and unpublished pre-clinical data developed with its catalytic antioxidant compound, AEOL 10150, and depending upon the results of its current single-dose safety and tolerability study of AEOL 10150 in patients with amyotrophic lateral sclerosis, or ALS, Aeolus Pharmaceuticals, Inc. anticipates scheduling a meeting and then meeting with the U.S. Food and Drug Administration in the second quarter of 2005 to discuss the filing of the required regulatory documents to initiate a Phase 2 efficacy study of AEOL 10150 in patients with stroke.

The information furnished in this Item 7.01 shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific release in such a filing.

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 thereunto duly authorized.

AEOLUS PHARMACEUTICALS, INC.

Date: January 28, 2005

/s/ Richard W. Reichow

Richard W. Reichow
Executive Vice President and Chief Financial Officer